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Evaluation of Risk Factors and Postoperative Outcomes in Surgical Laryngectomies with Intraoperative Hypothermia

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DNP Final Project Report

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Dedication

This DNP Project is dedicated to my husband, who's constant support of my dream to be a great nurse practitioner by talking me through my constant self-doubt, bringing me cinnamon rolls from my favorite bakery, and allowing me time to be selfish and focus on my goals to make a bright future for us and our future children. Furthermore, none of this would be possible without the support of my parents. I hope to honor my father's legacy in medicine by listening to his advice, and to actively participant in making medicine better for future patients, as he did during his thirty-six years in medicine. This is for my sister, who gets me. This paper would have never been completed without my sweet fur babies, Gale (who let me massage her fluffy paws like stress balls) and Loki (who encourage me to get out of the house and walk him already and leave my stress behind if only for thirty minutes). This paper I hope encourages future nursing students to follow their dreams and never allow anyone or anything to stand your way (even yourself).

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Abstract

PURPOSE: The purpose of this study is to determine whether intraoperative hypothermia exposure would be identified as an independent risk factor for surgical laryngectomy patients' rate of postoperative complications within their surgical admission. The findings would help to justify the institution of "pre-warming" laryngectomy patients to prevent detrimental effects postoperatively.

METHODS: Retrospective chart review of 245 patients who had laryngectomies at the University of Kentucky from 2010-2017. Rate of complication and variables predictability of postoperative complications was evaluated.

RESULTS: In the sample, 157 patients developed complications. Complications included 35 transpharyngeal fistulas, 29 free flap failures, 43 hematomas, 50 wound infections/ wound breakdowns. Patients who were hypothermic had a significantly higher rate of complications that normothermic patient among all complications. Logistic regression identified intraoperative hypothermia as a significant predictor for the development of postoperative complications TPF ($p=0.01$) and SSI ($p=0.012$; odds ratio [OR], 2.80; 95% confidence interval, 1.02-12.66; OR, 2.44, CI, 0.78-7.58), and Chi-square analysis found significance among patients who experienced intraoperative hypothermia and who experienced both TPF and SSI.

CONCLUSION: Intraoperative hypothermia in head and neck surgery is positively correlated with postoperative complications in the development of complications, especially TPF and SSI. Maintaining normothermia through aggressive warming prior to intraoperative transport may decrease the incidence of perioperative morbidity for these patients.

Evaluation of Risk Factors and Postoperative Outcomes in Surgical Laryngectomies with Intraoperative Hypothermia

Introduction

Unplanned intraoperative hypothermia remains a threat to all surgical patients undergoing general anesthesia for greater than 60 minutes (Kurz, 2008; Forbes et al., 2008; Sessler, 2009). As many as 20%-40% surgical patients experience intraoperative hypothermia and suffer from short-term and long-term postoperative complications (Kurz, 2008; Hendrick et al., 2007; Forbes et al., 2008). These include a five-fold risk of surgical site infection, prolonged anesthesia emergence, increased blood loss and blood product administration, and longer healing time (Kurz, Sessler & Lenhardt, 1996).

Intraoperative hypothermia is defined as a drop in core body temperature to less than 36 degrees Celsius, while in the perioperative setting (AORN, 2016). Certain patient and environmental factors have shown to increase patients' risk for intraoperative hypothermia, and risk factor assessment has been included in many hypothermia prevention guidelines. However, research to determine the significance of perioperative factors on intraoperative hypothermia prevention is varied and further research is necessary to advance prevention measures. Current findings suggest that the following factors may contribute to hypothermia development and associated postoperative complications and should be evaluated perioperatively: Age greater than 65, female gender, BMI less than 25, preoperative core body temperature less than 36 degrees Celsius, general anesthesia, surgery time greater than two hours, un-warmed intraoperative fluids greater than 1000 ml, surgeries defined as intermediate and major, and cold intraoperative setting at induction (Yi et al, 2015; Kasi et al, 2002).

Sumer et al. (2009) conducted a retrospective chart audit of 136 patients who had laryngectomies with free flap placement to determine prevalence of hypothermia and if hypothermia was correlated with post-operative complications and morbidity. Their findings indicated that 43 patients experienced complications that were not associated with age, sex, presence of comorbidities, tobacco use, previous chemotherapy or radiation, having stage IV cancer, length of surgery, or the administration of blood products preoperatively. However, there was a significantly higher rate of complications in patients who were hypothermic compared to normothermic. By using a stepwise logistical regression model, the researchers determined that intraoperative hypothermia was a strong independent indicator of post-operative complications (Sumer et al., 2009). However, research has also shown the benefits of induced hypothermia when it is planned and administered according to a predetermined protocol.

In contrast to reports of negative outcomes associated with hypothermia, other researchers report outcome benefits. Induced hypothermia appears to provide a neuroprotective benefit for patients undergoing cardiac and neurosurgical procedures in addition to a benefit to individuals after cardiac arrest with return of spontaneous circulation, also known as ROSC (Bernard et al., 2002; Pebrey et al., 2010; Kim et al., 2014). In the study from Bernard et al. (2002), their findings suggest improved discharge rates, either to home or to a rehabilitation facility, among patients treated with induced hypothermia post-cardiac arrest compared to normothermic patients (49% vs. 26%). However, the sample size was small (N=76) with more patients in the hypothermic group compared to the normothermic group (43 vs. 34). In addition, the authors excluded patients with poor prognosis, excluding a large group of cardiac arrest population. Furthermore, the process in which they maintained normothermia patients was achieved passively, which entails using warmed cotton blankets on comatose-induced patients, which when compared to air-circulating blankets was considered less effective (Beedle et al., 2017). However, contrary findings by Chan et al. (2017) suggest induced hypothermia compared to normothermic patients after cardiac arrest patients had a lower hospital survival (27.4% vs 29.2%) and lower rates of favorable neurological outcomes (17.0% vs 20.5%).

These polar findings suggest the benefit of further research on causation assessment between temperature management and post-operative complications for vulnerable populations, including cancer patients undergoing surgical laryngectomies. Furthermore, additional research will support findings like Graboyes et al.(2013), who found that new total laryngectomy had presence of a complication prior to discharge, and were at an increased risk for unplanned 30-day readmission and increased length of stay (LOS) compared to other risk factors (Graboyes et al., 2013).

Background

The IOWA Model of Evidence-Based Practice (IOWA) helped to guide the development of this project by first identifying a problem-focused trigger. The primary researcher identified a vulnerable population in the operating room through observations made during their time working with the surgical laryngectomy population over four years. Next, the IOWA model states the need to review the literature thoroughly to ensure the researcher’s knowledge of all known current practices and research on the subject of temperature management in the perioperative setting. The researcher read past and current literature on hypothermia management. This included the benefits of therapeutic hypothermia (induced hypothermia), the risks hypothermia (inadvertent hypothermia) poses on perioperative patients’ recovery, and hypothermia prevention measures. Once the researcher identifies the most relevant articles for the project's objectives, the next stage of the IOWA model indicates to evaluate the evidence. See appendix i for model of the IOWA Model of Evidence-Based Practice.

