A randomized-clinical trial examining a neoprene abdominal binder in gynecologic surgery patients

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Summary

Purpose of Investigation: Pain control and early ambulation are two important postoperative goals. Strategies that decrease morphine use while increasing ambulation have the potential to decrease postoperative complications. In this study the authors sought to determine the effect of an abdominopelvic binder on postoperative morphine use, pain, and ambulation in the first day after surgery. *Materials and Methods:* The authors randomly assigned 75 patients undergoing abdominal gynecologic surgery to either binder or not after surgery. Demographic data and surgical characteristics were collected. Outcome variables included morphine use, pain score, time to ambulation, and number of ambulations. *Results:* A group at high risk for decreased mobility was identified and the binder increased the number of ambulatory events by 300%, 260%, and 240% in patients with vertical incisions, age over 50 years, and complex surgeries, respectively. Morphine use and pain scores were not significantly different. *Conclusion:* The binder increased ambulations in the subset of patients at the highest risk for postoperative complications: elderly, cancer patients, and vertical incisions. Routine use of the binder may benefit particularly high-risk gynecologic surgical patients.

Key words: Surgery; Pain control; Mobility.

Introduction

One of the primary goals of postoperative pain management is to relieve pain so that normal physiologic functions including ventilation, gastrointestinal function, and mobility are minimally impaired [1]. It is standard practice is to provide postoperative pain relief with the use of parenteral, epidural, or oral analgesics. Patients undergoing laparotomy for gynecologic surgery are typically offered either patient controlled analgesia pumps (PCAs) or epidural catheters for initial postoperative pain management. However, narcotic use is associated with undesirable side effects including nausea, vomiting, ileus, headache, sedation, respiratory depression, and postoperative hyperalgesia [2]. Despite the frequent use of narcotics, pain after surgery continues to be a major management challenge. In a recent meta-analysis covering 800 publications and over 20,000 patients, it was found that 41% of all surgical patients experience moderate to severe acute postoperative pain and 24% report inadequate pain relief [3]. Portenoy *et al*. found that 42% of patients with ovarian cancer reported persistent and frequent postoperative pain [4]. Uncontrolled pain during the postoperative period interferes with recovery from surgery, contributes to fear and anxiety during continued treatment, and delays return to usual life activities [5, 6].

Novel pain control strategies have been developed in an attempt to provide better postoperative pain control and avoid the disadvantages of narcotic medications. These strategies generally incorporate traditional analgesic medications with non-pharmacologic or complementary strategies to provide both improved pain control and decrease the amount of required analgesic medication. Non-pharmacologic and complementary strategies which have been investigated include the use of support devices (binders), focused imagery, relaxation, distraction, therapeutic music, acupressure, acupuncture, electroacupuncture, massage, cold and hot compresses, transcutaneous electrical nerve stimulation (TENS), and osteopathic manipulation [7-12]. It is estimated that greater than 50% of patients use at least one non-analgesic pain control strategy in combination with traditional analgesics for the management of postoperative pain [7].

Wong *et al.* from the University of Texas Medical Branch at Galveston described the use of a novel light-weight neoprene abdominopelvic binding device in post-cesarean section patients [13, 14]. The binder consisted of a traditional abdominal elastic support device that was incorporated into an elastic pant component. The pant component was hypothesized to provide additional support to the lower abdominal musculature. The study compared the new abdominal binder to a traditional fishnet abdominal wound dressing in patients who underwent cesarean section. Their study showed that when compared to the traditional postoperative dressing the abdominopelvic binder decreased postoperative narcotic use as well as wound complications.

The purpose of this study was to determine if patients undergoing gynecologic surgeries through abdominal incisions would benefit from postoperative use of the abdominopelvic binder in a similar fashion to the study of Wong *et al.* The present authors' hypothesis was that use

Revised manuscript accepted for publication September 14, 2013

of the neoprene abdominopelvic binder would provide mechanical splinting resulting in decreased abdominal pain and thus decreased pharmacologic analgesia.

