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Optimize patient outcomes among females undergoing gynecological surgery: A randomized controlled trial



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ABSTRACT

Background: Optimizing early education in gynecological procedures utilizing an Enhanced Recovery after Surgery (ERAS) program and a bundle concept may optimize patient outcomes after surgery.

Purpose: Evaluate whether an ERAS bundle compared to standard education can affect length of stay, 30 day readmission, and patient satisfaction among patients undergoing gynecologic surgery.

Design: Prospective, comparative, randomized design

Setting: 28 bed Medical Surgical Unit

Sample/Intervention: 50 patients undergoing hysterectomy, 25 who received post-operative evidence based bundle/standard education, and 25 who received standard education packet. Bundle components included 1) early mobilization, 2) early transition to oral pain medication, 3) early feeding, and 4) chewing gum. A follow-up phone call was made in two to three days following discharge for both groups utilizing teach-back.

Results: 84% (n = 21) patients in the bundle group were discharged in one day. There were no 30 day readmissions for both groups. Twenty two (88%) participants met the bundle components 100% of the time. For the indicator “walking helped with recovery” 100% (n = 25) responded “very good to excellent” for bundle group and 96% (n = 24) responded “very good to excellent” for standard group. Twenty three (92%) of the bundle group felt that that overall nursing care received was very good to excellent and 24 (96%) of the general group felt that overall nursing care received was very good to excellent.

Conclusion: Optimizing peri-operative education using a bundle approach to provide evidence based interventions can minimize risk and enhance early recovery for females undergoing gynecological surgery.

1. Introduction

A hysterectomy is a common gynecological surgical procedure with minimally invasive methods including vaginal or laparoscopic procedures. Studies have shown that preoperative patient education can improve patient outcomes after surgery, including reduced length of hospital stay, decreased post-operative complications, and increased patient satisfaction with the surgical experience (Modesitt et al., 2016; Steiner & Strand, 2017; Wijk, Franzen, Ljungqvist, & Nilsson, 2014). Enhanced recovery programs (ERP) is a concept that focuses on early patient education, multimodal pain control, early mobility, and alternate diet plans so that the patient can recover faster, with fewer complications, and have a shorter hospital length of stay post-surgical procedure (Kalogera & Dowdy, 2016; Modesitt et al., 2016).

The Institute for Healthcare Improvement developed the “bundle”

concept with bundle design guidelines; 1) three to five interventions or elements with strong clinician agreement, 2) each bundle element is independent, 3) each bundle is used with a defined patient population in one location, 4) a multidisciplinary care team develops the bundle, 5) bundle elements should be descriptive rather than prescriptive to allow for local customization and appropriate clinical judgement, and 6) compliance with bundles is measured using all or none measurement with a goal of 95% or greater (Institute for Healthcare Improvement-innovations, 2016).

2. Purpose

The purpose of this study was to evaluate whether there was a difference in outcome measures (length of stay, occurrence of readmission, and patient satisfaction) with the addition of a post-operative

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evidence-based bundle/standard education compared to standard education alone.

3. Review of the literature

A review of literature evaluating ERAS interventions among patients who were undergoing gynecological procedures was conducted to characterize the strengths and limitations of this body of literature. Procedures included manual and computerized literature database searches of articles in the English-language literature from 2014 to present. The following databases were initially accessed: MEDLINE, PubMed, CINAHL, and EBSCO host. Key search terms used included Enhanced Recovery after Surgery, gynecological surgery, length of stay, perioperative care, guidelines, enhanced recovery pathways, patient satisfaction, and postoperative care. The search was conducted using terms both separately and in combination with each other.

