Preoperative Carbohydrate Loading in the Reduction of Postoperative Nausea and Vomiting

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Doctor of Nursing Practice Scholarly Project Proposal

Preoperative Carbohydrate Loading to Decrease Postoperative Nausea and Vomiting: A clinical Practice Guideline

Postoperative nausea and vomiting (PONV) is the most commonly reported complication following surgery (Yilmaz et al., 2013). It is defined as "…any episode of nausea, vomiting and retching during the first 24-hour period after surgery" (Singh et al., 2015, p. 3267). Common effects of PONV are dehydration, electrolyte imbalance, infections, aspiration and delay in hospital discharge (Yilmaz et al., 2013). Vomiting occurs in 30% of all surgical patients and nausea occurs in 50% of all surgical patients that require anesthesia nationally (Hooper, 2015, p. 377). Despite preventative measures such as the administration of perioperative antiemetic therapy, PONV still occurs in 20-40% of patients receiving anesthesia (Yilmaz et al., 2013).

Lee et al., 2015, concluded that there is a significantly higher occurrence in the female gender. Additional risk factors of PONV include patients with a history of motion sickness and PONV, and nonsmoking status (Lee et al., 2015). Opioids have also been sighted as a risk factor for PONV (Hausel, Nygren, Thorell, Lagerkranser, & Ljungqvist, 2005). The incidence of PONV in higher risk groups may be as high as 80% (Hooper, 2015).

A recent intervention that has been associated with decreased postoperative nausea and vomiting is preoperative carbohydrate loading (Yilmaz et al., 2013). In contrast to surgical patients fasting for eight hours before surgery, current research is now showing that there are benefits in allowing patients to drink carbohydrate loaded drinks up to 2 hours before surgery (Singh et al., 2015). A conclusion from a randomized clinical trial found that after elective laparoscopic cholecystectomy procedures, the incidence of PONV was higher in the patients who fasted overnight compared to the patients who received a carbohydrate loaded drink (Hausel et al., 2005). Research studies have shown that carbohydrate loading has reduced overall hospital

stays by 20% (Kratzing, 2011). Preoperative carbohydrate drinks have added benefits including shorter hospital stays that are a direct result of the decrease in PONV in patients undergoing colorectal surgery (Jones, Badger, & Hannon, 2011)

A tertiary facility located in Maryland was the target institution for this scholarly project. While quantitative data for incidence of PONV was not available for the target organization, an inference was made based on the conclusions from research that PONV occurs in 20-40% of surgical patients receiving anesthesia (Yilmaz et al., 2013). The purpose of this Doctor of Nursing Practice scholarly project was to develop and evaluate a clinical practice guidelines for preoperative carbohydrate loading to reduce PONV in patients undergoing cholecystectomy. The anticipated outcome of this project was a reduction in the occurrence of PONV with improved overall patient comfort and a reduction in readmission rates within the target institution.

Theoretical Framework

The theoretical model of choice for this project was *The Ottawa Model of Research Use* (Logan & Graham, 1998). This theoretical framework was used to guide the development of interventions based on key elements of the model. The Ottawa Model of Research of Use (OMRU), consists of six key elements which are: practice environment, potential adopters, evidence based innovation, transfer strategies, adoption and outcomes. These key elements influence and are influenced by each other to assess, monitor and evaluate research. Before, during and after research efforts, there is a systemic assessment, monitoring and evaluation of these key elements. The purpose of the assessment, monitoring and evaluation (AME) data, was to identify barriers to the research, identify selection direction to overcome those barriers, track transfer effort progress and evaluate evidence based innovations and their impact on outcomes of interest. The key elements of OMRU, are not unidirectional, as they take place over time, and

their order is dependent on each elements' state within a particular context (Logan & Graham, 1998).

The OMRU model guided the development of the proposed intervention, in this case, carbohydrate loading in surgical patients. The elements of practice environment, potential adopters and evidence based innovation were used to assess the prevalence of the problem, the organization that would benefit from the implementation of the guideline as well as assess the practice guideline created (Logan & Graham, 1998, p. 233). The key element of transfer strategies were used to monitor the acquired evidence based innovations. The last two elements, adoption and outcomes, were used to evaluate the quality of the clinical practice guideline (Logan & Graham, 1998). Successful use of the six key elements provided assessment, monitoring and evaluation of the development of an effective clinical practice guideline.

