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Efficacy of transversus abdominis plane (TAP) block in pain management after laparoscopic sleeve gastrectomy (LSG): A double-blind randomized controlled trial

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A B S T R A C T

Background: The aim of this randomized controlled trial was to assess the effectiveness of transversus abdominis plane (TAP) block in post-operative pain management in patients undergoing laparoscopic sleeve gastrectomy (LSG).
Methods: Ninety consecutive patients undergoing LSG were randomly assigned to three groups: placebo, TAP block with 0.25% bupivacaine (40mL total), and TAP block with 0.25% bupivacaine + 1/100,000 epinephrine (40mL total). Pain and nausea/vomiting scores were evaluated at varying times until discharge. Other parameters included, additional analgesia required, time to ambulation, length of stay and time required for return to work after discharge.
Results: There was decrease in post-operative pain 3 hours after surgery between the placebo group and the bupivacaine group and between the placebo group and the bupivacaine with epinephrine group, however, no difference in 1, 6, 12 and every 6 hours after. There was no significant difference in post-operative analgesia requirements, nausea/vomiting scores, time to ambulation, hospital length of stay, or time to return to work after discharge.
Conclusion: The efficacy of TAP block is not apparent likely due to the ERAS protocol set in place for bariatric surgery, which already targets early postoperative pain control and mobility.

Introduction

Optimal postoperative pain control is a difficult task in abdominal surgery, particularly, since anterior abdominal wall incisions can cause significant pain.[1,2] Effective pain control is associated with decreased post-operative opioid administration, faster mobilization, rapid recovery, and shorter hospital stay. This not only decreases postoperative complications and morbidity but can also diminish overall medical costs, shorten patients' time away from work, and increase patient satisfaction.[3,4]

Intraoperative nerve blocks using local anesthetics have shown to improve postoperative pain in a variety of abdominal surgeries both open and laparoscopic.[2] Transversus abdominis plane (TAP) block administers local anesthetics between T6 and L1 spinal nerve roots which provide somatic pain innervation to the abdominal wall.[1,2] With ultrasound guidance, local anesthetic can be injected in the proper neurofascial space while minimizing complications. Multiple studies have demonstrated the use of TAP block as an adjunct to postoperative pain control and resulting in reduced opioid use, reduced opioid related side effects, reduced antiemetic use, and increased time to request additional analgesia.[1–12]

Postoperative pain in bariatric surgery can be challenging due to the increased number of trocars for better intra-operative visualization and maneuver and higher body mass index (BMI) requiring a higher dosage of medicine. The aim of this RCT is to assess the effectiveness of TAP block in post-operative pain management in patients undergoing LSG. This is the first randomized controlled study to assess the efficacy of TAP block in pain control after LSG.

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Methods

Trial design

This prospective, randomized, double-blinded, placebo-controlled study was performed by the Department of Bariatric Surgery at The Brooklyn Hospital Center. The study was approved by the institutional review board (IRB-954,978-6). Written informed consent was obtained from all patients preoperatively. No additional risk beyond the risks of the actual surgery or additional cost was imposed to the patients.

Participants and settings

Inclusion criteria encompassed all morbidly obese patients aged between 18 and 65 years old who underwent LSG by our chief of bariatric surgery from March to October 2017 ($n = 90$). Patients who were allergic to Bupivacaine, American Society of Anesthesiologists (ASA) Class IV and V who were patients with severe systemic disease that is a constant threat to life or patients who were moribund and not expected to survive without the operation, had chronic pain conditions (consuming regular analgesics > 3-months), had prolonged intubation in recovery room, were chronic opioid users, and had neurological conditions were excluded.

Interventions

Ninety consecutive patients undergoing LSG were randomly assigned to three groups: placebo, TAP block with 0.25% bupivacaine (40 mL total), and TAP block with 0.25% bupivacaine + 1/100,000 epinephrine (40 mL total).

Outcomes

The primary outcomes of this study was to assess the postoperative pain score at rest using the visual analogue scaling (least: 0–10: worst) at 1, 3, 6, and then every 6 h post-surgery until discharge home. The total dosage of acetaminophen, gabapentin, opioid, and any other additional analgesic used was recorded.