Yoong et al. (2014) examined outcome measures including length of stay, pain scores, postoperative morbidity, and readmission rates after implementation of an Enhanced Recovery after Surgery (ERAS) program for vaginal hysterectomy. The ERAS program in benign vaginal hysterectomy demonstrated a reduction in length of stay by 51.6% with an increase in discharge within 24 h with no increase in patient readmissions rates (Yoong et al., 2014). Wijk et al. (2014) examined the effects of a modified ERAS protocol among 85 patients undergoing abdominal hysterectomy for benign or malignant indications measuring length of stay and complications. There was a reduction in length of stay in patients who received the ERAS protocol from a mean of 2.6 (Standard Deviation (SD) 1.1) days to a mean of 2.3 (SD 1.2) days ($p = 0.011$). The number of patients discharged at 2 days increased from 56% pre-intervention to 73% post-intervention ($p = 0.012$). There were no differences in complications (5% versus 3.5% during hospital stay, 12% versus 15% 30 days after discharge), surgical intervention (2% versus 1%) or readmission (4% versus 4%) (Wijk et al., 2014). Nelson, Kalogera, and Dowdy (2014) conducted a systematic review of enhanced recovery pathways (ERP) to identify common themes that resulted in optimal patient outcomes. Common strategies included better preparation of patients for surgery, reduction of the stress response of surgery, and hastened recovery. Improvements post ERP intervention included postoperative recovery, patient satisfaction, and cost reductions without additional risk to the patient. Interventions included oral fluid intake up to 2 h before anesthesia, solids up to 6 h before anesthesia, carbohydrate supplementation, euvoolemia, and oral nutrition and ambulation the day of surgery (Nelson et al., 2016). Johnson et al. (2016) examined whether implementing a bundle of evidenced based practices could reduce 30 day surgical site infections among patients undergoing gynecologic cancer surgery. Pre-intervention 30-day surgical site infection rate overall was 38 out of 635 (6.0%) among all cases. Post intervention the overall rate was decreased to 2 out of 190 (1.1%). Implementation of an evidence-based surgical site infection reduction bundle demonstrated a significant reduction in surgical site infection in high-risk cancer procedures (Nelson et al., 2014). De Groot et al. (2016) conducted a systematic review among adult female patients undergoing open abdominal surgery for malignant or benign gynecologic diseases who utilized an ERAS pathway with a minimum of four ERAS elements from January 1, 1990 to March 19, 2014 with a total of 31 records, including 16 studies who met inclusion criteria. There was a reduction in length of stay (1.57–3.05 days) without an increase in complications, mortality or readmission rate. Preoperative education, early oral intake, and early mobilization were elements included in all pathways. Miralpeix et al. (2016) conducted a systematic review of ERAS programs for general gynecologic surgery to identify key elements included in a successful ERAS program that improved patient outcomes. Key elements in a successful ERAS program included discontinuation of patient-controlled analgesia devices and urinary catheter on the morning of the first day after surgery, early feeding, early ambulation, and conversion to oral

analgesics with non-opioid medication (Miralpeix et al., 2016). Implementation of an ERAS program resulted in a decrease in length of stay without increasing morbidity or mortality, a decrease in readmission rates, and increased patient satisfaction (Miralpeix et al., 2016). De Groot, van Es, Maessen, et al. (2014) conducted a non-randomized pre-post intervention study among female patients undergoing gynecologic surgery comparing those patients who received an ERAS intervention and those who did not receive an ERAS intervention. Outcome measures included length of stay, length of functional recovery, and compliance to protocol care elements. The ERAS group had a reduction in functional recovery with a median of three compared to six days, ($p < 0.001$) and reduced length of stay from seven to five days.

4. Summary

Studies that were reviewed reported successful use of an ERAS intervention. There was a decrease in surgical site infections (Johnson et al., 2016), decrease in length of stay, increased patient satisfaction, a decrease in readmissions (De Groot et al., 2014; De Groot et al., 2016; Miralpeix et al., 2016; Nelson et al., 2016; Wijk et al., 2014; Yoong et al., 2014) and an increase in functional recovery (De Groot et al., 2014). Common elements in the ERAS bundle included early oral liquids and solids, early ambulation, early conversion to oral pain medications, and enhanced education (De Groot et al., 2014, De Groot et al., 2016, Miralpeix et al., 2016, Nelson et al., 2016, Wijk et al., 2014, Yoong et al., 2014).

5. Ethics

An application to conduct the research study was submitted and approved by the Institutional Review Board (IRB) at HonorHealth Healthcare Research Institute in Scottsdale, Arizona, #1088437-3. All policies, regulations and guidelines set forth by the Research Integrity and Assurance IRB at Scottsdale Healthcare Research Institute were adhered to. Surveys were anonymous and participation was voluntary. Upon publication of any results of this study data would be reported in aggregate form only so participants' identity would not be revealed. All questionnaires were kept confidential. Data were entered into a Microsoft Excel database. Data confidentiality was maintained throughout the study.

