

Research Article

Intravenous Acetaminophen Does Not Reduce Peri-Operative Acute Pain Scores or Narcotic Use in Bariatric Surgery Patients

Emily Sterbis, Amy Rosenbluth, Michael Kammerer, Morgan Bresnick, Renee Tholey, Alec Beekley, David Tichansky*

*Department of Surgery, Division of Minimally Invasive, Metabolic and Bariatric Surgery, Thomas Jefferson University, Philadelphia, Pennsylvania, USA.

***Corresponding author:** David S Tichansky, MD, FACS Jefferson Bariatric and Metabolic Surgery 211 S, 9th St, Suite 402, Philadelphia, PA 19107; Tel: 215-955-0020; Fax: 215-503-7577; Email: david.tichansky@jefferson.edu

Citation: Sterbis E, Rosenbluth A, Kammerer M, Bresnick M, Tholey R, Beekley A, Tichansky DS (2016) Intravenous Acetaminophen Does Not Reduce Peri-Operative Acute Pain Scores or Narcotic Use in Bariatric Surgery Patients. J Surg 2016: J109. DOI: 10.29011/JSUR-109.000009

Received Date: 06 December, 2016; **Accepted Date:** 4 January, 2017; **Published Date:** 11 January, 2017

Abstract

Introduction

Narcotic pain medications continue to be the mainstay of postoperative pain management. It has been previously shown that use of intravenous acetaminophen in the perioperative period can improve pain control. The objective of this study was to determine if perioperative use of intravenous acetaminophen would reduce perioperative pain and narcotic use in the bariatric surgery population.

Methods

In October 2011, routine administration of 1000mg of intravenous acetaminophen at the end of bariatric procedures was established. After obtaining IRB approval, the records of consecutive bariatric surgery patients were retrospectively examined. Patients were separated into two groups of fifty patients each: Group A - patients who received intravenous acetaminophen; and Group B - patients who did not receive intravenous acetaminophen. Pain scores and narcotic usage (morphine equivalents) in the PACU were recorded. Average pain scores and narcotic usage for the two groups were compared using XLSTAT software.

Results

The average PACU pain scores, on a 10-point scale, for group A and group B were 4.94 and 4.34, respectively. The average narcotic use, as measured in morphine equivalents, in the PACU for group A and group B were 8.67 mg and 8.81 mg, respectively. There was no statistical difference in either average pain scores ($p=0.15$) or narcotic use ($p=0.51$) between the two groups.

Conclusion

These data show that use of intravenous acetaminophen in the perioperative period does not reduce acute pain scores or narcotic use in the bariatric patient population. Thus, IV acetaminophen is not a cost-effective measure for pain control in the immediate postoperative period.

Introduction

Perioperative pain control has been a focus of surgeons since the end of the first surgical procedure. However, the entity has more recently become a scrutinized arena in patient care with some calling pain scores a new vital sign. Physicians, nursing groups, and patient advocacy groups, as well as pharmaceutical manufacturers, have embarked on a quest to best optimize perioperative pain care.

Narcotics have traditionally been the first line therapy, and are in many cases the only therapy, for pain control during the post-operative period. New efforts have concentrated on multi-modality therapy to optimize pain control rather than simply add more narcotics. The theoretical benefits of this approach are: better pain control, lower narcotic dosing requirements, less narcotic-related side effects, and potential avoidance of narcotic-related adverse events. While narcotics are well known to cause drowsiness, decreased ambulation, and bowel motility issues, the most serious side-effect is respiratory depression.

Bariatric surgery patients are particularly vulnerable to these adverse events related to narcotics, specifically those stemming from respiratory depression. Bariatric patients have a higher incidence of obstructive sleep apnea than the general population, as high as 55-70% in some studies [1,2], due to their body habitus. Sleep apnea puts these patients at higher perioperative risk just from the anesthesia medications given during surgery. This unavoidable respiratory compromise is certainly exacerbated by the respiratory depression caused by narcotics. While intensive perioperative monitoring has been helpful in improving the safety of bariatric surgery patients, the risk of life-threatening respiratory compromise is ever present and catastrophic events have occurred.

Ideally, perioperative pain in bariatric patients should be controlled by a regimen that minimizes respiratory depression risk or does not cause respiratory depression at all. In November 2010, intravenous acetaminophen received FDA approval for use in the United States for: mild to moderate pain, severe pain as an adjunct to opioids, and fever reduction. As such, it has been theorized that the addition of intravenous acetaminophen to established pain protocols could reduce, or eliminate, narcotic use in the perioperative period. The primary outcome of this investigation was to determine if perioperative use of intravenous acetaminophen would reduce average perioperative pain scores in the bariatric surgery population. Total narcotic use was also measured as a secondary outcome.

