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ORIGINAL RESEARCH

The Effects of Early Mobilization on Pain and Quality of Recovery in Patients Undergoing Laparoscopic Cholecystectomy Surgery

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Abstract

Objective: The present study was conducted to investigate the effects of early mobilisation on pain and quality of recovery in patients undergoing laparoscopic cholecystectomy.

Material-Method: The method of this study included a pretest-posttest experimental design with a control group. This study was conducted in the inpatient general surgery department of a government hospital between August 2021 and May 2022. A total of ninety patients were included in the sample. Starting two hours after surgery, patients in the intervention group were mobilised at least 6 times within 24 hours. A "Patient Description Form", the "Visual Analogue Scale for Pain" and the "Quality of Recovery-40 Questionnaire" were used to collect data. The Visual Analog Scale for Pain was administered at 2 hours, 24 hours, and 15 days postoperatively, and the Quality of Recovery-40 Questionnaire was administered 2 hours before surgery and at 24 hours and 15 days postoperatively.

Results: The baseline and medical characteristics of the patients in the intervention and control groups were similar. No significant difference was found between the mean pain and recovery quality scores of patients in the two groups at 2 hours postoperatively. The mean pain severity scores of the intervention group at 24 hours and 15 days postoperatively were found to be significantly lower than those of the control group. It was found that the mean quality of recovery scores of the intervention group at 24 hours and 15 days postoperatively were also greater than those of the control group.

Conclusion: Early mobilisation was found to reduce the level of pain and improve the quality of recovery in laparoscopic cholecystectomy patients.

Keywords: Pain, Quality Of Recovery, Early Mobilisation, Laparoscopic Cholecystectomy

INTRODUCTION

As technology has advanced, so too have surgical techniques. One such development is laparoscopic surgery.¹ Laparoscopic cholecystectomy, first used in 1987 for patients with cholelithiasis, is a procedure in which the gallbladder is removed through minimal incisions in the abdomen.^{2,3} Laparoscopic cholecystectomy has become one of the most commonly performed surgical procedures worldwide because it is safer for both the patient and the surgeon.⁴

Compared with open surgery, laparoscopic surgery has advantages such as less postoperative pain, faster recovery, earlier discharge and a more cosmetically pleasing result.⁵⁻⁷ Although the intensity of postoperative pain in patients who undergo laparoscopic cholecystectomy is less than in those who undergo open cholecystectomy, this pain can still be distressing for patients.⁵ Pain is an unpleasant emotional and sensory condition that can occur in any part of the body, whether or not it is due to tissue damage.⁸ Pain causes prolonged hospitalisation or readmission in patients after laparoscopic cholecystectomy.⁹

In the post-operative period, pain management is very important to improve the quality of the patient's recovery and to prevent potential complications.⁵ Adequate pain management is important to prevent deterioration of tissue perfusion, atelectasis and the likelihood of developing deep vein thrombosis.¹⁰ Pain in the postoperative period can vary depending on the dose of anaesthetic given to the patient and the patient's mental and physiological state.⁵ Therefore, "pharmacological" and "non-pharmacological" methods are used in pain management.^{11,12} Nonpharmacological methods, which can be used alone or in combination with pharmacological agents, are simple and usually have no side effects and are also very important in pain management. An important

of non-pharmacological component pain mobilisation.¹⁰ is early management Early mobilisation practices after all surgical procedures prevent many complications and improve the quality of the patient's recovery. Mobilising the patient after surgery increases venous return, regulates respiration and reduces the risk of abdominal dislocation by increasing the activity of the digestive system. In addition, early mobilisation reduces the patient's pain, shortens the length of hospital stay and reduces the cost of care.^{13,14} Late mobilisation reduces alveolar ventilation and oxygenation, increases respiratory and cardiac workload, and increases the risk of deep vein thrombosis, which negatively affects the patient's quality of recovery.¹⁵ In general, the concept of mobilisation encompasses many activities. Positioning in bed, sitting at the bedside and walking are different mobilisation activities. As with all surgical procedures, the quality of patient recovery after laparoscopic cholecystectomy is very important.¹⁶ Improving the quality of the patient's recovery regulates the stress response that may occur in the patient and reduces morbidity and length of hospital stay.¹⁷ To this end, enhanced recovery after surgery (ERAS) protocols have been developed. The early mobilisation included in these protocols improves the quality of the patient's recovery. Early mobilisation requires the patient to be out of bed for 2 hours on the first day and at least 6 hours a day until discharge.¹⁶ Some studies in the literature have investigated the effect of early mobilisation on pain.¹⁸⁻²⁰ However, the literature review for this study did not identify any previous studies that investigated the effect of early mobilisation on pain and quality of recovery in patients undergoing laparoscopic cholecystectomy. This study is expected to add important evidence to the literature and practice in this area. Based on this idea, the aim of this study was to determine the effects of early mobilisation on pain and quality of recovery in patients undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS Research design

