ORIGINAL ARTICLE

Comparative study of continuous surgical transverse abdominis plane block versus intravenous fentanyl infusion for postoperative pain management in open nephrectomy

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Abstract

Background: Role of continuous infusion of local anesthetic drug in the transverse abdominal plane using a catheter inserted during the surgical closure of the wound has not been evaluated as a "sole technique" in patients undergoing open nephrectomy. Thus we designed this prospective, randomized comparative study to evaluate this aspect. *Aim and Objectives:* To compare the efficacy of continuous surgical transverse abdominal plane block with intravenous fentanyl infusion in open nephrectomies. The primary outcomes were post-operative tramadol consumption, pain at rest and pain while coughing. The secondary outcomes were the level of sedation, time to mobilize, and the incidence of wound infection. *Material and Methods:* Fifty patients undergoing elective open nephrectomy were randomly divided into two equal groups to either receive intravenous fentanyl infusion (Group A), or continuous infusion of bupivacaine in the transversus abdominis plane through a surgically inserted catheter (Group B). The independent sample t-test was applied for numerical variables, while one way Analysis of Variance (ANOVA) repeated measure was used for analyzing the continuous variables. Chi-square and Fisher's exact tests were the tools used for analyzing the dichotomical variables. *Results:* Tramadol consumption, pain while resting, and pain during coughing were significantly lower in Group B ($p<0.001$, $p=0.003$, $p=0.001$ respectively). Level of sedation and time to mobilize were also significantly lower in patients of Group B. Adverse effects were not differing significantly between groups. No wound infection was noted in either group. *Conclusion:* Continuous surgical wound infusion of 0.25% bupivacaine through a catheter placed by the surgeon in the transverse abdominal plane in open nephrectomy patients can be considered as an effective and safe alternative of providing postoperative pain relief than intravenous fentanyl infusion.

Keywords: Surgical Transverse Abdominal Plane Block, Open Nephrectomy, Fentanyl Infusion, Pain Relief, Sedation Score

Introduction

Infusion of local anesthetic drugs over the wound, surgeon-placed catheter/single injection in Transverse Abdominis Plane (TAP), are being practiced since long time for various surgeries for providing analgesia in the peri-operative period [1-5]. Also, this method of pain relief is one of the simple and easy methods of pain relief in our day-to-day practice because of two factors: Firstly, there is always a potential possibility to proceed for open method in some cases where the initial

attempt of laparoscopic method would turn out to be technically difficult or impossible. Hence, this method would be handy in such cases if other method of pain relief such as epidural analgesia, regional blocks was not opted before the procedure. Secondly, although ultrasound-guided regional blocks have become popular in the recent years for pain relief in open nephrectomies [6-8], they require expertise, availability of equipment, time etc. This is particularly notable in resource-limited settings.

Continuous infusion of local anesthetics over the wound was proved as an effective alternative to the conventionally followed epidural analgesia and systemic opioid analgesia, in patients undergoing open nephrectomy. Indeed, Continuous Surgical Site Analgesia (CSSA) has been found to reduce the magnitude of residual pain one month following surgery significantly and optimizing the parameters that are considered as "quality-of-life" three months following the open nephrectomy when compared to epidural analgesia or patient controlled morphine infusion [5].

Although simple techniques are available for providing pain relief, some of them do have demerits. For instance, systemic administration of opioids produces side-effects such as drowsiness, ventilator depression, pruritus, Postoperative Nausea and Vomiting (PONV), urinary retention, ileus and constipation which can be cumbersome for the patients. Epidural analgesia has the disadvantages like inadvertent dural puncture, bradycardia, hypotension, respiratory depression, urinary retention, and most dreaded complications like hematoma and infection.

"Surgical Transversus Abdominis Plane (TAP) block" in a case of open nephrectomy had been described in the literature [9]. In this technique, the catheter is placed between the internal oblique and transverse abdominis muscle layers by the surgeon during the closure of the wound and the local anesthetic drug can be infused during the post-operative period. Our study had evaluated the effects of infusion of bupivacaine into the "surgical TAP" in patients who had undergone elective open nephrectomy through a lumbotomy incision. It was hypothesized that surgical TAP block would result in lesser opioid requirement in the post-operative period.

Material and Methods

This prospective, randomized, comparative study was carried out on fifty patients who were scheduled for open nephrectomy via a lumbotomy incision, following approval by the institutional ethical board. All patients enrolled in the study were explained about the protocol and their written consent was taken for participation.