Methods

After obtaining IRB approval, the prospectively collected records of consecutive bariatric surgery patients were retrospec-

tively examined to determine if the addition of intravenous acetaminophen at the completion of the index operative procedure has an impact on perioperative narcotic use and perioperative pain scores. In October 2011, the bariatric surgery team initiated routine administration of 1000 mg of intravenous acetaminophen upon completion of surgery. Beyond this change, the anesthesia during this procedure was the standard protocol for our institution involving rocuronium induction, followed by bolus dosing of narcotics and paralytics as needed based on vital sign and twitch monitoring. Sevoflurane is used as the general inhalant anesthetic unless otherwise dictated by medical history. One hundred patients encompassing a time period before and after this initiative were included in this study. Patients with history of chronic narcotic use were excluded from the study. All surgeries were performed by one of two experienced bariatric surgeons. Two groups of 50 patients were created: Group A includes 50 patients who received routine administration of intravenous acetaminophen and Group B includes 50 patients prior to October 2011 who did not receive intravenous acetaminophen. The sample size for this study was powered to detect a 25% pain score reduction which corresponds to a difference of one on a scale of zero to ten. Using an alpha of 0.05 and a power of 80% from previously noted pain scores (population mean 4, standard deviation 2), a sample size of 50 per arm was calculated.

Factors examined included patient demographics, surgical procedure type, pain scores in the Post Anesthesia Care Unit (PACU), morphine equivalents administered in the PACU, and antiemetic need while in the PACU. Pain scores were measured on the standard zero to ten point scale, with zero being no pain and 10 being "the worst pain imaginable". Pain scores while in the PACU are taken per anesthesia protocol of on arrival, then every 15 minutes times 4, then every 30 minutes times 2, then hourly, if the patient was still in PACU. If the patient was asleep during one of these times, no attempt was made at arousal and pain score was recorded as zero. The average pain score was then calculated by averaging all recorded intervals during the patient's PACU stay. Morphine equivalents were based on given doses of morphine, fentanyl, or hydromorphone according to each patient's recorded usage. While there is some minor variation in the literature, there seems to be consensus that 1 mg of morphine is equal to 25 mcg of fentanyl and 0.2 mg of hydromorphone. Morphine equivalents from each of these different medications were calculated.

Statistical comparison of the average pain scores and narcotic usage between the groups was performed using a two-tailed Mann-Whitney test through XLSTAT software (Version 2013.4.07, Addinsoft USA, New York, NY). Statistical comparison of the anti-emetic usage between the two groups was calculated using Fisher's exact test.

Statistical comparison of the patient demographics was cal-

culated with a student's t-test for BMI and age and a Fisher's exact test for the categorical variables of gender and the type of surgery to ensure there was no statistical difference in these characteristics between the two groups.

Results

100 patients were included within this study. The demographic data are summarized in (Table 1).

| | Group A | Group B | P-Value |
|-------------|----------|----------|---------|
| Number | 50 | 50 | |
| Sex F/M | 44/6 | 39/11 | 0.1714 |
| LSG/LRYGB | 31/18 | 21/26 | 0.1008 |
| LSG (%) | 31 (62%) | 21 (24%) | 0.0711 |
| LRYGB (%) | 18 (36%) | 26 (52%) | 0.1581 |
| BMI | 46.7 | 48.1 | 0.7615 |
| Age (Years) | 41 | 40 | 0.6328 |

Table 1: Patient Demographics.

Group A was 88% female and 12% male while Group B was 78% female and 22% male. Within Group A, 62% had a Laparoscopic Sleeve Gastrectomy (LSG) and 36% had a Laparoscopic Roux-en-Y Gastric Bypass (LRYGB). The remaining patient had a resection and recreation of jejunjejunostomy, laparoscopic cholecystectomy, and lysis of adhesions. Within Group B, 42% had a LSG, 52% had a LRYGB, 4% had a gastric band, and the remaining patient had a small bowel resection of a dilated Roux limb. The average BMI for group A before surgery was 46.7 while group B was 48.1. Group A had an average age of 41 and Group B had an average age of 40. There were no statistically significant differences in any of the demographic variables between the two groups.

