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Quality of Life after Total Laryngectomy

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Quality of Life after Total Laryngectomy

Brooke Baioni

Honors Thesis

Program in Communication Disorders

University of Arkansas

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Abstract

The purpose of this study is to understand the physical, psychological, and social changes that patients undergo post laryngectomy surgery that may impact their quality of life. The participants for this study included laryngectomized patients, family members or friends of patients, and speech pathologists. Data was gathered using an online questionnaire distributed through social media outlets, support groups, medical centers, speech clinics, and by word of mouth. A total of 35 responses were gathered with 29 surveys being fully completed. This research found that participants who reported being most satisfied with their life overall, were most satisfied with their social support systems.

Quality of Life after Total Laryngectomy

This past summer I participated in an internship at New York University Langone Medical Center in New York City. It was a month full of hands-on, observational clinical experience. I worked under a team of five speech pathologists that covered patients in the ICU, In-Patient Adult Rehab, and the NICU of Tisch Hospital. I spent many days testing patients for aspiration through Fiberoptic Endoscopic Evaluation of Swallowing exams and Barium Swallow tests. Other days I was in the NICU and PICU working with infants learning to feed correctly. However, my favorite moments of the internship were the opportunities I had to work with rehab patients who had recently undergone total laryngectomies.

My last week at NYU, I had the privilege of working with a recently laryngectomized patient. This particular patient spent the last fifteen years of his life living by himself, with no family and friends, under the care of hired help. He was diagnosed with cancer in his voice box and the doctors immediately went through with a total laryngectomy in order to remove the cancer from his body. Normally, this is an incredible and heroic act, one that saves the life of a patient. However this man was different. Our patient was about 40 years of age, had crippled hands, unemployed, and on Medicaid. Sadly, the total laryngectomy was going to change his life forever. Our patient was not educated enough on the forefront of the surgery to understand the impacts a laryngectomy would have on his life. His crippled hands did not allow him to independently take care of his stoma and trachea. He could not hire a certified aid to assist him because of his financial state. Our patient was instantly stripped of the little independence he once had. He no longer had a voice and was forced to move into long-term assisted living. In an instant, this man's quality of life was dramatically and permanently changed.

This internship at New York University broadened my view of speech-language pathology in unimaginable ways. The first time I saw a laryngectomized patient, I knew the exact field of patients with whom I wanted to spend my working career. Because a total laryngectomy changes the patient's physical life and social roles forever, this research aims to address the quality of life issues by focusing on the physical, psychological, and social changes that occur in laryngectomized patients.

Review of the Literature

This review of the literature will address medical aspects of laryngectomy, the social and psychology aspects of recovery, and key issues that can contribute to quality of life after surgery as an outcome of interest with this population. It ends with the specific questions of the study.

What is a Laryngectomy?

According to Jayasuriya et al. (2010), a total laryngectomy is described as a stressful experience that results in the complete loss of natural voice, subsequently poor quality of life, and changes the patient's social roles forever. Laryngectomies are performed in order to lengthen a patient's lifetime, but at the expense of committing to a completely different lifestyle than before. The advancement of health care and medicine has led to a shift over the years on what exact criterion qualifies a treatment as "worth it" and "successful." Length of survival is no longer a sufficient measurement; the expected and potential future quality of life must also be evaluated and given significant weight. Quality of life is defined as an "individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards, and concerns" (Di Donato Chaves et al., 2012, p. 483).

Physical Aspects

An abundance of research has been done to pinpoint specific complaints of the physical health of laryngectomized patients. The day-to-day life of laryngectomized patients is continually made difficult through a plethora of different pains and increased complexity of daily activities. Eating, breathing, sleeping, and bathing are examples of just a few that change dramatically (Jayasuriya et al., 2010). Personal interviews completed by 29 patients showed that they complained of daily headaches, altered smell, and nasal blockage (Jayasuriya et al., 2010). Not shockingly, dysphagia was a large issue in over half of the patients every day life. On a grander scale, post operation complications led to more serious and chronic physical health needs. Studies show that 62.1% of patients suffered hypocalcaemia and 58.6% suffered hypothyroidism (Jayasuriya et al., 2010). The research shows that patients deal with physical issues that range from minor aches and pains to major diseases that require daily medicine. What are the steps needed to decrease the previously stated illnesses? What can we do to ensure proper therapy steps are taken to help decrease physical disabilities? Research and answers to these questions will lead to more successful therapy for laryngectomized patients.