Review of the literature revealed empirical evidence supporting intra-operative hypothermia as a risk for the development of post op complications and also as a benefit for patients undergoing surgery (Benzinger, Pratt & Kitzinger, 1961; Blair, 1964; Lunn 1969; Newman, 1971; Morris, 1972; Morris & Kumar, 1972; Roizen, Sohn, L'Hommedieus et al., 1980; Dienes, 1981; White, 1981; Wong, 1983; Valeri, et al., 1987). These studies identified the effect anesthesia has on the body when it is not actively warmed prior to, or during the surgical procedure. Beneinger, Pratt and Kitzinger (1961) were first to identify how the body maintains thermostatic control. They corroborated even earlier findings of Iberlla (1921) that when patients' temperature drops between 33-34 degree Celsius, the body begins to actively warm itself by inducing deliberate movements, or shivering. Anesthesia prevents this natural thermoregulatory action, and the patient assumes the environmental temperature. Furthermore, Blair (1964), Morris (1972), and Morris and Kumar (1972) identified factors in the operating room which contribute to an accelerated drop in temperature after anesthesia induction, such as cooled air and anesthetic gases throughout the procedure, rapid infusing of cooler intravenous fluids, cooler environmental temperature, and inadequate skin surface warming. In addition, Morris (1972), Roizen, Sohn, L'Hommedieu et al. (1980) and Blair (1964) identified hypothermia prevention methods as warmed intravenous fluids, warmed-humidified air, and surface skin warming. Roizen et al. (1980) noted that patient who received active warming, both warmed humidified air and surface skin warming, were statistically more likely to have normothermia postoperatively (p=0.03).

Because early studies indicate beneficial effects of hypothermia in the intraoperative setting, a knowledge gap is created (Rose et al., 1957; Wong, 1983). Rose et al. (1957) found that a drop in a patient's temperature in a range of 33-35 degrees Celsius helped to improve cardiothoracic surgical patient's postoperative recovery. They noted that patients were less likely to experience reoccurrence ventricular fibrillation or post-operative myocardial infarction if hypothermia was maintained after induction, throughout the entire procedure, and rewarmed gradually in the ICU postoperatively. Wong (1983) noted a decrease in surgical site infection, in a meta-analysis, single-site study, among (include number of patients) patients undergoing cesarean sections. The study design included implementation of a warming trial, where half of the patients were actively warmed with forced-air warming blanket (n=20) and half, or control group, were not (n=21). The findings suggest that patients who were warmed were positively correlated with increased surgical site infection and need for additional surgery or treatment for infection (p=0.044). These foundational studies indicates both pros and cons to perioperative hypothermia, and further evaluation of more recent research is necessary to determine gap in practice.

The following sections, hypothermia risks, hypothermia benefits, and hypothermia prevention will outline research findings over the last 10 years and earlier landmark studies to provide the most relevant research in temperature management in patient.

Hypothermia Risks

Intraoperative hypothermia is defined as a drop in core body temperature to less than 36 degrees Celsius while in the perioperative setting (AORN, 2016). Certain patient (cancer, older, malnutrition, etc.) and environmental factors (cold exposure in perioperative setting, cold skin preparation solution, anesthetic effects, etc.) are known to increase patients' risk for intraoperative hypothermia, and risk factor assessment has been included in many hypothermia prevention guidelines (AORN, 2016; Graboyes et al., 2013). However, research to determine the significance of pre-and-intraoperative factors on intraoperative hypothermia prevention is limited. Current findings suggest that the following factors may contribute to hypothermia development and associated postoperative complications and should be evaluated perioperatively: Age greater than 65, female gender, preoperative core body temperature less than 36 degrees Celsius, preoperative lab derangements, surgery time greater than two hours, un-warmed intraoperative fluids greater than 1000ml, advance cancer stage, and cold intraoperative setting at induction (Yi et al., 2015; Kasi et al., 2002).

Laryngectomy patients were chosen as the population for this research project because they are at a higher risk for intraoperative hypothermia due to the lengthiness of the procedure, increased exposure to cooling effects within the intraoperative setting, and greater vulnerability to postoperative complications (Agrawal et al., 2003; Sumer et al., 2009). In patients undergoing laryngectomies, intraoperative hypothermia could increase their risk of experiencing a variety of complications during the postoperative recovery period. The most common postoperative complications following a laryngectomy include tracheopharyngeal fistula, incisional site infection, hematoma, and total or partial free flap failure (Alsam et al., 2006; Agrawal et al., 2003). Furthermore, complications such as tracheoesophageal fistula and wound infections have been shown to increase a patient’s mortality and lead to life-threatening complications, such as carotid arterial rupture, or “blow-out” (Wengen & Donald, 1994; Cavalot et al., 2000).

The goal of the project will be to determine if intraoperative hypothermia is an independent risk factor for postoperative complication development in 245 patients undergoing surgical laryngectomy at the University of Kentucky. Two sets of researchers have found this to be the case (Flores-Maldonado et al., 2001; Sumer et al., 2009). Flores-Maldonado et al. (2001) found that of the 209 patients undergoing abdominal hysterectomy, 158 experienced mild hypothermia. Of these patients who experienced hypothermia intraoperatively, 18% experienced surgical site infections, compared to a 2% infection rate in the normothermic group. Sumer et al. (2009) found that of the risk factors assessed to contribute to postoperative complications, only intraoperative hypothermia was considered statistically significant as an independent risk factor ($p=0.002$; odds ratio 5.122). However, further validation of these studies' findings are necessary to determine whether findings are reproducible and show generalizability among all surgery centers with a significant number of laryngectomy patients.

Hypothermia Benefits

To better understand the effect temperature has on the body, one must also review the cons in temperature management. Therapeutic hypothermia (induced hypothermia) is defined as purposefully placing a patient in a hypothermic state while comatose, between 33-35 degrees Celsius, therein improving patient outcomes after brain and cardiac injury (Bernard & Buist, 2003). Guidelines by the American Heart Association currently recommend therapeutic hypothermia post-cardiac arrest to promote better post-injury survival (Peberdy et al., 2010)

The positive physiologic effects of hypothermia include vasodilation improving oxygen delivery to vessels, while decreasing the metabolic needs of cardiac and neurologic tissues. Furthermore, the decrease in metabolic demand improves tissue oxygenation by decreasing oxygen demand, glucose consumption, intracranial pressure, heart rate, and lactate concentration (Nolan et al., 2003). In addition, hypothermia after myocardial infarction and stroke has been shown to prevent additional ischemic injuries after primary injury (Azoom et al., 2011).

