Sarcouncil Journal of Medicine and Surgery

ISSN(Online): 2945-3534

Volume- 03| Issue- 06| 2024

Research Article **Received:** 05-04-2024 | **Accepted:** 15-05-2024 | **Published:** 06-06-2024

Evaluation of Intraperitoneal Pressure in Laparoscopic Cholecystectomy by Using Deep Neuromuscular Blockade versus Adequate Neuromuscular Blockade

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Abstract: Background: Standard pressure pneumoperitoneum in laparoscopic cholecystectomy with a pressure range of 12-14 mm Hg in comparison with the use of low pressure pneumoperitoneum in the range of 8-10 mm Hg in an attempt to lower the effect of pneumoperitoneum while maintaining adequate working space. Our study proposes to do this comparison by the use of deep muscle relaxation to improve the surgical conditions during laparoscopic surgery. **Aim of the study:** To study the effect of deep versus adequate muscle relaxation in laparoscopic cholecystectomy and the effect on intraperitoneal pressure and surgical satisfaction. **Methods**: 50 patients enrolled in the study for elective laparoscopic cholecystectomy .randomly divided in to two groups; group A: deep muscle relaxation and group B: adequate muscle relaxation using Rocuronium in both group and vital signs ,IPP ,TOF ,PTC recorded every 10 minutes, reversal was done by the use of sugammadex . Surgical satisfaction assessed at the end of surgery according to visual analogue scale. **Results:** There is non-significant difference in demographic data between the two groups. But there was a significant difference in IPP between the two groups in group A the IPP is less than in group B. also significant difference in surgical satisfaction observed between the two groups ,in group A surgical satisfaction significantly higher than group B. **Conclusion:** The deep neuromuscular blockade lowers the IPP significantly and improve surgical space in elective laparoscopic cholecystectomy.

Keywords: laparoscopic cholecystectomy, low intraperitoneal pressure, deep neuromuscular blockade.

INTRODUCTION

Over one million cholecystectomies are performed in the U.S. annually, with over 96% of those being performed laparoscopically. (Walid, M. S. *et al*., 2010)

Two groups of surgical procedures are indicated for deep NMB. The first one include those precision procedures where unexpected movements can be deleterious. Examples are vocal cords and eye surgery with laser, neurosurgery, neuroradiology, embolization, robot-guided ablation, or other surgeries in critical areas. A second group of indications include procedures where there is a need to relax muscles to their maximal length. Examples can be found in orthopedic fracture repositioning or dislocation reduction, laparotomy, laparoscopy. (Dubois, P. E. *et al*., 2013) Different NMB levels are defined according to responses obtained during NMB monitoring, the levels are defined as follows:

- Intense NMB: no response to PTC.
- Deep NMB: from the reappearance of 1 PTC up to, but not including a TOF count of 1.
- Moderate NMB: form the reappearance of the first TOF responses up to fourth TOF response.
- Recovery in progress: from the detection of four clear TOF up to a TOF ratio of 0.9
- Extubation safety level TOF ratio of 0.9.(Dubois, P. E. *et al*., 2013)

The aim of this study to evaluate the effect of deep neuromuscular blockade on intraperitoneal pressure in laparoscopic cholecystectomy and the surgical satisfaction in comparison with adequate neuromuscular blockade.

PATIENTS AND METHODS

After obtaining the Iraqi council of Anesthesia and Intensive care approval, a prospective, non-blind, randomized study was carried out in general surgical operation theaters of Baghdad teaching hospital, during the period from 1st JUNE to 30th September 2016

50 patients enrolled in the study scheduled to have elective laparoscopic cholecystectomy.

Written informed consent was obtained from all patients before enrolling them in the study.

Inclusion criteria:

- ASA: I-II.
- Age: 18 – 60 years.
- BMI<30.
- Elective laparoscopic cholecystectomy.

Exclusion Criteria:

- Allergy to any drug used in the study.
- Patient refusal.
- Previous abdominal surgery.
- Pregnancy.
- Neuromuscular disease.

Data were collected using pre-constructed form sheet & a detailed history was taken from each patient, information about patient's medical history, age, height, weight.

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DOI- https://doi.org/10.5281/zenodo.11507714

A clinical examination was performed by general examination, vital signs measurement.

Monitors (ECG, NIBP, HR, SPO_2, neuromuscular monitoring) were attached after receiving patient in operator room. Baseline hemodynamic variables were recorded, mean arterial pressure, heartrate, oxygen saturation.