Psychological Aspects

The psychological disturbances that occur in patients can be easily overlooked. However, these are important to note and can easily determine major ways of increasing the quality of life of post-laryngectomy patients. Survey questionnaires measuring the psychological ailments of patients showed that concerns of appearance and loss of interest in hobbies were consistently present amongst all patients (Jayasuriya et al., 2010). The altered and “not-normal” appearance that a laryngectomy creates on a person is one to be taken into major consideration. Patients who

have undergone a traumatic surgery upon their face or neck are immediately put in the spot light when in public. We must consider how social interactions and emotional expression depend a great deal upon the structure and function of someone's head and neck region (Kazi et al., 2007). Laryngectomized patients are not ignorant to the fact that they look different and it is easy to become self-conscious of the issue. Why do patients lose interest in hobbies? The daily activities that were once so easy now take longer, and require more effort. A lack of self-confidence and a sense of sadness easily distract a person from enjoying the things they love. Established objective goals for therapy and patient education may prevent and help speed recovery of the psychological ailments laryngectomized patients experience.

Social and Relational Changes

A patient dealing with physical and psychological changes will, without a doubt, experience social and relational changes. Doctors and medical staff often overlook this, but therapists play a large role in preparing patients to re-enter everyday life. Hebel, Mantsopoulos, and Bohrs (2014) collected data on 71 patients using questionnaires. They found that social integration was the second most important aspect of a patient's rehabilitation as this is where patients found it very necessary to seek out help in their environment from fellow people to bear his/her burdens. Patient surveys showed that on average almost half of every patient lacks family and social support (Jayasuriya et al., 2010). It is well known that successful social integration, positive relationships, and communal support all have the power to create a more positive emotional, mental, and physical health recovery. Therefore, healthcare providers cannot undermine the importance of the social aspect of laryngectomized patient's therapy.

Summary and Questions of the Study

Since the day I learned of my NYU patients' situation, my curiosity and imagination have constantly wandered about the lives of laryngectomized patients. This patient's particular situation generated many questions in my mind concerning standard rehabilitation and therapeutic methods. What are the physical, psychological, and social changes that laryngectomized patients undergo? What are the biggest needs amongst patients with laryngectomies? The ability to communicate well has the strongest association with overall improved quality of life (Kazi et al., 2007), and speech-language treatment necessitates communication that utilizes experiences in the person's life as material for talk. The role of the speech pathologist must also in today's health care climate address quality of life as perceived by the patient. Therefore, it is timely as well as necessary to focus on what a speech language pathologists can do to help increase the satisfaction in the overall quality of life of laryngectomized patients. Speech-language pathologists must find specific and objective priorities for successful therapy. Research can very well pave the way to discovering the best possible patient education and rehabilitation for the future. Pinpointing the most important physical, psychological, and social areas of rehabilitation has the ability to achieve the optimal quality of life for laryngectomized patients. The specific questions of this study are as follows.

Questions of the Study

1. What will patient, family members, and/or friends, and speech language pathologists say are the quality of life things that matter to them prior to surgery, right after surgery, and long term (1-2 years or more)?
2. Are there differences in the perspectives between these groups over time post-surgery?

Methodology

Participants

Thirty-six participants were sought for this study. These were to optimally include 12 individuals in three categories: 12 patients, 12 friends/family of a person who had had a total laryngectomy, and 12 speech pathologists. There were no controls for the gender, age, or time since surgery. There were no requirements for speech-language pathologists, except to have worked with a laryngectomized client.

Materials

A questionnaire was developed from the literature and dispersed electronically to participants. (See Appendix A).

Procedures

The questionnaire was digitized using Qualtrics survey software. The questionnaire was field tested and checked prior to distribution through social media, support groups, medical centers, speech clinics, and word of mouth. The survey was available for six weeks.

Analysis

Descriptive analysis was completed using the tools available in the Qualtrics software. Analysis was completed separate in the three distinct categories (patient, friends/family, SLPs) and then linked across categories in order to discover the overarching themes.