A research project by the Hypothermic After Cardiac Arrest Study Group (2002) performed a randomized, double-blinded assessment of post-cardiac arrest patient outcomes with and without the initiation of therapeutic hypothermia. The findings suggest improved neurologic outcomes six months post-injury in the hypothermic group compared to the normothermic group (55% vs. 39%; risk ratio, 1.40; 95% CI, 1.08-1.81; p=0.009). In addition, the mortality rate after six months was lower in the hypothermic group compared to the normothermic group by 14 percentage points (41% vs 55%; risk ratio 0.74; 95%CI 0.58-0.95; p=0.02). However, they reported a trend of increased sepsis and pneumonia, but the findings were not statistical significance. In the hypothermic group, 17 of the 135 patients (13%) developed sepsis and 50 of 135 (37%) developed pneumonia, compared to the normothermic group where 9 of 138 patients (7%) developed sepsis and 40 of the 137 patients (29%) developed pneumonia. Even though the result was not significantly different when comparing the two groups (p=0.4), it leaves concern of possible deleterious effects of hypothermia.

Hypothermia Prevention

As mentioned earlier, complications associated with hypothermia can be decreased when hospitals adopt prevention measures. The UKMC Perioperative Services uses the guidelines from the Association of Perioperative Registered Nurses, or AORN (2016) to maintain compliance with quality measures. However, they do not currently follow many of the AORN hypothermia prevention measures for the adult patient. Findings by other institutions support the implementation of prevention measures on adult patients as they had lower hypothermia occurrences throughout perioperative setting, improved surgical outcomes, and better patient satisfaction (Lynch, Dixon, and Leary, 2010). However, guideline measures outlined for better practice implementation are only as effective as staff acceptance of new practices (Baker et al, 2010). When implementations of new guidelines vary greatly among staff, the positive influence of such evidence-based practice can be diminutive (Bakers et al, 2010). More research is necessary to overcome inconsistent, outdated practices among organizations and staff, especially in areas that pose great benefit toward patient safety, such as perioperative risk factor assessment with pre-warming implications.

The AORN guidelines state that strong evidence supports risk factor assessment in the preoperative setting to identify at-risk patients and communicate risk to all operative staff (AORN, 2015). Risk factor assessment is associated with earlier identification of vulnerable patients that would benefit the most from pre- and intra-operative active warming interventions (AORN, 2015). In addition, when perioperative staff were aware of patients' risk for hypothermia, staff was more likely to provide active warming measures before effects of anesthetic drugs, which is greatly associated with intraoperative hypothermia (Hooper et al, 2010; Seifert et al, 2014). However, research in support of individual risk factor predictability for post-operative complications is limited, thus it cannot generalize findings to practice in all surgical patients (Kasai et al, 2002; Frank, El-Rahmany, Cattaneo & Barnes, 2000; M.S. Vaughan, R.W.Vaughan, & Cork, 1981; Leslie & Sessler, 1996; Kongsayreepong et al, 2003; Kurz, Sessler, Narzt, Lenhardt & Lackner, 1995).

In contrast, pre-warming patients prior to surgical start has strong evidence in support of implementation, especially patients identified as high risk for post-operative complications. Hooper et al. (2009) found that surgical patients had improved temperature control postoperatively when at-risk patients were pre-warmed prior to anesthesia. Moreover, Horn et al. (2013) found that patients who were warmed for 30-minutes or more prior to anesthesia start had few patients experiencing hypothermia (6%) in PACU compared to patients warmed for 10-

minutes (13%), and with no warming (69%). Horn et al. (2013) found similar results to Burns et al. (2010), who compared the benefit of forced-air warming blankets to passive warming methods (two cotton blankets warmed to 42 degrees Celsius) in surgeries less than 60 minutes (minor) compared to greater than 60 minutes (major). They found no difference related to surgery length, but found more instances of hypothermia occurred in patients who were passively warmed (96%) compared actively warmed (4%). Furthermore, active warming was associated with improved patient comfort and satisfaction with care (Wagner, Bryne, and Kolcaba, 2006; Hooper et al, 2009; Horn et al, 2002; Bock et al, 1998; Leung, Lai, and Wu, 2007). Lastly, all guidelines recommend risk assessment and active warming prior to surgical start. The AORN guidelines (from which UKMC adapts their surgical protocols and guidelines) recommend using a combination of passive-warming and active warming (Bashaw, 2016). Lynch, Dixon, and Leary (2010) found when AORN guidelines were implemented, 75% of patients in the pre-warming group were normothermic upon arrival to PACU. The AORN recommendations demonstrate the capacity to improve practice, so why does UKMC not have a standard hypothermia prevention guideline or protocol?

The UKMC Perioperative Services have yet to establish hypothermia prevention strategies for the adult surgical patient. Moreover, their current practice does not support pre-warming the patient prior to anesthesia induction. As Nurse Practitioners, we are responsible for determining if current practice standards are enough to provide the best quality of care for our patients (AACN Scopes and Standard, 2006, p. 9). The benefit of evaluating risk factors and hypothermia prevalence in at-risk surgical population, like laryngectomies, can provide more evidence to support prevention practices, and support further research. If the findings from Sumer, Myer, Leach, and Truelson (2009) can be recreated at UKMC, one can support research on pre-operative, pre-warming protocol for laryngectomy patients in determining whether the intervention group would have improved post-operative recovery. Multiple studies support the utilization of pre-warming prior to surgical start to improve outcomes (Sessler, 1997; Sessler, 2009; Hooper et al, 2009; Horn et al, 2013; Wagner, Bryne, and Kolcaba, 2006; Hooper et al, 2009; Horn et al, 2002; Bock et al, 1998; Leung, Lai, and Wu, 2007), but in order to have the staff at UKMC Perioperative Services support and follow the protocol, one will have to demonstrate definitive evidence of the prevalence of hypothermia and associated risk factors within laryngectomy patients and independently associate these findings to the lack of hypothermia prevention.

As noted earlier, the study of Sumner et al. (2009), found hypothermia in the laryngectomy population as an independent risk factor for complications during patients' recovery period. This article was the most recent article on the effects of hypothermia on laryngectomy and no recent follow-up research with this population had been done to provide further support of Sumner et al. (2009) findings. As a result, the researcher built on the findings of Sumner et al. (2009) and sought to develop a similar project at the University of Kentucky.

After thorough study of the literature, the goal of this project was to identify risk factors of postoperative complications in a larger, sicker group of laryngectomy population compared to population in Sumner et al. (2009) project. A theory was developed to identify if the following concepts are associated: 1) Laryngectomy patients experience hypothermia more often than normothermia in the operating room, 2) laryngectomy patients at University of Kentucky, within the timeline, experienced a greater percentage of complications compared to the national average, and 3) the patients' length of stay was extended related the complications accrued within their recovery postoperatively.