Patients were divided into 2 groups randomly (group A: deep neuromuscular blockade, group B: adequate muscle blockade).

All patients were induced with peripheral wide bore cannula (18G) and fluid replacement was according to role of 4-2-1 with crystalloids, pre-oxygenation with 100% O_2 for 3 minute, 0.01mg/Kg midazolam, ranitidine 50 mg IV, metoclopramide 10 mg IV, dexamethasone 8 mg IV, Tramadol 1 mg/kg IV. anesthesia was induced with propofol 1-3mg/kg followed by 0.6 mg/kg rocuronium to facilitate endotracheal intubation, mechanical ventilation 6-8 ml/kg tidal volume all patients received 1mcg/kg fentanyl just before the surgical incision. Pneumoperitoneum was obtained with insufflation ofCO_2 through a Veress needle to 12 mmHg, but reduced after the introduction of the 4 trocars. After insufflations, patients were positioned in 20° reverse Trendelenburg.

Anesthesia maintained with 1-1.2% isoflurane intermittent boluses of rocuronium in both group. In group A to keep PTC<3 and group B to adequate muscle relaxant. Vital signs, intraperitoneal pressure, TOF and PTC assessed every 10 minutes.

Sugammadex 2 to 8 mg/kg IV was given at the end of Surgery according to TOF, Endotracheal extubation was only performed when the patients meets the extubation criteria. At the end the surgical satisfaction assessed according to visual analogue scale from 0 to 10, where 0 is poor satisfaction and 10 is the optimum satisfaction.

All patients' data entered using computerized statistical software; Statistical Package for Social Sciences (SPSS) version 21 was used.

Descriptive statistics presented as (mean ± standard deviation) and frequencies as percentages. Kolmogorov Smirnov analysis verified the normality of the data set. Multiple contingency tables conducted and appropriate statistical tests performed, Chi-square used for categorical variables and t-test was used to compare between two means. One way ANOVA analysis was used to compare between more than two means. In all statistical analysis, level of significance (p value) set at ≤ 0.05 and the result presented as tables and/or graphs. Statistical analysis of the study was done by the community medicine specialist.

RESULTS

A total of 50 patients undergoing elective laparoscopic cholecystectomy were included in present study; 25 patients were received deep dose of muscle relaxant and 25 patients were received adequate dose of muscle relaxant. Mean age of patients receiving deep dose was 42.6±13.7 years and mean age of patients receiving moderate dose was 43±12 years. No significant differences were observed between two groups of patients regarding their age and gender. All these findings were shown in table 1.

Table 1: Distribution of age and gender according to study groups

Variable	Deep dose		Adequate dose		P
	No.	%	No.	%	
Age					0.4**
<30 years	6	24.0	4	16.0	
30-39 years	2	8.0	5	20.0	
40-49 years	9	36.0	6	24.0	
≥50 years	8	32.0	10	40.0	
Mean±SD	42.6±13.7		43±12		0.9***
Gender					0.5*
Male	7	28.0	5	20.0	
Female	18	72.0	20	80.0	

**Chi-square test, **Fishers exact test. ***One way ANOVA.*

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According to American Society of Anesthesiologists criteria (ASA), 28% of patients receiving deep dose had mild systemic diseases and 32% of patients receiving moderate dose had mild systemic diseases, no significant difference was observed between two study groups regarding ASA (p=0.7). Mean BMI of patients receiving deep dose was 34±2.7 Kg/m2 and mean BMI of patients receiving moderate dose was 37.2±1.9 Kg/m2, no significant difference observed between two study groups regarding BMI (p=0.8). All these findings were shown in table 2.

Table 2: Distribution of ASA and BMI according to study groups

Variable	Deep dose		Adequate		P
	No.	%	No.	%	
ASA					0.7*
Normal healthy patient	18	72.0	17	68.0	
Mild systemic disease	7	28.0	8	32.0	
BMI					0.8*
Normal	6	24.0	5	20.0	
Overweight	19	76.0	20	80.0	
Mean±SD	±2.7		37.2±1.9		0.8***

**Chi-square test, ***One way ANOVA.*

As shown in table 3: no significant difference were observed between study groups regarding preoperative mean arterial pressure (p=0.1). No significant differences were observed between study groups regarding preoperative heart rate (p=0.1).