This study was performed with an experimental research design including a pretest, a posttest, and a control group. The protocol of the study followed the TREND Statement principles, which were developed specifically to guide the standardized reporting of non-randomized controlled trials.

Population and sample of the research

The study population included patients who "underwent laparoscopic cholecystectomy" at the

inpatient general surgery unit of a state hospital between August 2021 and May 2022. In this study, an a priori G*Power analysis was performed to determine the power of the included sample to represent the study population. Using a medium effect size (0.5), an alpha value of 5% and a theoretical power of 95%, the minimum sample size required for each group was calculated to be 45 patients. Ninety patients completed the study, "45 patients in the intervention group" and "45 patients in the control group". Patients were allocated to the two groups using simple random sampling by tossing a coin.²¹ Individuals who met the inclusion criteria were included in the study, and those who tossed tails were allocated to the intervention group, and those who tossed heads were allocated to the control group.

Inclusion and exclusion criteria

Patients were included if they agreed to take part in the study, were over 18 years of age, had no cognitive behavioural problems, had or undergone laparoscopic cholecystectomy, and had an ASA I or Π (American Society of Anesthesiologists) classification. Patients who underwent open cholecystectomy, those who did not want to take part in the study and those with a high ASA score were excluded from the study.

Data collection tools

A patient information form, mobilisation follow-up form, visual analogue scale for pain (VAS) and the Quality of Recovery 40 (QoR-40) questionnaire were used to collect data.

Patient information form

This data collection form was designed by the researchers to collect information on the sociodemographic and medical characteristics of the patients, including their age, sex, marital status, level of education, occupation, presence of chronic diseases, history of previous surgical intervention, smoking status, and presence of physical inactivity.

Mobilisation follow-up form: This is the chart prepared by the researchers to determine the time and duration of mobilisation applied to the patients after surgery.

Visual analog scale for pain (VAS)

The Visual Analogue Scale (VAS) for Pain, developed by Price et al, is used to rate the severity of the pain that the respondent is currently experiencing. This scale consists of a 10 cm ruler with 0 at one end and 10 at the other. An increase in the number marked by the patient is directly proportional to an increase in the pain they are currently experiencing.²²

Quality of recovery 40 (QoR-40) questionnaire

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The OoR-40 was developed by Myles et al. (2000). The validity and reliability study of the questionnaire in Turkey was conducted by Karaman et al. QoR-40 has five dimensions, namely physical comfort, emotional state, physical independence, patient support and pain. The questionnaire consists of 40 items scored on a five-point Likert scale. Each item has response options ranging from "none of the time 1' to 'all the time: 5' for positive statements and from 'none of the time 5' to 'all the time: 1' for negative statements. The lowest and highest possible total scores on the QoR-40 are 40 and 200. Higher total scores indicate better mood and physical condition of The Cronbach's alpha the patient. internal consistency coefficient of the scale is reported to be 0.936.²³ In this study this coefficient was 0.86.