Literature Review

Four randomized control studies (RCT) that demonstrated the benefits of preoperative carbohydrate loading on postoperative nausea and vomiting (PONV) in patients undergoing colorectal surgery were selected for this review. The literature review highlights the importance and significance of each of the studies selected, and discusses the similarities and differences among the studies.

Hausel et al., (2005) conducted a RCT on the effect of preoperative carbohydrate loading on PONV in patients undergoing laparoscopic cholecystectomy. Though the study was conducted more than ten years ago in 2005, it is a hallmark study that has been referenced in recent clinical trials by other researchers including two that are being analyzed in this review, Singh et al., (2015) and Yilmaz et al., (2013). The sample size for this clinical trial was 172, divided into two groups of 127 women and 45 men. The study was conducted in three hospitals,

all in Stockholm: Karolinska, St Göran and Ersta Hospital. The participants were randomly assigned to three treatment groups: fasting from midnight, receiving placebo drink, receiving carbohydrate drink (CHO). All participants could eat and drink before midnight and participants in the placebo and the CHO group each ingested 800ml of either the CHO or the placebo, the evening before surgery. They were also given an additional 400ml of the appropriate drink at least two hours before surgery.

Hausel et al., (2005) concluded that the incidence of PONV was the lowest in the CHO group and therefore, pre-operative carbohydrate loading is beneficial in decreasing PONV in this surgical population. The incidence of PONV was significantly decreased over time in the CHO group compared to the other two groups. The researchers clearly defined their exclusion and inclusion criteria and had a clear operational definition of nausea, vomiting and retching. The demographic data, details of the anesthetic and treatments as well as the results of the study were clearly presented in tables and in text. The limitations of this study were its small sample size of 50 participants per group, which increased the risk of a Type II error. Participants were allowed oral intake after six hours, which made it difficult to evaluate whether it was their food intake postoperatively that was causing their PONV or the anesthetic. The intravenous volume infusions administered also potentially obscured the benefits of the oral drinks given.

A more recent RCT by Sada et al., (2014), explored the effect of preoperative carbohydrate drinks on clinical status in patients undergoing abdominal surgery. The study was conducted over 24 months, at the University Clinical Center of Kosovo. A total of 142 patients were divided into two groups, 71 patients undergoing colorectal operations (CR) and 71 patients undergoing open cholecystectomy (CH). The patients were randomly assigned to three groups: study group, placebo and control group. The placebo and study group patients each received

800ml of the appropriate beverage the evening before surgery. They received an additional 400ml two hours before receiving anesthesia while the control group fasted after midnight. Although no statically significant benefits were noted in the CR group, there was a decrease in hunger, thirst, mouth dryness, nausea and weakness in the CH study group compared to the control group. These differences were noted within the first 24 hours after surgery. The conclusion of the study was that carbohydrate drinks improve the well-being of patients following open cholecystectomy.

Sada et al., (2014) clearly defined inclusion and exclusion criteria and there were similar American Society of Anesthesiologist (ASA) classifications of preoperative health among all patients. The evaluation instruments that were used, the Kruskal-Wallis test and the Dunn test, have established reliability and validity. The study was limited by the small sample size of 71 in each group.

In another study conducted by Singh et al., (2015), researchers explored the effect of preoperative carbohydrate drinks on postoperative outcomes 24 hours after laparoscopic cholecystectomy. The study was conducted over 17 months, in the Department of General Surgery, Postgraduate Institute of Medical Education and Research, Chandigarh, India. The total sample size was 120, and the patients were randomized into three groups of 40 each: Group A (receiving preoperative carbohydrate drink, CHO), Group B (receiving a placebo drink) and Group C (fasting from midnight before surgery). Patients in Group A and B, received 400 ml of the appropriate drink on the evening before surgery and 200 ml at least two hours before surgery. The laparoscopic cholecystectomy, anesthetic and the postoperative medications, were similar among the three groups. Nausea and vomiting mean scores were lower in the first four hours in

Group A compared to B and C. Singh et al., (2015) concluded that preoperative carbohydrate loading leads to a reduction in the incidence of PONV.