Purpose

A large body of literature suggests that intraoperative hypothermia (for any amount of time) is an important risk factor for perioperative complications and should be avoided. Hypothermia can be in part prevented by controlling intraoperative temperature through preoperative warming at least 20 minutes prior to their transfer to the operating room. The purpose of this study is to determine whether intraoperative hypothermia in patients undergoing surgical laryngectomy is an independent risk factor for postoperative complications. The findings would help to justify a prospective study of “pre-warming” laryngectomy patients at the University of Kentucky Medical Center. Pre-warming prior for at least 10-20 minutes prior to anesthesia induction was shown to improve intraoperative temperature management and decrease the amount of time a surgical patient was hypothermic (Fettes, Mulvaine & Van Doren, 2013). If that study demonstrates reduced complications, it would confirm benefits of pre-warming to decrease the occurrence of these complications. The questions this project will focus on answering the project aims are the following:

1. Show the sample population’s demographic data
2. Verify hypothermia is occurring in the laryngectomy population
3. Determine the percentage of patients experiencing complications
4. Identify other pertinent risk factors associated with increased risk of postoperative complications
5. Determine if intraoperative hypothermia is a relevant risk factor for development of complications
6. Demonstrate whether hypothermia is associated with prolonging length of stay (LOS)

7. Uncover if patient with/without postoperative complications associated with extended LOS.

Methods

A cross-sectional analysis using a retrospective chart review was conducted on patients that underwent total laryngectomies at the University of Kentucky admitted within the Otolaryngology, Head and Neck Cancer Surgical service line. Data was collected through convenience sample from January 1, 2010 to January 1, 2017 from electronic medical records (EMR) gathered by the CCTS from the KMSF database. The principal investigator (PI) de-identified data using cross-walk table to assign patients' medical record number (MRN) to a research code (i.e. 1-245). The de-identified data was placed into Excel data collection tool and stored on REDCaps protected server. Once the data is collected and entered into the data collection tool, the de-identified excel file will be uploaded into SPSS version 24 statistical software for data analysis with statistical significance to be a p-value of <0.05.

Hypothermia was defined as a ureteral (core) temperature lower than 36 degrees Celsius (AORN, 2016). We evaluated only complications requiring operative intervention within the first 30 days after total laryngectomy. These were readily identified in the medical record by operative diagnoses and procedural coding. Current Procedural Terminology (CPT) codes and intraoperative diagnoses were recorded for analysis. All CPT codes are listed on Table 1. Comorbidity burden was measured using the Charleston Comorbidity Index (CCI), and is valid in evaluating comorbidity risk in laryngectomy patients according to the findings of Singh et al. (1997) and is currently utilized at the University of Kentucky. The goal of the chart review is to determine if correlation are significant among intraoperative hypothermia and the occurrence of postoperative complications.

Setting

The study was conducted at the University of Kentucky Medical Center, Perioperative Services-Otolaryngology Service. The University of Kentucky Medical Center (UKMC) is a Level-1 Trauma Center located in Lexington, KY. The Perioperative Services consist of three practice settings: Preoperative, Intraoperative, and Post Anesthesia Care (PACU) units. Pre-operative and the PACU settings have a combined total of 42 beds, which share space, as needed, for either setting. The intraoperative setting consisted of 26 surgical suites, including one hybrid room (advanced radiography for vascular procedures) and one trauma suite.

Sample

The patient inclusion criteria was: 1) adult patients (18 years of age or older); 2) received a laryngectomy; 3) surgical procedure lasted longer than 60 minutes, and 4) patients were not intentionally hypothermic. The exclusion criteria were: 1) otolaryngology surgical patients not undergoing laryngectomy; 2) children (<18 years of age); 3) surgical cases stopped related to patient deterioration, and 4) post-operative complications occurring greater than 30-days after discharge. We reviewed all patients' charts that were identified as undergoing laryngectomy surgery from January 1, 2010 to January 1, 2017. 305 charts were reviewed. We excluded 59 patients as not meeting criteria leaving 245 laryngectomy patients who meet the inclusion and exclusion criteria.

Features

ENT Clinic to Preoperative Setting. There were three Head and Neck Surgeons who performed all of the surgeries in this study. Each patient was evaluated typically as an out-patient, and at times during an in-patient by the surgeon of record and prepared for surgery.. The preparation was not analyzed as a part of this study. The patient arrives to the preoperative suite two hours prior to surgery, and changes into a hospital gown and a pair of socks, and is given a blanket. Then the preoperative nurse starts the intravenous access, while asking the patient's past and current medical history and performing a physical examination including vital signs and lab review. The surgical team then completes their own history and physical examination, completes surgical consent, and answers the patient and family's questions. The surgical nurse and anesthesia providers then meet the patient in the preoperative setting and ask them appropriate questions to determine their own assessment of the patient's readiness for surgery (i.e. greater than 12 hours since last meal or drink, laboratory results indicating need for prior treatment); confirms that the patient understands the procedure they have consented to; and ensures the patient is free of jewelry, glasses, contacts, dentures, or any other personal effects. Then Anesthesia administers sedation IV Valium (weight-dependent) per protocol and transports to the operating room, which takes an average of 5 minutes, depending on operating room location.

Intraoperative Setting. The operating rooms vary in temperature, and pre-warming rooms prior to adult patient entry is not recommended practice at this time at UKMC. The patient is then placed on a room temperature mattress with or without a new warm blanket. Anesthesia reassesses the patient's vitals prior to anesthetic induction, with repeat assessment after administration of anesthetic. Once the patient is sedated, operating room staff, including Anesthesia attending and certified registered nurse anesthetist (CRNA), surgical scrub tech, circulating nurse, resident, and attending, begin to prepare the patient for surgery. The circulating nurse places a urinary catheter with a temperature sensing probe, and then exposes the patient for surgeons to place markings. While the nurse is working, Anesthesia places an arterial line to better monitor the patient's blood pressure, continually assess their arterial blood gas for changes in ventilator settings, and determines the need for blood administration. Meanwhile, the resident surgeon simultaneously marks the patient for surgical incisions, clips body hair at surgical sites, and injects neck wounds with epinephrine for hemostasis. The site prepared frequently includes the resection site, gastrostomy site and potential sites for free tissue transfer (free flap placement). Up to 50 percent of the body surface area may be prepared, including lower extremity, upper extremity, chest, abdomen, and neck. . This flurry of activity makes application of the forced-air warming blanket quite challenging until late in the preparation process. Lastly, the circulating nurse prepares the patient's skin, over all potential sites and scrubbing skin with room temperature betadine on all exposed areas. At this time, the patient is losing body heat from the effects of anesthetics, causing redistribution of peripheral and core blood, and exposure of a large body surface area to a cold room (between 60-65 degrees Fahrenheit). As soon as the drapes are placed on the patient, the forced-air warming blanket is turned on at 42 degrees Celsius. The time the patient is exposed without warming varies from 45 minutes to an hour. Throughout the procedure, the anesthesia team turns the forced-air warming blanket on and off depending on the temperature readings every 15 minutes. After surgery, warming procedures vary among anesthesia providers; some request the room temperature to be turned up to 70 degrees Fahrenheit, while others simply place a new warmed cotton blanket after the patient is transferred to an ICU bed.

PACU/ICU Setting. Patients are either transferred to the Post-Anesthesia Care Unit settings (PACU) or to their assigned ICU bed. Upon arrival, the patient’s temperature is evaluated along with other vitals. More often than not, patients are placed in a warmed room, and the forced-air warming blanket is utilized only if the patient’s temperature is lower than 37 degrees Celsius. In addition, the patient’s pain is assessed and controlled, and if shivering occurs, it is treated immediately to prevent further pain and stress, which increases the patient’s metabolic demand, and places the patient at risk for cardiac incident.