Implementation

Intervention group

The patients' vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation, blood glucose concentration) were measured in the 2nd hour after surgery. Patients whose vital signs were not negative were slowly seated in their beds. After the patients were allowed to sit in bed for 3 minutes, their blood pressure was measured again to check for orthostatic hypotension. The mobilisation of the 2 patients whose blood pressure was not within the normal range was postponed for 30 minutes and they were returned to bed. These patients then met the same mobilisation criteria as the patients in the intervention group. Those whose blood pressure was within normal limits were allowed to stand up slowly with the help of at least one 'relative'. After 10 minutes of mobilisation by walking in the corridor of the inpatient clinic, the patients were allowed to lie down again. The mobilisation times of the patients in this group were continued during the following mobilisation hours, with the time of mobilisation being increased with each step. During the first 24 hours of the postoperative period, patients were mobilised at least 6 times in total. This ensured that patients were mobilised for at least 2 hours in the first 24 hours after surgery.^{16,24} Mobilisation times and durations were recorded. In the following days, patients and their relatives were informed that they should be active out of bed for at least 6 hours a day. The application times of the data collection instruments were determined based on a review of the relevant literature.^{23,25,26} Preoperative QoR-40, VAS at 2 hours postoperatively, VAS at 24 hours postoperatively, and postoperative QoR-40 were applied face-to-face. On the 15th postoperative day, VAS and QoR-40 were administered for the last time by telephone interview.

Control group

Data from patients in the control group were obtained using the same measurement procedures as for the intervention group. Patients in the control group were mobilised at 6-8 hours post-operatively according to the clinic protocol, depending on their condition.

Statistical analysis

The statistical analyses of the collected data were conducted using the Statistical Package for the Social (version 22.0) software Sciences package. Frequencies, percentages, means, and standard deviations, Chi-squared test, paired-samples t-test, and Cronbach's Alpha internal consistency analysis were utilized to analyze the data. To compare the pretest-posttest mean scores of the patients in the groups, analysis of variance (ANOVA) and independent-samples t-tests were employed for repeated measurements. Skewness and kurtosis values were checked for testing the normality of the distribution of scale scores.

Ethical disclosure

Before starting the study, approval was obtained with the application made to the Non-Invasive Research Ethics Committee of a university. Written permissions were obtained from the Provincial Directorate of Health and the state hospital to carry out the study. Approval to use the scale in this study was obtained from the principal investigator. The verbal and written permission of the patients to be included in the study was obtained following their provision with the necessary explanations regarding the objective of the study and how it would be implemented.

RESULTS

It was determined that the differences between the intervention and control groups regarding their descriptive characteristics were not statistically significant, and the groups had similar characteristics (p>0.05, Table 1).

The mean 2nd-hour VAS scores of the intervention and control groups did not significantly differ compared to each other (t=1.358, p=0.178) (Table 2). It was observed that the mean 2nd-hour VAS score of the intervention group was significantly higher than their mean 24th-hour and 15th-day VAS scores (F=622.842, p=0.000, respectively).

It was found that the mean 2nd-hour VAS score of the control group was significantly higher than their mean 24th-hour and 15th-day VAS scores (F=499.076, respectively, p=0.000) (Table 2).

Table 1. Descriptive Characteristics

Descriptive Characteristics	Intervention (N=45)	Group	Control Group (N=45) 48.33±12.97		Test and p-value T=0.494 P=0.623***	
Age (Years)	46.91±14.30					
	S	%	S	%		
Gender						
Female	34	75.6	34	75.6	$X^2 = 0.000$	
Male	11	24.4	11	24.4	P=1.000*	
Education						
Illiterate	4	8.9	5	11.1		
Primary Education	21	46.7	20	44.4	$X^2 = 0.236$	
High School	10	22.2	11	24.5	P=0.972**	
University And Above	10	22.2	9	20.0		
Marital Status						
Married	41	91.1	44	97.8	$X^2 = 1.906$	
Single	4	8.9	1	2.2	P=0.167*	
Occupation						
Housewife	21	46.7	29	64.5	$X^2 = 4.348$	
Officer	7	15.6	2	4.4	P=0.114**	
Other	17	37.7	14	31.1		
Chronic Disease						
No	38	84.4	38	84.4	$X^2 = 1.400$	
Hypertension	4	8.9	6	13.3	P=0.497**	
Diabetes Mellitus	3	6.7	1	2.2		
Previous Surgical İnterventi	on					
Yes	13	28.9	16	35.6	$X^2 = 0.458$	
No	32	71.1	29	64.4	P=0.652*	
Smoke						
Yes	18	40.0	15	33.3	X ² =0.431	
No	27	60.0	30	66.7	p=0.512*	
Lack of activity					*	
Yes	4	8.9	2	4.4	$X^2 = 0.714$	
No	41	91.1	- 43	95.6	p=0.398*	