Comparing the average pain scores obtained over the PACU stay, there was no statistical difference between the groups (Group A = 4.98 versus Group B = 4.34, p=0.15). Examining the average narcotic usage in the PACU (in morphine equivalents), there was no statistical difference in narcotic usage between the groups (Group A = 8.67mg versus Group B = 8.81mg, p=0.51). As an aside, the percent of patients requiring antiemetic usage was similar between the groups (Group A = 52% versus Group B = 54%, p=0.55). The data on pain scores and drug usage are also shown in (Table 2).

| | Group A | Group B | P-Value |
|----------------------------------|---------|---------|---------|
| Average Pain Score while in PACU | 4.98 | 4.34 | 0.15 |
| Average Narcotic Usage in PACU | 8.67 mg | 8.81 mg | 0.51 |
| Antiemetic Usage | 52% | 54% | 0.55 |

Table 2: Pain Scores, Narcotic Usage, and Antiemetic Usage.

Discussion

Intravenous acetaminophen would theoretically be an ideal alternative to narcotics in the perioperative period. Acetaminophen does not carry the risk of respiratory depression, is not addictive, is not sedating, and does not carry the significant risk of adverse events that traditionally used narcotic pain medications do. The published data on administration of intravenous acetaminophen is quite variable with many sources showing effectiveness of intravenous acetaminophen as an adjunct to narcotics in a diverse array of surgical patients, while other studies have found intravenous acetaminophen to have no effect on pain scores and/or morphine usage. It should be noted that those studies that demonstrate improved pain control, imply the effect is short-lived and diminishes with time.

In their prospective, randomized double-blinded study of 79 cardiac surgery patients, Lahtinen et al. investigated the effect of propacetamol, a prodrug of paracetamol (acetaminophen), versus placebo as an adjunct to PCA opioid use. They found the paracetamol group to use significantly less narcotic in the first 24 hours after surgery. At 72 hours, however, there was no difference between the groups in narcotic use, pain scores, pulmonary function, or adverse events to conclude there was overall no significant effect of using propacetamol as an adjunct [3]. In a meta-analysis of 75 studies totaling 7200 patients, McNicol et al. found 36% of patients achieved 50% or greater pain relief over a four hour period after receiving one dose of paracetamol, or its analogs, compared to 16% in the placebo group; and required 26% less opioid. Both of these effects diminished over 6 hours. There were no differences in adverse events between the groups. A downfall of the IV propacetamol was that patients were more likely to complain of pain at the site where their medication was infused [4]. A more recent study by El Chaar et al. in the bariatric patient population found no statistical difference in narcotics usage between patients receiving IV acetaminophen 30 minutes before surgery and a placebo group receiving IV saline. This study also found no significant difference in pain scores between the two groups [5]. While our study looked at the effects of a single dose of IV acetaminophen, a recent study by Wang et al. found that the use of at least four doses of acetaminophen following bariatric surgery did not reduce opioid use. Instead, those receiving IV acetaminophen used more opioids than patients not receiving acetaminophen [6].

To the contrary, Hernandez-Palazon et al. found in their randomized study of paracetamol versus placebo as an adjunct to morphine PCA that there was a significant decrease in narcotic usage and sedation in the paracetamol group over a 3 day period following spinal fusion surgery. Pain scores and opioid side effects were not different however [7]. Another study examining patients undergoing major orthopedic surgery, found similar results.

Sinatra et al. administered paracetamol or placebo in response to reported pain in 151 patients to observe the single dose efficacy with morphine rescue available to patients not achieving pain control. Pain relief was significantly greater in the paracetamol group from 15 minutes to 6 hours after administration. Morphine usage was also reduced significantly in this group. However, the number of adverse events was not significantly different between the study groups [8]. In their study including orthopedic, abdominal, pelvic, and cervical surgeries, Aubrun et al. found that morphine requirements decreased in patients with moderate and severe pain who received propacetamol infusions following surgery. However, the incidence of morphine-related adverse effects did not change [9]. With these conflicting results, this investigation examined the immediate effect of a single dose of intravenous acetaminophen specifically in the bariatric surgery population during their most vulnerable time for respiratory depression and greatest discomfort. Complete narcotic avoidance would be most ideal in bariatric surgery patients for several reasons. Early mobilization is key for the recovery of bariatric surgery patients. Patients using narcotics have an increased incidence of drowsiness, thus impeding ambulation. Narcotics can additionally inhibit recovery by affecting bowel activity. The constipation experienced by post-surgical patients affected by narcotics in this way may lead to longer hospital stays if it causes slower bowel recovery. In addition to physiologic dysfunction, bariatric patients are at a higher risk for addictive behaviors. A new trend being observed is addiction transference which infers that bariatric patients are transferring an addiction to food onto other substances. Many patients become addicted to the narcotics they are prescribed after surgery, often citing the ease in obtaining them as the reason. If acetaminophen can reliably control pain in the perioperative period, fewer narcotics will need to be used thus reducing the chance of addiction transference to narcotics [10-12].