Out of 56 patients selected, fifty patients were randomly assigned to either Group A (n=25) or Group B (n=25) after computer randomization using sealed envelope technique. Group A received intravenous fentanyl infusion, while Group B received bupivacaine infusion into the wound. All patients who were 18 to 65 years of age, posted for planned open nephrectomy through a lumbotomy incision, who were fulfilling the American Society of Anaesthesiologists (ASA) physical status I or II, were included in this study. Patients with ASA status III or above, having allergic reaction to local anaesthetics, serum creatinine above 2 mg/dl, obesity (BMI >30), chronic pain, chronic opioid intake, chronic hepatic disease, psychiatric disturbances were excluded.

All patients were operated by the same team of experienced surgeons. The method of anesthesia administration was standardized for all the patients of both groups. All patients were pre-medicated with tablet alprazolam 0.5 mg per orally with sips of water, 2 hours before the scheduled time of surgery. On arrival into the operating room, monitoring of parameters was started as per the ASA standards. All the baseline values were recorded. Fentanyl 2 μg/kg was given intravenously before induction of anesthesia. Propofol (2 mg/kg) was used as an induction agent and endotracheal intubation was facilitated with atracurium 0.5 mg/kg. Anesthesia was maintained with 66% nitrous oxide, 33% oxygen and desflurane 3% following confirmation of the position of the endotracheal tube placement. Patients were positioned laterally depending on the side of the nephrectomy. Anesthesia ventilator (Aestiva 5, Datex Ohmeda) was used in the volume control mode to achieve target end-tidal CO_2 of 30-35 mmHg. A tracurium 0.12 mg/kg was repeated as and when required and fentanyl 0.5 μg/kg was given if plane of anesthesia was inadequate based on the heart rate and blood pressure. Residual neuromuscular blockade was antagonized using neostigmine 50 g/kg with glycopyrrolate 10 g/kg.

Extubation of trachea was accomplished when the patient was hemodynamically stable, responsive and cooperative. The duration of surgery was noted in all patients. All parameters were noted in the post-operative care area by another anesthesiologist who was not involved in the operating room management of the cases.

In Group A, all patients received continuous intravenous fentanyl infusion 1 μg/kg/hr through an infusion pump for 48 hours postoperatively. In Group B, after closure of the transverse abdominis muscle, a multi holed flexible soaker catheter was placed in the inter-muscular plane between transverse abdominis and internal oblique muscles and 10 ml of bupivacaine 0.25% was given as a bolus as soon as the muscle layers were closed. This was followed by an infusion at the rate of 2 ml/hr through an infusion pump for 48 hrs post-operatively. Drugs were prepared by an operation room staff. In the postoperative care ward, when a patient developed pain of Visual Analogue Scale (VAS) score $\geqslant 4$, in a 10 point scale (where 0-none; 10-very severe), they received injection tramadol intramuscularly at 1.5 mg/kg.

Heart rate, rate of respiration, pain at rest as well as during a cough, 4 point sedation score, were assessed at 0.5 hours [30 minutes after extubation], subsequently every 2 hours for 6 hours and every 6 hours for 48 hours. The primary outcomes namely tramadol consumption, pain at rest (VAS) and pain while coughing incident [(c) VAS] were measured using the VAS 0-10 scale. The secondary outcomes analyzed were the level of sedation, time to mobilize, and wound infection. The sedation level was assessed using a four point rating scale i.e. 0 - completely alert; 1- drowsy; 2-sleepy, however, easily arousal; 3 - sleepy but barely arousable. The amount of tramadol consumption as rescue analgesic and its side effects like ileus, pruritus, nausea and vomiting, bupivacaine toxicity like nystagmus, vertigo, tinnitus and dysrhythmias, time to mobilize the patient, wound infection were also recorded.

Statistical analysis

Software version 23 of Statistical Package for Social Sciences (SPSS Inc, Chicago, Illinois) was used for interpretation of our findings. The independent sample t-test was applied for numerical variables, while one way Analysis of Variance (ANOVA) repeated measure was used for analyzing the continuous variables. Chi-square and Fisher's exact tests were the tools used for analyzing the dichotomical variables. Significance with regard to statistical analysis was considered when the value of p was less than 0.05.

Sample size calculation

A pilot study was conducted to calculate the sample size involving a total of ten patients (five in each group) with an intention of assessing the mean dose of tramadol consumption. The mean dose of tramadol required in patients who received intravenous fentanyl infusion was 35 mg, while it was 15 mg in patients who received surgical TAP. Hence, we arrived at a sample size of 25 cases in each arm. (Level of significance 5%, power 80%, difference =20 mg, effect size 0.9)

Results

Demographic parameters such as age, sex, height and weight of both Group A and Group B were comparable (p>0.05). The mean surgery duration in Group A was 219.80 min with shortest time being 130 minute and longest time being 300 minute. In Group B, the mean duration was 204.70 minute with shortest time being 120 minute and longest time being 270 minute. The difference was not statistically significant (p=0.057).

