

## RESEARCH PAPER

# Open Cholecystectomy in Respiratory and Cardiovascular disease patients under Lumbar combined Spinal-Epidural Anesthesia

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### ABSTRACT:

**Background and Aims:** Regional anesthesia gained popularity over the last three decades due to the technical advances across subdisciplines, better understanding of the physiology, the advances in the field of anesthetic drugs, and the better approach in training for such techniques. The technique is currently used in many anatomical levels and most surgical procedures can be performed using the combined spinal epidural type.

The aim of this study is to evaluate the feasibility of the combined spinal-epidural anesthesia in patients with respiratory and cardiovascular diseases who underwent open cholecystectomy.

**Patients and methods:** This prospective cross sectional study which was done on patients undergoing elective open cholecystectomy (n=119) for whom the general anesthesia was contraindicated due to major cardiovascular and pulmonary diseases, under lumbar combined spinal-epidural anesthesia.

**Results:** The mean age of our patients was 64.33(SD: 12.085) years; females constituted 73 of them (61.3%) and males 46 (38.7%). Most patients (73) were complaining from the cardiovascular diseases (61.34%). In most patients the onset of the action of the anesthesia was between 10-12 minutes. In 55 patients (46.2%) no extra-drugs were required, and in the rest of patients intravenous mediations were given to relieve anxiety, pain, or both. In 81 patients (68.1%) no intraoperative complications were reported, the most common intraoperative complication was hypotension in 31 patients (26.1%), post-operatively no complications were reported in 86 patients (72%), and hypotension was reported in 12 patients (10.1%), nausea & vomiting in 11 patients (9.2%). The surgeon's satisfaction was excellent in 73.11% of the surgeries, as was good in 23.53%. Most patients gained the lower limb movement within 2 hours. There was a significant correlation between the need for extra drugs and both comorbid diseases and the development of intraoperative complications (P values 0.022 & 0.000) respectively and no significant correlations with other parameters such as the gender, postoperative complications and the surgeon's satisfaction (P values 0.707, 0.522, and 0.056) respectively.

### Conclusion:

The technique of the combined spinal epidural anesthesia is safe and very effective when used for American Society of Anesthesiologist (ASA) patient classification class III and IV patients who need open cholecystectomy. This technique should be used by expert anesthetists who are well trained and gained skill in this technique, and it may be used in fields other than surgery such as trauma victims and for cancer patients.

**KEY WORDS:** open cholecystectomy, combined lumbar spinal-epidural anesthesia, patients with respiratory morbidity, patient with cardiovascular morbidity.

List of abbreviations:

AF: Atrial fibrillation

ASA: American Society of Anesthesiologist.

COPD: Chronic obstructive pulmonary disease

CVA: Cerebrovascular accident

HF: Heart failure

IHD: Ischemic heart disease

MI: Myocardial infarction

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TAP: Transversus abdominus plane.

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## 1. INTRODUCTION :

Regional anesthesia gained tremendous popularity over the last three decades, which is attributed to advancement in the technology, better understanding of the physiology, the advancement in the anesthetic drugs, and the better training in such techniques. In some centers the regional anesthesia procedure may reach up to 40% of the anesthetic treatment. (Clemente & Carli, 2008)

The technique is currently used for many anatomical levels and most surgical procedures can be performed using the combined spinal epidural type. Jonnesco, described the feasibility of this technique at various anatomical levels, such as the head and neck, upper limbs, and the thoracic levels. (M. Ellakany, 2013)

This technique is used not only in surgery, but also may be adopted for trauma patients, in obstetric practice, and for patients with cancer who suffered from severe pain. (Clemente & Carli, 2008)

Patients with severe cardiovascular and pulmonary diseases present a very significant challenge to the surgeons and the anesthetists due to the high morbidity and mortality rates which follow general anesthesia. (Gramatica et al., 2002; Kumar Ashish, Koshire Alka, & Bharadwaj Deepti; Van Zundert et al., 2006)

The respiratory function remains intact during the regional anesthesia, the diaphragm and the respiratory muscles remains functioning which will maintain the ventilation and causing minimum CO<sub>2</sub> retention, with resultant normal ventilator measurements. (Kumar Ashish et al.)