Materials and Methods

This study was approved by the Wilford Hall Medical Center and Brooke Army Medical Center joint Institutional Review Board. Individual participants were enrolled in the study and written consent was obtained prior to the date of surgery. Patients were eligible for participation if they were scheduled for gynecologic surgery through an abdominal incision. Epidural analgesia, intravenous or intramuscular ketorolac, and oral analgesics were not used during the 24-hour study period. Patients with an allergy to morphine sulfate were excluded. Eligible participants were randomly assigned to either no binder or binder for the first 24 hours after surgery with the use of opaque, sealed envelopes containing assignments to either "binder" or "no binder." All patients followed a standardized pain control protocol for the first 24 hours postoperatively consisting of a morphine sulfate patient controlled analgesia (PCA) pump with demand a dose of one mg intravenously every ten minutes, no lock-out, and no basal rate. All patients wore sequential compression devices on their lower extremities while in bed and participated in aggressive bed side pulmonary incentive spirometry. Patients received standard postoperative intravenous fluids until tolerating clear liquids. Patients' diets were advanced as tolerated. A Foley catheter and the bandage remained in place for at least 24 hours postoperatively. After the 24-hour study period patients were managed at the discretion of their attending surgeon.

No placebo was used. Patients were allocated in a parallel fashion to receive the "binder" or standard treatment with a fishnet bandage support "no binder" in the pre-anesthesia holding area prior to moving the patient to the operating room by random drawing of an envelope assigned by the study nurse. There were no restrictions on the randomization. The surgical team was blinded to patient's study group allocation until after the surgery was completed and the binder was fitted and placed on the patient before leaving the operating room.

Detailed patient and clinical information was collected including: age, weight, co-morbid medical conditions, past surgical history, indication for surgery, type of surgery, incision type, and incision length. Abstracted co-morbidities included hypertension, diabetes mellitus, coronary artery disease, chronic obstructive pulmonary disease, asthma, thromboembolic disease, cerebral vascular accident, epilepsy, chronic migraine headaches, depression requiring medication, moderate to severe fibromyalgia, and severe degenerative joint disease. For statistical analysis the co-morbidities were stratified to groups with no co-morbidities, one co-morbidity, or two or more co-morbidities, respectively. Prior surgeries were similarly stratified between no prior surgeries, minor surgery only, or one or more abdominal surgeries. The surgical indications were uterine leiomyomata, gynecologic cancer, and other indications, which included adnexal masses, pelvic pain, and menorrhagia. The type of surgical procedure was simple or complex. Simple surgeries included ovarian cystectomy, unilateral or bilateral salpingo-oophorectomy, myomectomy, and simple abdominal hysterectomy with or without salpingo-oophorectomy. Complex surgeries were gynecologic oncology procedures or extensive urogynecologic procedures. Type of surgical incision was horizontal and or vertical; the length of the incision was also recorded.

The amount of morphine sulfate used in the first 24 hours was determined by the PCA pump reading. All patients were asked to fill out a visual linear analog pain scale (VAS) preoperatively, as well as at 24 hours after surgery [15]. Patients were given a data collection sheet and asked to record the time of their first ambulation. Additionally they were asked to record each time they ambulated. The compliance with data collection was assured by the patient's primary surgeon who saw all patients at least three times during the 24-hour study period. At the end of the 24 hours study period the patients were asked if they felt that binder helped relieve their discomfort and if they desired to keep the binder on beyond the 24 hours of the study.

The primary outcome studied was total morphine use (mg) in the first 24 hours postoperatively. Secondary outcomes include: postoperative VAS pain scores, time from surgery to the first ambulation, and the total number of ambulatory events in the first 24 hours postoperatively. Based on prior experience on the present post-surgical ward, the expected morphine use in the control group was 20 to 40 mg during the 24-hour study period. A 10% decrease in morphine use was considered to be clinically significant. A look up table based on employing the method of Kraemer and Thiemann [16] to obtain an initial estimate of the sample size was confirmed with 1,000 iterations of a Monte Carlo simulation until the power was between 80% and 85% with a level of confidence of 95%. According to this method, 37 subjects per group (74 total) would be needed to detect the expected difference with the desired level of confidence and power.

