ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Comparison the effect of two methods, patient controlled analgesia and non-steroidal anti-inflammatory drugs after elective cesarean: A Patient Education Program.

Negin Rezavand[1], Roya Raeisi[2], Ali Reza Ghorbani[3], and Majid Ahmadi[4]*.

[1]Department of Associate Obstetrics & Gynecology, Kermanshah University of Medical Sciences, Kermanshah, Iran.
[2]Department of Pediatrics, Faculty of Medicine, Hamadan University of Medical Sciences, Hamadan, Iran.
[3]Department of Anesthesiology, Sadjad General Hospital, Kermanshah, Iran.
[4]Department of Anatomical Sciences and Genetics, Faculty of Medicine, Kurdistan University of Medical Sciences, Sanandaj, Iran.

ABSTRACT

Lack of pain relief after Cesarean section can lead to the postoperative complications, prolongation of hospitalization and it may delay recovery. Patient controlled analgesia (PCA) is an effective and modern method for reducing pain. Hence, this study aims to compare PCA and non-steroidal anti-inflammatory drugs (NSAIDs) after elective Cesarean section. This clinical trial study, using purposive sampling method, was conducted on 100 elective cesarean section patients. The patients were randomly divided into two groups of 50 people, namely, pain control using intravenous injection pump this group also received a patient education program on how to use injection pump (intervention group) and pain control using NSAIDs group who did not receive any special training program (control group). Data collection included demographic information and visual analog scale. Pain intensity and administered analgesics within 24 hours after surgery were assessed every 6 hours. After data collection, they were analyzed using repeated measures ANOVA test and Chi-square test and *t*-test. The average of postoperative pain immediately after the surgery, after 6, 12, 18, 24 hours were significantly different in the intervention group (use injection pump) than in the control group (using NSAIDs) (p=0.099). The effect of PCA was clearly determined after 6 hours (p=0.137). While this figure, in NSAIDs group, started reduction after 12 hours (p=0.018). hezhDespite a better and more effective impact of PCA usage on in comparison with other analgesia methods, it is recommended to using of PCA method for decreasing the dependence of patients to nurses and health care staffs and tolerating pain after Cesarean section.

Keywords: Cesarean section, Patient controlled analgesia, Non-steroidal anti-inflammatory drugs, Patient education.

Corresponding author

ISSN: 0975-8585

INTRODUCTION

Increased birth by cesarean section in recent years has brought maternal and fetal complications of delivery into the focal attention [1]. Cesarean section is the most common surgery in reproductive age [2]. Child birth is a stressful event [3, 4]. It is associated with maternal anxiety and if this is accompanied with cesarean delivery and related issues, maternal anxiety is consequently increased [5, 6]. Indeed, maternal anxiety results in the inhibition of the secretion of Oxytocin and as a result lactation is reduced [7]. On the other hand, increasing levels of stress and anxiety in mothers increases the risk of postpartum depression [4, 8]. Pain is considered as one of the large dimensions of stress [4, 9].

Postoperative pain is the most common complication of surgery which more than 70 % of patients may experience after surgery [10]. Therefore, levels of pain control and management is always discussed as a professional challenge [11]. Hence, prevention and treatment of postoperative pain is one of the main issues in the surgical care unit which play a notable role in accelerating and improving the general condition of hospitalized patients in the surgical ward [12-14].

Nowadays, opioids are the most common method of pain relief after surgery [15]. Since, taking opioids result in opioids tolerance and increasing the frequency of taking drug. As a result, these repetitions result in the emergence of numerous complications [16]. These complications lead to the increase of using non-steroid anti-inflammatory drugs in surgeries. For example Diclofenac is one of the NSAIDs which have shown to be effective in reducing postoperative pain (14). Diclofenac is available in different forms including injections, suppositories and oral enteric-coated tablets with different doses, among them rectal Diclofenac is rapidly reabsorbed.

On one hand, patient controlled analgesia (PCA) is an effective and modern method for reducing pain. This method has a computerized pump containing the initial dose, required dose, the time when the pump is locked and continuous injection of Analgesic [17]. These pumps act as a lock and prevent the entering of excessive doses of medicine to the body. The patient pushes the control button to enter the medicine to his or her body but the pump only injects the programmed amount [18]. The advantages of such method include reducing patient's waiting time since the initiation of feeling pain to the time of getting analgesic, reducing the workload of nurses and staffs, reducing the likelihood of medical errors and recording the amount of injected medicine quantitatively and precisely [19, 20].