The strengths of the study included: an even match among the three groups in age and sex of the patients, clear definition of nausea and vomiting, reliable evaluation tools and similar preanesthetic medication, anesthetic and surgical technique, and postoperative medications among the three groups. However, the sample size of 40 patients per group was small and increased the chance of Type II error.

Yilmaz et al., (2013) conducted a randomized, prospective, controlled study to compare the effects of preoperative carbohydrate loading to preoperative fasting on PONV, gastric effect and residual volume, and antiemetic consumption in patients undergoing laparoscopic cholecystectomy. The study was conducted over four months at Gulhane Medical Faculty and Guven Hospital Department of Anesthesiology and Reanimation. The sample consisted of two groups of 20 each. Group F fasted from midnight and Group C received 400ml of a carbohydrate drink at least two hours before surgery. Yilmaz et al., (2013) concluded that preoperative carbohydrate loading is safe, leads to a decrease in PONV scores, reduces antiemetic consumption and improves patient satisfaction. There were no significant differences in demographic data, hemodynamics and complications between the two groups. The demographic variables were clearly represented in tables and in text. A limitation of the study was its small sample size of 20 patients per group.

All four studies had a common procedure, cholecystectomy, though there was a variance in the surgical approach. Sada et al., (2014) conducted their research on patients undergoing colorectal surgery and open cholecystectomy compared to the other three researchers whose patients were undergoing a laparoscopic cholecystectomy. The sample sizes among the four

research groups ranged between 40 and 172. Three had more than 100 patients compared to Yilmaz et al., (2013) whose sample of 40 patients was significantly smaller. Yilmaz et al., (2013) divided up their sample into two groups, fasting and CHO group, which may have been due to their small sample size. The other researchers randomized patients to three groups, a study group, placebo group and a control group. Yilmaz et al., (2013) also had the shortest study time, which was four months. The other three research groups ranged between 17 months (Singh et al., 2015) and 24 months (Sada et al., 2014).

A commonality among the patients in all groups was their American Society of Anesthesiologists (ASA) classifications, which are the classifications of preoperative health among all patients. Patients in three of the research groups had an ASA classification of I-II except participants of the Singh et al., (2015) research group, where ASA classification was not specified. The volume of beverages used in the placebo and control groups was variable throughout the groups. Sada et al., (2014) and Hausel et al., (2005) used identical volumes, 800ml the evening before surgery and 400ml at least two hour before the procedure. Singh et al., (2015) patients received 400ml of the appropriate beverage the evening before surgery and 200ml in the morning while Yilmaz et al., (2013) participants only received 200ml of beverage the morning of surgery. Despite the differences in methods of conducting their trials, all four groups of researchers concluded that preoperative carbohydrate loading is beneficial in the reduction of PONV in patients undergoing cholecystectomy.

Methods

Design, Sample and Setting

This project is a quality improvement project which was implemented in the anesthesia department of a small community hospital on the east coast. There were three phases of the project, which took place over a total of three months (Appendix C). One month was allotted for each phase of the project. The sample was inclusive of the SRNAs who developed the guideline, the selected expert panel, and the participating staff member at the target location. There were different samples for each stage of the project and the samples are described in detail under each phase of the project.

Procedures

Phase I of the project involved recruiting the expert panel in the first two weeks, who participated in the evaluation of the developed CPG. The proposed expert panel consisted of an anesthesiologist, and two nurse anesthetists. After the expert panel was identified, the draft of the CPG was sent to them electronically via email along with the tool chosen to evaluate the CPG, the Appraisal of Guidelines for Research and Evaluation (AGREE II) tool (Appendix D: AGREE Next Steps Consortium, 2013). A date was determined in advance, to discuss the results of the AGREE II tool. The expert panel evaluated the CPG using the AGREE II tool and returned the evaluations electronically. After analyzing the data from the AGREE II tool, the appropriate changes were made and the final stage of Phase I involved resubmitting the updated CPG to the expert panel for review.