Continuous variables were presented as the mean +/- standard deviation and categorical variables as frequencies (percentage of patients) with 95% confidence intervals. Patient characteristics in each treatment group (no binder versus binder) were compared by using the Chi square test for categorical variables and the Kruskal-Wallis test or Student's t-test for continuous variables, as appropriate based on the variance of the data. Spearman rank correlation was used to determine if significant relationships existed between the clinical variables of binder status, age, weight, co-morbidities, prior surgeries, indication for surgery, type of surgery, incision type, incision length, and the outcome variables. Significant relationships and trends identified by the Spearman rank correlation were subjected to hypothesis testing with the Student's t-test. An unplanned subgroup analysis also took place following the initial analysis, again using the Student's t-test. A p-value < 0.05 was considered statistically significant. All data were analyzed using the Sigma Plot version 11.

Results

Between January 2001 and November 2005, 75 patients were enrolled in the study and randomly assigned to one of the treatment groups (no binder versus binder) and enrollment was discontinued due to accrual of enough patients. Thirty-nine patients were randomized to the no binder group while 36 patients were randomized to the binder group. All patients received the allocated intervention. No patients were excluded from analysis. Comparison of patient characteristics in each of the treatment groups is shown in Table 1. The two treatment groups were similar with respect to all patient characteristics.

The major indication for abdominal gynecologic surgery was uterine leiomyomata (39.5%); gynecologic malignancy was the second most common surgical indication, (36.8%). Other indications included endometriosis, pelvic pain, adnexal mass, and menorrhagia (23.7%).

Table 1. — *Comparison of patient characteristics.*

Variable	Binder Mean (SD)	No binder Mean (SD)	*p* value
Age (years)	42.53 (9.4)	47.39 (12)	0.056
Weight (kg)	80.47 (18.0)	75.02 (17.0)	0.141
Incision length (cm)	18.02 (5.0)	17.07 (5.6)	0.185
	% (95% CI)	% (95% CI)	
Co-morbidities			0.226
None	36.1 (20.4 - 51.8)	35.9 (20.8 - 51.0)	
1	33.3 (17.9 - 48.7)	48.7 (33.0 - 64.4)	
2 or more	30.6 (15.5 - 45.6)	15.4 (4.1 - 26.7)	
Prior surgeries			0.751
None	33.3 (17.9 - 48.7)	30.8 (16.3 - 45.3)	
1	19.4 (6.5 - 32.4)	25.6 (11.9 - 39.3)	
2 or more	47.2 (30.9 - 63.5)	43.6 (28.0 - 59.2)	
Surgical indication			0.748
Leiomyomata	41.7 (25.6 - 57.8)	39.5 (23.9 - 55.0)	
Cancer	41.7 (25.6 - 57.8)	36.8 (21.5 - 52.2)	
Other	16.7 (4.5 - 28.8)	23.7 (10.2 - 37.2)	
Surgery type			0.904
Simple	72.2 (57.6 - 86.9)	65.8 (50.7 - 80.9)	
Complex	27.8 (13.1 - 42.4)	34.2 (19.1 - 49.3)	
Incision type			0.276
Transverse	36.1 (20.4 - 51.8)	51.3 (35.6 - 67.0)	
Vertical	63.9 (48.2 - 79.6)	48.7 (33.0 - 61.8)	

Preliminary data analysis using the Spearman rank correlation revealed statistically significant relationships between the number of postoperative ambulatory events and age ($p = 0.014$), complex surgery type ($p = 0.029$), and incision type ($p = 0.014$). Fewer ambulatory events were observed in older patients, those undergoing complex surgeries, and those with vertical incisions. This defined a high-risk population for poor postoperative ambulation. Morphine use, postoperative pain score, and time to first ambulation were not significantly influenced by the binder or the other clinical variables.

