

Evaluation of a protocol for pediatric thyroidectomy guidelines to diminish post-operative
hypoparathyroidism medication use.

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Abstract

Introduction/Purpose:

The purpose of this retrospective study is to compare patients who received early preventative treatment in patients identified at risk for hypocalcemia, while avoiding treatment in those patients found to be normocalcemic.

PICOT

In pediatric patients who underwent a total thyroidectomy at Valley Children's Hospital (VCH), can implementation of post-operative hypoparathyroidism disease management guidelines decrease the amount of prescribed calcium and calcitriol.

Methods:

Approval for study and waiving of informed consent was obtained from the Institutional Review Board at Valley Children's Hospital (IRB No. HSC2297) and The University of Alabama in Tuscaloosa (IRB No. 20-07-3767). This was a retrospective chart review study. Medical records of all patients undergoing a Total Thyroidectomy at Valley Children's Hospital between August 2018 – January 2021 were reviewed (N = 41).

Exclusion Criteria: Age >21 years old, history of chronic renal insufficiency, patients taking medications known to affect calcium or PTH levels, known pre-operative hypocalcemia, and those who already have hyperparathyroidism or hypoparathyroidism

Statistical Analysis: Parathyroid hormone levels and calcium levels were recorded as well as if there was medication use. The Fisher- Freeman-Halton exact test was used to evaluate medication in 4 separate groups.

Results:

Of the 41 patients that underwent total thyroidectomies, 25 (61%) of the patients did not need medication. Medication use was separated in to 4 possible outcomes. The variable $PTH \leq 10 \text{ pg/mL} + S. \text{ Calcium} < 8 \text{ mg/dL}$ (A), $PTH \leq 10 \text{ pg/mL} + S. \text{ Calcium} \geq 8 \text{ mg/dL}$ (B), $PTH > 10 \text{ pg/mL} + S. \text{ Calcium} < 8 \text{ mg/dL}$ (C), $PTH > 10 \text{ pg/mL} + S. \text{ Calcium} \geq 8 \text{ mg/dL}$ (D). In B and D group variables it was proven to have a statistical significance where $p < 0.001$. However, A and C groups we cannot compare because there was only 1 patient within that group and the sample size is too small.

*Due to the coronavirus pandemic a retrospective chart review was the only avenue open for data collection

Discussion:

Children may undergo a total thyroidectomy for hyperthyroidism, thyroid nodules, or thyroid cancer. One of the most common complications following a total thyroidectomy can be permanent hypoparathyroidism. The primary role of parathyroid hormone (PTH) is to regulate calcium levels. Post-operative PTH alone does not predict hypocalcemia in patients undergoing a total thyroidectomy and thus calcium levels would also need to be done. Prior to the initiation of the 2018 guidelines, patients were prescribed prophylactic calcium and calcitriol after a total thyroidectomy. In general, our body needs calcium to help with bone mineralization, blood clotting factors and the contraction of muscles. Too much calcium can cause a child to have kidney problems, muscle weakness and increase their risk of fractures

Keywords: post-operative hypoparathyroidism, thyroidectomy, hypocalcemia, calcium and PTH

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Evaluation of a protocol for pediatric thyroidectomy guidelines to diminish medication use.

Introduction

Patients who undergo a total thyroidectomy will be on lifelong thyroid hormone replacement. In addition, there are risk factors that go along with having thyroid surgery. One of the risk factors is developing post-operative hypoparathyroidism. Prior to August 2018 patients that underwent a total thyroidectomy at Valley Children's Hospital (VCH) would prophylactically be put on calcium medications such as calcium carbonate and calcitriol. To reduce unnecessary medication usage, I will do a retrospective chart review measuring the use of parathyroid hormone (PTH) and calcium levels at four hours post total thyroidectomy.

Background

Children may undergo a total thyroidectomy for diagnoses that includes hyperthyroidism, thyroid nodules, or thyroid cancer. One of the most common complications following a total thyroidectomy can be permanent hypoparathyroidism. The primary role of PTH is to regulate calcium levels. In the literature it has shown that post-operative PTH alone can predict hypocalcemia in patients undergoing a total thyroidectomy but also having calcium levels would further confirm the hypothesis. Prior to the initiation of the 2018 guidelines at VCH, patients were prescribed prophylactic calcium and calcitriol after a total thyroidectomy. In general, our body needs calcium to help with bone mineralization, blood clotting factors and the contraction of muscles. The problem is prescribing unnecessary medications to pediatric patients. Too much calcium can cause a child to have kidney problems, muscle weakness and increase their risk of fractures. There are adult guidelines for patients undergoing a thyroidectomy in the United States (US) but there have not been any official guidelines for pediatric patients in the US.

Problem Statement

The purpose of this retrospective study is to compare patients who received early preventative treatment in patients identified at risk for hypocalcemia, while avoiding treatment in those patients found to

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be normocalcemic. There has been a limited number of studies done in children that identify early use of PTH hormone to prevent medication use.

Hypothesis

The null hypothesis is that there was no significant difference between serum PTH and calcium levels 4 hours post total thyroidectomy without calcium administration post-operatively.

Measuring post-operative PTH levels following surgery does not predict hypocalcemia in patients undergoing a total thyroidectomy.