Most of the inotropic and the chronotropic actions of the heart are mediated by the afferent and efferent nerve fibers carried through reflex neuronal arches. Blocking these pathways by the mean of regional anesthesia, may abolish many of these affects. (Clemente & Carli, 2008)

There are many types of regional anesthesia that are used for various surgical procedures such as the spinal, paravertebral and the celiac plexus block, the combined spinal epidural anesthesia is a relatively easier technique with a relatively lower learning curve and is effective with lower dose of anesthetic drugs. Ultrasound guided block is

usually performed to guide for the injection of the anesthetic medications. (Ortiz et al., 2012; Tulgar et al., 2018; Van Zundert et al., 2006)

Segmental epidural anesthesia has some benefits over the spinal one in that the incidence of cardiopulmonary suppression, easier titration of the anesthetic dose, urinary retention is very low and the earlier regain of the movements and activities, it may be done on day case bases. (J. H. Lee et al., 2010; R. Lee, Van Zundert, Visser, Lataster, & Wieringa, 2008) Lee, R., et al., 2008]

Pain is the most common complain after surgery and it spikes within the first hour after surgery, the use of regional anesthesia have been shown to be very effective in reducing the postoperative pain. (Bisgaard et al., 1999; Mehta, Chavda, Wadhwana, & Porecha, 2010)

Patients must be assessed very carefully and frequently during the procedure and any adverse events must be well documented, and when indicated an appropriate intervention must be carried out. Also careful assessment of the postoperative complications should be done in order to assess the safety of the procedure. (Hamad & El-Khattary, 2003; J. H. Lee et al., 2010; Van Zundert et al., 2006) Lee, J.H., et al., 2010 & Hamad, M. and O.I. El-Khattary, 2003]

As gall stone diseases are very common and many patients require surgical removal of the gall bladder, patients with no comorbidities and when general anesthesia is not contraindicated, the surgery can be done easily, but the main concern is that in patients who are ASA class III and IV and they require surgical intervention, this will make the need for an alternative for such patients. The laparoscopic technique has many effects on both the cardiovascular and the pulmonary physiology, this is mainly due to the effects of pneumoperitoneum which cause raise in the intra-abdominal pressure and the CO<sub>2</sub> retention. The technique of surgery doesn't require any change whether it is performed adopting general or regional anesthetic technique. [Mehta, N., et al., 2015, Mohammed, A.A. and S.H. Arif, 2019, Khetarpal, R., et al., 2016, Tzovaras, G., et al.,

2008, Sinha, R., A. Gurwara, and S. Gupta, 2009 & Saliminia, A., et al., 2015]

The aim of this study is to evaluate the feasibility of the combined spinal-epidural anesthesia in patients with respiratory and cardiovascular diseases who underwent open cholecystectomy.

## 2. Patients and methods:

After the approval of Institutional Ethical Committee and taking written informed consent, this prospective observational study involved a total number of 119 patients, who were complaining from major cardiovascular and pulmonary diseases and in whom the general anesthesia was contraindicated.

The data collected from 2 medical centers, Gulan General Governmental and Azadi Teaching Hospitals in the time between 1<sup>st</sup> of June, 2016 to the 20<sup>th</sup> of February, 2019. The anesthesia was given by two specialist anesthetists and the operations were performed by one specialist general surgeon. Patients' enrollment followed a consecutive manner.

**Inclusion criteria:** American Society of Anesthesiologists (ASA) class III and IV patients who underwent open cholecystectomy were included.

**Exclusion criteria:** Patients with emergency operations, having contraindications of regional anesthesia and patients who refused to be included in this study were excluded.