Fisher's Exact Test **Pearson Chi-Squared Test ***Student's t-test

Table 2. Comparison of VAS Scores within and between Groups

	Intervention g	group	Control group	Test and p-	
	X±SD	Test and p- value	X±SD	Test and p- value	value
2nd-hour VAS	6.16±0.97	F=622.842*	5.89±0.88	F=499.076*	t=1.358 p=0.178
24th-hour VAS	4.13±1.10	p=0.000 1>2,3	5.38±0.98	p=0.000 1>2,3	t=5.658** p=0.000
15th-day VAS	0.47±0.66	2>3	1.33±0.95	2>3	t=5.012** p=0.000

*Fisher's Exact Test **Pearson Chi-Squared Test ***Student's t-test

While no significant difference was found between the preoperative mean scores of the patients in the intervention and control groups in any dimensions of QoR-40, significant differences were determined between the mean 24th-hour and 15th-day scores of the intervention and control groups (p<0.001) (Table 3). It was determined that the mean 24th-hour QoR-40 score of the patients in the intervention group was

significantly lower than their mean preoperative and 15th-day scores (F=50.965, p=0.000, respectively). It was found that the mean 24th-hour QoR-40 score of the patients in the control group was significantly lower than their mean preoperative and 15th-day (F=97.520, p=0.000, respectively). While there was

no significant difference between the mean preoperative total QoR-40 scores of the patients in the intervention and control groups, the mean 24th-hour and 15th-day scores of the two groups were significantly different from each other (p<0.001) (Table 3).

		Intervention group		Control	Test and a	
		X±SD	Test and p- value	X±SD	Test and p- value	Test and p- value
Physical comfort	Preoperative	55.88±3.32	F=35.131* p=0.000	56.46±3.91	F=50.954* p=0.000	t=0.755** p=0.452
	24th-hour	55.64±3.47		52.86±3.14		t=3.974** p=0.000
	15th-day	59.84±0.42		59.31±0.84		t=3.773** p=0.000
Emotional state	Preoperative	39.71±2.97	F=53.939* p=0.000 1<2 1<3 2<3	40.06±2.50	F=51.377* p=0.000 1<3 2<3	t=0.613** p=0.541
	24th-hour	41.26±2.92		39.62±1.99		t=3.116** p=0.002
	15th-day	44.37±1.07		43.13±1.37		t=4.788** p=0.000
Physical independence,	Preoperative	23.28±1.90	F=71.007* p=0.000 2<1 2<3	23.35±1.76	F=173.386* p=0.000 1>2 3>2	t=0.173** p=0.863
	24th-hour	18.42±3.15		16.42±2.27		t=3.454** p=0.001
	15th-day	23.55±1.19		21.82±1.74		t=5.486** p=0.000
Patient support	Preoperative	32.02±1.68	F=32.019* p=0.000	31.62±1.33	F=12.686* p=0.000	t=1.248** p=0.216
	24th-hour	33.33±1.31		32.62±1.26		t=2.614** p=0.011
	15th-day	33.24±1.15	1<2 1<3	32.26±1.26	- 1<2 1<3	t=3.829** p=0.000
Pain	Preoperative	33.55±2.41	F=49.266* p=0.000 2<1,3	33.71±2.15	F=97.088* p=0.000 2<1,3	t=0.322** p=0.748
	24th-hour	30.88±1.69		29.46±1.61		t=4.071** p=0.000
	15th-day	34.60±0.49		33.93±0.75		t=4.972** p=0.000
Healing Quality Questionnaire Total	Preoperative	184.46±8.86	F=50.965* p=0.000 2<1,3	185.22±8.42	F=97.520* p=0.000 2<1,3	t=0.414** p=0.680
	24th-hour	179.55±10.79		171.00±7.71		t=4.325** p=0.000
	15th-day	195.62±3.26		190.46±4.22		t=6.479** p=0.000