Spearman rank correlation was also performed to evaluate for potential relationships between the four outcome variables: morphine sulfate used in the first 24 hours, postoperative VAS pain scores, time from surgery to the first ambulation, and the total number of ambulatory events in the first 24 hours postoperatively. Patients with increased postoperative pain scores were less likely to ambulate ($p = 0.024$), suggesting that the number of ambulatory events could be used as an adjunct for pain control. No correlation was observed between morphine use and the other outcome variables.

Table 2 shows the analysis of outcome variables based on binder allocation. There was not a significant difference between the amount of morphine used, postoperative pain scores, and time to first ambulation in the study and control groups. Abdominal binder use was correlated with increased ambulatory events ($p = 0.068$), however this relationship did not reach significance.

Table 2. — *Analysis of outcome variables.*

Variable	Binder	No binder	*p* value
Morphine usage (mg)	37.6	40.5	0.927
Incision			
Horizontal	34.5	33.6	0.908
Vertical	39.5	47.8	0.252
Age			
Age < 50	40.2	38.2	0.281
Age ≥ 50	25.2	43.8	0.085
Surgery type			
Simple	41	37	0.341
Complex	27.8	49.4	0.07
Postoperative pain (#)	30.9	27.2	0.634
Incision			
Horizontal	29	24.8	0.723
Vertical	32.1	30.3	0.866
Age			
Age < 50	33.6	24.9	0.356
Age ≥ 50	14.8	31.5	0.286
Surgery type			
Simple	29.3	24.9	0.623
Complex	35.7	37	0.942
Time to first ambulation (hrs)	17.8	19.2	0.17
Incision			
Horizontal	17	17.8	0.724
Vertical	17.6	21.2	0.014
Age			
Age < 50	17.8	18.4	0.459
Age ≥ 50	17.6	20.3	0.319
Surgery type			
Simple	17.5	18.1	0.643
Complex	18.7	22	0.197
Ambulatory events (#)	2.4	1.6	0.068
Incision			
Horizontal	2.83	1.95	0.15
Vertical	2.52	0.84	0.002
Age			
Age < 50	2.5	2.26	0.863
Age ≥ 50	2	0.75	0.014
Surgery type			
Simple	2.72	1.95	0.34
Complex	1.78	0.73	0.066

Subgroup analysis was performed by stratifying the highest risk patients identified by the initial analysis: incision type, age, and complex surgery. The abdominal binder increased the number of postoperative ambulatory events ($p = 0.068$) when all of the data was analyzed together. Patients with vertical incisions who used the binder averaged 2.52 ambulatory events in 24 hours versus 0.84 ambulatory events in the no binder group ($p = 0.002$). In patients with vertical incisions, further data analysis revealed that 87% (20/23) of patients in the binder group had at least one ambulation during the 24- hour study period compared to only 58% (11/19) in the no binder group, ($p = 0.038$).

Patients over age 50 years in the binder group had more postoperative ambulatory events than patients in the no

binder group, 0.75 to 2 ($p = 0.014$). Patients with complex surgeries in the binder group had more postoperative ambulatory events than patients in the no binder group, 0.73 to 1.78 ($p = 0.066$).

Compliance with wearing the binders for the 24-hour duration of the study was 100%. Seventy percent of patients elected to continue wearing the binder beyond the 24-hour study duration. All but one patient felt that the binder helped decrease their postoperative pain and helped with walking. That one patient was under age 50 and underwent a simple surgery through a vertical midline incision. Her indication for surgery was chronic pelvic pain. There were no adverse effects from the binder.

Discussion

The time period after a major abdominal surgery is associated with complex, potentially harmful physiologic changes. These physiologic changes place patients at risk for several well described complications including thromboembolic disease, pneumonia, and gastrointestinal tract dysfunction [3]. The control of postoperative pain frequently requires the use of significant amounts of narcotic medications leading to impaired mobility and respiratory function. Risk factors for thromboembolic disease include, but are not limited to: pelvic surgery, immobility, malignancy, and increasing age [17]. Risk factors for postoperative pneumonia include: increasing age, smoking, poor nutritional status, COPD, immobility, and respiratory splinting due to pain [18,19].