The patients were informed during the preoperative visit that any anxiety, pain or discomfort occurring during surgery would be dealt with intravenous medications or if they wished. During and after the procedure, the patients were informed to report any dyspnea, abdominal discomfort or pain, nausea and vomiting. In the preoperative room an 18 G IV line secured and all patients received adequate preloading with 15 ml/kg of Ringer's lactate solution over 30 min. The patients were then shifted to the operation theatre and all routine monitors namely, noninvasive blood pressure, peripheral oxygen saturation by pulse oximetry (SpO<sub>2</sub>) and electrocardiogram were attached and after obtaining baseline vital signs, oxygen at 5 L/min was commenced through a face mask.

The patients were positioned in sitting position, and under strict aseptic precautions the L<sub>4</sub>–

L<sub>5</sub> epidural space was accessed using an 18G Tuohy needle and loss-of-resistance technique and spinal anesthesia was then performed with 2 ml that is, 10 mg of 0.5% heavy bupivacaine by a set combined 27G Quincke 15 cm long spinal needle through the already inserted epidural needle after free flow of cerebrospinal fluid, figures 1, 2a & 2b.

The accompanied epidural catheter was threaded cephalad through the Tuohy needle after spinal needle removal and fixed at 4 cm within the epidural space, figure 2c. Patients were turned to the supine position and a 10-degree Trendelenburg tilt was given to achieve the required level of block.

Heart rate, blood pressure, and SpO<sub>2</sub> were recorded every minute for the first 15 min and every 5 min thereafter. The level of sensory (pinprick) block was assessed and recorded every 2 minutes until the start of surgery and every 15 min thereafter. Once the block was considered adequate (minimum block T5—as assessed by pinprick), the surgery was commenced by Kocher (right subcostal) incision.

Pain was treated with meperidine 50 mg or fentanyl 5 mcg/kg/dose initially and then 1-2 mcg/kg/hr. as a maintenance infusion dose, anxiety with midazolam 2 mg and hypotension with ephedrine 30 mg, all as IV boluses as and only when required during the intraoperative period separated or in combined. Only one patient needed TAP block while other one needed spinal adjuvant. The systemic analgesic drugs were administered only if epidural injections were ineffective in controlling pain. Surgeons were free to ask for general anesthesia if they felt that the anesthetic technique was adding technical difficulty for the surgical procedure. An orogastric tube was inserted to decompress the stomach only if the surgeon demanded it. They were also requested to rank the associated technical difficulty after the procedure.

The surgical procedure of open cholecystectomy was carried out according to standard protocol. Operative time as well as any intraoperative or postoperative events was recorded include (hypotension, hypertension, nausea & vomiting, anxiety, dyspnea, shivering).



Figure 1: Touhy needle and spinal needle.

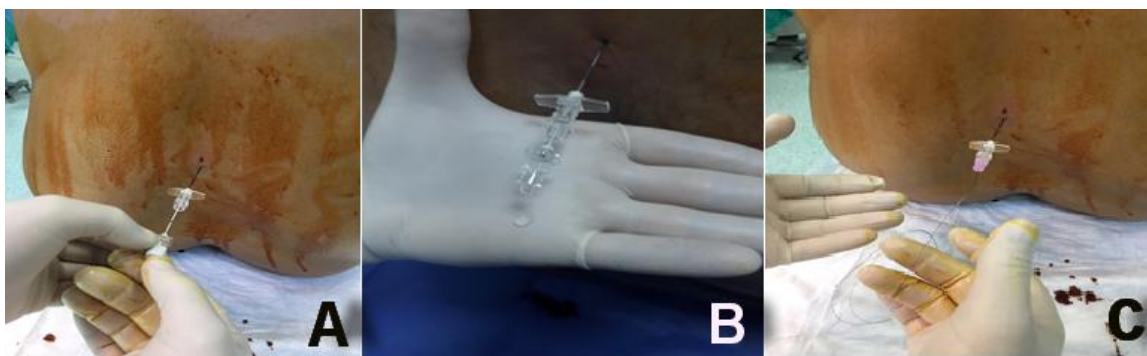


Figure 2: Showing the method of the needle insertion; A: spinal needle through epidural needle, B: CSF dropped through spinal needle, C: epidural catheter in place.