There was significant reduction of pain during rest as well as pain at coughing episode in the Group B when compared to Group A, during the entire 48 hours following the procedure (Table 1). Total number of tramadol injections required were 37 in Group A vs 12 injections in Group B (p <0.001) (Table 2). At 0.5 hour, the difference of sedation scores between the two groups was statistically comparable. However, it was significantly lower in the patients of Group B during the rest of the postoperative phase completely (Table 3).

Patients in Group B were able to ambulate approximately 9 hours earlier than those in Group A. The mean time taken to mobilize the patient after the surgery in Group B was 28 hours, whereas it was 37 hours in the Group A and the difference was statistically significant (p = 0.001). Six patients developed an episode of vomiting in the Group A. Only one patient vomited in the Group B. Although the number signifies the difference between two groups, it was not significant statistically (p=0.059). No significant difference was observed between the two groups regarding the mean arterial pressure, heart rate and respiratory rate. None of the patients included in the Group B had any adverse effect to bupivacaine. In addition, the review of medical records of all fifty patients was completed, with a specific focus on wound healing and infection (if any) during the follow up for a month. In all patients the scar was healthy and there was no difference in the date of suture removal. Based on this, the wound infection rate was found to be 0% in both groups.

Table 1: Pain scores while resting and during cough

Postoperative Time (hours)	Pain while resting			Pain during a cough		
	Group A	Group B	p	Group A	Group B	*p*
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
0.5	4.12 ± 1.83	2.52 ± 1.71	0.003*	5.88 ± 1.12	3.72 ± 1.27	0.001*
2	2.40 ± 0.76	1.28 ± 1.06	0.001*	5.40 ± 0.76	3.28 ± 1.06	0.001*
4	2.28 ± 0.73	1.32 ± 1.10	0.001*	5.32 ± 0.74	3.12 ± 1.23	0.001*
6	2.38 ± 0.71	1.42 ± 1.49	0.001*	5.00 ± 0.70	3.52 ± 1.38	0.001*
12	2.40 ± 1.19	1.48 ± 1.32	0.013*	5.40 ± 1.19	3.48 ± 1.32	0.001*
18	1.76 ± 0.52	1.20 ± 1.15	0.032*	4.76 ± 0.52	3.20 ± 1.15	0.001*
24	1.80 ± 0.76	1.08 ± 0.99	0.006*	4.80 ± 0.76	3.08 ± 0.99	0.001*
30	1.48 ± 0.58	0.96 ± 1.02	0.032*	4.48 ± 0.67	2.96 ± 1.01	0.001*
36	1.28 ± 0.67	0.92 ± 0.95	0.031*	4.28 ±0.58	2.88 ± 0.83	0.001*
42	1.28 ± 0.67	0.76 ± 0.83	0.019*	4.20 ± 0.81	2.76 ± 0.83	0.001*
48	1.28 ± 0.68	0.72 ± 0.84	0.013*	4.16 ± 0.68	2.64 ± 0.63	0.001*

**Statistically significant*

Table 2: Comparison of tramadol consumption

Number of Tramadol injections required	Group A	Group B	*p*
Nil	1	16	<0.001*
1	13	6	
2	9	3	
3	2	0	
Total	**25**	**25**	

**Statistically significant*

Table 3: Comparison of sedation scores

Postoperative time (hours)	Group A	Group B	*p*
	Mean ± SD	Mean ± SD	
0.5	1.12 ± 0.33	1.04 ± 0.20	0.307
2	1.36 ± 0.64	0.40 ± 0.50	0.001*
4	1.48 ± 0.65	0.24 ± 0.43	0.001*
6	1.60 ± 0.64	0.16 ± 0.37	0.001*
12	1.56 ± 0.65	0.04 ± 0.20	0.001*
18	1.32 ± 0.80	0.04 ± 0.20	0.001*
24	1.24 ± 0.78	0.08 ± 0.28	0.001*
30	0.88 ± 0.83	0.04 ± 0.20	0.001*
36	0.60 ± 0.71	0.04 ± 0.20	0.001*
42	0.52 ± 0.65	0.04 ± 0.20	0.001*
48	0.52 ± 0.65	0.04 ± 0.20	0.001*

**Statistically significant*

Discussion

Our study found that the continuous infusion of bupivacaine in the TAP by placing a catheter during closure of the wound could produce beneficial effects such as reduction of analgesic requirement, and early ambulation without any adverse effects.