6. Sample selection

This study was conducted in a 28 bed Medical Surgical Unit at a community hospital in Arizona. Recruitment included the first 50 patients undergoing hysterectomy from October 1, 2017 to March 1, 2018; 25 who received the post-operative evidence based bundle/standard education, and 25 who received the standard education packet. Fig. 1 outlines the flowchart for the study consistent with the Consolidated Standards of Reporting Trials (CONSORT) (Thabane et al., 2016). The PI obtained a list of patients from the physician's office two weeks prior to the patient's scheduled surgery. The PI called the scheduled patients to introduce the study and reviewed the consent, risks, benefits, and details of study participation. Patients who were interested in participating and met inclusion criteria were invited to participate. Verbal consent was obtained over the phone and documented in the electronic medical record (EMR). If interested in participating in the study, each eligible patient was mailed a consent form and the patient was asked to bring the signed consent form with her education packet to the hospital. Participants were withdrawn from the study in the event they were no longer willing to participate. Inclusion criteria included able to speak and understand English, the same surgeon performing the surgery to minimize selection bias, and discharged home. The sample size was based on historical data of numbers of all hysterectomies performed at this hospital from October 1, through

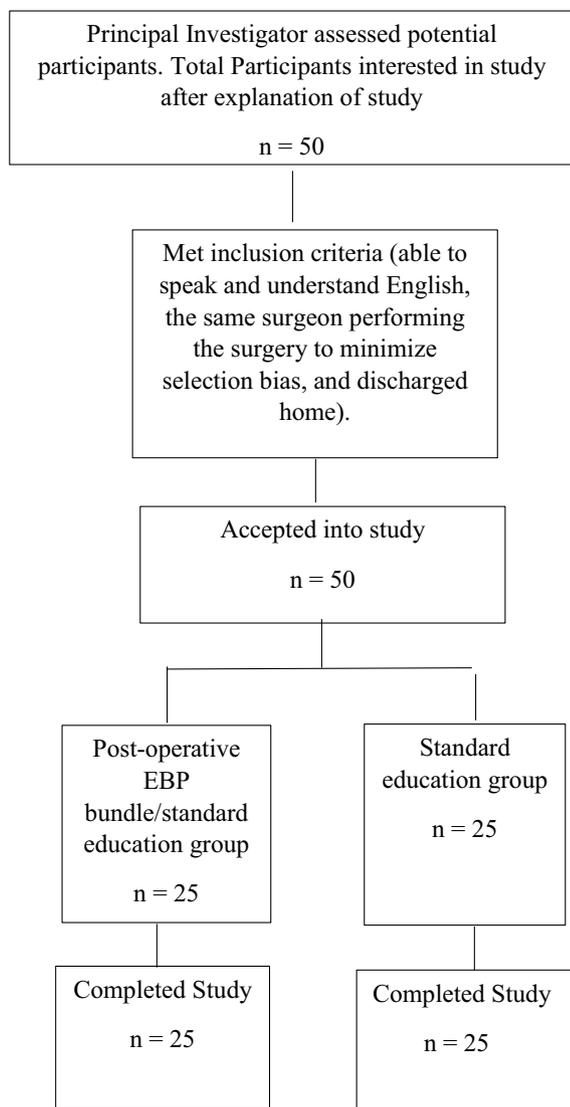


Fig. 1. CONSORT Flowchart.

December 31, 2016. A sample size of $n = 25$ per group yielded 80% power to identify a difference of effect size, $d = 0.80$ two-tailed, in length of stay and satisfaction.

7. Design and method

A prospective, comparative, randomized design with two groups undergoing all hysterectomies (open, vaginal, or laparoscopic). Participants were randomly assigned 1:1 to receive a post-operative evidence-based bundle in addition to the standard education, or the standard education alone using a table of blocked ($n = 6$, up to 48) random numbers generated from **Statistical Package for the Social Sciences** (SPSS). The final two patients were randomly assigned 1:1. The list of random assignments was kept with the principal investigator (PI) who assigned the education to the two groups of participants.