Secondary outcomes measures included TAP block-related complications (vascular puncture, local hematoma, and need for intravascular local anesthetic injection), nausea/vomiting score (least: 0–4: worst), dosage of antiemetic usage, dosage of antipruritic usage, time to move on-feet, length of hospital stay, time to get back to work, and 30-day postoperative complications. At the time of the one week postoperative follow up, a standardized questionnaire was filled out by the patients assessing their recovery post-discharge home.

Sample site

A total of 20 ml of anesthetic agent (0.25% Bupivacaine) ± (1/200′000 Epi), or placebo was injected into the transversus abdominis plane on each side. A long spinal needle attached to a 30 cc syringe with the TAP block solution or placebo was used to inject the patient. The needle puncture was halfway between the subcostal margin and anterior superior iliac spine at the mid-clavicular line. Then under ultrasound guidance, the blunt tip needle was introduced midway between the anterior superior iliac spine and costal margin. Needle went through the skin, soft tissue, external oblique and internal oblique, and injection was performed between the internal oblique and transversus abdominis muscle. This was repeated on the contralateral side of the abdomen. The operating bariatric surgeon performed all of the TAP block procedures to ensure that the correct methodology with each patient and with consistency.

Randomization and blinding

SPSS for windows (PASW Statistics, Version 18, Chicago, Inc.) was used to randomize the samples for all 90 patients and the spreadsheet was distributed to the pharmacy department to prepare the TAP block/placebo solutions in a blinded bottle. Patient were allocated to three groups to receive ultrasound-guided TAP block bilaterally: 40 mL of 0.25% Bupivacaine +1/200′000 Epinephrine (TAP block w/Epi group), 40 mL of 0.25% Bupivacaine (TAP block group), or 40 mL of 0.9% normal saline (placebo group). Intra-operatively, the circulating nurse opened a sealed envelope designated to each patient and the surgical technician prepared the solutions in blank syringes to blind the surgeon performing the TAP block to group assignment. The patients, the surgeon, and the resident who was in charge of the postoperative pain evaluation were aware of the allocated group allowing for double blinding.

Statistical methods

A standard enhanced recovery after surgery (ERAS) protocol was used by our bariatric team perioperatively for all of the study patients. Preoperative liquid acetaminophen 900 mg PO was given approximately 90 min before surgery. Intraoperatively, intravenous metoclopramide 10 mg, dexamethasone 8 mg, and heparin 5000 units were given pre-induction. For induction, propofol, midazolam, and fentanyl were given in a weight based dosing. Lidocaine gel was used on the endotracheal tube. Intravenous ondansetron 4 mg intravenous push before extubation. Postoperatively, the patients were given acetaminophen 650 mg q6 hours standing and gabapentin 100 mg q8 hours standing for pain control. If the patient was still in severe pain beyond the standardized postoperative pain regimen and requested further pain relief, opioids such as morphine and hydromorphone were given. For postoperative prevention of nausea and vomiting, intravenous metoclopramide 10 mg q 6 h standing and intravenous ondansetron 4 mg q 6 h PRN were given.

Participant flow

All data were analyzed with the Statistical Program for Social Science (SPSS) Statistics V19. Data were allocated into three groups based on whether they had received 40 mL of 0.9% normal saline (placebo group, **Group 1**), ultrasound-guided TAP block bilaterally 40 mL of 0.25% Bupivacaine (TAP block group, **Group 2**), or 40 mL of 0.25% Bupivacaine + 1/200′000 Epinephrine (TAP block w/Epi group, **Group 3**). Scalar variables were analyzed with a one-way analysis of variance (ANOVA); binomial variables were analyzed with Chi-Square test. Ordinal variables were analyzed on a Likart scale. No ordinal variables were normal along any axis ($p < 0.05$, Shapiro-Wilk). All ordinal data were analyzed using Kruskal-Wallis test for significant difference between groups. All primary and secondary study endpoints were analyzed identically. For endpoints for which there was insufficient data to proceeded with statistical analysis, the results were reported descriptively. Means, 95% CI, and p-values were reported for statistically significant outcome variables.