Results

Demographics

A total of 35 responses were gathered and 29 of those were fully completed through the dispersion of the questionnaire using Qualtrics software. There were no controls for participants, except to have identified as a laryngectomized patient, family member, or service provider for a

laryngectomized patient. Twenty-three patients, one spouse, five family members, five speech-language pathologists, and one service provider completed the questionnaire. Of the 23 laryngectomized participants, 13 were male and 10 were female. Seven were over the age of 75, five were between 66 and 75 years of age, seven were between the ages of 56 and 65, and five were between the ages of 41 and 55, as seen in Figure 1.

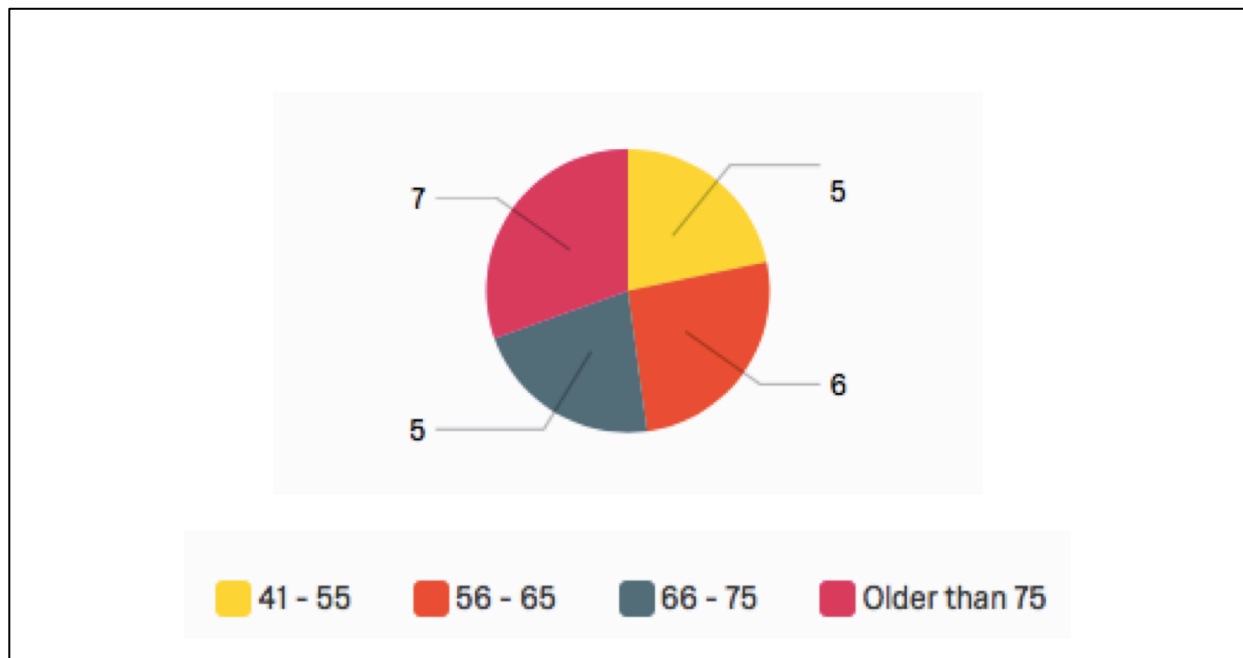


Figure 1. Laryngectomized participants by age.

As seen in Figure 2 below, of the 23 total responses recorded by laryngectomized patients, 11 participants received the laryngectomy more than ten years ago, one participant received the laryngectomy 6-10 years ago, eight participants received the laryngectomy between two and five years ago, and four participants received the laryngectomy less than two years ago.

