Global Journal of Surgery, 2016, Vol. 4, No. 1, 5-8
Available online at http://pubs.sciepub.com/js/4/1/2

DOI:10.12691/js-4-1-2

Preoperative Intravenous Methylprednisolone to Reduce Postoperative Pain: VAS Assessment

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Abstract This study examines the results of VAS score of the effect of preoperative intravenous methylprednisolone to reduce postoperative pain. This clinical trial was a double blind randomized controlled trial, using patients undergoing open cholecystectomy surgery in general anesthesia. The level of pain was assessed using VAS pain scoring by asking how much pain experienced during the first hour of surgery, 2nd, 4th, 8th, 12th and 24th consecutively. Methylprednisolone 125 mg was injected intravenously at 60 minutes preoperatively and 30 minutes before completing the skin sutures. Group I: methylprednisolone given postoperatively; Group II: methylprednisolone given before surgery; Group III: as a Control Group, with each Group number of sample was 10 patients with inclusion criteria: ASA clinical classification I-II, age 20-60 years. Results showed that the treatment produces significantly on VAS levels (p = 0.0000) in every hour, except in the 24th hour (p=0.4999) all Groups resulted the same VAS levels of three. **Conclusion:** the VAS score of open cholecystectomy given preoperative intravenous methylprednisolone is lower postoperatively than in patients given methylprednisolone at the end of the operation.

Keywords: *Intravenous methylprednisolone, Visual Analogue Scale, Cholecystectomy*

Cite This Article: Suwarman, and Hendro Sudjono Yuwono, "Preoperative Intravenous Methylprednisolone to Reduce Postoperative Pain: VAS Assessment." *Global Journal of Surgery*, vol. 4, no. 1 (2016): 5-8 doi: 10.12691/js-4-1-2.

1. Introduction

Today medical progress is still unsatisfactory in dealing with postoperative pain management. Post-surgical pain is a major problem to consider in the patient prior to surgery and is often causing anxiety. [1,2] Therefore, post-surgical pain management will both improve health care quality and reduce anxiety in patients undergoing surgery. Economic and medical implications of this complication is the prolonged duration of treatment, re-treatment, as well as the dissatisfaction of patients to medical services. [3,4] Open cholecystectomy is an operation which is often carried out with the aim to remove the gallbladder. Because the surgical wound is located in the upper abdomen, then the problem of postoperative pain is a problem that must be taken seriously to ensure that the patient is more comfortable. Inadequate pain control can cause the patient to feel pain with every breath so that the patient will tend to breathe shallow or even hold his breath that may result in pneumonia and pulmonary atelectasis. Measurement of the degree of pain experienced by patients can be done by using a visual analog scale (VAS) pain intensity score.[5] This scale of measurement is one subjective method of measuring pain that can be used to assess postoperative pain. Methylprednisolone is a type of steroid, a glucocorticoid, which has been reported to reduce the cytokines of postoperative pain. Quality of life is an important measure to clinical selection of drugs in relieving postoperative pain.

The following study will answer the question whether the VAS score in open cholecystectomy patients given methylprednisolone preoperatively is lower than when methylprednisolone is given postoperatively. The results of this study can indicate the quality of life of patients.

2. Materials and Methods

2.1. Research Design

This clinical trial was a double blind randomized controlled trial, on patients undergoing open cholecystectomy surgery under general anesthesia.

2.2. Visual Analog Scale

This scale is one subjective method of measuring pain that can be used to assess postoperative pain.[6] Measurement of the degree of pain with this method can describe the pain experienced by the patient is assessed from the number one to ten, as number one indicating no pain, and ten indicating unbearable pain. VAS is a single-item visual analogue scale indicates quality of life. [6]

2.3. Hamilton Anxiety Rating Scale (HARS)

Anxiety is an emotional reaction to perceived danger, whether real or unreal which is measured using a scale of Hamilton Anxiety Rating Scale (HARS). [7] On this scale, 14 parameters such as anxious, tension, fears, sleep disturbances (insomnia), intellectual impairment, depressed mood, somatic (muscular) symptoms, somatic sensory

symptoms, cardiovascular symptoms, respiratory symptoms, gastrointestinal symptoms, urogenital symptoms, autonomic symptoms, behavior at intervieware assessed. The scale's range from 0 to 56, without anxiety determined with the score <5, and severe anxiety determined with the score> 35. [7] The results of all Groups were <5 (no anxiety), although Group I was higher than the other Groups (p=0.016).