Continuous infusion of local anesthetic over the surgical wounds as a method of pain relief got a boost following the introduction of the special catheters in this century [10]. In addition, this technique of placing these special catheters (having multiple holes and flexible in nature) on the surgical wounds would result in uniform spread of the drug over a duration of clinician's choice [10]. The local anesthetics infused over the wound might prevent the tissue damage by modulating the inflammatory response due to the accumulation of Polymorphonuclear (PMN) cells and relieve the pain by inhibiting the noxious afferent transmitters from the peripheral nerve fibers [11]. This method of pain relief has advantages like ease of placement, lesser complications when compared to epidural or peripheral nerve blocks [10]. Furthermore, this technique results in considerable reduction of the post-operative opioid requirements, thereby their side effects too, and can be used in the ambulatory patients also with the portable infusion pumps [12].

The effectiveness of "surgical TAP block" technique in an open nephrectomy case [9], and another novel surgical approach with dual catheters [anterior and posterior] in a case series of three patients [13] had been mentioned in the literature. To our knowledge, there is no randomized comparative clinical study available in the literature to date, that had tested the effects of "surgical TAP block" as a sole technique in a group in open nephrectomy patients. Although Forastiere

et al. [14] had studied the effects of continuous infusion of ropivacaine through a catheter placed in the muscle layers between the transversus abdominis and the internal oblique during wound closure in this population, they had not used it as a "sole technique". They had used an additional catheter in the subcutaneous space. Because of this, we cannot be sure of the exact proportion of the contribution of two catheters in relieving the pain. Forastiere *et al*. concluded that continuous infusion of ropivacaine over the surgical wound had produced better post operative pain relief and quicker recovery and discharge thereby resulting in reduction of the total costs [14].

Another study published recently by Capdevila *et al*. [5] had also used one catheter in TAP and an additional catheter in the subcutaneous space in the same population, similar to the study of Forastiere *et al*. [14]. However, Capdevila *et al*. [5] had compared this technique with epidural and control group that received patient controlled morphine administration. Hosgood *et al*. [15] and Araújo *et al*. [16] had compared the effects of ultrasound-guided TAP block in laparoscopic nephrectomy patients.

Furthermore, the technique of surgical TAP block was evaluated in other category of patients [17-18]. Owen *et al*. had observed that cesarean section patients who had received the surgical TAP block had more prolonged time for the "first request of morphine" and reduction of overall need of morphine. They also observed that this technique was easier and free from complications. This was not a randomized study, but a comparison of two sets of case series [17]. Aykut *et al*. had compared the effectiveness of ultrasound-guided TAP block with surgical TAP block in obese cesarean section patients. They concluded that the surgical approach was technically easier and consumed significantly lesser time than the ultrasound-guided group. Both techniques were equally effective and safe [18].

Although laparoscopic approach for the urological procedures [19] has gained popularity in the recent years, there is still a possibility of requirement of an open procedure as mentioned in the "Introduction". Hence, we need to focus more about the post-operative pain relief in such open cases. Intrathecal opioids are used as an adjuvant in various lower abdominal open procedures [20] to extend the postoperative analgesia. In addition, intrathecal morphine in combination with Intravenous Patient-Controlled Analgesia (IV-PCA) has resulted in lesser side effects when compared to IV-PCA alone in open nephrectomies [21]. In our study, we found that surgical TAP was associated with lesser requirement of tramadol, thus reducing its side-effects.

Limitations

The limitation of our study was firstly, we didn't analyze the exact cost required per patient in the postoperative period. Hence, we could not assess the mean cost of stay in the hospital. Secondly, the time to discharge the patients was also not recorded. This is because of lack of standardized discharge criteria followed by the surgeons. Another limitation of this study is that blinding could not be done because of the study design wherein the catheter was placed in one group of patients. "Blinding" would have been possible if we had adopted a control group receiving the saline through the catheter. Furthermore, we also feel that it would have been better if the technique of "surgical TAP block" was compared with other techniques of pain relief such as ultrasound

guided TAP block, epidural or pleural block.

Conclusion

Continuous surgical wound infusion of 0.25% bupivacaine provides superior postoperative pain relief than intravenous fentanyl infusion and significantly reduces the requirement of post-operative opioids and its side effects thereby producing quicker patient ambulation in open nephrectomy procedures. In addition, this method is safe too when compared to systemic administration of opioids.

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