8. Intervention

In the outpatient physician office setting during the preoperative period from October 1, 2017 through March 1, 2018, all patients scheduled for hysterectomies and who gave consent were randomly assigned to receive a post-operative evidence-based bundle/standard education packet or a standard education packet alone on their last visit

prior to surgery. Patients were asked to bring their education packet with them to the hospital. If the patient forgot her packet (s) the Medical Surgical nursing unit had additional packets on the unit to dispense to patients.

9. Standard education packet

The standard education packet included: 1) pre-op teaching and testing (24 to 72 h before surgery and a checklist about what to bring to hospital), 2) gynecological surgery, day of surgery (treatments, medications, activity, and diet), and 3) gynecological surgery, first day after surgery through discharge (treatment, medications, activity and diet). Participants received education throughout the hospital stay.

10. Evidenced based bundle protocol

A team was formed including nurses on the medical surgical unit, physical therapy, and the surgeon who performed the surgical procedures to discuss study implementation and components of the bundle. The team reviewed studies to evaluate ERAS interventions among patients who were undergoing gynecological procedures and reviewed the current standard education packet. Elements of care included in a bundle protocol were chosen based on existing supporting evidence reported in the literature utilizing an ERP for gynecologic surgery (Meyer et al., 2015) and identified opportunities to improve surgical outcomes for those patients on this unit by team members. The chosen components of the post-operative bundle protocol included 1) early mobilization, 2) transitioning to oral pain medication, 3) early feeding, and 4) chewing gum.

Early mobilization was identified as a key element to improve patient care based on historical data for that unit by the physical therapy team. Early mobilization can protect against muscle loss and deconditioning by avoiding prolonged bed rest and immobility, reduce pulmonary and venous thromboembolic complications, improve insulin resistance, and contribute to shortening hospitalizations (Kalogera & Dowdy, 2016). Early mobilization can also increase blood flow throughout the body and enhance gastric emptying (Fiore et al., 2017).

Although the Guidelines for postoperative care in gynecologic/oncology surgery ERAS recommendation could not find evidence to recommend one analgesic intervention over another (Nelson et al., 2016), transitioning to oral pain medications was chosen as this element was associated with earlier discharge and faster resumption of daily activities (Kalogera & Dowdy, 2016).

Early feeding was chosen based on the Guidelines for postoperative care in gynecologic/oncology surgery ERAS recommendation rating a regular diet within the first 24 h after surgery as high evidence with a strong recommendation (Nelson et al., 2016).

Early feeding is considered taking in oral fluid and solid intake within 24 h after surgery (Kalogera & Dowdy, 2016). Early feeding results in earlier return of bowel function and shorter length of stay with no change in postoperative complications, including pulmonary complications, anastomotic leak, and wound healing (Kalogera & Dowdy, 2016; Miralpeix et al., 2016; Terzioglu et al., 2013).

Even though the Guidelines for postoperative care in gynecologic/oncology surgery ERAS recommendation rated gum chewing as moderate evidence with a weak recommendation (Nelson et al., 2016) the team decided to incorporate gum chewing as an element of the bundle as an adjunct treatment to aid in bowel motility. Although with minimal research that examined the effect of postoperative gum chewing on bowel motility after abdominal and laparoscopic gynecologic surgery the study outcomes that were reviewed found that the time when bowel sounds were heard was shorter, the time first passage of flatus was shorter, and first bowel movement occurred earlier in women who chewed gum, (Chuamor & Thongdonjuy, 2014; Ertas et al., 2013; Husslein et al., 2013; Park & Choi, 2018; Terzioglu et al., 2013). Chewing gum early in the postoperative period following total

abdominal hysterectomy is inexpensive, tolerated, and can hasten return of bowel function (Park & Choi, 2018).