Accordingly, as patient-controlled analgesia is a new method in the field of pain control and pain reduction and little research has been conducted in this field in Iran [21], this study was aimed to compare two methods of pain control in patients undergoing caesarian section.

PATIENTS AND METHODS

This clinical trial study aimed to compare two methods of patient controlled analgesia including PCA and NSAIDs was conducted in 2014. The population of the study was all of the patients undergoing Caesarean section in the Sadjad general hospital in Kermanshah. 100 patients who were candid for surgery were chosen using purposive sampling method based on sample size formula of previous studies [22].

The criteria for entering the study included; age between 20 to 35, no history of cesarean surgery, not suffering from chronic pain, Body mass index (BMI) less than 30, no sensitivity to opioids drugs, chronic diseases and patient's written consent. The exclusion criteria included a history of addiction to opioids, history of liver and kidney diseases, the existence of mental illness verified by a physician and lack of interest or withdrawal during the conduction of the study.

Spinal anesthesia in L2-L3 or L3-L4 levels was performed similarly by injecting 100 milligram Lidocaine along with epinephrine and patients were under non-invasive monitoring Electrocardiography (ECG), heart rate, blood pressure, and pulse oximeter). To control postoperative pain, infusion of analgesic solution by PCA pump was implanted in all patients immediately after transference to the ward. The patients were randomly divided into two groups. In this study only pain was analyzed in both groups through visual analog scale by questionnaire at five times including the time of arrival, 6, 12, 18, 24 hours after surgery. In this study, the

visual analog scale of pain includes a straight 10 centimeter line without rating scale where the left end represents analgesia and the right end represent unbearable pain and the ranges of pain intensity is 0-100. The patient showed pain by marking the proper point. This scale gives the client complete freedom to determine the intensity of pain. Reliability and validity of the visual analog scale have been approved in many studies domestically or internationally [12, 17, 18]. In the intervention group, namely injection by pump, analgesic pump contains 20 milligrams Morphine, which is diluted with normal saline to a volume of 100 cc. were injected by the patients at injection speeds of 8cc per hour. They were instructed to press the infusion button to receive more medication as soon as feeling of pain started. By pressing the button, each time patient receives 0.5 cc serum-containing analgesics. In the control group, whenever there analgesics were needed 100 milligrams Diclofenac was injected intramuscularly or Diclofenac suppository was used in turn (tow times in a day and maximum amount was 200 milligrams). Comprehensive explanations have been presented to the patients regarding the research and the method of evaluating pain through visual analog scale. Moreover, it was mentioned that they have to respond to the questions regarding pain levels after their surgery at regular intervals.

In order to comply with ethical considerations, the researcher entered the hospital environment after obtaining permission from the Medical Ethics Committee of the hospital. After getting written consent from the patients, they were assured that their information was absolutely confidential and their information would be analyzed anonymously and the results would be reported entirely rather than case by case. Furthermore, the patients and the hospital officials were assured to be informed regarding the results of the study.

Normal distribution of data were analyzed and approved through Kolmogorov Smirnov test. As the two methods of analgesia were conducted in 5 different times, a two-factor design where each factor has 5 times was obtained. Thus, appropriate two-way ANOVA test was considered.

SPSS version 20 was used to do this. At first, the subject was analyzed by descriptive statistics and graphing. Data entered to Excel 2007 software and reviewed via software package used for statistical analysis version 20 (SPSS Inc., Chicago). Descriptive analysis of quantitative and qualitative data presented as mean ± standard deviation and frequency tables respectively. Furthermore, nominal data analyzed using repeated measures ANOVA and Chi-square test and *t*-test used for examining the difference between sample means in two groups. Significance level determined ≤0.05.

RESULTS

Results indicated that the mean age of subjects was 28.7 and mean weight was 74.3 Kg. 47.7 percent of the patients in the intervention group has one-time history of hospitalization in the hospital and 52 percent in the control group has no history of hospitalization. Moreover, the majority of patients in both groups had no surgical history (table 1). As can be seen in diagram 1, in all the pain assessment occasions, the average pain of patients undergoing patient controlled analgesia was less than the patients who take the NSAIDs. Moreover, the effect of intravenous pump was clear after 6 hours; pain decreased significantly in the next assessment times whereas, in injecting NSAIDs, pain decreased after 12 hours. According to the values obtained for the p-value, theory of equality of means of two groups at different times were evaluated with respect to the p-value <0.05 only after 12 hours and after 24 hours was significantly higher, and the mean number of pain in the group receiving NSADIs were higher than the PCA group (table 2).