The second month marked the beginning of Phase II of the project. The sample for this phase of the project involved the chief anesthesiologist. The updated CPG was sent electronically to the administrator, along with the AGREE II tool for evaluation. The CPG was reevaluated based on feedback from administration and appropriate changes were made. The updated CPG was then resent to the expert panel.

The final phase of the project, Phase III, took place over the final month of implementation. Phase III involved the end users who are the CRNAs, anesthesiologists in the surgery department, with a projected n of 20. The CPG was presented to the staff during grand rounds. The Provider Feedback Survey (PFQ), Appendix E, was distributed for evaluation of the CPG by providers. An analysis of the data from the survey was then be made, after which a meeting date with the expert panel and administration was requested. During the final meeting, in the third week of the final month, changes that were made to the CPG were discussed by the SRNAs along with any recommended additional updates. The final week of the phase was reserved for the final edits to the CPG.

Data Collection

Collection of data in the first two phases of the project were made using the updated Appraisal of Guidelines for Research and Evaluation (AGREE), now referred to as the AGREE II tool (Appendix B). The tool was distributed electronically via email to the expert panel as well as the chief anesthesiologist. The AGREE II tool, is used to assess the quality of guidelines, provide a strategy for guideline development and guide the information reported and how that information is reported in guidelines (AGREE Next Steps Consortium, 2013). The tool consists of 23 key items which are divided into six domains: Scope and purpose, Stakeholder involvement, Rigour of development, Clarity of presentation, Applicability, and Editorial Independence. All items are scored on a seven point Likert scale, ranging from 1= ‘strongly disagree’ to 7 = ‘strongly agree’. A score of 1 is where no information is available and the scores increase as more criteria is met. A score of 7 is for exceptional quality of reporting and where considerations and full criteria have been met (AGREE Next Steps Consortium, 2013).

The Provider Feedback Questionnaire (PFQ) is another tool that was distributed in paper and pencil format to the end users, anesthesiologists, and CRNAs. The PFQ is an assessment tool used by clinicians to evaluate drafts of CPGs (Brouwers, Graham, Hanna, Cameron, & Browman, 2004). There are 23 core items on the PFQ which assess: Scientific quality, methodological rigor, implementability and applicability, and acceptability of recommendations. All items are scored on a three point Likert scale (strongly agree, strongly disagree, neither agree nor disagree). Based on the tool recommendations, at least two appraisers have been chosen to use this tool to increase its reliability.

Data analysis

Analysis of the AGREE II scores is based on the scores calculated for each domain. Each of the six domains are scored individually with maximum scores dependent on the number of appraisers. The items on each domain are summed up and scaled as a percentage of the maximum score of that domain (AGREE Next Steps Consortium, 2013). The scores are used to compare guidelines and whether those guidelines should be recommended for use. To analyze the PFQ, a frequency table will be used to determine the years of experience for each provider. Based on the results of the frequency table average responses will be collected for each category. There are three categories which are: 0 – 5 years' experience, 5 -10 years' experience, > 10 years' experience. The Kruskal-Wallis statistical test will be used to analyze the differences in answers based on what category the providers are in.

Protection of Human Rights

This project was considered a quality improvement project for the purposes of a specific organization and was intended neither for generalizable knowledge nor to be applied to another health setting. This project was also submitted to the organization's IRB and the IRB of University of Maryland Baltimore for a determination of non-human subject research. All participants in all phases of the project were volunteers and no identifiers were used for anonymity. The Provider Feedback Survey, which was distributed in paper and pencil format, was collected in a secure box. A password protected computer was used to enter the data into Excel for analysis and the data forms were kept in a locked box.

Results and Discussion

The AGREE II tool results from the expert panel, one MDA and two CRNAs, were evaluated. Percentages from each of the six domains were calculated. Five of the six domains had a score of 100%. Domain 1 scored 100% confirming that the objective of the guideline, the health questions and the population targeted by the guideline are specifically described. Domain 3 also scored 100%, indicating that the evidence used was adequate, externally reviewed and that the conclusions made, were in line with the evidence provided. Domain 4 also had a score of 100%, supporting the clarity of the CPG. Domain 5 focused on the applicability of the guideline and whether the CPG provided recommendations on overcoming potential barriers. This domain also had a score of 100%. The final domain that acquired a score of 100% was Domain 6. This domain focused on evaluating whether there were any competing interest and if there was any influence from a funding body. All evaluators found that there was no competing interest during the guideline development. No additional recommendations were made for the above discussed domains by any member of the expert panel.