Data Collection

Approvals from the University of Kentucky Institutional Review Board (IRB) and the University of Kentucky Nurse Research Board were obtained prior to the collection of data. This study was based on a retrospective chart review. Patient charts were obtained from the KSMF electronic patient database. Charts were identified using the CPT codes listed in Table 1. During data collection, patient records were accessed using the patient medical record number (MRN), data was abstracted based on listed variables in Table 2, and data was transferred to an EXCEL spreadsheet. Please refer to Table 2 and Table 3 for a list of variables that were reviewed, which included demographic variables (age, ethnicity, sex, co-morbidity[CCI]),preoperative variables (current smoker [smoke], chemotherapy [CHEMO] and/or radiation therapy [RAD], pre-operative labs [hematocrit {HCT}, platelets{PLT},white blood cells {WBC}, and Albumin {ALB}], overall cancer stage {CA}, intraoperative setting variables (length of surgery [LOS], hypothermia present [Hypo<36C], admission temperature, discharge temperature, 1st hour temperature, 2nd hour temperature, hypothermia time [hypotime], postoperative labs [WBC, HCT, PLT], and postoperative/ outcome variables (postoperative complication [transpharyngeal fistula {TPF}, surgical site infection {SSI}, hemorrhage/hematoma {HEMO}, free flap failure {FFF} and length of stay{LOS}).

Data Analysis

Descriptive statistics, including frequency distributions, means, and standard deviation (SD), median and range were used to describe patients' demographic characteristics, preoperative, and postoperative values. Continuous variables were compared using the Independent Sample *t*-tests. For categorical variables the chi-squared test for independent samples was used. Logistical regression was used to analyze significant predictors of perioperative complications, and determine if the presence of hypothermia during the intraoperative setting would influence patients' risk for developing postoperative complications. All analysis was conducted using SPSS version 24; an [*alpha*] level of .05 was used for statistical significance in all analysis.

Results

Sample Characteristics

A total of 245 patients who met inclusion/exclusion criteria were included in the study. The mean age in the studied population was 59.6 years old, with the majority of patients being white, and three fourths being male (75.1%). The demographic characteristics as to age, sex, ethnicity, smoking status, cancer stage, co-morbidity score, prior treatment with either chemotherapy or radiation therapy, and preoperative lab values are presented in Table 3.

Co-Morbidity Score

Patients' comorbidities were assessed using the Charleston Co-morbidity Index (CCI) score. The CCI score was made into binomial variables. The patients who scored less than five had a greater than 50% chance of survival, while patients scores who scored from five to sixteen has a less than 50% chance of survival after surgery. The laryngectomy patients demonstrated a near equal percentage of patients in either low (*n*=131[53.4%]) and high survival CCI groups (*n*=112 [46.1%]).The CCI predictability of postoperative complications is demonstrated on Table 4. Among the complication groups, odds ratio (OR), 95% confidence interval (95%CI) and p-value were utilized, and only the free flap failure (FFF) group was found to be statistically significant in the presence of CCI (0.85 [0.74-0.98], *p*=0.03) compared to transpharyngeal fistula (TPF), surgical site infection (SSI), and hemorrhage/hematoma (HEMO) complication groups (0.97[0.86-1.08], *p*=0.59; 0.88[0.75-1.03], *p*=0.12). In addition, an independent T-test was preformed to determine the influence of CCI scores when compared with postoperative complications presence for each complication and found no association with complications TPF, HEMO, with exception again to the FFF and SSI variable. CCI was determined to be an significant predictor of FFF when equal variance assumed (*t* [245], *p* =0.04; 95%CIs [2.78—0.07]; *t*[242], p=0.009; 95% CI [0.033-0.24]). T-test results shown on Table 7.

Occurrence of Postoperative Complications

Postoperative complications were treated separately to determine the influence of relevant variables on each type of complication. The percentage of patients experiencing TPF, SSI, FFF, and HEMO is demonstrated in Table 3. When determining the influence of variables on individual complications, logistical regression was performed using only associated risk factors identified in previous studies. The only time covariance assessment differed among groups was when including perioperative lab values. For example, transpharyngeal fistula (TPF) is defined as the formation of a fistula within the pharynx. Prior studies determined this occurred due to initial malnutrition upon surgical date, infection, and decreased tissue perfusion (Sumner et al., 2009; Wulff et al., 2015). In considering these physiologic causes for tissue breakdown, platelet count was excluded, while albumin, hematocrit, and white blood cell count were included. In the same respect, surgical site infections showed similar physiological causes and platelet count was excluded. For free flap failure and hematoma formation, platelet count was included related to complications which disrupt flap perfusion. Poor perfusion to flap occurs when the following are present: thrombosis of flap vessels, anemia, and pressure on main vessels from seroma, abscess, or hematoma formation (Sumner et al., 2009; Ganly et al., 2005). Table 4 demonstrates the findings from significant variables per complication assessed.

The overall percentage of postoperative complication in the laryngectomy population within 7 years was greater than half of laryngectomy patients (157 of the 245; 64%), which is significantly higher than the previous complication studies by Sumner et al. (2009) with a rate of 31.6% overall, Wulff et al. (2015) with a rate of 56.6% overall, and Ganly et al. (2005) with a rate of 28% overall. See Table 3 for individual percentage per complication group. The higher rate of complication could be related to the high percentage of late-stage cancer resection (this study, 83% vs. Sumner et al., 2009, 66.4% vs. Wulff et al., 2015, 14% vs. Ganly et al., 2005, 46%) also known as salvage laryngectomies.

Intraoperative Hypothermia

The prevalence of hypothermia within the study group was 44%. Using an independent sample T-test, significance between hypothermia presence and complication development was analyzed. The test found only TPF and SSI to be significant with the presence of hypothermia when equal variance are assumed (*t* [243], *p* =0.005; 95%CIs [-0.213- -0.038]; *t*[243], p=0.026; 95% CI [0.217—0.014] compared to FFF and HEMO (*t* [243], *p* =0.20; 95%CIs [-0.135- 0.029]; *t*[241], p=0.173; 95% CI [-0.165-0.029].Furthermore, the regression model demonstrated similar findings. Only TPF and SSI were significant findings (2.8 [1.02-12.66], *p*=0.01; 2.44 [0.78-7.58], *p*=0.012) compared to HEMO and FFF (1.58 [0.79-3.18], *p*=0.19; 1.64 [0.71-3.79], *p*=0.25). These results are consistent with previous findings that hypothermia was more highly correlated with TPF and SSI compared to other surgical complications (Wulff et al., 2015 & Ganly et al., 2005). Sumner et al (2009) presented complication findings as binomial (either present or not present) with respect to hypothermia. Influence of hypothermia upon the individual categories studied here was not indicated. However, Sumner et al (2009) found that among a group of 15 patients who experienced hypothermia, 10 experienced complication, which is a 67% occurrence rate within the sample (p=0.002).