The alternate hypothesis is that there is a significant difference between serum PTH and calcium levels 4 hours post total thyroidectomy without calcium administration post-operatively as indicated by a p-value of <0.05 .

Gap Analysis

Currently at many hospitals the standard of care is to give patients prophylactic calcium following a total thyroidectomy. At VCH there have been 41 total thyroidectomies since August of 2018. Part of the gap is that many hospitals do not have the capability of doing PTH labs at their facility. Due to the literature VCH decided to purchase the machine and start doing PTH labs at the hospital instead of sending them to an outside facility. By sending them to an outside facility, the PTH would not be resulted for 2-3 days. By that time, many patients were already discharged and at home on supplemental medication. Typically, the provider would start weaning the patient off the calcium at their next visit anywhere between 2-6 weeks post-operatively. The end goal is to ensure that with early PTH monitoring patients will not be prescribed unnecessary medications. Best practice guidelines ensures that in-house PTH monitoring is a must to accurately predict if they need medication or not.

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Review of the Literature

An initial database search using post-operative hypoparathyroidism, thyroidectomy, calcium and PTH in CINHAL database only yielded 2 articles. I then changed my database search to intraoperative PTH and calcium levels and 46 articles populated. Using exclusion criteria (within last 5 years) only 22 articles remained. With more diagnosis than the ones I reviewed I further isolated it down to post-thyroidectomy or post-surgical. I used the same search words in EBSCO, and it yielded only 3 journal articles. When I removed post-operative hypoparathyroidism, I had 360 articles to choose from, but a majority did not have to do with my project. I added hypocalcemia and pediatrics and 29 articles remained. Exclusion criteria for articles included surgery for the parathyroid gland as that was not relevant to a total thyroidectomy. In addition, many articles discussed PTH as a measurement, but it involved other types of surgeries than the total thyroidectomy.

Currently management for post-operative guidelines have been presented in monitoring serum calcium and PTH levels. The levels would be monitored at 4 hours post-operatively and on day 1 following the thyroidectomy. Hypocalcemia is defined as a serum calcium level <8 mg/dL. Symptomatic hypocalcemia is defined as presence symptoms that range from mild to moderate: tingling, paresthesia, muscle cramps, and carpopedal spasm. Severe hypocalcemia symptoms are defined as seizures, tetany, mental status changes, and laryngospasms. If a patient with PTH levels >10 pg/mL and calcium levels >8 mg/dL they will not be started on calcium or calcitriol per the post-operative guidelines.

Calcium is generally prescribed 4 times a day and issues with compliance can be a problem. One of the main arguments for prophylaxis treatment with calcium and calcitriol is that it is more cost-effective (Wang, Cheung, Roman, & Sosa, 2011). However, cost-effective is not the best evidence-based practice outcome for a patient. By utilizing guidelines postoperative PTH levels following a thyroidectomy would allow the patient to be safely discharged sooner without unnecessary treatment (AES guidelines, 2007). Thus, being discharged sooner would allow for a shorter hospital stay and can reduce the overall cost.

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According to Overman, Hseih, Menon, Thomas and Bruch (2020), their results did show that 4-hour PTH levels after surgery can predict hypocalcemia and prophylactic medication would not be recommended. In their study (N=56) they also found that by early identifying those that do not need calcium supplementation they reduced the number of times the child had to get lab work done.

The American thyroid Association (ATA) systematic review position statement of post-thyroidectomies states that “early postoperative intact PTH levels following thyroidectomy can help guide patient management” (Orloff et al., 2018). The initiation of early PTH can decrease the amount of unnecessary treatment. The most common complications after thyroidectomy are endocrine related and include transient or permanent hypoparathyroidism, with an average rate of approximately 30-40% with the majority transient (Kundel et. al., 2014; Morris et al., 2012). That number is statistically high and translates to an overwhelming number of children put on unnecessary medication.

Patients following a total thyroidectomy who had normal PTH level (>1.6 pmol/l or >15 pg/ml) on day 1 did not develop permanent hypoparathyroidism (Almquist, Hallgrimsson, Nordenström & Bergenfelz, 2014). This study did take place by measuring labs within 24 hours. This could lead to longer hospital stay by waiting to measure later.

In one study that had 77 patients, a PTH level ≥ 10 pg/mL drawn at 4 hours post operatively was accurate in identifying patients that needed calcium and the level was accurate in providing same-day discharge (Carr et al., 2014). Of those 77 patients, 21 need calcium supplementations. This study only used 4-hour PTH and did not include calcium levels. This study did prove that PTH levels alone can be of statistical significance. Another study decreases the time the PTH level was drawn and suggests that measurements of PTH 1-hour postoperatively was a strong predictor of postoperative hypocalcemia (Almquist, Hallgrimsson, Nordenström, & Bergenfelz, 2014). With 1-hour PTH as a predictor the patient could ultimately be discharged same day, off medications, and no cost to be admitted to the hospital. The literature all leads to

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postoperative PTH as a strong predictor of post-operative hypocalcemia and is useful in preventing patients from being prescribed unnecessary medications.