In the current study the authors have defined a subset of patients at high risk for postoperative immobility. This subset includes patients greater than age 50 years, those who are undergoing complex surgeries for gynecologic malignancies, and those who have vertical midline abdominal incisions. As defined above, this subset of patients is at high risk for thromboembolic disease and pneumonia after gynecologic surgery. Interventions that decrease the risks of venous thromboembolic disease and pneumonia should be aggressively pursued in this very high risk patient population. Early ambulation in the postoperative period has been shown to decrease the risks of both venous thromboembolic disease and pneumonia [20, 21]. In combination with venous thromboembolic prophylaxis, early and persistent mobilization is recommended in all patients undergoing abdominal gynecologic surgery [17]. While bed rest had been shown to promote venous stasis, ambulation has been demonstrated to promote venous flow through contractions of the lower extremity muscle groups. In addition, a recent study demonstrated that moderate-intensity exercise suppresses platelet activation and polymorphonuclear leukocyte adhesion to platelets deposited at sites of vascular injury under flow and thereby reduces the risk of vascular thrombosis and inflammation [22].

Early postoperative ambulation has further been shown to improve pulmonary function and reduce risk of postoperative pneumonia [21]. Decreased respiratory effort due to excessive opioid use or due to inadequate pain control reduce the depth of breathing and increase the chances a patient will develop pneumonia. Ambulation results in improved lung expansion compared with a supine position, in addition to the added respiratory effort due to the work of walking.

While there was no difference in the primary study variable, milligrams of morphine used in 24 hours, the neoprene abdominopelvic binder used in the present study resulted in a marked improvement in postoperative ambulation in those patients at highest risk for thromboembolic disease and pneumonia: patients with age greater than 50 years, patients undergoing complex pelvic surgeries, and patients with vertical incisions. The present study was not powered to detect differences in morphine use between patients in the subgroup with all three risk factors and further studies of patients in this high risk group could be of use since the number of ambulatory events was correlated with the pain score in our multivariate analysis.

The mechanism of how the abdominal binder contributes to increased postoperative ambulation is likely multifactorial. The binder reduces shear forces at the incision interface resulting in less discomfort with sitting up, standing, and ambulating. Additionally, the pressure from the binder widely disperses the pain from the abdominal incision, resulting in the perception of pressure rather than pain. Finally, as the study was not placebo controlled, the binder group may have experienced a placebo effect, motivating patients to ambulate at a higher rate.

The time to first ambulation and the number of ambulatory events are also influenced by multiple factors. Specifically, some of the important factors include preoperative counseling and expectations for the postoperative course, postoperative counseling, postoperative pain control and the ability of the patient to ambulate without extra discomfort, the availability of nursing and ancillary staff to help the patient ambulate, postoperative encouragement by the operating team as well as the nursing and ancillary staff, and timing of Foley catheter removal.

A limitation of the current study was that it used morphine requirement through 24 hours instead of more clinically relevant variables such as pneumonia and venous thromboembolic events. The authors' assumption was that morphine use would be inversely related to the postoperative pain and that decreased pain would increase ambulation. The reason for choosing this endpoint is that both pneumonia and venous thromboembolic events are relatively rare and would require a longer patient follow-up that outlasts most postoperative hospital stays as well as a significantly increased number of patients in the study. This assumption was valid, based on the post hoc analysis between all outcome variables.

Conclusion

The authors have defined a group of patients who averaged less than one ambulation in the first 24 hours postoperatively, those patients who are greater than age 50 years, have undergone complex surgeries, and who have vertical abdominal skin incisions. These patients are also at high risk for postoperative pneumonia and thromboembolic disease [17-19]. Early and frequent postoperative ambulation has been shown to decrease these complications and should be aggressively pursued [21]. They have shown that the use of a neoprene abdominopelvic binder results in increased ambulation in this high-risk population. Furthermore, the binder was well-tolerated, had no adverse side effects, and is relatively inexpensive. The authors recommend the use of a binder in patients with one or more of the following characteristics: over age 50 years, complex gynecologic surgery, or have vertical skin incisions.

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