Results

Outcomes pre-operative (demographic) data

There was no statistically significant difference in age, pre-operative weight, or pre-operative BMI among the three groups. There was no statistically significant difference in pre-opearative comorbidity prevalence among the three groups for hypertension (HTN), hyperlipidemia (HLD), or obstructive sleep apnea (OSA). There were statistically significant difference in gender and pre-operative diabetes mellitus (DM), however, these differences are likely due to the low numbers of patients who were either male or had DM in our study (Table 1).

Intra-operative data

There were no statistically significant difference in OR times, estimated blood loss (EBL), or the performance of concomitant intraoperative hiatal hernia (HH) or umbilical hernia (UH) repair between the three groups (Table 2).

Post-operative data

There was a statistically significant difference in pain scores at 3 h post-operatively: for placebo; mean = 7.87, 95% CI (6.94, 8.80), for bupivacaine; mean = 6.90, 95% CI (5.69,8.10), and bupivacaine + epinephrine; mean = 6.46, 95% CI (5.38,7.55) ($p = 0.036$)] (Fig. 1). Mean pain scores were lower with bupivacaine and bupivacaine + epinephrine when compared to placebo.

There was no statistically significant difference in postoperative pain scores at 1, 6, 12, 18, and 24 h between the three groups. Means for post operative pain scores are reported below (Table 3). While post operative pain score data was collected every 6 h for 48 h for patients who remained admitted, most patients (70) were discharged prior to 30 h and data after 30 h were not sufficient for statistical analysis.

There was no statistically significant difference in the total dosage of acetaminophen, gabapentin, opioid, and any other additional analgesic medication during the hospital stay between the three groups. Means are reported below (Table 4).

There was no statistically significant difference in nausea/vomiting score at 1, 3, 6, 12, 18, and 24 h between groups. Means are reported below (Table 5). While nausea/vomiting score data was collected every 6 h for 48 h for patients who remained admitted, most patients (70) were discharged prior to 30 h and data on time points after 30 h was not sufficient for statistical analysis.

There was no statistically significant difference in amount of nausea/vomiting medication given between the three groups. Means are reported below (Table 6).

There was no statistically significant difference in time to move on-feet, length of hospital stay (LOS), time to get back to work between the three groups. Means are reported below (Table 7).

There were six post-operative complications in the study. Four post-operative complications occurred in the placebo group, and one in each bupivacaine and bupivacaine + epinephrine groups. A list of post-operative complications is presented in Table 8.

Discussion

The main objective of this randomized controlled trial was to assess the effectiveness of intraoperative TAP block on post-operative pain control. Our results showed a statistically significant lower pain score at 3 h after surgery in the experimental groups vs placebo. However, no significant difference was observed at hours 1, 6, 12 and every 6 h after until discharge. In addition, there was no significant difference in post-operative analgesia requirements between all 3 groups.

Based on a literature review, there have been five prospective trials on TAP block efficacy in bariatric surgery (Table 9).[13–17] Of these, two have explicitly studied pain control with TAP block in LSG.[13,14] Wassef et al. did a double blinded, prospective, randomized controlled trial on single port LSG and the results showed significantly decreased pain scores in the first 12 h after surgery in the TAP block group, while observing no difference in pain scores at 24 h post-operatively.[13] However, in their case, there was only a

Table 1
Comparison of demographic data.

Demographic Data	Group 1 (placebo)	Group 2 (bupivacaine)	Group 3 (bupivacaine + epinephrine)	ANOVA	p-value
Age (years)				2.715	0.072
Mean ± SD	40 ± 11.2	37 ± 10.7	27 ± 11.2		
95% CI	36–44	33–41	39–48		
Weight (lbs)				1.225	0.299
Mean ± SD	257 ± 44.0	274 ± 40	269 ± 52		
95% CI	241–272	258–288	249–290		
Body Mass Index				0.259	0.773
Mean ± SD	44 ± 7.1	44 ± 4.8	43 ± 10.3		
95% CI	42–47	42–45	39–47		1
				Chi-Square	**p-value**
Gender				96.167	0.000
Male	2	4	5		
Female	30	27	22		
Diabetes Mellitus(DM)				94.445	0.000
Yes	6	4	4		
No	26	27	23		
Hypertension(HTN)				1.187	0.552
Yes	13	9	11		
No	19	22	16		
Hyperlipidemia (HLD)				5.773	0.056
Yes	2	5	8		
No	30	26	19		
Obstructive Sleep Apnea (OSA)				0.178	0.915
Yes	7	8	7		
No	25	23	20		

Table 2
Comparison of intraoperative data.