### 3.Results:

A total number of 119 patients were included in this study; the mean age of our patients was 64.33 (12.085 SD) years and females constituted the majority of them. Most patients were complaining from the cardiovascular diseases, table 1 and figure 3.

In most patients the onset of the action of the anesthesia was between 10-12 minutes; however in some patients it started much earlier or later. In most surgeries the operating surgeon reported a good muscle relaxation with no pain within a feasible time, figure 4.

In more than 50% of patients there was indication for further administration of medications to relieve anxiety, pain, or both, table 2.

The rate of intra and post-operative complications were not very high, making this technique relatively safe and effective. Hypotension was the

commonest one both intraoperatively and postoperatively, other types of complications were reported less frequently, table 3.

The surgeon's satisfaction was excellent in the majority of surgeries, and was accepted in only 3.36%, figure 5.

Most patients gained the lower limb movement within 2 hours (the mean time was 117 minutes: Std. deviation 25 minutes), however in some patients this period was extended to 3 hours, figure 6.

Correlations were made between the need for extra drugs or not and various parameters. There was a significant correlation between the need for extra drugs and both comorbid diseases and the development of intraoperative complications (P values 0.022 & 0.000) respectively and no significant correlations with other parameters, table 4.

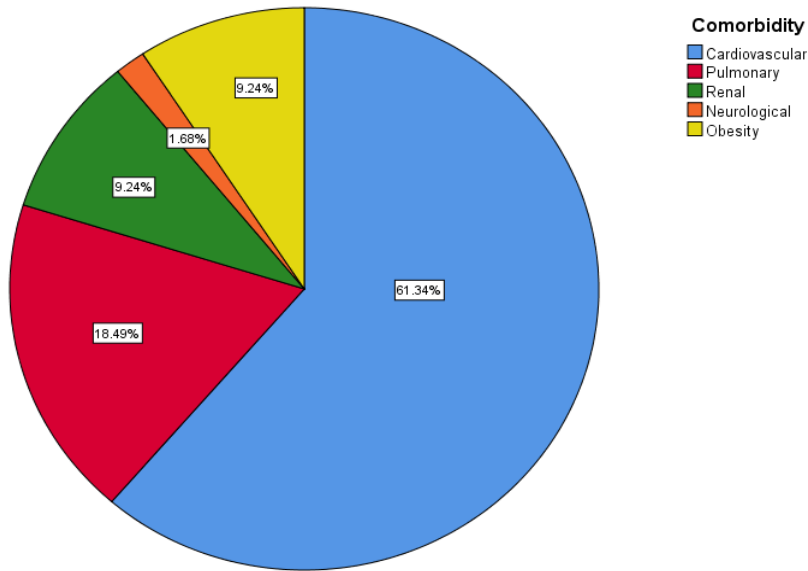


Figure 3: A simple pie chart showing the comorbidities of the patients.

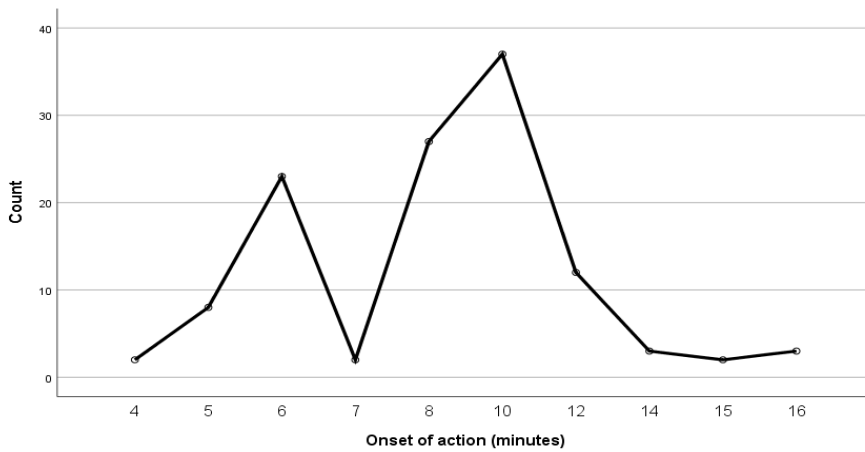


Figure 4: A simple line graph showing the onset of action of the anesthesia.