The intervention of initiating adult guidelines postoperatively will help to add to the few studies that are done on pediatric patients. Peker et al.(2020), found that using PTH and calcium levels together could help predict hypocalcemia. Similarly, to the previous studies only 7 of the 57 patients developed permanent hypoparathyroidism following a post-operative thyroidectomy (Pecker et al., 2020).

Based on the finding's early utilization of PTH and calcium levels have shown to be an important tool in decreasing the amount of calcium and calcitriol prescribed. In the literature we see that some studies compare PTH levels only and some compare calcium levels. One thing that is consistent regardless of the study is that early utilization of PTH has shown to be important tool in predicting the need for calcium medications. The time when the PTH was drawn does not appear to be of significance whether it is 1 hour, 4 hours or 12 hours, the criteria is that it was within twenty-four hours of surgery. Despite the current literature many patients are still being discharged in the US with calcium supplementation.

Evidence-based Practice

Based on the literature that was presented in adults and children, there would be a benefit to measuring PTH and calcium levels following surgery. In pediatric patients who underwent a total thyroidectomy at Valley Children's Hospital (VCH), can implementation of post-operative hypoparathyroidism disease management guidelines decrease the amount of prescribed calcium and calcitriol. The retrospective study done at VCH following a total thyroidectomy measured calcium and PTH levels drawn at 4 hours. The parameters for the low threshold of lab level were if the PTH level is >10 pg/mL and calcium ≥ 8 mg/dL then the patient will be sent home and discharge will be initiated early (Cannizzaro, Okatyeva, Lo Bianco, Caruso, & Buffone, 2018).

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Theoretical Framework

Jean Watson's caring theory discusses transpersonal caring relationships, caring moment, multiple ways of knowing, the 10 carative factors and reflective approach. The theory takes a family centered approach which is important for a project working with children. When working with children and disease processes there are always another factor that plays a role in the child's health and that is the parent. The care provider and pediatric patient evolves from the encounter with the nurse (Butts & Rich, 2018, p. 549). The child and their family are one unit and whether medication is needed or not follow up care is needed. The caring theory will help guide my project by incorporating the family and patient in the care plan. By understanding the family's health needs it will lead to better care, expectations and ultimately if we are able to identify a pattern where a patient does not need medication it will further benefit the child.

10 carative factors

The 10 carative factors from Jean Watson's theory are: the formation of a humanistic-altruistic system of values, the instillation of faith-hope, the cultivation of sensitivity to one's self and others, the development of helping-trust relationship, the promotion and acceptance of the expression of positive and negative feelings, the systematic use of scientific problem solving methods for decision making, the promotion of interpersonal teaching-learning, the provision for a supportive, protective, and (or) corrective mental, physical, sociocultural and spiritual environment, assistance with the gratification of human needs, and the allowance for existential-phenomenological forces (Ryan, 2005). The carative factors allow the patients to discuss their feelings and have the advanced practice nurse (APN) encourage those expressions.

In addition, one of the reasons to have a total thyroidectomy is due to thyroid cancer. There are 4 types of thyroid cancer which include, papillary, follicular, medullary and anaplastic. Depending on the type of cancer, most often papillary thyroid cancer, the treatment is less invasive due to the slow growing cancer. A more aggressive form of cancer like follicular can often metastasize and other treatment options are needed. With follicular cancer, the survival rate decreases to 80% because it often has spread to lymph nodes or the

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lungs at time of diagnosis. The instillation of hope and faith helps the family in a time of cancer diagnosis. We may not know the answer to what is going to happen, but we must allow the patient to get well and give them dignity. Early utilization of PTH and calcium levels can help to ensure that they do not have yet another diagnosis to add to their care plan (see Appendix A).

Transpersonal caring

Allowing spiritual environment and the patient being one ties in with transpersonal caring. The family and patient can have complete autonomy and can express their feelings as to which treatment plan they feel is best for the patient. Taking the time to explain the procedure and the results with standard practice fulfills the family's needs and promotes a teaching and learning experience. Transpersonal caring and coming together with the patient and the family to embody and accept the treatment process.

Multiple ways of knowing

Through early lab utilization we have developed tools that we could use to detect post-surgical hypoparathyroidism. The early diagnosis of post-surgical hypoparathyroidism leads us to allow better care and that was done through science. Ethics is a huge part of multiple ways of knowing and nursing care in general. As APNs we take an oath to hold the best care and ethics for our patients. Incorporating that into our care is an everyday process that has been instilled in every nurse.

Reflective Approach

As an APN we seek to define how we were able to change or make a difference in our patient's health and our own. I would reflect that I did make a difference in my patients' life in a positive and spiritual way. One's own health and wellness is equally important in Jean Watson's caring theory. To care for your patient, the APN must be of sound mind on their own in order to carry out the theory-based practice.

Goals, Objectives, and Expected Outcomes

Identifying patients that need a total thyroidectomy is the first step to produce an outcome. Once the patient is determined to need a total thyroidectomy then they will be evaluated, and all possible risks are

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explained. The PTH and Calcium results combined will show the 4 possible outcomes. The general surgeon or the Ear, nose and Throat (ENT) doctor will do the surgery and order the labs specified. The labs are measured into 4 specific categories. Refer to table 2 for the possible outcomes. All these outcomes would correlate with Jean Watsons caring theory and promoting healing with the mind and body. The PTH and calcium levels are specifically drawn at 4 hours post-operatively.