The evidence-based bundle protocol included post-operative interventions, descriptions of what the bundle interventions were and the importance of the interventions for post-operative recovery. Education on the post-operative bundle protocol/standard education packet included the importance and benefits of participating in the bundle protocol. Participants received education on the reason for the post-operative interventions. The bundle included: 1) take a walk with help at a minimum for 5 min within 4 h after your surgical procedure on the day of surgery, (Castelino et al., 2016; Fiore et al., 2017), 2) take a walk with help as needed at a minimum for 10–15 min four times a day beginning on post-op day one through discharge (Fiore et al., 2017), 3) sit in a chair with all meals, 4) transition to oral pain medications within 24 h of surgery (Kalogera & Dowdy, 2016), 5) drink and or eat within 4 h post-operatively (Miralpeix et al., 2016), and 6) when fully awake from your anesthesia and when you have no nausea or vomiting, you will be asked to chew sorbitol-free gum three times during the first postoperative morning. Each chewing session will last 30 min with the head of your bed elevated 30° during gum chewing (Park & Choi, 2018). A checklist was used by the registered nurse (RN) after each bundle was completed. Post-op day one through discharge, the RN educated the patient and family, reinforcing and reviewing with both groups the bundle protocol/standardized education office packet or the standardized education office packet alone.

11. Follow-up phone call

A follow-up phone call was made by the co-investigators on the unit within two to three days following discharge from the hospital for both groups utilizing teach-back (Miller, Lattanzio, & Cohen, 2016). The teach-back method is used in patient education to confirm that the patient or family member understands the education they've received (Miller et al., 2016). Patient and family understanding is confirmed when they explain in their own words, what was taught and what the patient had difficulty learning so that the provider can fill the gap through ongoing education, ensuring effective communication (Miller et al., 2016). A script was used for the follow-up phone calls and started with an introduction of "I want to be sure that you understand your discharge instructions" 1) are you walking daily and how far are you walking daily, 2) what are you having for breakfast, lunch and dinner; 3) how often are you drinking water during the day; 4) how should you be taking your medication; 5) how often are you having a bowel movement; and 6) how often are you voiding. During the follow-up phone call, the patient was asked to complete a patient satisfaction survey.

12. Main outcome measures

Main outcome measures included length of stay, occurrence of readmission, and patient satisfaction following all hysterectomies. Readmission within 30 days was measured through the EMR. Length of stay was defined as the numbers of days spent in the hospital from the first post-operative day to the day of discharge, counting the operation day as day zero. Patient satisfaction was measured by the Patient Satisfaction survey consisting of seven questions utilizing a Likert scale from excellent to poor (Kalogera et al., 2013). Permission to use and modify the survey was obtained by the authors with an additional question added; "did you feel that walking during your hospital stay helped in your recovery".

Demographic variables measured included a) age, b), race, and c) marital status. Age, race and marital status were obtained from the admission assessment in the EMR.

13. Data management and analysis

Data collected during the study period were stored under lock and key in the PI's office and entered into a password protected EMR database by the co-investigator. Summary statistics, including means (SD) and counts (percentages) were used to describe demographic characteristics and outcome data. Chi-square tests were conducted to determine if the two groups differed on key baseline demographic variable (age, race, tobacco use, and marital status). Analyses of variance (or covariance) were used to assess potential differences in continuous outcome variables (length of stay and patient satisfaction) across treatment groups. Rates of hospital readmission within 30 days for the two treatment groups, along with 95% confidence intervals, were reported, but the sample size did not allow an inferential test under reasonable assumptions. Significance was set at ($p < 0.05$, two-tailed). Analyses were performed using the IBM SPSS software package, version 23.

14. Intervention fidelity

To maintain intervention fidelity the study was a standing agenda item at daily huddles on both shifts for intervention review and clarification. Daily huddles were developed by the unit and consisted of five minute group meetings led by a nurse supervisor at the beginning of each shift where information important to the daily function of the unit and the network was disseminated.

15. Confounding variables

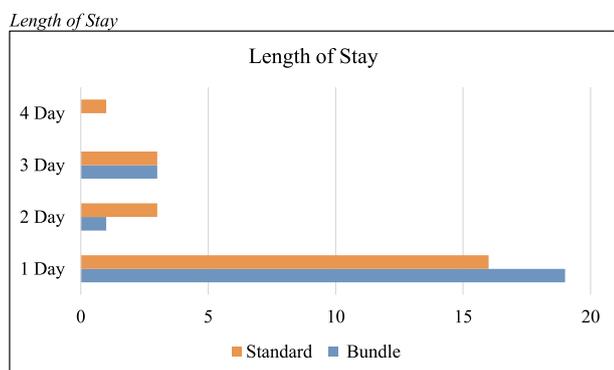
Age can be a confounding factor as older people may be more likely to be inactive, and may be at risk of developing complications. The majority of participants for both groups had an age range of (51–64) years with age distribution similar in both groups reducing the effect of confounding variables. Type of surgical procedure (open, vaginal, or laparoscopic) can be a confounding factor as laparoscopic surgery can reduce postoperative pain, reduce hospital stay, and result in a faster return to recovery. The majority of participants for both groups had laparoscopic procedures with similar distributions, the bundle group (20 patients) and the standard group (19 patients) reducing the effect of confounding variables.