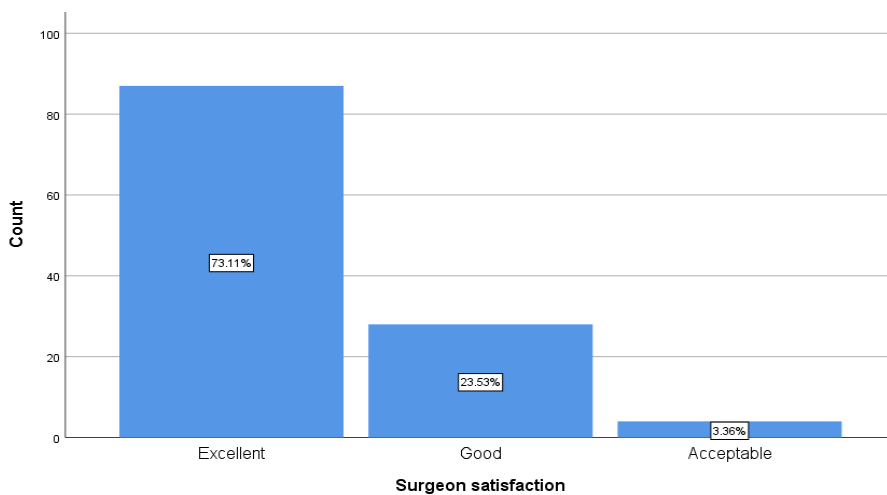


Figure 5: A simple bar chart showing the level of the surgeon satisfaction during surgery.

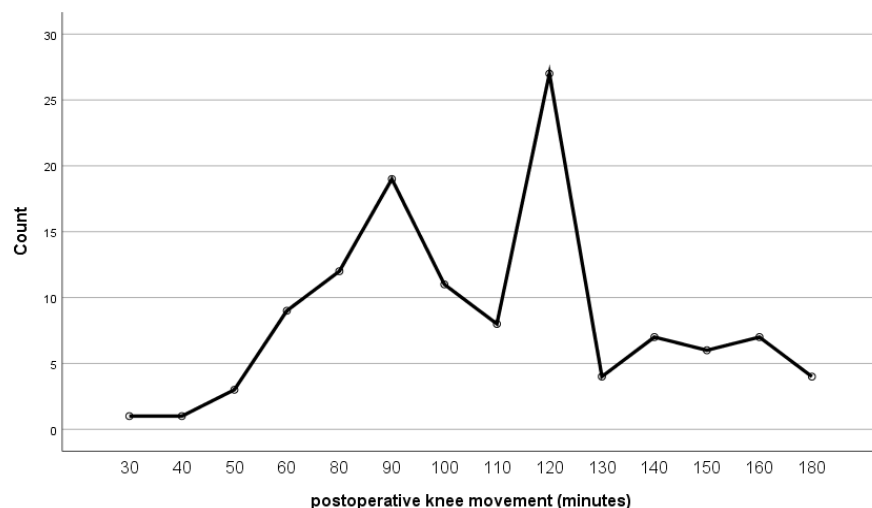


Figure 6: A simple line chart showing the time of return of the lower limb movement after the surgery.

Table 1: The patient's characteristics.

Main category	Subcategories	Frequency	Percentage
Age*		64.33	8.799
Range: 43-90 years			
Gender	Male	46	38.7
	Female	73	61.3
Comorbid diseases	HF+IHD	33	27.7
	HF	14	11.8
	ESRD	11	9.2
	Morbid obesity	11	9.2
	AF+IHD	8	6.7
	Uncontrolled hypertension	8	6.7
	COPD	7	5.9
	Chronic bronchitis	5	4.2
	Bronchial asthma	5	4.2
	HF+ Valvular heart disease	4	3.4
	Complete heart block	3	2.5
	IHD+ Recent CVA	3	2.5
	Pulmonary fibrosis	3	2.5
	Recent MI	2	1.7
	Respiratory failure	1	.8
	Pneumonectomy	1	.8

\*The age is presented as mean and standard deviation

Table 2: The need for extra drugs during surgery.