Methods (Plan)

In August of 2018, Valley Children's Hospital (VCH) started monitoring post-operative parathyroid hormone and calcium levels. To start to identify patient I searched using the International Statistical Classification of Diseases and related health problems (ICD) codes. Due to the timeframe ICD-10 codes with post-operative hypothyroidism from August 2018 to January 2021(N=41) were populated. I then recorded the calcium, PTH levels drawn at 4 hours following a total thyroidectomy and a medication column that would identify if they did or did not get started on medication. Other information that was collected was date of birth and sex that could later be used for further analysis. The time and date the lab was ordered was collected, along with the lab result, and date of surgery. Approval for the study and waiving of informed consent was obtained by the IRB at VCH (IRB No. HSC2297) and The University of Alabama in Tuscaloosa (IRB No. 20-07-3767). The following exclusion criteria was used: Age >21 years old, history of chronic renal insufficiency, patients taking medications known to affect calcium or PTH levels, known pre-operative hypocalcemia, and those who already have hyperparathyroidism or hypoparathyroidism.

The research data was collected on an excel work sheet that helped organize the data. Data was collected by manual chart audits and was stored on Valley Children's Hospital password protected computer. The data was de-identified, and a codebook was created for further analysis at California State University, Fresno statistics lab. As this study was a retrospective chart review no ethical considerations would need to be evaluated.

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Project Design

The type of project that I am implementing is a practice intervention project. We hope to change the clinical practice at VCH and make it a standard when treating kids who undergo a total thyroidectomy. The quantitative data is measurable based on the findings. The project will evaluate if early utilization of PTH and calcium levels will be useful. Labs are typically ordered following a post thyroidectomy and there is no extra labs that will be needed or more harm to the patient.

Project Site and Population

Children under the age of 21 years old is the chosen population for my project. The data is lacking due to the smaller number of patients, their rapid growth over the years, and any possible risks to the patients. The site location of where the total thyroidectomies was done was at Valley Children's Hospital (VCH) in Madera, CA. VCH currently serves twelve counties and covers the entire middle of the state of California. The population served is primarily 80 percent medical insurance and is greatly underserved. The average education level of the parent is third grade level. The importance of Jean Watson's caring theory is significant because giving unnecessary medication to lower education population are components of the caring theory and is imperative for appropriate treatment outcomes.

There are no recruitment strategies. Inclusion criteria includes patients (ages 0-21 years) who underwent a total thyroidectomy from August 1, 2018- January 21, 2021 at VCH. Exclusion criteria includes patients with chronic renal insufficiency, patients taking medications known to affect calcium or PTH levels, known pre-operative hypocalcemia, and those who already have hyperparathyroidism or hypoparathyroidism.

This is a retrospective chart review without any intervention or interaction with the patients and families involved. This information was part of the standard of care for these patients. Therefore, assent would not need to be obtained. There were 41 patients included in the sample study. The sample size that I originally would have liked was 50 and that was listed in the Institutional review board (IRB). However, when the coronavirus pandemic started in March 2020 all surgeries that were not emergencies would not be

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performed. There were only a few patients during that time when the previous year there was a significant amount.

Electronic medical records of children undergoing the surgery were reviewed from the ICD-10 codes. The code book on the excel spreadsheet has a deciphered password. The code book was stored in a separate drive. All participating patients will also be de-identified and assigned an identification number. No internal identifiers were shared with any external collaborators or national registries. Data was only be shared with the statistic team. Any published data will only be aggregate data.

The current practice is after a referral for a total thyroidectomy is initiated a nurse within the practice with add the patient to their database that was specifically created. The surgeon (ENT or general surgery) will then order the post-operative labs as a standard set of labs. The organization is excited about the project as it can prove the cost-effectiveness of their new laboratory equipment and that the patient is receiving the best care. There will be no interaction with patients for this study as they do not need to give consent.

Barriers

One of the main barriers is that there are not always the same surgeons that are doing the total thyroidectomy. By having the same surgeon, we can also remove the bias of some skill sets. Some of the problems that was faced early on was that labs were not always ordered correctly and there were inconsistencies in time. To overcome the barriers a committee was formed and 1-2 physicians within the ENT and general surgery practice would do the total thyroidectomies. The outcome was implemented and there was a change and now labs are drawn appropriately. By implementing these changes and having consistency we did see an improvement (see Appendix B).

Measurement Instruments

The data that was collected included demographic data and was recorded. The instruments used was laboratory data that was recorded, calcium and PTH levels. Calcium and PTH levels were documented into an excel spreadsheet. There was no specific tool that was created besides headers and columns in the excel

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spreadsheet.

Data Collection Procedures

Initially the idea for implementation of these guidelines came when I was having issues with compliance of patients taking multiple calcium tablets a day. Sitting down and educating the families about the possibility of not needing the medications I could see that they were relieved. I would often get asked “why even prescribe the medications if it is not needed?” After further research and finding that I could come up a solution, I became aware that there was a significant need for PTH to be resulted in the hospital.

Currently, the PTH level can be resulted within 30 minutes from the time that it was received in the lab.