One domain, domain 2, had a score of 94%. The variance in the scores was with question 5 which addressed stakeholder involvement. One panel member strongly agreed that the views and preferences of the target population were sought, whereas the other two panelists somewhat agreed. Feedback from the Anesthesiologist was that it is not clear whether the opinions of the public or potential patients were sought regarding preoperative carbohydrate loading as a treatment for PONV. No potential patients were interviewed during the development of this guideline however, we used the alternative method stated under the User's Manual Description of the AGREE II Tool. The tool states that an alternative method is using data obtained from literature reviews of public values, preferences and experiences (AGREE Next Steps Consortium, 2013, Page 20). Hausel et al., 2005, is one such study that summarized the views of a patient population, and concluded that there was a lower incidence of hunger, thirst and higher comfort in patients consuming carbohydrate loaded drinks prior to surgery compared to those who did not (Hausel et al., 2005).

During Phase III, which involved the CPG being presented to the CRNA and Anesthesiologist end users, the Provider Feedback Questionnaire (PFQ) was distributed. The PFQ was used as a tool for the providers to assess the CPG and to collect demographic data of the anesthesia providers. Eighteen providers were in attendance and there was 100% response rate based on the eighteen PFQs returned. There were no indicators on the questionnaire of whether the provider responding was a CRNA or an MDA, all providers received the same questionnaire. Item 1, was the demographic data, which was only based on the number of years of experience of each provider, with years ranging from 0 to greater than 10 years. There were seven respondents with 0-5 years' experience, four providers with 5 to 10 years' experience and seven providers with greater than 10 years' experience.

Items 2 – 23 were specific questions addressing the provider's assessment of the CPG, rated on a three point Likert scale, strongly agree, neither agree or disagree or strongly disagree. All the providers who participated answers all the 23 items on the questionnaire. Seven items had variances in answers and those were items: 3, 7, 8, 10, 11, 20 and 22. Item 3 asked whether the provider thought there was a need for a guideline on this topic. 94% of the providers agreed whereas 6% neither agreed nor disagreed. The evidence is consistent in determining that PONV is a commonly reported complication of surgery. Item 7 addressed the clarity of the draft recommendations. 88.8% agreed that the recommendations were clear and 11% neither agreed nor disagreed. The providers were encouraged and given an opportunity after the presentation to ask questions about the guideline. Some of the concerns from providers were regarding certain populations of patients like diabetics who were excluded because of adequate research. Item 8 had the same results as item 7, where 88.8% agreed and 11% neither agreed nor disagreed. This was a question of whether the provider agreed with the draft recommendations as stated.

Item 10 had the largest variance in answers. This item asked if the draft recommendations were too rigid to apply to individual patients. 33.3% agreed that they were, 44.4% neither agreed nor disagreed, and 22.2% disagreed. This concern was also addressed during the meeting and most providers were concerned that there was not enough evidence to apply the guideline to all patient populations, such as diabetic patients. For item 11, 83.3% of the provider group agreed that when applied, the draft recommendations will produce more benefit than harm, while 16.6% neither agreed nor disagreed. The randomized controlled studies included, indicated that there was an overall improvement in patient wellbeing after preoperative consumption of a preoperative carbohydrate drink.

The last two items, item 20 and 22, were specific to provider comfort with patients receiving the care recommended by the guideline and whether they would use it in their own practice. 77.7% of the provider group agreed that they would feel comfortable with patient receiving the care recommended, 16.6% neither agreed nor disagreed and 5% did not respond. 83.3% of the providers indicated that they would use the CPG in their own practice, while 11.1% neither agreed or disagreed with this statement, and 5% did not answer. Overall, the item that scored the highest was item 3, where 94% of the provider group indicated that there is a need for a CPG on the topic of PONV.