Our finding was that the short-term reduction in pain and narcotic usage demonstrated in other studies was not translated to the bariatric surgery population. During the 24 hours following surgery, there was no significant difference in pain scores or narcotic use between the two study groups. Additionally, we found that antiemetic usage also did not significantly differ between the two study groups. Madan et al. have proposed that inpatient narcotic use by bariatric surgery patients is already minimal [13]. Perhaps the pain elicited by laparoscopic bariatric surgery is not to the degree where a noticeable difference of this adjunct therapy can be detected. It appears from this investigation, that single dose use of IV acetaminophen cannot be justified. While some studies, often related to orthopedics, show some benefit to the administration of acetaminophen to reduce narcotics use and/or perioperative pain levels, these studies also tend to show areas without improvement such as incidence of opioid adverse effects. Our study showed that the use of IV acetaminophen does not lead to significant reduc-

tions in pain levels or narcotics use in the perioperative period for bariatric surgery patients.

In an effort to evaluate this conclusion, the average pain scores were compared to the average narcotic usage. There was a very weak correlation between the two variables as shown in (Figures 1 and 2).

Group A - PACU Pain Score vs. Narcotics Usage $R^2 = 0.2962$

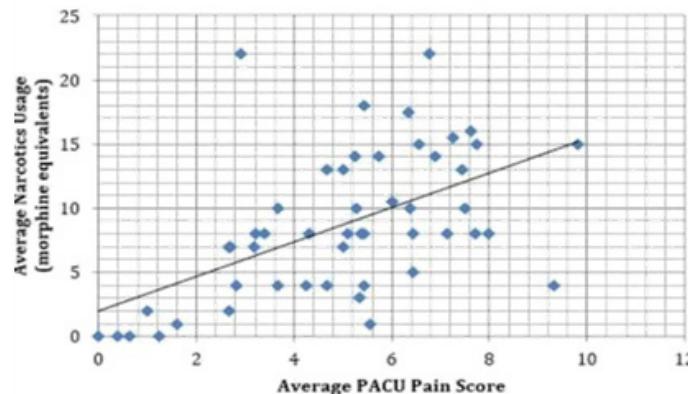


Figure 1: Group A - PACU Pain Score vs. Narcotics Usage This figure shows the relationship between the average pain score of patients who received intravenous acetaminophen while they were in the PACU and the average number of morphine equivalents they were given during this same time period.

Group B - PACU Pain Score vs. Narcotics Usage $R^2 = 0.4172$

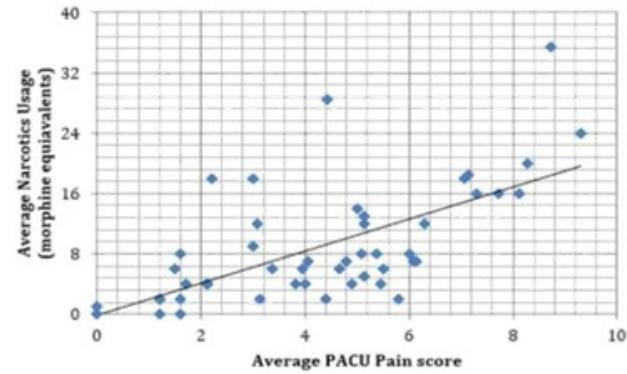


Figure 2: Group B - PACU Pain Score vs. Narcotics Usage This figure shows the relationship between the average pain score of patients who did not receive intravenous acetaminophen while they were in the PACU and the average number of morphine equivalents they were given during this same time period.

When a linear regression was run between the average PACU pain score and the average narcotics usage there was no significant correlation between the two variables. The regression correlation coefficient for patients receiving IV acetaminophen was 0.2962

while the regression correlation coefficient for those not receiving it was 0.4172. Using Fisher's r-to-z transformation, there was no statistical difference between these two correlation coefficients ($p=0.50$). This is of note as opioid usage and pain scores are common outcomes studied in the perioperative period. One might think that the more pain an individual has, the more narcotics he/she would use. However, this relationship is not perfect, as shown by the correlation coefficients. The inconsistency between pain scores and narcotics usage did not significantly vary between the two study groups.

One potential explanation of this weak relationship could be non-standardized treatment of pain in the PACU. Despite strict protocols for pain management, many different nurses cared for the PACU patients and as such, patients could have received varying doses of varying medications for varying indications by pain score. Another potential explanation is there are significant individual differences in the amount of narcotics needed to relieve an individual patient's pain.