Lastly, a Chi-square test was performed on the presence of hypothermia and the rate of each postoperative complication. Again, as indicated in the previous test and model discussed, TPF and SSI were statistically significant (p= 0.005; p=0.03) as opposed to HEMO and FFF (p=0.17 and p=0.20), which were not. These findings affirm data findings by Flores-Maldonado et al., 2001, who noted how hypothermia limits blood, antibodies, platelets from getting to the surgical incision due to vasoconstriction at the microvascular level, and results in limiting the body's natural ability to fight lingering bacteria from migrating to patients' open wound.

Length of Stay

Length of stay (LOS) variable was assessed to determine the effect intraoperative hypothermia had on the laryngectomy patients' recovery To assess LOS, the date of surgery (DOS) and discharge date were recorded. The median LOS was 9 days, range was 73, after adjustment was made to exclude an outlier (*n*=78 days). Even with the exclusion of the outlier, there was no statistical difference in LOS between patients with or without hypothermia (p=0.09), but there was a noted difference among patients who scored into the higher number

CCI group ($p=0.001$) and patients who experienced any of the complication observed in this study (All complications, $p<0.001$). This suggests that all complications studied, with the exception of HEMO ($p=0.61$), were significantly affected by a CCI score of greater than 4, indicating a survival rate less than 50% overall. Furthermore, the 64% of patients who experienced complications in this study had a longer length of stay than the individuals without. Please see Tables 4-8 for additional statistical data.

Discussion

This study aimed to better understand the impact on hypothermia in the intraoperative setting on the surgical patient receiving a partial or total laryngectomy, to discuss the influence hypothermia has on the occurrence of postoperative complications when compared to other noted risk factors, and to determine the prevalence of hypothermia in the population and the potential hazard hypothermia has on the study group. Understanding the findings in this study will promote awareness of the risk hypothermia has on vulnerable populations, and how it should be recognized as a substantial risk in the operating room setting.

Postoperative Complications and Risk Variables

As shown in other research, postoperative complications in the laryngectomy population are a real threat to patients' postoperative recovery and timely discharge from the hospital. As noted earlier in this paper, Flores-Maldonado et al. (2001) wanted to determine if mild hypothermia was a risk factor for surgical site infection after abdominal hysterectomy. They found that a majority of the study population experienced a varied time of mild hypothermia (<36 degree Celsius). Of these patients, 18% experienced surgical site infections, compared to a 2% infection rate in the normothermic group. Furthermore, Duff et al. (2015) noted patients undergoing colorectal surgery for colon cancer experienced more surgical site infections when hypothermia was present in the intraoperative setting and patients with a lower body mass index (BMI) compared to patients who were actively warmed in prior to anesthetic induction (intraoperative hypothermia, $p=0.42$ and lower BMI $p<0.001$). This study corroborates the findings of both Flores-Maldonado et al. (2001) and Duff et al. (2015) on intraoperative hypothermia posing a significant threat to surgical patients in concerns for surgical site infections. This study found statistical significance ($p=0.005$) between patients experiencing any amount of hypothermia and SSI. 25.9% of hypothermic patients experienced a SSI, compared to 15.3% of patients who were normothermic.

A logistical regression model was developed to better determine the independent predictability of hypothermia in evaluating risk of laryngectomy patients experiencing postoperative complication. The model did indicate significant predictability of hypothermia in two of the four complications. The regression model suggests that patients with hypothermia at any point during the intraoperative setting are at a higher risk of developing TPF and SSI ($p=0.01$ and 0.012). HEMO and FFF did not show statistical significance in regards to hypothermia ($p=0.19$ and $p=0.25$). However, HEMO did correlate with the female gender ($p=0.03$) and current smokers ($p=0.02$). This suggests that a female undergoing laryngectomy has a 3-fold greater risk (OR, 3.84, CI, 1.106-13.32), and that individuals who currently smoke, or had smoked in the last 30 days, were at a 2-fold higher risk (OR, 2.54, CI, 1.20- 5.41) of needing additional surgery related to hemorrhage.

Furthermore, a CCI score greater than four and presence of smoking were statistically significant ($p=0.03$ and $p=0.008$) with the development of FFF. The patients with higher CCI scores had a 0.8-fold greater risk of developing FFF than people with a lower CCI score (1-4).

This is logical because patients with more comorbidity (higher CCI score) have less than 50% chance of survival, indicating poorer overall health, increasing their risk for FFF.

The disparity among postoperative complications found in this study compared to others (Sumner et al., 2009; Wulff et al., 2015; Herranz et al., 2010; Ganly et al 2005) demonstrates a clear gap in practice that needs to be contended. If addressed, this may improve patient outcomes. My data points to hypothermia, comorbidity and active smoking as factors that may be areas where changes in practice may lead to improvement in surgical outcomes. Through further assessment of potential practice changes, such as hypothermia prevention rather than treatment, and utilizing prevention measures already used in other institutions (i.e. forced-air warming gown in preoperative), the percentage of laryngectomy patients experiencing complications could be decreased, thereby improving University of Kentucky's patients' LOS and saving the hospital costly surgical procedures and other incurred complication costs not covered by Medicare/Medicaid.

Length of Stay and Risk Variables

Length of stay (LOS) is an important variable to assess. LOS helps the provider determine whether current care practices are meeting patients' needs during their recovery period. The 2017 national average for LOS, noted by Surveillance, Epidemiology, and End Results (SEER)Cancer database, stated laryngectomy patients' LOS around 8-10 days (Howlander et al., 2016). According to the findings of this project, after excluding the outlier LOS (N=78), the average LOS for UKMC laryngectomy patients was 9 days, which is within the national average. As noted earlier, hypothermia did not have a significant effect on the patient LOS (p=0.089). This suggests that hypothermia in the operating room alone had little effect on patients' length of hospitalization. However, hypothermia did increase the laryngectomies patients risk for SSI and TPF, and these complications (along with FFF and HEMO) were found to statistically affect patients' LOS ($p>0.001$). This finding suggest that prevention efforts towards hypothermia occurrence in the perioperative setting would in turn decrease the number of patients experiencing TPF and SSI, thus improving patients outcomes and decreasing the patients recovery time in the hospital (LOS). See table 8 for additional statistical data.

In addition, a patient who experienced FFF, TPF, and SSI and had a higher CCI (greater than 4) score was associated with greater LOS. This was founded after an independent t-test found p-values less than 0.001 in complications, with exception of HEMO. This is consistent with findings from other authors who noted similar correlations among laryngectomy patients and scoring higher on the comorbidity index, with an increased risk for extended LOS (Burns et al., 2010; Alsam et al., 2006; Agrawal et al., 2003).

Limitations

There were limitations identified in the design of this study. Data was collected by reviewing charts retrospectively, and there was no way to verify reported results. The researcher was unable to identify if patients' medical information was correctly entered into their appropriate electronic medical record. This would negatively influence the data distribution in this study, and distort the significance of predictability of risk variables within the studied groups. This includes the charting of intraoperative temperatures by anesthesia. I recorded, admission, 1st, 2nd, and discharge temperatures, but for 62 charts, admission and 1st/2nd hour temperatures were not recorded, and gaps in the data may have biased the significance of hypothermia's effect on the other influencing predictability of the complications assessed. In addition, the electronic medical records (EMR) did not have all of the Anesthesia records needed for the initial 10 year span I wanted to collet, leaving out years 2007 through 2009, or 59 patient charts. This is important because the reduced sample size precluded evaluation of some variables, because the threshold of 10 patients per assessed variable could not be met.