*Fisher's Exact Test **Pearson Chi-Squared Test ***Student's t-test

DISCUSSION

Wounds, drains and pain, which are inevitable consequences of surgery, result in patients being confined to bed for short or long periods of time, preventing their mobilisation.²⁷ The prevention of mobilisation after abdominal surgery leads to various complications such as digestive problems,

thromboembolic conditions and respiratory dysfunction. Early mobilisation, which is an important part of Enhanced Recovery After Surgery (ERAS), can minimise these complications.^{28,29} Early postoperative mobilisation accelerates postoperative recovery by preventing the negative physiological

effects of immobility and surgical stress after abdominal surgery.³⁰ It has been reported that early mobilisation improves postoperative pulmonary function, aids pain management and has a positive effect on improving physical function, and patients can return home in a shorter time.³¹⁻³³ The positive outcomes of early mobilisation are considered to be beneficial to patients and have advantages in terms of efficient use of hospital resources and patient beds, as well as working conditions for hospital staff.³⁴ In light of this information, early mobilisation after abdominal surgery can be considered a key component of clinical management.³⁰ In this study, early mobilisation was found to reduce pain levels and improve the quality of recovery in laparoscopic cholecystectomy patients.

It was found that the differences between the patients enrolled in the intervention and control groups based on their baseline information were not significant, and therefore the groups were similar to each other (Table 1). It can be stated that this similarity between the groups is important for the efficacy and reliability of the study.

When the mean VAS scores of the intervention and control groups were evaluated at 2 hours after surgery, it was found that moderate pain was present in both groups, with the intensity of pain in the intervention group decreasing 24 hours after surgery, but moderate pain persisting in the control group. It was also found that the pain of patients in the intervention group had disappeared 15 days after surgery, whereas the intensity of pain remained, albeit at a low level, in patients in the control group (Table 2). In their study of the effects of early mobilisation on abdominal pain in laparoscopic cholecystectomy cases, Başar (2020) reported no significant difference between the pain scores of the intervention and control groups at 2 hours postoperatively.³⁵ In the same study, it was found that the pain scores of patients in the intervention group decreased significantly at 4 and 6 hours postoperatively. Studies have found that early mobilisation after surgery has a beneficial effect on patients' pain and reduces the severity of pain.^{18,19,36,37} When the results of this study and those of the above studies are taken together, it is observed that early mobilisation has a beneficial effect in reducing pain. The results of previous studies in different patient groups support the results of this study. Early mobilisation is considered to be a nursing intervention that has a positive impact on patient outcomes in the postoperative period. Both reducing pain and achieving independence in patient activities may also be beneficial. Both reducing pain and achieving independence in activities for patients may also lead to a reduction in their sense of dependence on others as a result of their surgery.

In this study, based on the QoR-40 physical comfort dimension scores of the patients, it was found that the preoperative physical comfort levels of the patients in the intervention and control groups were similar. However, the patients in the intervention group had better physical comfort at 24 hours postoperatively and at 15 days postoperatively compared to the patients in the control group (Table 3). It was concluded that the physical comfort of patients who were mobilised early increased over time. It has been reported that early mobilisation has a positive effect on the comfort of patients undergoing abdominal surgery.^{35,38} Comfort is defined in the dictionary of the Turkish Language Association (2017) as "ease that facilitates daily life".³⁹ The concept of comfort is a concept that is integrated with the nursing services provided to the patient to regain their health.⁴⁰ Good postoperative comfort of the patient has a positive effect on their healing process.⁴¹ One of the important contributions of early mobilisation of postoperative patients is that the patient gains independence in the early period. It is thought that in this study, the mean OoR-40 physical comfort subscale score of the patients in the intervention group was higher because early mobilisation could affect the independence of the patient. Considering that one of the goals of care for patients undergoing surgery is to achieve and maintain patient comfort, it is reasonable to assume that this goal was achieved in this study by early mobilisation.

While no significant difference was found between the mean preoperative QoR-40 emotional state dimension scores of patients in the intervention and control groups, it was found that the emotional state scores of patients in the intervention group were higher at 24 hours and 15 days postoperatively compared to patients in the control group (Table 3). It has been reported that the practice of gradual early mobilisation in mechanically ventilated patients had a positive effect on their mood and reduced their anxiety.⁴² Akkaya (2020) found that the duration of mobilisation was inversely related to anxiety and depression in patients undergoing open abdominal surgery.43 Physical activity or exercise is an important part of a healthy lifestyle. While it allows the individual to distance themselves from negative moods such as depression, it increases positive moods such as excitement, joy, pride and confidence.⁴⁴ This study showing the positive

influence of early mobilisation on the emotional state of patients is supported by findings from studies with different samples. Considering that the surgical process produces different emotional states in patients, it is believed that early mobilisation will not only relieve the patient emotionally, but also improve physiological parameters that develop due to emotions.