Intraoperative Data	Group 1 (placebo)	Group 2 (bupivacaine)	Group 3 (bupivacaine + epinephrine)	ANOVA	p-value
OR Time (Minutes)				0.934	0.393
Mean ± SD	54.8 ± 17.5	56.4 ± 13.5	61 ± 21.9		
95% CI	48.5–61.1	51.4–61.3	52.3–69.7		
Estimated Blood Loss (EBL) (ml)				0.913	0.405
Mean ± SD	15.3 ± 19.5	20.0 ± 20.2	22.8 ± 21.3		
95% CI	8.2–22.5	12.6–27.4	13.1–32.4		
				Chi-Square	**p-value**
Intraoperative Umbilical Hernia Repair				0.447	0.800
Yes	7	8	5		
No	25	23	22		
Intraoperative Hiatal Hernia Repair				1.099	0.577
Yes	3	5	5		
No	29	26	22		

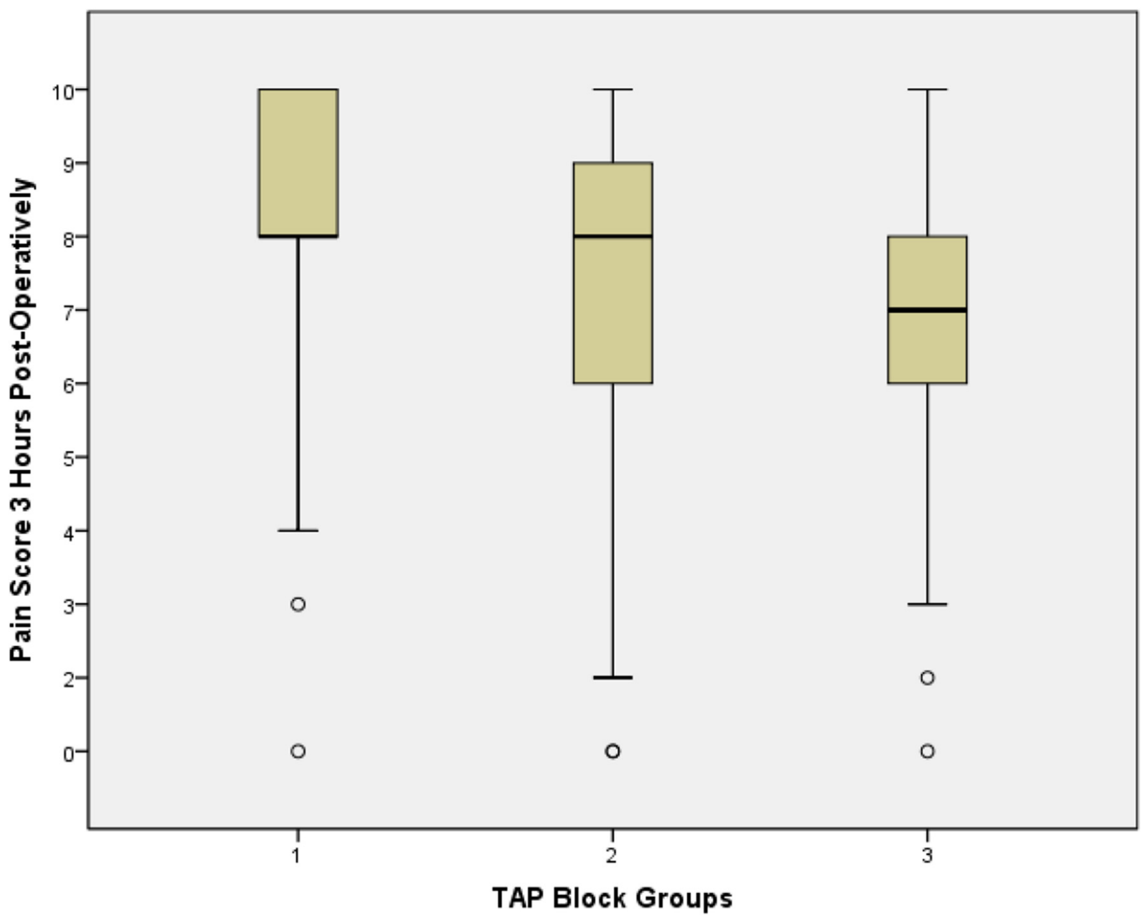

Fig. 1. Pain Scores at 3 h postoperatively.

Table 3
Comparison of pain scores.

Post-Operative Pain Score Means						
	1hr	3hr	6hr	12hr	18hr	24hr
Placebo	8.48	7.87	6.13	5.97	4.55	3.44
Bupivacaine	7.21	6.90	6.63	4.83	3.89	3.83
Bupivacaine + Epinephrine	7.58	6.46	5.38	4.77	3.81	3.18

Table 4
Comparison of analgesia used.

Analgesia Used Means (mg)							
	Tylenol (postoperatively)	Gabapentin	Fentanyl **(MSE)**	Morphine	Dilaudid **(MSE)**	Toradol	Oxycodone **(MSE)**
Placebo	2645	445	168	4.45	1.636	15.0	3.3
Bupivacaine	2296	327	168	2.85	0.856	–	2.6
Bupivacaine + Epinephrine	2690	354	216	4.09	1.680	22.5	2.3

MSE = morphine sulfate equivalent.

Table 5
Comparison of post-operative nausea and vomiting scores.

Nausea Vomiting Score Means						
	1hr	3hr	6hr	12hr	18hr	24hr
Placebo	1.48	0.81	0.61	0.55	0.45	0.60
Bupivacaine	1.24	1.00	0.57	0.83	0.56	0.65
Bupivacaine + Epinephrine	1.52	1.08	0.69	0.81	0.54	0.36

Table 6
Comparison of post-operative nausea and vomiting medicine used.