Furthermore, I only assessed smoking prevalence from the records as a yes or no, self-report. I did not go into how many packs per day, or how soon had patients quit smoking prior to surgical date. This would explain the nearly split among smokers vs. non-smokers considering the statistical evidence from the American Health Ranking National Database (2017), indicated that 24.5% of Kentuckians smoke more compared to the 17.1% national average. These limitations would be approached in future research, which will be discussed in the next section.

Recommendations for Future Studies

Recommendations for future study would look into implementing and assessing a pre-warming protocol for patients at-risk for hypothermia in the intraoperative setting as well as developing additional studies from other statistical findings, and no. The researcher would receive IRB approval for paper chart review of hypothermia occurrence over the entire 10 year span that was initially planned. These findings would be used as the historical data and compared to the data collected prospectively after implementation of the protocol. Data comparison would determine whether pre-warming at-risk surgical patients correlated with lower rates of intraoperative hypothermia and fewer postoperative complications. Furthermore, the direct assessment of hospital cost would be beneficial to providing a financial incentive for implementation of a pre-warming protocol in the perioperative setting. Cost evaluation would assess the money saving potential of implementation of the protocol by comparing current cost to the hospitals according to patients' insurance status, LOS, and non-reimbursable-additional surgical procedures. The goal of cost-evaluation would be to show how implementation of a pre-warming protocol would not only be cost saving for the hospital, it would show improved patient outcomes and satisfaction. Lastly, the findings that indicated an three-folds higher risk of complications in female patients versus males would be further assessed. A prospective research project would collect data in laryngectomy patients' gender and compare other covariates for significance. This research project would answer the following questions: 1) What is the laryngectomy sample's gender percentage comparable to other research project sample?; 2) Why do female laryngectomy patients have a higher risk for complications?; 3) What complications are more prevalent in female laryngectomy patients?; 4)What other factors in the female laryngectomy patients would explain this increased risk for hypothermia and 5) does intraoperative prevention measures also decrease incidence of hypothermia in women?

The further research would elaborate on the findings of this study. The goal of further research would be to utilizing these findings to improving patient outcomes and patient satisfaction scores.

Conclusion

The goal of this study is to demonstrate the impact hypothermia has on the outcomes of laryngectomy patients. Over the last seven years, 64% of laryngectomy patients experienced complications, and 44% experienced hypothermia in the perioperative setting. Not all of the assessed postoperative complications in this study were significantly correlated with hypothermia. Hypothermia was only noted as a statistically significant risk factor in patients who experienced TPF ($p=0.005$) and SSI ($p=0.03$). Other risk factors noted as significant were dependent on the patients' complication. Being female increased the patients risk for developing TPF and HEMO (2.5% and 3.8%) compared to male gender. Patients who had undergone radiation were more likely to experience TPF compared to patients who had not received radiation treatments. Patient who had smoked within 30 days of their surgery date were at a higher risk of developing all risk factors, with exception of SSI ($p=0.58$).

Length of Stay (LOS) and postoperative complications were assessed to determine their influence on patients' recovery period. LOS was positively correlated with the occurrence of all complications after surgery, $p>0.001$. These findings suggest that perioperative hypothermia play an important role in patients' risk for complications, this affecting their recovery postoperatively. Further research in this area will help to strengthen the findings noted in this study. Thereby, encouraging medical staff to utilize prevention measures and institute protocols of "pre-warming" preoperatively. By instituting a protocol and continuing the assess whether hypothermia prevention benefits patients, hospitals can improve postoperative recovery, starting with at-risk laryngectomy patients, and further expanding to all surgical patients with noted risk factors.

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Inclusion Criteria List of CPT Codes	
CPT Codes	Diagnosis Definition
39220	Partial Laryngectomy
15757/31390/38724/38525/43219/43246/43030/60512	Total laryngopharyngectomy
31360/31365/38542/38724/43030/42953	Total Laryngectomy, bilateral neck dissection, pectoralis major flap reconstruction
CPT Codes	Postoperative Complications
42953/75989	TPF, fistula repair; salivary bypass tube placement
10180/11043/21501/43200/97605	SSI, I&D for abscess of soft tissues of neck or thorax
35201/35231/31535/35875-35876	FFF, bring back flap
21501/31535/35800/43219/43410	HEMO, Washout/I&D for hematoma of neck or thorax;
TPF=transpharyngeal fistula; FFF-free flap failure; HEMO=hematoma; SSI= surgical site infection; I&D=irrigation and debridement	

Table 1. Inclusion Criteria List of CPT Codes

List of Variables per Category	
Category	Variables/Measures
Demographic /Preoperative Variables	
Age	age of participants in years
Ethnicity	African American/Black, Caucasian/White, Asian, Other
Cancer Stage	overall cancer stage (I-VI); 1=early stage, 2=advance stage
Co-morbidity	CCI score
Sex	male, female
Smoking Status	yes or no
Prior Radiation	yes or no
Prior Chemotherapy	yes or no
Pre-op Labs	HCT, ALB, PLTWBC
Operative Variables	
Hypothermia Occurrence	Yes or No; AD 1, 2, and DC
Hypothermia Time	measured in minutes; At <36 Celsius
Length of Surgery	measured in minutes
Intraoperative Warming Present	yes or no; [warming blanket]
Post-Op Labs	HCT, ALB, PLT, WBC
Outcome Variables	
Prevalence Rate	prevalence of hypothermia in surgical laryngectomy
Relevant Risk Factors	identify independent risk factors for postoperative complications intraoperative laryngectomy patients
Service use	LOS, unexpected surgeries
Patient Postoperative Outcomes	types of postoperative complications and types: surgical site infection irrigation and debridement; neck washout) vs. hematoma development (exploration hematoma and/or hemorrhage); vs. tracheopharyngeal fistula (transpharyngeal fistula repair) vs. free- or local flap failure (bring-back flap)
Notes: Charlson Comorbity Index (CCI), length of stay (LOS), preoperative (pre-op), postoperative (post-Op), hematocrit (HCT), albumin (ALB), platelets (PLT), white blood cell (WBC); operating room (OR); discharge (DC); admission (AD)	

Table 2. List of Variables per Category

	Mean (SD) or *n* (%)
Age	59.6(9.8)
Sex Male Female	 184 (75.1%) 61 (29.9%)
Ethnicity White Black Hispanic Other	 232(94.7%) 12(4.9%) 0(0%) 1(0.4%)
Smoke (last 30-days) Yes No	 120(49%) 125(51%)
CCI Score (1=>50% survival;2=<50%survival) 1(0-4) 2 (5-16)	 131(53.2%) 112(46.1%)
Cancer Stage 0-2 3-4	 40 (16.3%) 204 (83.3%)
Rad Yes No	 150(61.2%) 95(38.8%)
Chemo Yes No	 106(43.3%) 139(56.7%)
Preoperative labs WBC HCT PLT ALB	 11.3(5) 32.9(5.6) 243.3(97.1) 2.9(3.2) (missing 139)
Postoperative Labs WBC HCT PLT	 13.5(5.1) 29.8(5.2) 229.6(85.6)
Length of Surgery	542 (167.749)
Admission Temp	36.7 (0.4198)
1st hour Temp	36.2(0.6296)
2nd hour Temp	36.2(0.6027)
Discharge Temp	37.3(3.9476)