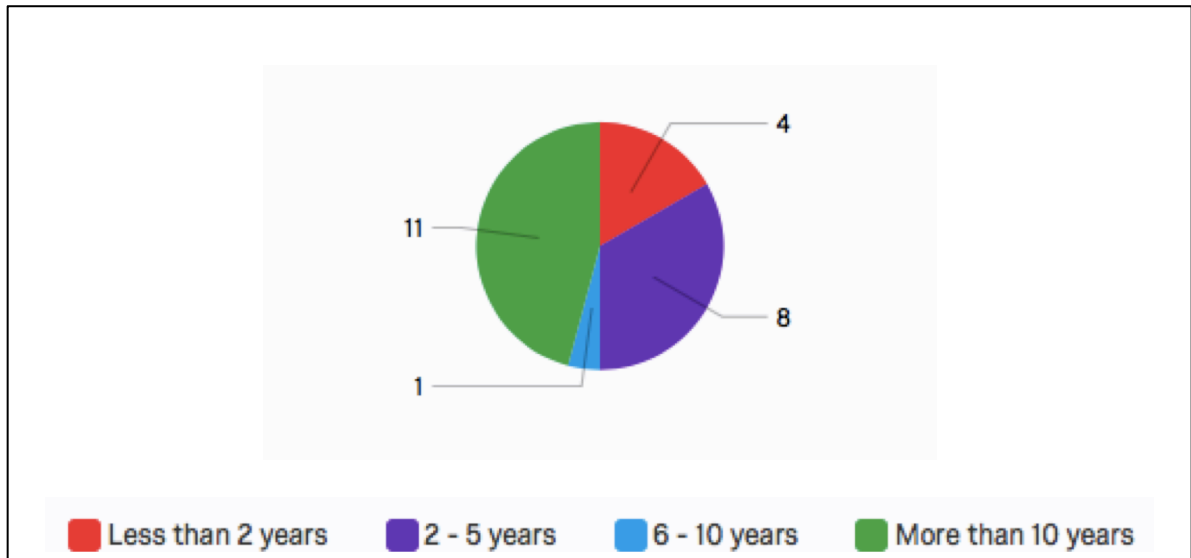


Figure 2. Length of time since surgery.

One spouse/partner, five family members, five speech-language pathologists, and one service provider began the survey. However, only two family members of laryngectomized patients, one service provider, and 4 speech-language pathologists fully completed the questionnaire. As shown in Table 1, all of these participants were female.

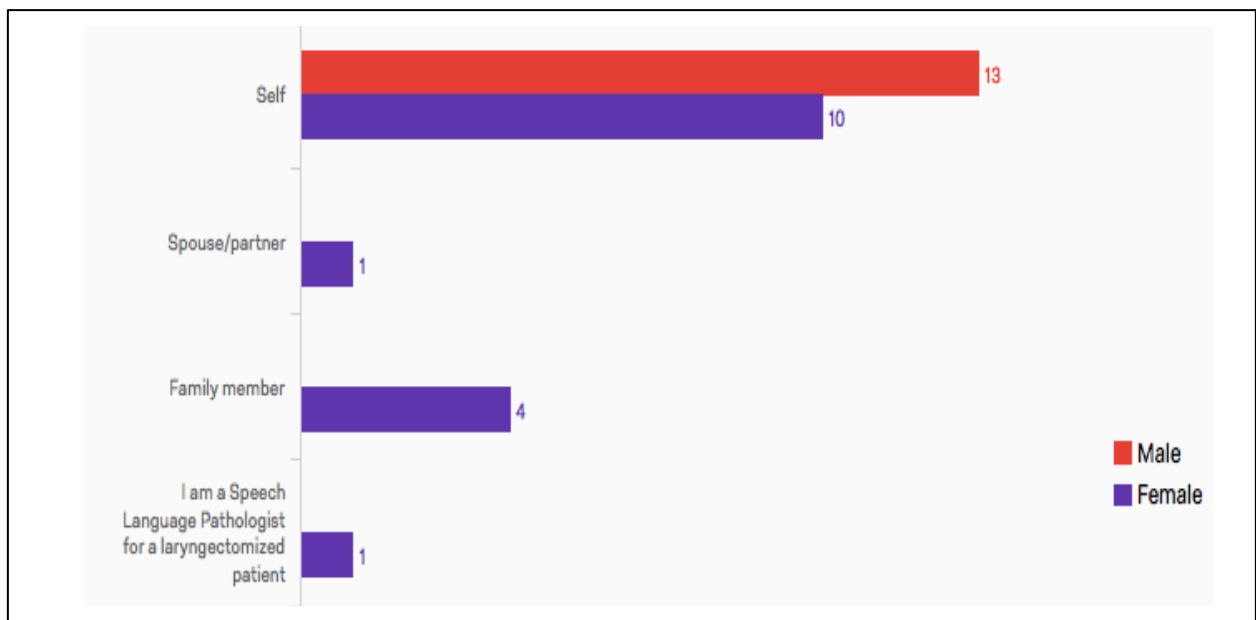


Table 1. Total questionnaires completed.