Nausea/Vomiting Medication (mg)			
	Ondansetron (Zofran)	Metoclopramide (Reglan)	Scopolamine
Placebo	8.8	38.2	1.4
Bupivacaine	6.3	36.7	1.1
Bupivacaine + Epinephrine	7.8	46.2	1.0

Table 7
Comparison of Time to Feet, Length of stay (LOS), Time to Work.

	Time to Feet (minutes)	LOS (days)	Time to Work (days)
Placebo	559	1.61	15
Bupivacaine	581	1.37	11
Bupivacaine + Epinephrine	530	1.31	12

Table 8
Comparison of postoperative complications.

Post-Operative Complications		Numbers
Placebo	nausea/vomiting requiring EGD balloon dilation	1
	hematoma above supraumbilical incision	1
	uncontrolled incisional pain due to high narcotic tolerance	1
	umbilical hernia	1
Bupivacaine	Post-operative shortness of breath	1
Bupivacaine + Epinephrine	Allergic reaction to enoxaparin	1

single port site incision versus the five port sites we used in our standard LSG. When comparing the data from our study to theirs, we found no significant difference after 3 h post-operatively and we attribute to the possibility that greater pain control is need for increased number of port sites.

Said et al. studied the effect of continuous infusion of TAP block via a laparoscopically placed catheter for patients undergoing LSG and their results showed a significantly lower pain score throughout the admission after surgery in the TAP block group.[14] Our patients received a one-time TAP block dose of either bupivacaine or bupivacaine with epinephrine which has a half-life of 4–7 h compared to the continuous infusion of TAP block for 24 h after surgery, thus, explaining the potential difference in outcomes.