IO hypothermia	
Yes	108(44.1%)
No	137(55.9%)
Hypothermia Time	52.18 (80.434)
TPF	
yes	35(14.3%)
no	210(85.7%)
SSI	
Yes	50(20.4%)
No	195(79.6%)
Hemo	
Yes	43(17.6%)
No	202(82.4%)
FFF	
Yes	29(11.8%)
No	216(88.2%)
Length of Stay	Median (Range)
	9 (73)

Table 3. Demographic and clinical characteristics of study patients (N=245)

	TPF		SSI		HEMO		FFF	
	OR (95% CI)	p	OR(95 %CI)	p	OR (95%CI)	p	OR (95%CI)	p
Hypothermia present: yes vs. no	2.80(1.02-12.66)	**0.01**	2.44(0.78-7.58)	0.**012**	1.583(0.788-3.182)	0.19	01.64(0.71-3.79)	0.248
Age	0.974(0.98-1.07)	0.24	1.02(0.97-1.08)	0.52	0.10(0.96-1.03)	0.80	0.98(0.93-1.06)	0.24
Sex: Female vs. Male	2.55 (1.11-5.87)	**0.03**	1.60(0.48-5.31)	0.45	3.837(1.106-13.31)	**0.03**	1.2(0.46-3.22)	0.69
Cancer stage: 0-2 vs. 3-4	0.34(0.07-1.60)	0.17	0.26(0.03-2.5)	0.24	0.68(0.24-1.97)	0.49	0.21 (0.03-1.64)	0.14
CCI: 0-4 vs 5-16	0.97 (0.86-1.08)	0.59	0.88(0.75-1.03)	0.12	1.073(0.916-1.258)	0.38	0.85(0.74-0.98)	**0.03**
Radiation: Yes vs. No	0.35(0.12-1.04)	0.06	1.50(0.36-6.23)	0.58	0.569(0.500-3.527)	0.57	0.76(0.24-2.40)	0.64
Chemo: Yes vs. No	1.89(0.42-8.43)	0.41	1.07(0.29-3.89)	0.92	1.43(0.59-3.50)	0.43	0.670(0.149-3.006)	0.60
Smoking: Yes vs. No	2.34(1.0-75.47)	**0.05**	1.36(0.45-4.12)	0.58	2.54(1.20-5.41)	**0.015**	3.427(1.372-8.560)	**0.008**
Preoperative WBC	1.02(0.95-1.09)	0.63	1.13(1.00-1.27)	**0.04**	N/A	N/A	1.67 (0.99-1.15)	0.09
Preoperative HCT	0.91(0.25-1.07)	0.26	0.54(1-.45)	0.54	0.99(0.93-1.06)	0.96	0.99(0.94-1.15)	0.43
Preoperative PLT	N/A	N/A	N/A	N/A	0.997(0.993-1.002)	0.23	0.1(0.98-1.00)	0.14
Preoperative ALB	01.46(0.319-6.30)	0.65	0.24(0.03-1.59)	0.14	0.54(0.09-3.04)	0.57	0.73(5.9-0.89)	0.57
Length of Surgery	1(1-1.00)	0.93	1(0.1-1.0)	0.931	1(0.97-1.00)	0.82	1 (0.99-1.00)	0.41

Table 4. Logistical Regression Model: Postoperative complications vs. Corresponding variable; {Overall Risk (OR) and 95% Confidence Interval (95%CI) measured p-value <0.05 considered statistically significant; TPF-transpharyngeal fistula, SSI-surgical site infection, HEMO-hemorrhage/hematoma, and FFF- free flap failure.}

	TPF		SSI		HEMO		FFF	
	Y	N	Y	N	Y	N	Y	N
Hypothermia present: (%with hypo) Y	21.3%	8.8%	26.9%	15.3%	21.3%	14.6%	14.8%	9.5%
P	0.005		0.03		0.17		0.20	

Table 5. Chi-square: Percentage of patients with/without complications in the presence of hypothermia .{Transpharyngeal Fistula (TPF) and Surgical Site Infection (SSI) had significant p-value (<0.05) Indicating more patient who experienced hypothermia had higher rate of TPF and SSI compared to normothermia.}

	TPF		SSI		HEMO		FFF		LOS	
	df	95%CI	df	95%CI	df	95% CI	df	95%CI	df	95%CI
Hypothermia present: (%with hypo) Y	243	-0.213 - - 0.038	243	-0.217- -0.014	243	-0.163 -- 0.029	241	-0.163- 0.029	241	-0.299 -4.196
P	**0.005**		**0.03**		0.17		0.20		0.089	

Table 6. Independent sample T-Test: Postoperative complications occurrence and LOS with hypothermia; {Equal variance assumed for all; p-value <0.05; Findings suggest that transpharyngeal fistula(TPF) and Surgical Site Infection (SSI) are more likely to occur in patients who experience hypothermia in the perioperative setting.}

	TPF		SSI		HEMO		FFF		LOS	
	df	95%CI	*df*	95%CI	*df*	95%CI	*df*	95%CI	*df*	95%CI
CCI: survival rate less than 50% 2	32	-0.213- -0.038	32	-0.217- - 0.014	32	-0.163-- 0.029	32	-0.163- 0.029	32	-0.299 - 4.196
P	**0.000**		**0.000**		0.612		**0.000**		**0.001**	

Table 7: Independent sample T-test: Postoperative complication correlate with CCI score of 2 {CCI score of 2 (less than 50% survival rate); Equal variance assumed only for LOS. Transpharyngeal Fistula(TPF), Surgical Site Infection (SSI), Free Flap Failure (FFF), and Length of Stay (LOS) were more likely to occur in patients with a higher comorbidity rate.}

Complications	Length of Stay	P-value
	Median (IQR)	
Transpharyngeal Fistula		
Yes	19(11-29)	**<0.001**
No	8(7-11)	
Surgical Site Infection		
Yes	18(10-25)	**<0.001**
No	8(7-10)	
Hemorrhage/Hematoma		
Yes	16(9-25)	**<0.001**
No	8(7-11)	
Free Flap Failure		
Yes	14(9-30)	**<0.001**
No	8(7-12)	

Table 8. 2 Independent-Sample T-Test & Descriptive Statistics: Length of stay (LOS) for patients with /without complications {Descriptive statistics comparing LOS median and interquartile range (IQR) within groups with/without complication; 2 Independent -Sample T-test for p-value; All complications were within a p-value <0.05 and found statistically significant}

Appendix i. IOWA Evidence Based Model