2.4. Inclusion Criteria

Patients undergoing open cholecystectomy surgery, ASA clinical classification I-II, age 20 -60 years.

2.5. Exclusion Criteria

Patients with chronic pain, females with positive pregnancy test, taking long-term glucocorticoid, drug hypersensitivity to the drug to be used in the cholecystectomy operation, patients with diabetes mellitus, cholecystectomy with operative duration more than 4 hours.

2.6. Sample Size:

The comparison between preoperative-VAS with postoperative-VAS, using the statistical formula to analyze the sample size:

$$n = \frac{2(Sd)^2 (Z\alpha + Z\beta)^2}{E^2}$$

n = sample size; Sd= standard deviation; E = effect size; Zα and Zβ are the value obtained from the normal distribution table. By setting the level of 95% confidence interval and 90% power test, the Sd is determined by:

$$Sd = 0.24 \text{ x range} = 0.24 \text{ x } 8 = 1.92 \approx 2.0.$$

The magnitude of standardized effect size for the difference in VAS are E/Sd= 2, which is clinically considered significant. Based on the above formula obtained a minimum sample size n = 8, so it can be concluded the necessary number of sample is 10.

2.7. Research Procedures

This clinical trial has been approved by the Research Ethics Committee of the School of Medicine, Padjadjaran University and Hasan Sadikin General Hospital. After all procedures have been explained in detail, all participant-patients eventually signed the informed consent. Permutation block randomization was used. All patients were fasting and received intravenous-infusion of Lactated-ringer 15 mL / kg body weight; the standard-monitoring tools were started. Systolic and diastolic blood pressure, heart rate and respiratory rate were recorded, as well as to fill VAS score during preoperative and postoperative-period. The level of pain was assessed using VAS pain scoring by asking how much pain experienced during the first hour after surgery, 2^{nd}, 4^{th}, 8^{th}, 12^{th} and 24^{th} consecutively. Subject instructed to assess the intensity of the pain felt by marking a line along the 100 mm that describes the degree of pain intensity.

2.8. Steroid Injection

Methylprednisolone 125mg (Medixon, Ferron) was injected intravenously at 60 minutes preoperatively and 30 minutes before completing the skin sutures.

2.9. Open-cholecystectomy

Open cholecystectomy surgery is a gallbladder excision, in patients with gallstone disorder or infection in the gallbladder, which is done through along 10-15 cm skin incision in right subcostal or in the midline region. Sixty minutes before anesthetic-induction, patients in preoperative group (PR) were given 125 mg methylprednisolone intravenously, while those in the postoperative methylprednisolone group (PC) and the control group (K) were given 1 cc 0.9% NaCl intravenously. Induction of anesthesia in both groups was carried out by administering propofol 2-3mg / kg body weight, and ventilation with N_2O / O_2 = 50%: 50%, and 2 volume % of isoflurane after 3 minutes of intubation. General anesthesia using an Isoflurane vaporizer and anesthesia machine (Draeger) with nitrous oxide, oxygen, isoflurane and atracurium. Analgesia using fentanyl 1-3 mg / kg intravenously during surgery.

2.10. Statistical Analysis

One way ANOVA test was used when the data were normally distributed to test about the decline in postoperative VAS score, but when the data were not normally distributed Kruskal-Wallis test was used. Shapiro-Wilk test was used for normal distribution testing. Data analysis was performed using SPSS for Windows version 13.0 on a confidence level of 95% with regarded a significant value of p <0.05.

3. Results

Table 1. Patient's characteristic.

Patient's characteristic	Group			p
	I (n=10)	II (n=10)	III (n=10)	
Gender:				1,000
man	6	6	6	
woman	4	4	4	
Age (year) :	42,6	52,8	54,2	0,085
Standard Dev.	(13,5)	(11,8)	(11,2)	
Median	45	53	53	
Range	22-68	30-72	38-73	
Education :	2	4	5	0,710
High school	4	3	2	
University	4	2	3	
HARS:	3,5	3	3	0,016#
Median	3 – 4	2 – 4	2 – 3	
Rentang	(a)	(ab)	(b)	

Legend:
All were calculted by Chi-square test, except for age by t-test.
Group I: methylprednisolone given postoperatively;
Group II: methylprednisolone given before surgery;
Group III: Control Group.
HARS-Hamilton Anxiety Rating Scale.

Anxiety scores were measured using the Hamilton Anxiety Rating Scale (HARS) and showed that all patients in all three groups showed no anxiety with HARS <5, although not statistically significant. This means that all three groups deserve to be comparable (Table 1).