Pain scores, even when ranked on a standard scale of 0-10, are sure to be subjective as each person's personal experience and expression of pain will differ. This lack of a relationship brings up important questions of how future studies should potentially analyze the effectiveness of perioperative pain treatment. The reduction of both a patient's subjective pain and their use of narcotics are unfortunately not correlated well, so it may take a multi-modal approach to individually optimize both outcomes.

Some of the potential weaknesses of this study include the gathering of information from PACU nursing notes in a retrospective manner and occasional inconsistent time intervals at which pain scores were taken.

From our study we conclude that intravenous acetaminophen does not appear to be a cost effective method for pain control as an adjunct to narcotics in the immediate postoperative period for bariatric patients. However, the inconsistency between pain scores and medication used indicates high likelihood that no routine pain management plan is likely to improve pain control and narcotic usage in all patients. These two endpoints should be evaluated in future studies as two independent outcomes which will not always agree with one another.

References

1. Kalra M, Inge T, Garcia V, Daniels S, Lawson L, et al (2005) Obstructive Sleep Apnea in Extremely Overweight Adolescents undergoing Bariatric Surgery. *Obes Res* 13: 1175-1179.
2. Lopez PP, Stefan B, Schulman CI, Byers PM (2008) Prevalence of Sleep Apnea in Morbidly Obese Patients Who Presented for Weight Loss Surgery Evaluation: More Evidence for Routine Screening for Obstructive Sleep Apnea before Weight Loss Surgery. *Am Surg* 74: 834-838.
3. Lahtinen P, Kokki H, Hendolin H, Hakala T, Hynynen M (2002) Propacetamol as Adjunctive Treatment for Postoperative Pain After Cardiac Surgery. *Anesth Analg* 95: 813-819.
4. McNicol ED, Ferguson MC, Haroutounian S, Carr DB, Schumann R (2016) Single dose intravenous paracetamol or intravenous propacetamol for postoperative pain In: Cochrane Database of Systematic Reviews [Internet]. John Wiley & Sons, Ltd 2016.
5. Chaar ME, Stoltzfus J, Claros L, Wasyluk T (2016) IV Acetaminophen Results in Lower Hospital Costs and Emergency Room Visits Following Bariatric Surgery: a Double-Blind, Prospective, Randomized Trial in a Single Accredited Bariatric Center. *J Gastrointest Surg* 20: 715-724.
6. Wang S, Saha R, Shah N, Hanna A, DeMuro J, et al (2015) Effect of Intravenous Acetaminophen on Postoperative Opioid Use in Bariatric Surgery Patients. *Pharm Ther* 40: 847-850.
7. Hernández-Palazón J, Tortosa JA, Martínez-Lage JF, Pérez-Flores D (2001) Intravenous Administration of Propacetamol Reduces Morphine Consumption After Spinal Fusion Surgery: Anesth Analg 2001: 1473-1476.
8. Sinatra RS, Jahr JS, Reynolds LW, Viscusi ER, Groudine SB, et al (2005) Efficacy and Safety of Single and Repeated Administration of 1 Gram Intravenous Acetaminophen Injection (Paracetamol) for Pain Management after Major Orthopedic Surgery. *J Am Soc Anesthesiol* 102: 822-831.
9. Aubrun F, Kalfon F, Mottet P, Bellanger A, Langeron O, et al (2003) Adjunctive analgesia with intravenous propacetamol does not reduce morphine-related adverse effects. *Br J Anaesth* 90: 314-319.
10. Ivezaj V, Saules KK, Wiedemann AA (2012) "I Didn't See This Coming.": Why Are Postbariatric Patients in Substance Abuse Treatment? Patients' Perceptions of Etiology and Future Recommendations. *Obes Surg* 22: 1308-1314.
11. Steffen KJ, Engel SG, Wonderlich JA, Pollert GA, Sondag C (2015) Alcohol and Other Addictive Disorders Following Bariatric Surgery: Prevalence, Risk Factors and Possible Etiologies. *Eur Eat Disord Rev J Eat Disord Assoc* 23: 442-450.
12. Wendling A and Wudyka A (2010) Narcotic Addiction Following Gastric Bypass Surgery--A Case Study. *Obes Surg* 21: 680-683.
13. Madan AK, Ternovits CA, Speck KE, Tichansky DS (2005) Inpatient Pain Medication Requirements after Laparoscopic Gastric Bypass. *Obes Surg* 15: 778-781.