16. Results

Demographic characteristics for study participants are presented in Table 1. Participants ranged in age from 50 years to > 85 years, with

Table 1
Demographic variables.

Variable	Education bundle	Standard education
	<i>n</i>	<i>n</i>
Age		
(≤50)	4	2
(51–64)	12	16
(65–74)	4	3
(75–84)	5	4
Race		
Caucasian	23	22
Non-Caucasian	2	3
Marital status		
Married	14	12
Divorced	4	5
Single	3	5
Widowed	3	3
Tobacco		
Yes	2	2
No	23	23



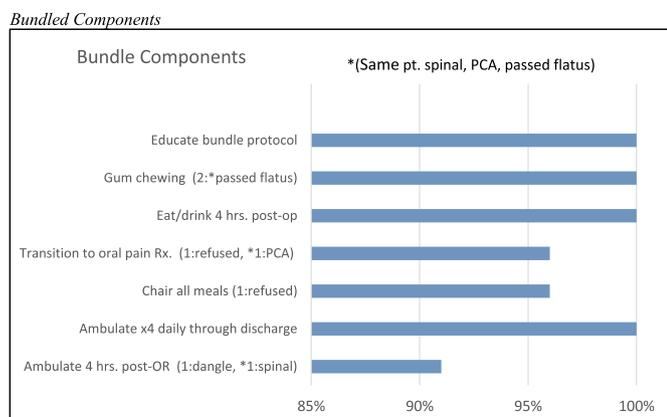
Graph 1. Length of stay.

the majority of participants in the age range of (51–64) years, 27 (54%) with a mean and SD of 2.300 (0.9313) years. The majority of participants were white Caucasian 43 (86%), with Non-Caucasian 2 (4%), Asian 2 (4%), Latino 2 (4%), and Greek 1 (2%). Twenty-six (52%) were married, nine (18%) were divorced, eight (16%) were single, six (12%) were widowed, and one (2%) were not recorded.

Overall one day length of stay in the bundle education group was 84% (n = 21) and 68% (n = 17) in the standard education group Graph 1. There were no patients who were discharged on the day of surgery. There were four patients with one day length of stay who did not meet discharge criteria for same day surgical discharge due to pain control, nausea, increased blood loss, and findings to include cancer diagnosis. Overall one day length of stay in the bundle education group was 21 and 17 in the standard education group. There were no readmissions within 30 days for both groups.

Bundle component results are presented in Graph 2. Twenty-two (88%) participants met the bundle components 100% of the time. Three (12%) of participants that did not meet the bundle components included one participant that refused to get up in a chair for one meal, one that refused to walk surgical day, and one that refused to transition to oral pain medication within 24 h of surgery. Participant comments from the bundled education group included “I will admit, initially I was not very happy to walk so soon but I am glad you made me, it made a difference”, “Walking helped me, I was hemming and hawing about getting up and walking, I am glad the nurse nagged me”, “Best thing was making me walk day of surgery even though it was hard”, and “I was grateful they pushed me to walk”.

Table 2 outlines Mean and Standard Deviation for Demographic Variables. Graph 3 outlines frequencies and percentages for variables from the Patient Satisfaction Survey. Ninety-two percent of the bundle group felt that that overall nursing care received was very good to excellent and 96% of the general group felt that overall nursing care



Graph 2. Bundled components.

Table 2 Mean and standard deviation for demographic variables.

Variable	Education bundle			Standard education		
	n	M	SD	n	M	SD
Age	25	2.36	0.907	25	2.24	0.969
Race	25	1.44	1.583	25	1.48	1.446
Gender	25	2.00	0.000	25	2.00	0.000
Marital status	25	1.92	1.256	25	1.96	1.098
Tobacco	25	1.92	0.282	25	2.04	0.4546

received was very good to excellent. For the indicator “walking helped with my recovery” 100% responded from very good to excellent for the bundle group and 96% from the standard group.