Plan

As stated, the problem was prescribing unnecessary medication to pediatric patients. It was further found that by utilizing PTH and calcium levels could play a key role in reducing the amount of medication prescribed.

The plan was to start 4-hour measurements of PTH and calcium levels and creating a protocol.

Do

For this part of the project, guidelines needed to be established for laboratory measures. After looking at the literature we ultimately decided on the parameters of when to start treatment. The people involved were myself as the principal investigator and the statistics team that would run my analysis.

Check

During this stage I began to collect data over a 4-month period. The data that I recorded would be PTH and calcium levels at 4 hours post-operatively. In addition, whether they were started on medication, date of birth, sex, and date of surgery were also all recorded.

Act

Forming a committee and standardizing the protocol was the final part. After reaching parameters and establishing how and when the labs would specifically be ordered we were able to move forward.

Informed consent was not necessary as there was no extra labs that were ordered and no harm to the patient.

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I received approval from VCH IRB to conduct my study (see Appendix C).

Data Analysis

Parathyroid hormone levels and calcium levels were recorded at 4-hours post thyroidectomy and as well as if there was medication use. The Fisher- Freeman-Halton exact test was used to evaluate the variables and categorize if there were medication use or not.

There were (N=41) patients charts that were reviewed. A retrospective study can have some bias as there can be discrepancies in when the labs were ordered as different surgeons are performing the surgery. For the analysis we only used labs that were drawn at 4 hours postoperative. PTH levels were categorized based on above or below 10. In addition, levels that are above or below 8 were also categorized.

This test was important because we had 4 separate variable groups. The 4 variable groups are PTH ≤ 10 pg/mL + Serum Calcium < 8 mg/dL (A), PTH ≤ 10 pg/mL + Serum Calcium ≥ 8 mg/dL (B), PTH > 10 pg/mL + Serum Calcium < 8 mg/dL (C), PTH > 10 pg/mL + Serum Calcium ≥ 8 mg/dL (D) (see table G2). Reviewing the 4 groups there was only 1 patient in categories B and D. There was not enough data to analyze those categories but it was significant to show.

Cost-Benefit Analysis/Budget

There was no cost to the principal investigator or to the participant. The hourly wage for the advanced nurse practitioner are \$65 per hour. The amount of time to do data collection total was 80 hours total. There was no cost to have the team do the analysis as the stat team volunteered their time to my clinical site. (See Appendix D). No external funding was needed.

Timeline

In the Spring semester of 2019, I began my project implementation. My initial DNP project proposal started and was submitted to my faculty preceptor in Fall 2019. In the spring semester of 2020, I began to prepare my IRB application for the institution- VCH where I would conduct my project and The University of

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Alabama. The University of Alabama IRB was approved in August 2020 along with the VCH IRB. Data collection began immediately starting at the end of August 2020 and lasted until the end of October 2020. Data analysis started in November 2020 and due to the coronavirus pandemic, it was delayed, and it was resulted at the end of February 2021. Because the data analysis was postponed, 1 more patient was able to be added to the analysis. The findings of the data analysis were discussed and submitted in Spring 2021 (See Appendix E).

Ethical Considerations/Protection of Human Subjects

The University of Alabama (UA) Institutional Review Board (IRB) approval will be obtained prior to initiating the project. The only risk is loss of confidentiality with retrospective chart reviews. In order reduce this data will be collected using the least amount of information necessary. The data will be stored on the hospital intranet drive in a secured password-encrypted document which only investigators and designated research staff will have access to. The research will be put on a codebook. No patient identifiers will be linked to the data. Each patient will be given a study identification number to represent the data gathered from the patient's records. Once the information is quantified the data will be destroyed. Potential benefits of this retrospective study show that by doing clinical and biochemical evaluations we can reduce and avoid treatment in those who remain normocalcemic following a total thyroidectomy. The research presents no greater than minimal risk to children (See Appendix F).

All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other guarantees, protects the privacy of patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). Additionally, Standards of Care for practice in a primary care office were carefully followed. All information collected as part of evaluating the impact of this project was aggregated data from the project participants and did not include any potential patient identifiers.

The risk to patients participating in this study was minimal and a waiver of patient authorization for

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the use of protected health information was requested and granted. The study procedures do not adversely affect the rights and the welfare of the individuals and pose minimal risk to the patients.

Results

Of the 41 patients that underwent total thyroidectomies, 25 (61%) of the patients did not need medication. Medication use was separated in to 4 possible outcomes. The variable $PTH \leq 10 \text{ pg/mL} + \text{Serum Calcium} < 8 \text{ mg/dL}$ (A), $PTH \leq 10 \text{ pg/mL} + \text{Serum Calcium} \geq 8 \text{ mg/dL}$ (B), $PTH > 10 \text{ pg/mL} + \text{Serum Calcium} < 8 \text{ mg/dL}$ (C), $PTH > 10 \text{ pg/mL} + \text{Serum Calcium} \geq 8 \text{ mg/dL}$ (D). In B and D group variables it was proven to have a statistical significance where $p < 0.001$. However, A and C groups we cannot compare because there was only 1 patient within that group and the sample size is too small to even yield statistical significance. Of the 41 patients, 21 (51%) were diagnosed with cancer, 9 (22%) had thyroid nodules, and 11 (27%) had their thyroid removed due to hyperthyroidism.