Question One

The first question of the study sought to understand what patients, family members, and speech-language pathologists identify as the quality of life things that matter to them prior to surgery, right after surgery, and long term. Items 18, 19, and 20 on the questionnaire were used to answer this question. These ask the participants to rank their opinion on various aspects of life based on experiences in the past month. The participants were able to choose five categories: very dissatisfied, moderately dissatisfied, slightly satisfied, moderately satisfied, and very satisfied. Amongst those, patients were asked how satisfied they were with their life in general. 11 reported very satisfied, 2 reported being moderately satisfied, 2 slightly satisfied, 1 moderately dissatisfied, and 1 very dissatisfied.

The two participants who reported being dissatisfied with their life in general, were most dissatisfied with their ability to communicate with strangers, and their opportunities to take part in leisure activities. These participants also frequently reported being dissatisfied with their ability to take care of themselves independently and their overall health. Other factors that affected satisfaction included achievement of personal goals, general happiness, chance at a happy future, peace of mind, and the emotional aspects of daily life.

On the contrary, participants who reported feeling most satisfied with their life were very satisfied with the support they received from their friends and their ability to communicate with strangers. These participants also most often reported being satisfied with their ability to take care of themselves independently, their overall health, and the amount of energy they had each day. Notably, of the 11 patients who reported being very satisfied with their life in general, 8 reported that there were no changes to being able to do the things they enjoyed most in life after

their laryngectomy. Figure 3 below shows the categories of quality of life participants most frequently reported as the most dissatisfying or satisfying aspect of their life. It highlights the overlapping aspects reported between the two groups.

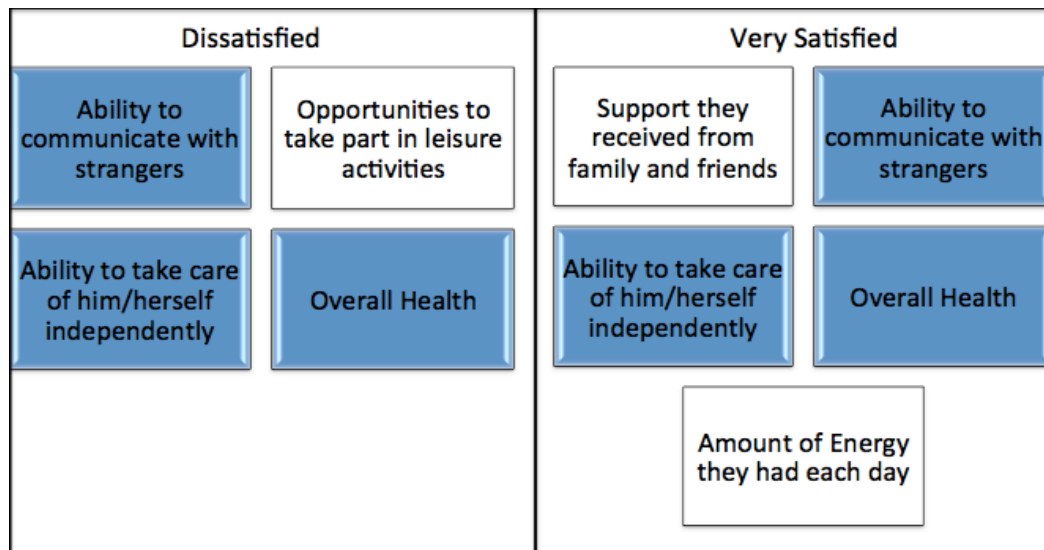


Figure 3. The overlapping aspects associated with quality of life.

Question Two

The second question of the study sought to identify differences in the perspectives of quality of life between each of the three groups over time post-surgery. The fifth item of the questionnaire had each participant identify the amount of time since the laryngectomy. Of the 35 total responses, 15 participants received the laryngectomy more than ten years ago. Three participants received the laryngectomy 6-10 years ago. Twelve participants received the laryngectomy between two and five years ago. Six participants received the laryngectomy less than two years ago, as seen in Figure 2 above.