Table 1. Demographic characteristics of the two groups.

Demographic Indicators	Analgesic methods		P-Value
	PCA Mean ±SD	NSAIDs Mean ±SD	
Average of age (years)	2.6±28.7	3.3±29.7	0.988
Average of height (cm)	24±163	33±162	0.382
Average of weight (kg)	1.13±74.3	1.19±75.3	0.988

ISSN: 0975-8585

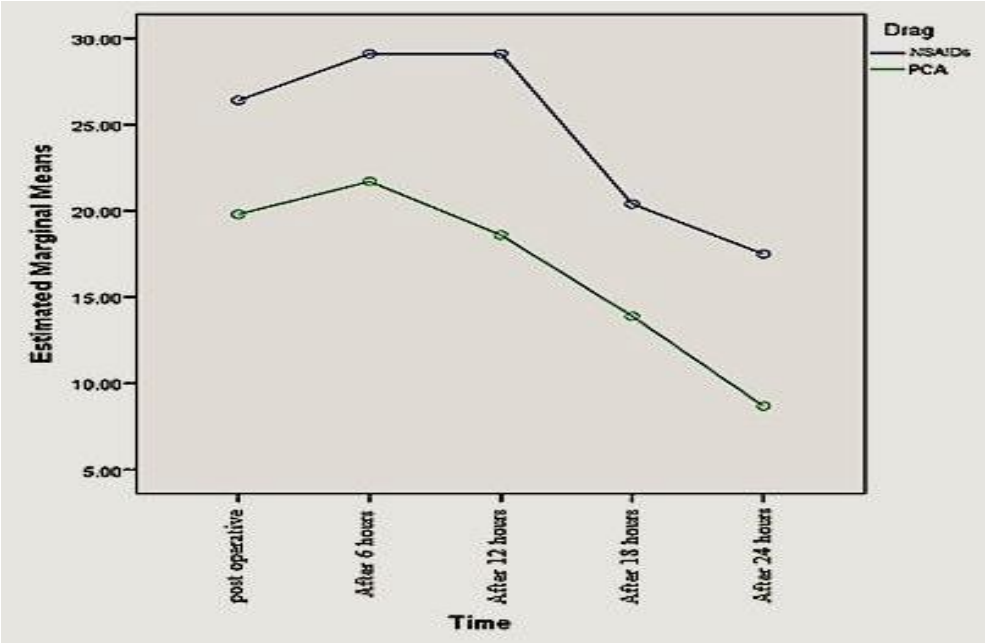

Diagram 1. Estimated of pain intensity assessment.

Table 2. The comparison of pain intensity based on (VAS) in PCA and NSAIDs group after cesarean section surgery

(I) Time	(J) Time	Mean Difference (I-J)	Sig.	95% Confidence Interval	
				Lower Bound	Upper Bound
After operation	After 6 hours	-2.3000	.468	-8.5175	3.9175
	After 12 hours	-.7500	.813	-6.9675	5.4675
	After 18 hours	5.9500	.061	-.2675	12.1675
	After 24 hours	10.0000*	.002	3.7825	16.2175
After 6 hours	After operation	2.3000	.468	-3.9175	8.5175
	After 12 hours	1.5500	.624	-4.6675	7.7675
	After 18 hours	8.2500*	.009	2.0325	14.4675
	After 24 hours	12.3000*	.000	6.0825	18.5175
After 12 hours	After operation	.7500	.813	-5.4675	6.9675
	After 6 hours	-1.5500	.624	-7.7675	4.6675
	After 18 hours	6.7000*	.035	.4825	12.9175
	After 24 hours	10.7500*	.001	4.5325	16.9675
After 18 hours	After operation	-5.9500	.061	-12.1675	.2675
	After 6 hours	-8.2500*	.009	-14.4675	-2.0325
	After 12 hours	-6.7000*	.035	-12.9175	-.4825
	After 24 hours	4.0500	.201	-2.1675	10.2675
After 24 hours	After operation	-10.0000*	.002	-16.2175	-3.7825
	After 6 hours	-12.3000*	.000	-18.5175	-6.0825
	After 12 hours	-10.7500*	.001	-16.9675	-4.5325
	After 18 hours	-4.0500	.201	-10.2675	2.1675

* The mean difference is significant at the 0.05 level.