Descriptive statistics were discussed in Table G1 and the average mean age was 14.5. Table G1 discussed descriptive statistics. Twenty- nine patients had PTH levels above 10 pg/mL. In addition, patients that need lymph node dissection due to the thyroid cancer are at a higher risk for developing post-operative hypoparathyroidism. Half of the patients did have a total thyroidectomy due to thyroid cancer and 8 of those patients needed lymph node dissection. The gender of the patients did not appear to be significant. Age can also play a role and smaller children cannot express their symptoms if they were starting to develop hypocalcemia.

In this study, PTH levels alone were not statistically significant and therefore calcium levels would need to be done in addition to the PTH levels (see Appendix G). While the literature review did show that there are studies that showed statistical significance in only measuring PTH levels. Some of the discrepancies in significance could further be discussed in how lymph node dissection played a role in needing calcium supplementation.

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Discussion

There were 41 patients (N=41) that had total thyroidectomies from August 2018- January 2021. The Fisher-Freeman-Halton-Exact test was used because there was 4 x 2 dimensions. Looking at and comparing the column proportions you will see that there is a relationship and that there is a statistical significance in measuring 4 hours post-operative PTH and calcium levels.

The initiation of the 2018 protocol is cost-effective and has shown that it can decrease the medication use in children who undergo a total thyroidectomy. In moving forward, order sets should be built, and any surgeon can implement following a total thyroidectomy. To implement the orders sets the information technologies (IT) department would need to be involved to create the set once the diagnosis is entered. There may be some initial costs to have them build the order sets but, in the future, there would be no additional cost to VCH or to the patient. Jean Watsons caring theory takes the approach of the patient and understanding how their care affects them. Decreasing anxiety in regards to the potential complications that would follow a total thyroidectomy and then knowing that they would not need another medication on top of the thyroid hormone would also be significant.

The protocol has shown that ultimately if PTH and calcium levels are drawn within the first 4 hours it can predict the need for calcium supplementation. This protocol should be implemented at other hospitals and can serve as more evidence in initiating the protocol. In the future monitoring pre-operative calcium and vitamin D levels can also be important to monitor. If vitamin d levels are low, PTH levels will try to compensate and will appear higher then normal. Further studies in the future will benefit from measuring vitamin d levels and calcium levels pre-operatively.

Conclusion

In summary, this study only further indicates that hospitals should be ordering PTH and calcium levels 4 hours postoperatively. While there can be limitations to getting the appropriate lab work done and implemented over time the ability to order in house PTH levels has been shown in the numerous literatures to be predictive in determining the need for calcium or calcitriol.

The null hypothesis was proven wrong, and the alternative hypothesis was correct. It was shown through the data that there is a significant difference between serum PTH and calcium levels 4 hours post total thyroidectomy without calcium administration post-operatively as indicated by a p-value of <0.05 .

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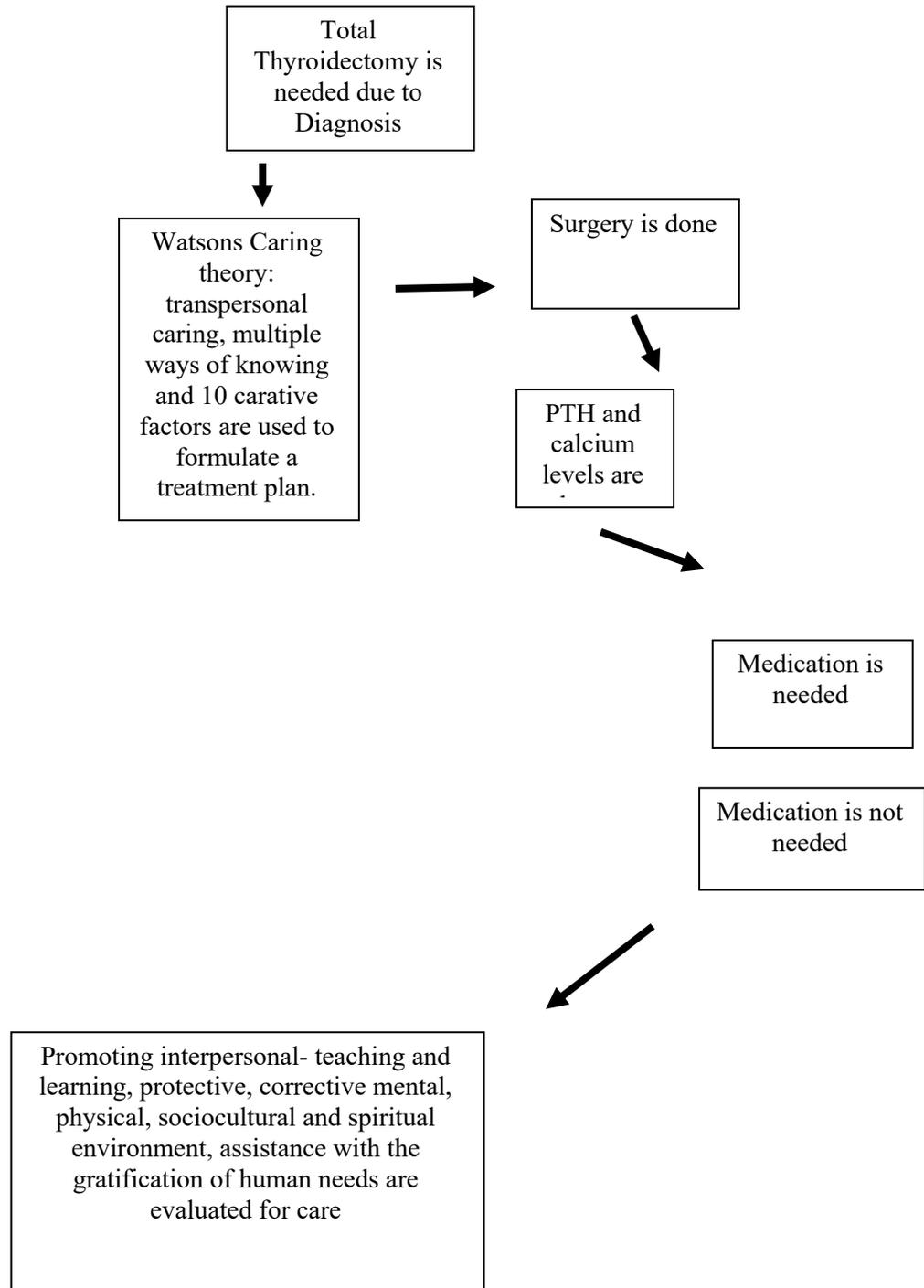
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Appendix A