Need for extradugs	Frequency	Percentage
No need for extra-drugs	55	46.2
50 Mg fentanyl	10	8.4
2 mg midazolam	11	9.2
30 mg ephidrene	29	24.4
30 mg ephidrene + 50 Mg fentanyl	2	1.7
2 mg midazolam + 50 Mg fentanyl	7	5.9
Spinal adjuvant	1	.8
2 mg midazolam + TAP block	1	.8
2 mg midazolam + 50 Mg fentanyl + 30 mg ephidrene	1	.8
50 mg meperidine	2	1.7

Table 3: The intra and the post-operative complications.

Main category	Subcategories	Frequency	Percentage
Intraoperative complications	No complications	81	68.1
	Hypotension	31	26.1
	Dyspnea	5	4.2
	Anxiety	1	0.8
	Nausea	1	0.8
Postoperative complications	No complications	86	72.3

Hypotension	12	10.1
Nausea & vomiting	11	9.2
Shivering	6	5.0
Hypertension	2	1.7
Dyspnea	2	1.7

**Table 4: The correlation between the need for extra drugs and various parameters using the Chi Square test.**

Categories	Need for extra drugs		Sig. (2-sided)
	No (n=55)	Yes (n=64)	
<b>Gender</b>			
Male	20(36.4%)	26(40.6%)	0.707
Female	35(63.6%)	38(59.4%)	
<b>Comorbidities</b>	30(54.5%)	43(67.2%)	<b>0.022</b>
Cardiovascular	13(23.6%)	9(14.1%)	
Pulmonary	3(5.5%)	8(12.5%)	
Renal	0(0.0%)	2(3.1%)	
Neurological	9(16.4%)	2(3.1%)	
Obesity			
<b>Intraoperative complications</b>	43(78.2%)	38(59.4%)	0.000
No complications	1(1.8%)	0(0.0%)	
Anxiety	0(0.0%)	1(1.6%)	
Nausea	6(10.9%)	25(39.1%)	
Hypotension	5(9.1%)	0(0.0%)	
Dyspnea			
<b>Postoperative complications</b>	43(78.2%)	43(67.2%)	0.522
No complications	3(5.5%)	9(14.1%)	
Hypotension	0(0.0%)	2(3.1%)	
Hypertension	1(1.8%)	1(1.6%)	
Dyspnea	5(9.1%)	6(9.4%)	
Nausea & vomiting	3(5.5%)	3(4.7%)	
Shivering			
<b>Surgeon satisfaction</b>	45(81.8%)	42(65.6%)	0.056
Excellent	9(16.4%)	19(29.7%)	
Good	1(1.8%)	3(4.7%)	
Acceptable			

**4.Discussion:**

General anesthesia is usually adopted for patients who need open cholecystectomy because it provides effective and satisfactory muscle relaxation, but it has many adverse effects especially in patients with major comorbidities particularly cardiovascular and pulmonary diseases. The intubation may have many negative impacts on the pulmonary function due to laryngeal spasm and edema.(M. H. Ellakany, 2014; Khan, Ashraf, & Khan, 2013)

Despite the effectiveness of combined spinal-epidural anesthesia in the surgical practice, there are some limitations that block practicing this technique, this may include the lack of the organized training courses and the fear that this technique may not work sufficiently. (Clemente & Carli, 2008)

The mean age of the patients who were involved in the study was 64.33 years (SD: 12.085). Female patients constituted 61.3% (73 patients) and males

constituted 38.7% (43 patients), 61.34% of patients (73) had cardiovascular comorbidities and 18.49% had pulmonary ones (22). Table1 & Figure3. Patients experience anxiety at different levels starting from the insertion of the spinal needle, and during the whole surgical procedure, however anxiety was reported in the minority of our patients, only 0.8% of our patients experience anxiety during the procedure as shown in table3. (Van Zundert et al., 2006)