Assessment of Implementation

The Context Assessment Index (CAI, Appendix F) is the tool that was used to determine the clinical environment in which the developed CPG will be implemented. The tool consists of 37 item, rated on a four point Likert scale, and it assesses the context of the clinical areas in which care is provided. Context is defined as the "…setting or environment where people receive healthcare services." (McCormack, McCarthy, Wright, & Coffey, 2009). There are three elements which are assessed on a continuum ranging from weak to strong. The three elements are culture, leadership and evaluation. An assessment evaluation of strong in all these three elements indicates that a facility has a strong culture that is receptive to change. The end goal is to provide evidence on what changes need to be made, to create a strong healthcare environment.

The results of the CAI were computed and can be viewed in Appendix C. The results indicated that the leadership element within the organization, though strong, was the weakest of the three elements. The culture element score was 82.8%, followed by the evaluation element at 74.8% and finally the leadership element scored 71.4%. The three scores of the individual

elements were used to calculate the overall score, which was 76.3%. This score indicates that the organization has a strong receptiveness to change.

Barrier and Enablers

Four barriers to the implementation of this CPG were identified: patient compliance, cost associated with implementation, surgeon willingness to have their patients participate, and the effect of implementation on perioperative turnover times. If the implementation of the CPG negatively affects perioperative times, it would create a resistance to the change among the surgeons and perioperative staff. Despite positive overall outcomes of the CPG, an increase in turn over times could lead to noncompliance. This behavior would be in line with what the CAI defines as their 'culture'. It would be easy for staff to want to revert to previous behaviors and maintain shorter turnover times. In a study of nurses' perceptions and barriers for adoption of Evidence Based Practice (EBP) in primary care, a group of researchers concluded that although EBP is viewed positively by nurses, the process of accepting the evidence and implementing it, is usually very slow. The questions that were asked during this study were: what the nurses' beliefs and attitudes are towards EBP; whether they understand and would apply EBP; what their barriers are towards implementing EBP; and is the adoption of EBP affected by educational level and years of experience (Mohsen, Safaan, & Okby, 2016).

Other barriers that can be tied to the CAI element of culture are surgeon willingness for their patients to participate, and the cost of implementation of the CPG. Surgeon resistance may be related to having positive outcomes with current methods and a misunderstanding on the need for change based on the severity of the problem. The study conducted by Mohsen et al. 2016, has recommendations that may be adopted to overcome these barriers. The recommended were: presenting problems in a clear, precise way to facilitate faster implementation; increasing time

availability for implementation of EBP; and facilitating access to online resources for online search of EBP (Mohsen et al., 2016). These recommendations can all be applied to implementation of a CPG in a clinical setting.

The final barrier identified was the lack of patient compliance with home instructions to take the carbohydrate drink the night before surgery. One way to overcome this barrier is to ensure adequate patient education, and provide the patients with additional reference information that is succinct. Enablers can be adopted and applied from a study conducted to improve management of urinary tract infections and sore throat. This study identified several enablers to improve implementation of a CPG. Two of those enablers were patient information in printed and electronic format and laminated posters with short versions of the guideline (Flottorp & Oxman, 2003). Both these enablers can help to ensure that patients have easy access to their instructions and that they have a quick reference of the CPG for clarification of information.

Summary

Despite prophylactic antiemetic therapy, PONV continues to be a significant complication of surgery. Preoperative carbohydrate loading has been proven through multiple randomized control studies, to significantly reduce PONV. Additional benefits of preoperative carbohydrate loading include a reduction in hospital stays by an estimated 20% (Kratzing, 2011). An expert panel was identified during the development of this CPG, and the AGREE II tool was used by the expert panel, to evaluate the strength of the CPG. Following strong positive reviews by the expert panel, the CPG was presented to the clinical providers during a staff meeting. Final amendments were made to the CPG based on all the feedback provided. Successful implementation of any CPG, includes identification of barriers to implementation. The CAI was used to assess the target site's readiness for change based on its culture, context and leadership.

The target site was determined to have a strong receptiveness to change based on their CAI scores.

Future Plans

Future plans include: the expert panel monitoring future patient outcomes. Outcomes to be monitored include: incidence of PONV, length of stay because of PONV, perioperative antiemetic use, costs involved with the treatment of PONV, and patient satisfaction. Based on the results of these outcomes, the expert panel can reevaluate the CPG and make additional changes or modifications in accordance with the results.

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