All of our patients went through our strict bariatric ERAS protocol including intraoperative anti-emetics, analgesia, and steroids as well as postoperatively analgesia and anti-emetics. Multiple studies and meta-analyses of ERAS in bariatric surgery have all shown to decrease post-operative morbidity and length of stay. We attribute the lack of significant difference in post-operative analgesia requirements, nausea/vomiting scores, time to ambulation, hospital length of stay, or time to return to work after discharge between the study groups to the ERAS protocol which targets all of these outcomes.[18–20]

A major limitation of the study is the fact that we analyzed pain scores beyond the half-life of the local anesthetic. Moreover, in the immediate post-operative period, TAP block's clinical efficacy may not be as pronounced due to general anesthetic medications still present in the patient's system. In addition, we did not differentiate the effect of ERAS on post-operative outcomes including pain, nausea/vomiting, time to ambulation, and hospital length of stay.

Moreover, the amount of TAP block given to the patients may have not been sufficient to improve postoperative pain control given the elevated BMI of bariatric patients. TAP block as an adjunct to postoperative pain control has been studied in many different

Table 9
Literature review of studies on the effect of TAP block in bariatric surgery.

Study Design							Postoperative Outcomes						
Study	Study Type	Surgery	TAP Block Method	Intervention	Control	Study Size	Pain Scores	Nausea/ Vomiting	Adverse Events (AE)	Analgesia Required	Time to Ambulate	LOS	Patient Satisfaction
Sinha et al.[16]	Double Blinded Prospective Randomized	Laparoscopic Gastric Bypass	US guided	0.375% Ropivacaine (40 mL total)	Normal Saline (40 mL total)	n = 100 (TAP = 50 NS = 50)	Significant decrease in TAP group	NA	None	Significant decrease in TAP group	NA	No significant difference	Significant increase in TAP group
Albrecht et al.[15]	Double Blinded Prospective Randomized	Laparoscopic Gastric Bypass	US guided	0.25% Bupivacaine (60 mL total)	No TAP Block	n = 57 (TAP = 27 No Block = 30)	No significant difference	No significant difference	None	No significant difference	NA	No significant difference	NA
Wassef et al.[13]	Double Blinded Prospective Randomized	Single Port LSG	US guided	0.2% Ropivacaine (60 mL total) + IV PCA	IV PCA	n = 35 (TAP + IV PCA = 10 IV PCA = 25	<12 h Postop = significant difference At 24 h Postop = No significant difference	NA	None	No significant difference	NA	NA	NA
Said et al.[14]	Double Blinded Prospective Randomized	LSG	Laparoscopic placed catheters (24 h Infusion)	0.25% Bupivacaine (4 mL/h)	IV Morphine	n = 90 (TAP = 45 IV Morphine = 45)	Significant decrease in TAP group	NA	Morphine related AE significantly lower in TAP group	Significant decrease in TAP group	Significant decrease in TAP group	NA	Significant increase in TAP group
Bhakta et al.[17]	Prospective Chart Review	Laparoscopic Gastric Bypas and LSG	Laparoscopic guided	2.2 mg/mL liposomal Bupivacaine (80 mL total) w/o PCA	0.25% Bupivacaine (80 mL) + PCA	n = 476 (Liposomal = 233 Bupivacaine = 243)	No significant difference	Increased antiemetic use <24 h, no significant difference over LOS	NA	Significant decrease in liposomal group	NA	NA	NA

areas of surgery, particularly, in colorectal surgery where it has seen success in improvement of early postoperative pain control consistently. However, most of these studies had patients whose BMI were significantly lower than in the bariatric surgery department, usually below BMI 30.[6,7] Elamin et al. demonstrated a therapeutic effect of TAP block in postoperative pain in laparoscopic cholecystectomies in a randomized controlled trial. The mean BMI in this trial was below 30.[4,9] Further studies are needed to analyze the effect of TAP block in postoperative pain control in bariatric patients with different amount of local analgesia being given during the block. Our patients may have seen a significant difference in postoperative pain improvement between the TAP block and the placebo group had the TAP block group received a larger amount of local analgesia bilaterally given their increased BMI.

In conclusion, TAP block may not be as effective in patients who are already undergoing ERAS protocol. Further studies investigating the use of TAP block in patients participating in ERAS protocol versus those who are not would be warranted to see the true efficacy of TAP block in relieving post-operative pain.

Conflicts of interest

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amjsurg.2018.07.010.

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