When participants were asked what has been the most difficult social transition since their laryngectomy surgery, patients who had received their laryngectomy in the past five years or less, most often noted difficulty with not being able to speak and not feeling comfortable

going out in public places. However, participants who had received their laryngectomy more than ten years ago did not report any issues associated with going out in public, and some did not recall any social changes at all. When family members were asked to identify what aspects of the social transition was difficult for them and their loved one post-surgery, those whose loved ones underwent surgery 6-10 years ago reported communication with others and making phone calls. Family members whose loved ones underwent surgery more than ten years ago reported making phones calls and talking while trying to use hands for other things. These responses were similar to those provided by speech-language pathologists (SLP) on item 39 of the questionnaire. Specifically, the SLPs reported that most patients have the most difficulty transitioning to staying home more often.

Item 62 of the questionnaire asked participants to share what has been the most emotionally difficult transition since their laryngectomy surgery. Participants who had undergone surgery less than two years ago reported being mostly emotionally affected by others difficulty understanding them. Participants who had undergone surgery between 2-5 years most often reported that not being able to normally converse was the most emotionally difficult transition. Some participants over ten years reported no change in their emotional health, while others most often reported the loss of their voice. In item 55 of the questionnaire, participants were asked to identify the most difficult emotional transition for them and their loved one after receiving a laryngectomy. Family members whose loved one underwent surgery 6-10 years ago reported that the most difficult transition after surgery was not hearing their loved ones laughter anymore. Family members whose loved ones had surgery 10+ years ago reported that dealing with a messy stoma was the most emotionally difficult transition after surgery.

Item 13 of the questionnaire asked participants to identify what was most difficult to accomplish when communicating. For participants, between 2 and 5 years, they most often reported issues with being heard and understood. For participants who received their laryngectomy over ten years ago, they most often reported that speaking in noisy environments and talking on the phone were the most difficult things to accomplish when communicating. Item 48 of the questionnaire asked family members to identify what was most difficult for their loved ones to accomplish while communicating. All family members reported that the most difficult issue was being heard and understood. In item 34, speech-language pathologists were also asked to identify what was most difficult for their patients to accomplish when communicating and most often reported being understood by others.

Discussion

The purpose of this study was to pinpoint physical, psychological, and social changes that laryngectomized patients undergo, in order to understand how these aspects associate with different levels of quality of life. The first question of the study sought to understand what patients, family members, and service providers would identify as the most important aspects of quality of life, before and after surgery. The two participants, who reported being dissatisfied with their life in general, were most dissatisfied with their ability to communicate with strangers, their relationships, their opportunities to take part in leisure activities, their ability to take care of themselves independently and their overall health.

On the contrary, participants who reported feeling most satisfied with their life were very satisfied with the support they received from their friends, their relationships, support outside of their family, and their ability to communicate with strangers. These participants also most often

reported being satisfied with their ability to take care of themselves independently, their overall health, and the amount of energy they had each day.

Notably, of the 11 patients who reported being very satisfied with their life in general, eight reported that there were no changes at all to being able to do the things they enjoyed most in life after their laryngectomy, whereas that was a major complaint of patients who were dissatisfied with their quality of life. Overall, more patients reported being satisfied with their quality of life, rather than dissatisfied. However, most speech-language pathologists reported being only slightly satisfied and moderately dissatisfied with the quality of life in different areas of their patients' lives. One speech-language pathologist did note that patients tend to do better when they have a great social support system.

The second question of the study sought to understand the differences in the perspectives of quality of life between each of the three groups over time post-surgery. Participants were asked to identify the most emotionally difficult transition after laryngectomy. Patients most often cited different aspects of communication as the most emotionally difficult transition. However, family members never mentioned communication and reported not hearing their loved ones voice and laughter, and dealing with their loved ones stoma. Most speech-language pathologists did not know the patients most emotionally difficult transition. Overall, the longer the patient had been laryngectomized, the more positive their outlook.

Participants were asked to identify the most socially difficult transition post surgery. Laryngectomized patients who received their surgery less than 5 years ago most often reported negative feelings toward public places. However, participants who had their surgery more than ten years ago did not report any issues with going out in public, and some noted no social

changes. Family members most often reported that the most difficult social change was telephone calls. Speech-language pathologists most often reported that the patient's transition to staying at home more often to avoid noisy environments and crowds was the most difficult social transition. Patients and speech-language pathologists had similar views on the most difficult social transitions for patients. Once again, overall, the longer the patient had been laryngectomized directly correlated with a more positive outlook.

Lastly, all participants were asked to report what was most difficult for the laryngectomized patient to achieve in communication. All categories of participants, patients, loved ones, and speech-language pathologists reported that being heard and understood by others in group settings or high noise level environments were difficult experiences with communication, despite the length of time since the laryngectomy surgery.