Theoretical Concept Map



Appendix B

Letter of support from VCH



9300 Valley Children's Place
Madera, CA 93636

(559) 353-3000
valleychildrens.org

To Whom It May Concern,

I am writing this letter in support of Pamela Marsh doctoral project. The evaluation of a protocol for Pediatric thyroidectomy to diminish medication usage is a study that will be beneficial to our endocrine practice.

Please do not hesitate to contact me with any other questions.

A handwritten signature in black ink, appearing to read "Nedim Cakan M.D.".

Thank you,

Nedim Cakan M.D.

Clinical Associate Professor of Pediatrics and Pediatric Endocrinology (Affiliated),

Stanford University School of Medicine

Medical Director and Academic Chief

Pediatric Endocrinology and Diabetes



9300 Valley Children's Place | Madera, CA 93636

D: (559) 353-6620 | C: (559) 353-6600 | F: (559) 353-6612 | valleychildrens.org

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Appendix C

VCH IRB approval



August 10, 2020

Pamela Marsh, PPCNP-BC
Dept. of Endocrinology
Valley Children's Healthcare
9300 Valley Children's Place
Madera, CA 93636

Initial Approval – Expedited Review
HSC2297 Evaluating Guidelines for Pediatric Patients Undergoing a Total Thyroidectomy

Study Risk Assignment: Minimal Risk
Approval Date: August 10, 2020
Expiration Date: None

Dear Ms. Marsh:

All documents for the above-referenced study were reviewed and approved via expedited review on August 10, 2020.

The study was approved in accordance with regulations found at 45CFR46.110(5) – Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes and Subpart D 45CFR46.404.

Your request for a waiver of consent was approved in accordance with regulations at 45CFR46.116(f)(1).

A waiver of HIPAA Authorization is acceptable for the conduct of the study.

1. The study procedures do not adversely affect the rights and welfare of the individuals and pose minimal risk to their privacy, based on, at least, the presence of the following elements:
 - a. An adequate plan to protect the identifiers from improper use and disclosure;
 - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law;
 - c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;
2. The research could not practicably be conducted without the waiver; and
3. The research could not practicably be conducted without access to and use of the protected health information.

In the future, if you wish to make subsequent changes to the study, they must be re-approved by the IRB prior to implementation of the changes.

It has been determined that this study does not require future continuing review, per the regulatory criteria set forth in 45CFR46.109(f)(1). Changes to the study must be reported promptly so the IRB can determine whether the protocol still meets this regulatory criteria, and all mandatory reporting obligations are still in effect. In the future, if you wish to make subsequent changes to the study, they must be re-approved by the IRB prior to implementation of the changes.

Please notify the board immediately of any proposed changes to the protocol, amendments, revisions, or any unanticipated problems involving risks to subjects or others in the protocol. If there are any serious or unexpected adverse events, please send a written response, as to your opinion whether it was study-related and whether it is safe to continue the study.

To ensure adherence to good clinical practice, the IRB may audit your study in the future. If you have questions, please do not hesitate to contact the IRB at (559) 353-5171. As soon as the study closes, please inform the IRB immediately with a summary report and submit a Study Retirement Form.