Table 3: Distribution of preoperative MAP and HR means according to study groups

Variable	Deep dose	Adequate	t-test	P
	Mean±SD	Mean±SD		
Preoperative MAP	111.9±14.7	100.8±13.8	3.6	0.1
Preoperative HR	86.4±9.2	81.8±11.6	1.5	0.1

As shown in table 4: no significant association between higher mean of train of fitness (TOF) after 5 minutes and patients receiving deep dose of muscle relaxant (p=0.05). No significant differences were observed between study groups regarding TOF after 10 minutes, after 15 minutes, after 20 minutes and after 25 minutes.

Table 4: Distribution of TOF means according to study groups

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
TOF after 5	0.1±0.5	0.0±0.0	2.0	0.16
TOF after 10	0.04±0.2	0.0±0.0	1.0	0.3
TOF after 15	0.0±0.0	0.04±0.2	1.0	0.3
TOF after 20	0.08±0.2	0.04±0.2	0.5	0.5
TOF after 25	0.0±0.0	0.04±0.02	0.9	0.3

As shown in table 5 and figure 1: no significant differences were observed between study groups regarding post-titanic count (PTC) after 5 minutes (p=0.3). PTC means for patients receiving adequate dose after 10 minutes, 15 minutes, 20 minutes and 25 minutes were significantly higher than PTC means of deep dose patients (p=0.01, p<0.001, p<0.001, p<0.001, respectively).

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Table 5: Distribution of PTC means according to study groups.

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
PTC after 5	3.2±1.3	4±3.8	0.9	0.3
PTC after 10	2.3±3.1	4±1.7	2.4	**0.01**
PTC after 15	2.4±1.6	5.5±1.9	6.2	**<0.001**
PTC after 20	2.5±1.5	7.6±2.7	8.1	**<0.001**
PTC after 25	2.6±1.3	7.7±3.3	6.9	**<0.001**

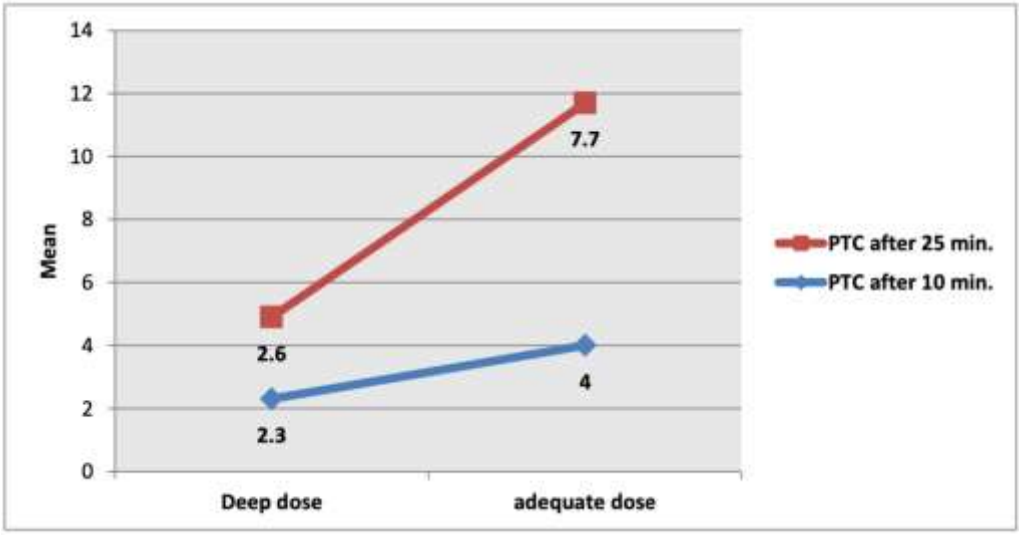

Figure 1: Distribution of PTC means after 10 and 25 minutes according to study groups.

As shown in table 6 and figure 2: no significant differences were observed between study groups regarding intra-peritoneal pressure (IPP) after 5 minutes (p=0.3). IPP means for patients receiving adequate dose after 10 minutes, 15 minutes, 20 minutes and 25 minutes were significantly higher than PTC means of deep dose patients (p=0.01, p<0.001, p<0.001, p<0.001, respectively).