The preoperative physical independence status of patients in the intervention and control groups in this study was found to be similar according to their OoR-40 physical independence dimension scores. Patients in the intervention group were found to have a better physical independence status at 24 hours and 15 days postoperatively (Table 3). The reason for this may be that patients should be mobilised early in the second hour after surgery and should be informed about their continued mobility at home. At the same time, the decrease in patients' pain levels after mobilisation may be a factor that allows for better physical independence. In a study of patients undergoing cardiac surgery, it was reported that patients who mobilisation positive underwent early had developments in their physical functioning.45 It was found that early mobilisation of critically ill patients in the intensive care unit had positive outcomes, such as independent walking at discharge.⁴⁶ It was thought that as patients' physical independence increased in the period after their operations, they would feel more competent and less dependent on others.

The mean preoperative scores of the patient support dimension of QoR-40 for patients in the intervention and control groups in this study were similar, while the mean scores of patients in the intervention group were significantly higher at 24 hours and 15 days postoperatively (Table 3). Nurses should support the patient for mobilisation early in the postoperative period.⁴⁷ In the items of the patient support dimension of QoR-40, there is an option to receive support from nurses in the hospital. It is thought that patients in the intervention group felt more supported because nurses explained the procedures and interventions, clearly explained the benefits of early postoperative mobilisation to the patient, and provided a safe environment for the patient prior to mobilisation.

In this study, no significant difference was observed between the mean preoperative QoR-40 pain dimension scores of patients in the intervention and control groups, while the mean 24-hour and 15-day postoperative scores were higher in the intervention group (Table 3). Dehghani et al (2020) reported that the mean pain scores of patients decreased with the early mobilisation programme they applied in patients underwent who laparoscopic cholecystectomy.²⁰ Ni et al (2018) observed that the mean pain scores were lower in patients who were mobilised early after liver resection.18 In agreement with the results of other studies in the literature, it can be argued that early mobilisation after laparoscopic cholecystectomy has a positive effect on the reduction of pain and the quality of recovery. In the comparisons between groups in this study, the difference between the intervention and control groups in terms of mean preoperative total QoR-40 scores was not significant, but there was a significant difference between the groups at 24 hours and 15 days postoperatively. Lee et al (2011) found that the early nutrition and early mobilisation programme applied after colorectal surgery shortened the recovery time of patients.⁴⁸ A systematic review found that early mobilisation of patients in the first 24 hours after surgery had a positive effect on rapid recovery.⁴⁹ Zang et al (2020) found that early mobilisation and rehabilitation of patients in the intensive care unit improved the quality of recovery of patients.⁵⁰

The ERAS protocol, which includes early mobilisation, reduces the risk of postoperative complications and ensures early recovery and discharge.⁵¹ Nechay et al (2021) found that the ERAS protocol followed after laparoscopic cholecystectomy accelerated recovery and reduced the length of hospital stay in patients.⁵²

Inactivity causes many complications in patients, including muscle weakness and atrophy. Early mobilisation reduces the possibility of developing various complications and ensures early recovery of the patients.⁵³ It can be seen that the results of previous studies conducted in different patient groups support the result of this study.

LIMITATIONS

This study had some limitations. The results of the study can only be generalised to patients undergoing laparoscopic cholecystectomy who meet the inclusion criteria. The fact that the data in the study were based on self-reports by the participants may also have been a limitation. Another limitation was the sample size and the fact that the study was conducted in a single hospital. The random allocation of patients to the groups and the statistical analyses performed by an expert statistician were the strengths of this study.

CONCLUSION

In conclusion, early mobilisation after laparoscopic cholecystectomy was found to be beneficial in reducing patients' pain and improving the quality of their recovery. It is recommended that patients undergoing surgery should be informed about the importance and timing of early mobilisation, that in-service training programmes on early

mobilisation should be organised for nurses working in surgical clinics, that these programmes should be repeated at regular intervals, and that the effects of early mobilisation should be studied in different samples.

It can be argued that early mobilisation in laparoscopic cholecystectomy is a non-pharmacological nursing intervention that reduces the level of pain and improves the quality of recovery in patients. Early mobilisation has a positive impact on postoperative patient outcomes. **Disclosure statement:** The authors have no conflicts of interest to declare.

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