Considering tale 2 and the amounts obtained in the P-value column, it can be seen that there is a significant difference in terms of average pain figure in pain after entrance to the ward and after 24 hours. Furthermore, there was significant difference between the average pain figure “after 6 hours and after 18 hours”, “after 6 hours and after 24 hours”, “after 12 hours and after 18 hours” and “after 12 hours and after 24 hours”.

DISCUSSION

The results of this study showed that pain intensity mean in the intravenous pump group were lower. In another study conducted by Alavi et al. in 2010, PCA was presented to be one of the most effective methods of pain control in which due to the analgesia and minimal usage of opioids, less side effects was seen in comparison with other methods of analgesia [23]. Trikoupi et al conducted another study in 2008, to compare postoperative pain control and patients' satisfaction by using two methods, namely PCA ad intramuscular analgesia. Pain intensity mean, nausea and vomiting was reported to be less in the PCA group whereas, patients' satisfaction in the group which took opioids intramuscularly was more than the PCA group [24].

Thurlow et al (2008), In another PCA study, aimed at evaluating the effectiveness of these methods in relieving labor pain, the results indicated significant statistical difference in terms of reliving pain in both groups(p=0.004). Indeed, the pain intensity mean in the PCA group was less than the intramuscular group [25]. In another study, the control group in the first 3 to 12 hours after the surgery had less pain than those patients who received analgesic in the common method. In addition, the need for analgesic in the patients who managed their own pain was less [26]. Furthermore, Gepstein et al (2007) in another study indicated that patient-controlled analgesia method result in more pain relief and more satisfaction, in comparison with the intramuscular injection of analgesia. In fact, these issues result in the improvement in the quality of care due to the decrease in the hospitalization of patients and conserving nursing care [27, 28].

The results of Everett et al (2005) study on the amount of taking analgesia in the two methods of PCA and intramuscular injection showed that the mean drug dosage within three days after the surgery in the PCA group was (136.89mg) more than the intramuscular injection (50.70 mg) [29]. Finally, the results of White et al (2012) study showed that controlled analgesia by the patient is one of the effective methods of pain control in which the administered dose is based on the need of the patient. This method not only conserves the amount of drug use but also reduces the risk of complications [30].

Limitations of this study include personality type, and the culture of people in responding to and tolerating pain in the population of patients undergoing cesarean section. These cases are out of the researcher's control and care should be taken into consideration in generalizing the results of this study to the other populations.

CONCLUSION

The results of the present study indicated that the PCA method has a better and more effective impact on the pain control in comparison with other analgesia methods. Moreover, the results indicates that time is an effective factor in decreasing the level of pain. The difference of average pain figure is significant and decreasing in comparison with other pain assessment occasions as well. Considering the descriptive section, it can be said that the analgesia with intravenous pump method was much better than NSAIDs. Therefore, it can be said that by teaching this method, effective measures for pain relief can be taken.
However, considering the novelty of this method, the rate of analgesia intake in comparison with the intravenous injection, the possibility of complications and financial issues need to be monitored. Therefore, further studies are needed to assess the outcomes of this study.

Furthermore, there is now a substantial evidence base on which to build effective strategies for informing and empowering patients and involving them in their health and health care **[14, 31]**. Patients receiving pain control instructions using a pump take more active responsibility toward their own care. Considering the psychosomatic nature of pain, taking more active role may help patients to identify their need of analgesics and reduce the amounts of drugs used.

REFERENCES

[1] S JIRASIRITHAM, K TANTIVITAYATAN, P SIRIVARAROM. *Journal of the Medical Association of Thailand= Chotmaihet thangphaet*, 2005, 88(7),914.

[2] Z FARGHANI, MR FAZEL, R SALEHIAN, ARE SOLTANI. *Feyz Journals of Kashan University of Medical Sciences*, 2003, 7(3).