Table 6: Distribution of IPP means according to study groups

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
IPP after 5	10.8±0.8	12±0.4	0.9	0.3
IPP after 10	10.9±0.7	12±0.4	2.4	**0.01**
IPP after 15	10.9±0.7	12±0.4	6.2	**<0.001**
IPP after 20	10.9±0.7	12±0.4	8.1	**<0.001**
IPP after 25	10.9±0.7	12±0.4	6.9	**<0.001**

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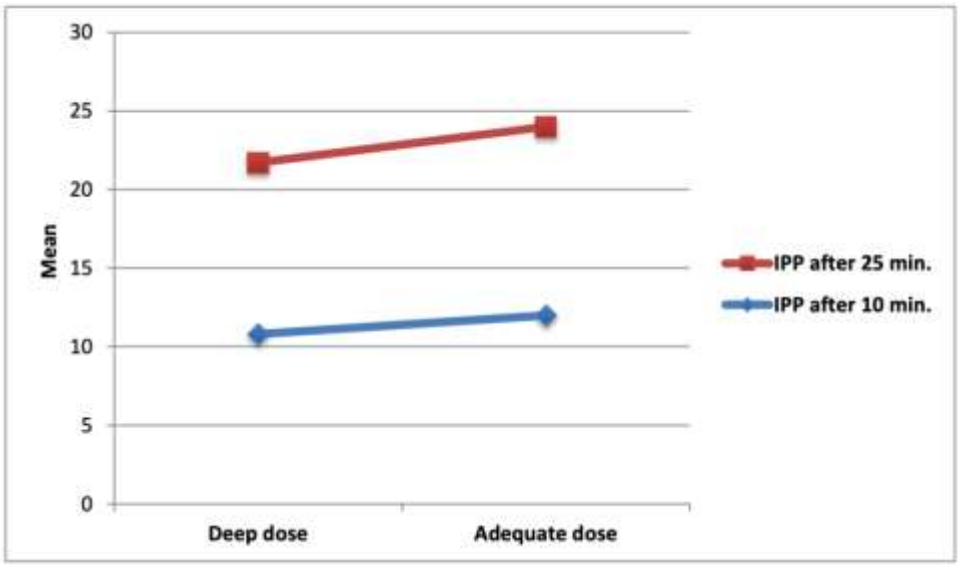

Figure 2: Distribution of IPP means after 10 and 25 minutes according to study groups.

No significant differences were observed between study groups regarding heart rate at different five periods. All these findings were shown in table 7.

Table 7: Distribution of HR means according to study groups

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
HR after 5	90.6±13.9	83.3±12.8	1.9	0.06
HR after 10	86.1±14	82.1±11.5	1.1	0.2
HR after 15	83.2±13.6	82±13	0.3	0.7
HR after 20	84.2±14.2	81.1±12.6	0.7	0.4
HR after 25	85.4±13.6	81.4±13.9	1.0	0.3

As shown in table 8: there was no significant association between higher mean of mean arterial pressure (MAP) after 5 minutes and patients receiving deep dose of muscle relaxant (p=0.06). No significant differences were observed between study groups regarding MAP after 10 minutes, after 15 minutes, after 20 minutes and after 25 minutes.

Table 8: Distribution of MAP means according to study groups.

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
MAP after 5	108.5±15.4	100.1±15.8	2.5	0.06
MAP after 10	110.3±27.1	99.7±13.6	1.7	0.08
MAP after 15	103.8±11	99.1±10	1.5	0.1
MAP after 20	103.8±12.8	101.2±9.7	0.8	0.4
MAP after 25	103.8±11.8	99.1±11.5	1.3	0.1

There was a highly significant association between higher mean of surgeon satisfaction and patients receiving deep dose of muscle relaxant (p<0.001). All these findings were shown in table 9 and figure 3.

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Table 9: Distribution of surgeon satisfaction according to study groups

Variable	Deep dose	Adequate dose	t-test	P
	Mean±SD	Mean±SD		
Surgeon	8±0.8	6.8±0.8	5.1	<0.001