Sincerely,

Carole Cooper, MSN, MHA, RN, CNS, ACCNS-P
Institutional Review Board
Valley Children's Healthcare

EVALUATION OF A PROTOCOL

Appendix D*Cost- Benefit analysis*

	Hours	Cost
Principal investigator hours	80 @ \$65	\$5200
Statistical analysis	15 @ \$0	\$0

EVALUATION OF A PROTOCOL

Appendix E*Timeline*

Date Proposed	Activity	Date Completed
Spring 2019	DNP Project Implementation	Fall 2019
Fall 2019	DNP Project Proposal was submitted	Fall 2019
Spring 2020	Prepare and complete IRB Application	Summer 2020
Summer 2020	Collect data	Winter 2021
Spring 2021	Data Analysis	Spring 2021
Spring 2021	Submit Final Proposal	Spring 2021
Spring 2021	Close out IRB	Spring 2021

Appendix F

The University of Alabama IRB Approval



The University of Alabama
801 University Blvd
Tuscaloosa AL
TEL: 205 348 6457
FAX:

NOTICE OF APPROVAL FOR HUMAN RESEARCH

DATE: August 27, 2020
TO: Marsh, Pamela, Capstone College of Nursing
 Collins-Yoder, Angela, Capstone College of Nursing, Carter, Patricia, Capstone College of Nursing
FROM: Graham, Jeanelle, MPH, Research Compliance Specialist, NM Expedited
PROTOCOL TITLE: Evaluating post-operative parathyroid hormone and calcium levels for pediatric patients undergoing a total thyroidectomy
FUNDING SOURCE: NONE
PROTOCOL NUMBER: 20-07-3767
APPROVAL PERIOD: Approval Date: August 27, 2020 Expiration Date: August 26, 2021

The Institutional Review Board (IRB) for the protection of human subjects has reviewed the protocol entitled: Evaluating post-operative parathyroid hormone and calcium levels for pediatric patients undergoing a total thyroidectomy. The project has been approved for the procedures and subjects described in the protocol. This protocol must be reviewed for renewal on a yearly basis for as long as the research remains active. Should the protocol not be renewed before expiration, all activities must cease until the protocol has been re-reviewed.

If approval did not accompany a proposal when it was submitted to a sponsor, it is the PI's responsibility to provide the sponsor with the approval notice.

This approval is issued under University of Alabama's Federal Wide Assurance 00004939 with the Office for Human Research Protections (OHRP). If you have any questions regarding your obligations under Committee's Assurance, please do not hesitate to contact us.

Please direct any questions about the IRB's actions on this project to:

Graham, Jeanelle

Graham, Jeanelle

Approval Period: August 27, 2020 through August 26, 2021
Review Type: FULLBOARD
IRB Number: 03

Appendix G

Table G1. Descriptive statistics of study sample, N = 41

Variable	n	(%)
Age, mean (sd)	14.5	(3.2)
PTH 1		
PTH ≤ 10 pg/mL	12	(29.3)
PTH > 10 pg/mL	29	(70.7)
Calcium 1		
S. Calcium < 8 mg/dL	2	(4.9)
S. Calcium ≥ 8 mg/dL	39	(95.1)
Group		
PTH ≤ 10 pg/mL + S. Calcium < 8 mg/dL	1	(2.4)
PTH ≤ 10 pg/mL + S. Calcium ≥ 8 mg/dL	11	(26.8)
PTH > 10 pg/mL + S. Calcium < 8 mg/dL	1	(2.4)
PTH > 10 pg/mL + S. Calcium ≥ 8 mg/dL	28	(68.3)
Medication Use		
Yes	16	(39.0)
No	25	(61.0)

Table G2. Medication use, by group, N = 41

Variable	PTH ≤ 10 pg/mL + S. Calcium < 8 mg/dL		PTH ≤ 10 pg/mL + S. Calcium ≥ 8 mg/dL		PTH > 10 pg/mL + S. Calcium < 8 mg/dL		PTH > 10 pg/mL + S. Calcium ≥ 8 mg/dL		p- value*
	n	(%)	n	(%)	n	(%)	n	(%)	
Medication									
No	0	(0.0)	2	(18.2)	0	(0.0)	23	(82.1)	<0.001
Yes	1	(100.0)	9	(81.8)	1	100.0)	5	17.9)	

* Fisher-Freeman-Halton Exact Test

EVALUATION OF A PROTOCOL

Table G3. Medication use, by PTH level ≤ 10 pg/ml

Variable	PTH ≤ 10 pg/mL + S. Calcium < 8 mg/dL		PTH ≤ 10 pg/mL + S. Calcium ≥ 8 mg/dL		p-value
	n	(%)	n	(%)	
Medication					
No	0	(0.0)	2	(18.2)	0.99
Yes	1	(100.0)	9	(81.8)	

Table G4. Medication use, by PTH level > 10 pg/ml

Variable	PTH > 10 pg/mL + S. Calcium < 8 mg/dL		PTH > 10 pg/mL + S. Calcium ≥ 8 mg/dL		p-value
	n	(%)	n	(%)	
Medication					
No	0	(0.0)	23	(82.1)	0.21
Yes	1	(100.0)	5	(17.9)	

Graduation Criteria Statement

The DNP Project Proposal and DNP Final Project submitted, revised, and completed by the student and approved by the Faculty Advisor are criteria for graduation from the DNP program. All DNP students are strongly encouraged to revise the final project as a manuscript for publication in collaboration with the faculty advisor and submit to the student and Faculty Advisor's peer reviewed journal of choice. However, this is not a graduation criterion.