Many of the findings of this study were consistent with the findings of Jayasuriya (2010) and colleague's research on the outstanding aspects of life most associated with good quality of life. Jayasuriya noted that social integration was the second most important aspect of a patient's rehabilitation. This research found that participants who reported being most satisfied with their life overall, were most satisfied with their social support systems. Moreover, Kazi (2007) and colleagues noted that the ability to communicate had the strongest association with overall improved quality of life. Patients who reported being dissatisfied with their life were the only ones who reported being dissatisfied with their ability to communicate with strangers. Those who were most satisfied with their life in general, reported being very satisfied with their ability to communicate with strangers. Moreover, when the participants in this study were asked what had

been the most difficult emotional aspect of a laryngectomy, most of them reported the ability to no longer normally converse.

However, concerns of physical appearance were not consistently present amongst all patients of this research, as it was in that of Jayasuriya and his colleagues. Only one participant reported being dissatisfied with their physical appearance, and only one family member reported negatively about appearance. The research of Jayasuriya (2010) and his colleagues noted that a loss of interest and hobbies was a consistent finding in all of their patients. However, when asked how often in the past month they have felt like doing the things they value most in life, only 50% of these 23 participants reported wanting to do those things less than half the time. Most family members also reported no change to doing the things they value most in life.

Limitations of the study

Thirty-six participants were sought for the study. This optimally included 12 individuals in three categories: 12 patients, 12 friends or family of a person who received a total laryngectomy, and 12 speech-language pathologists or service providers for laryngectomized patients. The first limitation of the study would be that we only received fully completed survey information from four family members of laryngectomized patients and three speech-language pathologists. Due to the small sample size of speech-language pathologists, service providers, family members, and spouses, it was difficult to find significant relationships from the data. A larger sample size, especially of equal size to our laryngectomy patient pool, would have been much more representative of these populations.

The first question of the study sought to understand what patients, family members, and speech-language pathologists identify as the quality of life things that matter to them prior to

surgery, right after surgery, and long term. However, a glitch in the Qualtrics software hindered some of the data needed from family members and speech-language pathologists to better answer this question from their perspectives.

Future Direction

Recommendations for future studies include retrieving data from patients, their family members, and their specific speech-language pathologist. The data should be paired in order to examine the similarities and differences between the three categories opinions and expectations on quality of life. Future research should also continue to build on qualitative data with interviews to understand details and other possible factors that could potentially explain extreme satisfaction or dissatisfaction with the patient's quality of life.

References

- Di Donato Chaves, A., de Araújo Pernambuco, L., Balata, P. M., Da Silva Santos, V., de Lima, L. M., Ribeiro de Souza, S., & Da Silva, H. J. (2012). Limits on quality of life in communication after total laryngectomy. *International Archives Of Otorhinolaryngology*, *16*(4), 482-491. doi:10.7162/S1809-97772012000400009
- Hebel, F., Mantsopoulos, K., & Bohr, C. (2014). Assessing quality of life in patients after partial laryngectomy. *Hippokratia*, *18*(2), 156-161.
- Jayasuriya, C., Dayasiri, M. B. K. C., Indranath, N., Jayasekara, D. D. N. P., & Lankamali, E. L. S. (2010). The quality of life of laryngectomised patients. *Australasian Medical Journal (Online)*, *3*(6), 353-357. Retrieved from <http://0-search.proquest.com.library.uark.edu/docview/613397961?accountid=8361>
- Kazi, R., De Cordova, J., Kanagalingam, J., Venkitaraman, R., Nutting, C. M., Clarke, P., . . . Harrington, K. J. (2007). Quality of life following total laryngectomy: Assessment using the UW-QOL scale. *ORL : Journal for Oto - Rhino - Laryngology and its Related Specialties*, *69*(2), 100-6. Retrieved from <http://0-search.proquest.com.library.uark.edu/docview/225066795?accountid=8361>

Appendix A

Quality of Life after Laryngectomy Questionnaire

Part 1: General Information.