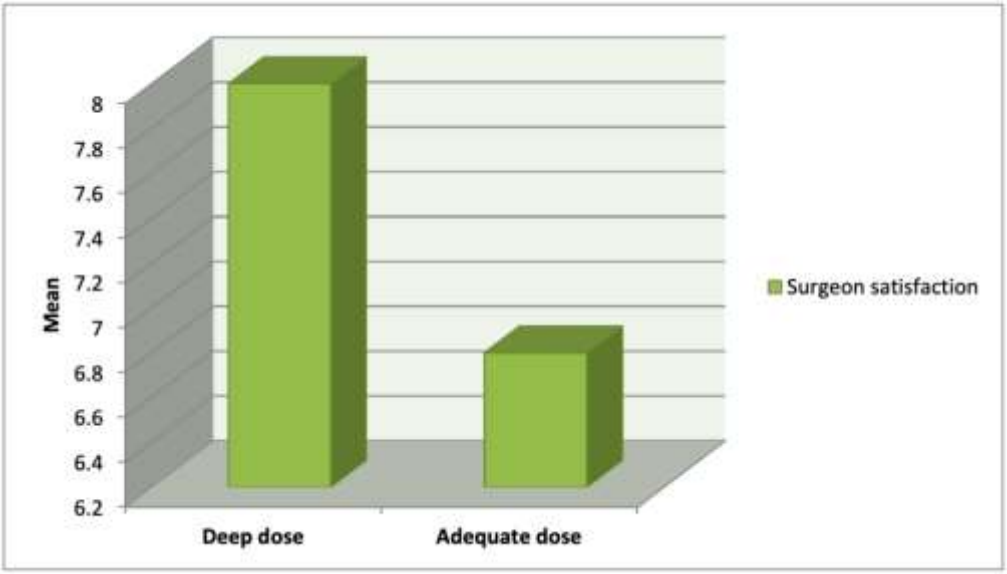

Figure 3: Distribution of satisfaction mean according to study groups.

DISCUSSION

Deep, continuous neuromuscular blockade was associated with surgical space conditions that were marginally better than with moderate muscle relaxation during low-pressure laparoscopic cholecystectomy. Deepaesh Benjamin Kanwer, *et al*., 2009; Standard pressure pneumoperitoneum for laparoscopic cholecystectomy employs a pressure range of 12-14 mm Hg.

An emerging trend has been the use of low pressure pneumoperitoneum in the range of 7-10 mm Hg in an attempt to lower the impact of pneumoperitoneum on the human physiology while providing adequate working space that agree with our study.(Kanwer, D. B. *et al*., 2009)

Myoung Hwa Kim, *et al*., suggest that deep NMB has benefits over conventional moderate NMB in laparoscopic surgery, including a greater IAP lowering effect, whereas surgical conditions are maintained, less severe postoperative pain and faster bowel function recovery. Therefore, low-pressure pneumoperitoneum with deep NMB is worth considering for patients undergoing laparoscopic surgery that agree with our study.(Kim, M. H. *et al*., 2016)

Anne K. Staehr-Rye *et al*., Deep neuromuscular blockade was associated with surgical space conditions that were better than with moderate muscle relaxation during low-pressure laparoscopic cholecystectomy that agree with our study.(Staehr-Rye, A. K. *et al*., 2014)

Anne K. Staehr-Rye, *et al*., This study is randomized study to assess the association between depth of neuromuscular blockade and surgical space conditions during low-pressure laparoscopic cholecystectomy. The study findings may be applicable to a general surgical population undergoing laparoscopic cholecystectomy. (Staehr-Rye, A. K. *et al*., 2013)

C. H. Martini *et al* , Application of the five-point SURGICAL RATING SCORE showed that deep NMB results in an improved quality of surgical conditions compared with moderate block in retroperitoneal laparoscopies, without compromise to the patients' peri- and postoperative cardiorespiratory conditions that goes with our study.(Martini, C. H. *et al*., 2014)

Kopman AF, Naguib M. shows that Performing laparoscopic surgery under low versus standard pressure pneumoperitoneum is associated with no difference in outcome with respect to surgical morbidity, conversion to open cholecystectomy, hemodynamic effects, length of hospital stay, or patient satisfaction. There is a limit to what deep neuromuscular block can achieve. Attempts to perform laparoscopic cholecystectomy at an

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inflation pressure of 8 mm Hg are associated with a 40% failure rate even at post-tetanic counts of 1 or less that against our study. (Kopman, A. F. *et al*., 2015)

CONCLUSION

Our finding suggest that deep NMB has benefits over adequate NMB in laparoscopic cholecystectomy, including a much lower IPP whereas surgical conditions are maintained with little impact on hemodynamics .

RECOMMENDATIONS

We recommend the use of deep neuromuscular blockade as possible due to its better effect regarding lower IPP and improved surgical work space in laparoscopic cholecystectomy.

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Source of support: Nil; **Conflict of interest:** Nil.

Cite this article as:

Aissa, D.M., Qasim, M.M. and Eassa, B.A. "Evaluation of Intraperitoneal Pressure in Laparoscopic Cholecystectomy by Using Deep Neuromuscular Blockade versus Adequate Neuromuscular Blockade." *Sarcouncil Journal of Medicine and Surgery* 3.6 (2024): pp 1-7.

Publisher: SARC Publisher