Most patients experienced an onset of action within 10-12 minutes, others experienced earlier onset of action within 6-7 minutes. The loss of the stress related sympathetic efferent pathways, may result in lack of the normal homeostatic response to stress and injury, together with the loss of the sympathetic vasoconstriction, resulting in hypotension. Figure4. In our study the rate of intra and postoperative hypotension was 26.1% and 10.1% respectively, in most of the published literature hypotension is one of the well

documented adverse events, this is due reduction in the mean arterial pressure, hypotension is easily controlled with ephedrine. (Clemente & Carli, 2008), (Clemente & Carli, 2008; Donmez et al., 2017; J. H. Lee et al., 2010)

Respiratory difficulties and dyspnea were among the other reported complications both intra and postoperatively in 4.2% and 1.7% respectively. This complication is well documented by most authors who reported higher rates (12%), this may be managed by assisted mask ventilation with oxygen. When more invasive monitoring is done many patients may have academia. Dyspnea during surgery may be explained by the stress of the anesthesia and the intra-abdominal manipulation, most patients may have associated cardiac and pulmonary disorders causing dyspnea. The segmental block may result in loss of the appropriate muscle function and blockage of the efferent or the afferent intercostal nerve roots pathways, this impairing effective respiration. About 46.2% (55 patients) required no extra-mediations during the procedure, the rest of patients required extra-mediations to alleviate pain, nausea, or other symptoms during the procedure. Intraoperatively, 68.1% of our patients (81 patients) had no intraoperative complications, and the most frequent intraoperative complication was hypotension which was reported in 26.1% of patients (31 patients). (Das et al., 2015; J. H. Lee et al., 2010; Mohammed & Arif, 2019)

The reported rate of postoperative nausea and vomiting may reach 20% in most cases, this is mostly centrally mediated, in our study 72.3% of patients reported no postoperative complications and the remaining percentage of patients reported postoperative complications, 10.1% (12 patients) developed postoperative hypotension, 9.2% of our patients (11 patients) had postoperative nausea and vomiting, this is relatively lower than the reported rate in most articles. (J. H. Lee et al., 2010). Table 3.

The major concern of the operating surgeon was the inadequate muscle relaxation during the procedure, in our study in most of the performed surgeries (73.11%) the surgeon's satisfaction was excellent, and was just acceptable in 3.38% of the surgeries. (Khan et al., 2013). Figure 5

Local complications are reported to be associated with this type of anesthesia, these may include; hematoma formation at the site of injection, pain at the site of catheter insertion, and infection. Intrathecal spread may also occur; inadvertent

vascular or pleural puncture have also been reported. (Naja & Lönnqvist, 2001)

Postoperatively, the majority of our patients started lower limbs movement after 120 minutes, few patients started to move their lower limbs within less than 60 minutes. The lower limb motor block is usually minor and transient and resolves with time, this is caused by the spread of the anesthetic drugs to the lumbar and the sacral motor nerve roots. (Van Zundert et al., 2007). Figure 6

In our study we included patients who underwent open cholecystectomy, however recently in many center they use this technique for patients with laparoscopic cholecystectomy, which is proved to be safe and very effective. This may be difficult for complicated cases such as the acute cholecystitis, tumors or cases who are ASA class III and IV. (Van Zundert et al., 2007)

There was a significant correlation between the need for extra drugs and both comorbid diseases and the development of intraoperative complications (P values 0.022 & 0.000) respectively and no significant correlations with other parameters such as the gender, postoperative complications and the surgeon's satisfaction (P values 0.707, 0.522, and 0.056) respectively. Table 4

### 5. Conclusion:

The technique of the combined spinal epidural anesthesia is safe and very effective when used for ASA class III and IV patients who need open cholecystectomy. This technique should be used by specialist anesthetists who are well trained in this technique, and it may be used in fields other than surgery such as trauma victims and for cancer patients.

### Declaration section:

**Ethics approval and consent to participate:** Ethical committee approval is granted from the research registration unit at the Duhok Directorate General of Health.

**Consent for publication:** A written consent was obtained from all the participants.

**Availability of data and materials:** Not applicable.

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