Patients were observed in the recovery room and then in the nursing-ward for up to 24 hours postoperatively. Patients were moved into the ward with stable vital signs, good orientation, no nausea or vomiting, no bleeding, and not feeling pain, VAS score less than 3 (Table 2 and Figure 1).

Results in Table 2 shows that the treatment produces different effects significantly on VAS levels (p = 0.0000) at the 1st hour until 12th hour. The VAS was not significant at 24th hour as all Groups went to the VAS score of three.

Table 2. The VAS pain intensity score on each hour

Hours	Control Group	Group:Pre-Operative	Group:Post-Operative	p
1st hour	4.68 (0.6)	3.25 (0.45)	3.90 (0.30)	**0.0000**
2nd hour	4.06 (0.57)	2.91 (0.51)	3.45 (0.52)	0.0000
4th hour	3.56 (0.51)	2.58 (0.51)	3.09 (0.30)	0.0000
8th hour	3.43 (0.51)	2.58 (0.51)	3.18 (0.40)	0.0002
12th hour	3.75 (0.50)	2.91 (0.28)	2.72 (0.46)	0.0013
24th hour	3.00 (0.00)	2.91 (0.28)	2.90 (0.30)	0.4999

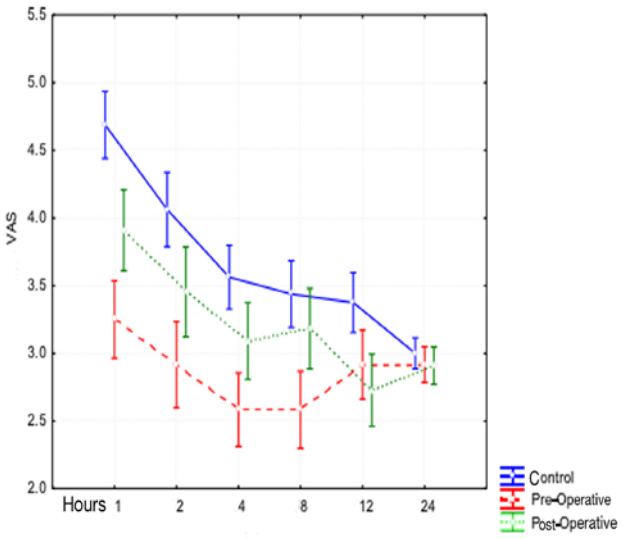

Figure 1. All VAS during 24 hours were decreasing to the score of 3

In Figure 1 showing the VAS score in the control group consistently located at the top, and the Pre-Operative VAS score is always the lowest, although in the last hour all Group lead to the same levels of VAS score of three.

4. Discussion

VAS is the score measuring the intensity of the sensation of pain, it is easy to use, general in nature, as well as provide a consistent measurement results either in clinical or experimental use. The VAS score is more superior in comparison with the fixed interval scale, relative pain scale, or any verbal information about the pain. [5,6] The VAS is simple, easy to administer, with good validity and excellent reliability in comparison with multiple-choice questions. [6] In many literature studies have mentioned that the VAS is recommended in clinical trial and also as a reliable test in the measurement of global quality of life. [6] VAS, in comparison with NRS-11 or with VRS-4, is better in the power to detect pain intensity. [8]

Submucosal dexamethasone injected preoperatively by Shah et al has a significant effect on suppressing postoperative pain (using VAS score) and swelling after oral surgical apicectomy. [9] Single-dose of methylprednisolone 125 mg was able to reduce postoperative pain, detected using VAS score, after intertrochanteric femoral fracture surgery according to a randomized double blind clinical study by Rahimzadeh et al. Those studies confirmed the present study that the single-dose parenteral methylprednisolone injected preoperatively reduces postoperative pain.

5. Conclusion

The VAS score following open cholecystectomy in patients given preoperative intravenous methylprednisolone is lower than in patients given methylprednisolone at the end of the operation. Nevertheless VAS value not significantly different at 24 hours postoperatively. The results of this study stated that the role of methylprednisolone provides a solution to the prevention of postoperative pain by VAS examination.

Author's Contribution

Suwarman designed the study and the statistical analysis, wrote the protocol, and wrote the first draft. H.S. Yuwono analysed the study and the references. Both authors read the last version and approved the manuscript.

Conflict of Interest

The authors confirm that this article has no conflict of interest.

Acknowledgement

None.

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