[3] MAS Dombrowski, GC Anderson, C Santori, M Burkhammer. *MCN: The American Journal of Maternal/Child Nursing*, 2001, 26(4),214-6.

[4] K Solati, AH Lo'Bat Ja'Farzadeh. *Journal of Clinical and Diagnostic Research: JCDR*, 2016, 10(7),VC01.

[5] M Keshavarz, SFN Norozi Fateme, H Haghani. *Knowledge and Health*, 2011, 5(4),1.

[6] A Hasanpour-Dehkordi, N Jivad, K Solati. 2016.

[7] L Speroff, M Fritz. Clinical gynoncology, endocrinology and infertility. Section2: Hormone biosynthesis metabolism and mechanism of action. New York: Lippincot, Williams and Wilkins; 2005.

[8] DE Procelli. 2005.

[9] RE Grunau, L Holsti, DW Haley, T Oberlander, J Weinberg, A Solimano, et al. *Pain*, 2005, 113(3),293-300.

[10] L Nikolajsen, S Haroutiunian. *European Journal of Pain Supplements*, 2011, 5(S2),453-6.

[11] ZA Elseify, SO El-Khattab, AM Khattab, EM Atta, LF Ajjoub. *Saudi journal of anaesthesia*, 2011, 5(1),45.

[12] F Imani, M Aleboye, H Farahini, H Tavvaf, M Sakhaei. *Razi Journal of Medical Sciences*, 2010, 17(75),16-22.

[13] M Jahangiri, F Karimi, A Gharib, F Rahimi. *Journal of Chemical and Pharmaceutical Sciences*, 2016, 9(2),690-2.

[14] A Hasanpour-Dehkordi, A Khaledi-Far, B Khaledi-Far, S Salehi-Tali. *Applied Nursing Research*, 2016, 31,165-9.

[15] L Speroff, MA Fritz. Clinical gynecologic endocrinology and infertility: lippincott Williams & wilkins; 2005.

[16] W-H Chen, K Liu, P-H Tan, Y-Y Chia. *Journal of clinical Anesthesia*, 2011, 23(2),124-9.

[17] AA Ghahiri, F Fereidoni, F Abdi, M Ghasemi. *Journal of Isfahan Medical School (IUMS)*, 2011.

[18] S Mercadante. *Surgical oncology*, 2010, 19(3),173-7.

[19] M Momeni, M Crucitti, M De Kock. *Drugs*, 2006, 66(18),2321-37.

[20] S Rafat, A Gharib, S Rafat, F Rahimi. *Der Pharmacia Lettre*, 2015, 7(10),198-201.

[21] M Rasolabadi, S Khaledi, F Khayati, MM Kalhor, S Penjvini, A Gharib. *Acta Informatica Medica*, 2015, 23(4),206-9.

[22] M Mordin, K Anastassopoulos, A van Breda, S Vallow, M Zhang, K Gargiulo, et al. *Journal of PeriAnesthesia Nursing*, 2007, 22(4),243-55.

[23] S Alavi, KR Farasat, TA Sadeghpour, T Babaei. *Iranian journal of Surgery*, 2010, 17(4),0.

[24] A Trikoupi, D Vassilakos, I Soultani, K Andreopoulos, K Matsi, V Metaxa. *Treatment approaches*, 2008, 9,197.

[25] J Thurlow, C Laxton, A Dick, P Waterhouse, L Sherman, N Goodman. *British journal of anaesthesia*, 2002, 88(3),374-8.

[26] S Oifa, T Sydoruk, I White, MP Ekstein, N Marouani, S Chazan, et al. *Clinical therapeutics*, 2009, 31(3),527-41.

[27] R Gepstein, Z Arinzon, Y Folman, I Shuval, S Shabat. *Surgical neurology*, 2007, 67(4),360-6.

[28] F Rahimi, A Gharib, M Beyramijam, O Naseri. *Life Science Journal*, 2014, 11(1 SPECL. ISSUE),136-40.

[29] B Everett, Y Salamonson. *Pain Management Nursing*, 2005, 6(4),137-44.

[30] I White, R Ghinea, S Avital, S Chazan, O Dolkart, AA Weinbroum. *Pharmacological research*, 2012, 66(2),185-91.

[31] A Coulter, S Parsons, J Askham, WH Organization. Where are the patients in decision-making about their own care?: World Health Organization Regional Office for Europe; 2008.