17. Strengths

Strength in study design included a level II randomized controlled trial (RCT) with participants randomly assigned to an IG and CG reducing the risk of selection bias and supporting cause and effect results. There were no significant differences in age, race, and marital status between the two groups.

18. Limitations

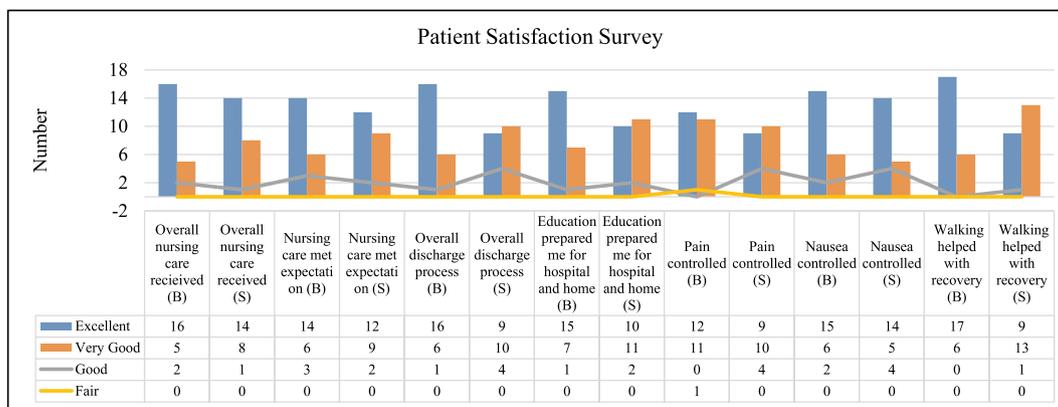
The sample size was based on historical data of numbers of all hysterectomies performed at this hospital from October 1, through December 31, 2016. Rates of hospital readmission within 30 days for the two treatment groups, along with 95% confidence intervals, were reported, but the sample size did not allow an inferential test under reasonable assumptions. The number of patients that received the intervention was small, limiting the feasibility of the intervention and the need for further investigation. All three bundle interventions, (gum chewing, early oral hydration, and early mobilization) can increase intestinal motility and are recommended during postoperative care to prevent postoperative ileus (Castelino et al., 2016; Fiore et al., 2017; Kalogera & Dowdy, 2016; Miralpeix et al., 2016; Wijk et al., 2014). It is hard to say whether gum chewing alone promoted intestinal motility. A limitation was performing a non-blinded study where the researchers knew what interventions were being given to the two groups generating potential observer bias.

19. Recommendations

Evidenced based ERAS protocol have been initially utilized in colorectal surgery with consistent outcomes including a reduction in length of stay, complication rates, cost reduction, and an increase in health care value and patient outcomes. Further studies are needed to target ERAS interventions for patients undergoing gynecological surgeries with attention to one specific type of gynecological procedure (laparoscopic or robotic, open, vaginal) to compare and optimize patient outcomes in all surgical groups. To add to the body of research to support use of ERAS guidelines for postoperative care in gynecologic surgery further studies can include only bundle elements that have high levels of evidence and a strong recommendation which may improve study outcomes (Nelson et al., 2016).

20. Implications

The ERAS protocol has been studied and used in different surgical procedures demonstrating safety and feasibility. There was high adherence with the bundle protocol for both new and established interventions. With clear patient information that participants received for the reason for the bundled post-operative interventions it can be safely assumed bundled compliance may have been impacted.



Graph 3. Patient satisfaction survey.

21. Conclusion

Optimizing peri-operative education using a bundle approach to provide evidence based interventions can minimize risk and enhance early recovery for females undergoing gynecological surgery. There was support in the literature for use of an ERAS program that included multimodal interventions developed to improve recovery, though there were minimal studies that included the “all or nothing” bundle concept with the multimodal interventions (The Institute for Healthcare Improvement, 2016) as part of the ERAS intervention. This study utilized both an ERAS intervention with a bundle concept to study whether both evidenced based concepts can optimize patient outcomes. Over all introduction and implementation of an ERAS intervention utilizing an all or nothing bundle concept resulted in outcome improvement.

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