What is your gender? Male Female

How old are you in years? below the age of 20 20-30 30-40 41-55
 56-65 66-75 older than 75

Who do you live with? (please check all that apply)

Alone Spouse Partner Children Parents
 Assisted Living Facility Other {text box for open ended response}

Did you or someone you know laryngectomy surgery? Self Spouse/partner
 family member Friend Service Provider Speech-language pathologist
 Other {text box}

How long has it been since the laryngectomy? Less than 2 years 2-5 years
 6-10 years More than 10 years

Was the laryngectomy total or partial?

The following is used for communication? Vocally Writing/pictures/ graphics
 Augmentative Communication Device Artificial Larynx Other {text box}

Part 2: For each of the following questions – please choose the answer that best describes how satisfied you are with that area of life. We ask that you think about your life in the past month. There are no right or wrong answers.

Answer Key (displayed as choice boxes for each closed set response question):

1. Very Dissatisfied
2. Moderately Dissatisfied
3. Slightly Satisfied
4. Moderated Satisfied
5. Very Satisfied

How satisfied are you with...

1. Your health?
2. The amount of sleep you get each night?
3. What you are able to eat?
4. The amount of energy you have each day?
5. Your sex life?
6. Your ability to take care of yourself independently?

7. Your job (if employed)?
8. Not having a job (if unemployed, retired, disabled)?
9. Your relationship with your spouse, lover, or partner?
10. Your relationships with your friends?
11. The support you receive from your friends?
12. The support you receive from people, other than your family?
13. Your ability to communicate with family and friends?
14. Your ability to communicate with strangers?
15. Your ability to take part in your leisure activities?
16. Are you apart of a Laryngectomy Support group? (lost chord club, UA, etc.)
17. Your opportunities for leisure activities?
18. Your chance for a happy future?
19. Your personal appearance?
20. Your faith in God?
21. Your achievement of personal goals?
22. Your happiness in general?
23. Your peace of mind?
24. Your life in general?
25. Emotional aspects of your daily life?

Part 3: Please use the text boxes under each question to share additional information. This can be solely about you or can include insights about key persons in your life.

Please let us know who the information is about.

Self Spouse Family Member Friend Client/ Patient

What daily activities are you now hindered from doing independently, if any?

Do you or others around you now experience limitations on the type of foods you can eat or where you are comfortable eating them?

What is most difficult for you to accomplish when communicating?

What did you know about different modes of communication prior to laryngectomy surgery?

List three things you enjoy doing. These can be anything.

- 1.
- 2.
- 3.

How often in the last month have you felt like doing the things you value most in life?

In what ways, if any, have the things you enjoy doing changed after laryngectomy surgery?
In what ways, if any, has your social life changed since laryngectomy surgery?

How have changes in communication related to laryngectomy surgery impacted social contacts and relationships?

What has been the most difficult social transition since your laryngectomy surgery?

What has been, emotionally, the most difficult transition since laryngectomy surgery?

What would you like others to know before laryngectomy surgery?

Appendix B

IRB Approval

November 9, 2016

MEMORANDUM

TO: Brooke Baioni
Fran Hagstrom

FROM: Ro Windwalker
IRB Coordinator

RE: New Protocol Approval

IRB Protocol #: 16-10-150

Protocol Title: *Quality of Life after Total Laryngectomy*

Review Type: EXEMPT EXPEDITED FULL IRB

Approved Project Period: Start Date: 11/08/2016 Expiration Date: 11/07/2017

Your protocol has been approved by the IRB. Protocols are approved for a maximum period of one year. If you wish to continue the project past the approved project period (see above), you must submit a request, using the form *Continuing Review for IRB Approved Projects*, prior to the expiration date. This form is available from the IRB Coordinator or on the Research Compliance website (<https://vpred.uark.edu/units/rscp/index.php>). As a courtesy, you will be sent a reminder two months in advance of that date. However, failure to receive a reminder does not negate your obligation to make the request in sufficient time for review and approval. Federal regulations prohibit retroactive approval of continuation. Failure to receive approval to continue the project prior to the expiration date will result in Termination of the protocol approval. The IRB Coordinator can give you guidance on submission times.

This protocol has been approved for 100 participants. If you wish to make *any* modifications in the approved protocol, including enrolling more than this number, you must seek approval *prior to* implementing those changes. All modifications should be requested in writing (email is acceptable) and must provide sufficient detail to assess the impact of the change.

If you have questions or need any assistance from the IRB, please contact me at 109 MLKG Building, 5-2208, or irb@uark.edu.