

Vibration and Exercise Maneuvers to Minimize Patients' Shoulder Pain Post laparoscopic cholecystectomy: A Randomized Clinical Trial

Noorah Mahmoud Ali, * Msc; Alaa Jawad Kadhim, ** PhD; Alice Khachian, *** PhD

* Clinical Nurse Specialist, AL-kindi Teaching Hospital, Ministry of Health. e-mail: noorahmali8@gmail.com

** Asst. Prof, adult Nursing Department, College of Nursing, University of Baghdad, Baghdad, Iraq.

ORCID: <https://orcid.org/0000-0002-4306-6830>, E-mail: alaa@conursing.uobaghdad.edu.iq

***Associate Professor, Nursing and midwifery Care Research Center, Department of Medical Surgical Nursing, School of Nursing and Midwifery, Iran University of Medical Sciences, Tehran, Iran.

E-mail: Alicekhachian@gmail.com

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ABSTRACT

Objective(s): To determine the effect of the application of vibration and exercise on shoulder pain for patients after laparoscopic cholecystectomy.

Methods: A Randomized Clinical Trial was carried out at Surgical Wards in AL-Kindi Teaching Hospital and Baghdad Teaching Hospital from November 13th to June 30th, 2023. After sample calculated from population, 70 patients were divided into two groups: the study group (35) and the control group (35) to achieve the objectives of the study. In the study group, a vibration device and shoulder exercises were used, both of which had validity and reliability, and pain was evaluated using numerical pain scale from (0-10). The researcher used a dice cube to investigate randomness, and the interview method was chosen for data collection.

Results: The results of the data showed that all 70 patients had severe shoulder pain after laparoscopic cholecystectomy in the pre-test, while the results in the post-test of the application were decrease pain level by the application of both vibration and exercises.

Conclusions: The study conclude that both vibration and exercises have a positive relationship in reducing shoulder pain, but the trail of vibration application on the shoulder has an effective effect on reducing the severity of shoulder pain compared to exercises.

Recommendations: The study recommended that the vibration and exercise experience be applied to all patients after laparoscopic cholecystectomy.

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*Corresponding author at: Clinical Nurse Specialist, AL-kindi Teaching Hospital, Ministry of Health, Baghdad, Iraq; E-mail: noorahmali8@gmail.com. (NM Ali). ORCID: <https://orcid.org/0009-0009-7122-9359>, <https://doi.org/10.58897/s4nm2z16>

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تطبيق الاهتزاز والتمارين لتقليل آلام الكتف لدى المرضى بعد استئصال المرارة بالمنظار: تجربة سريرية عشوائية

المستخلص

الأهداف: لتحديد تأثير تطبيق الاهتزاز والتمارين على آلام الكتف لمرضى بعد استئصال المرارة بالمنظار.
المنهجية: دراسة ذات تجربة سريرية معشاة منضبطة تم إجراؤها في الردهات الجراحية في مستشفى الكندي التعليمي ومستشفى بغداد التعليمي من ١٣ تشرين الثاني إلى ٣٠ حزيران ٢٠٢٣. عد حساب العينة من مجتمع الدراسة تم تقسيم (٧٠) مريضاً إلى مجموعتين: مجموعة الدراسة (٣٥) والمجموعة الضابطة (٣٥) لتحقيق أهداف الدراسة. استخدمت في مجموعة الدراسة جهاز اهتزاز وتمارين للكتف ، وكلاهما يتمتع بالصلاحية والموثوقية ، وتم تقييم الألم باستخدام مقياس الألم العددي من ٠-١٠. استخدم الباحث مكعب النرد للتحقيق العشوائية. وتم اختيار طريقة المقابلة لجمع البيانات.
النتائج: أظهرت نتائج البيانات أن جميع المرضى البالغ عددهم ٧٠ يعانون من ألم شديد في الكتف بعد استئصال المرارة بالمنظار في الاختبار القبلي ، بينما كانت نتائج في الاختبار البعدي أوضحت تخفيف من مستوى الألم من خلال التطبيق كل من الاهتزاز والتمارين.
الاستنتاجات: استنتجت الدراسة بان لكل من الاهتزاز والتمارين لهم علاقة إيجابية في الحد من آلام الكتف، ولكن لتجربة الاهتزاز المتكرر على الكتف اكثر فاعلية على تقليل شدة الم الكتف مقارنة بالتمارين.
التوصيات: توصي الدراسة بتطبيق الاهتزاز على الكتف والتمارين على جميع المرضى بعد استئصال المرارة بالمنظار.
الكلمات المفتاحية: الاهتزاز، التمارين، آلام الكتف، استئصال المرارة بالمنظار.

Introduction

Laparoscopic cholecystectomy (LC) is a minimally invasive procedure for removing a diseased gallbladder ⁽¹⁾. This method has replaced the efficient alternative for routine cholecystectomy, as it occurred in the early 1990s ^(2,3).

Carbon dioxide (CO₂) insufflation is a requirement for all laparoscopic surgeries. The preferred intra-abdominal pressure for proper working space and organ visibility is 12-15 mmHg ⁽⁴⁾. This pressure is also accompanied by harmful effects on the heart, lungs, and kidneys, as well as an increased prevalence of shoulder pain ⁽⁵⁾.

According to the Iraqi Ministry of Health, the number of adult people with laparoscopic cholecystectomy was about 10,000 persons ⁽⁶⁾. LC is the most frequent abdominal surgery in the United States, with over

Up to 80% of patients report higher shoulder pain after laparoscopic cholecystectomy. The phrenic nerve begins at the C3, C4, and C5 cervical nerve roots

before moving down deeply to the anterior scalene muscle ⁽⁹⁾.

The exaggerated lithotomy position was found to be fast and effective for relieving shoulder pain after laparoscopic cholecystectomy, decreasing the need to use additional analgesics and opioids ⁽¹⁰⁾.

The pain levels and the analgesic (pethidine and diclofenac sodium) usage of the patients in both the experimental and control groups were compared ^(11, 12).

Non-pharmacological techniques can be beneficial complementary approaches that can increase the effectiveness of treatment. They are not aimed at replacing pharmaceutical therapies ^(13, 14).

Exercises are often referred to as any controlled movement of the joints and relaxation of the shoulder muscles, or body activity that is followed by trials ^(15,16).

There is a gap in the methods for decreasing shoulder pain post laparoscopic cholecystectomy. Despite many clinical trials on ways to decrease shoulder pain after surgery, no research has been found using

vibration and exercises for patients with shoulder pain, so this study used these alternative therapeutic methods or non-pharmacological trial instead of medications and analgesics to relieve pain and reduce the burden on the patient and the hospital.

The current study was conducted to clinical trial of two non-pharmacology techniques for patients after laparoscopic surgery. Therefore, it aims to determine the effect of the application of vibration and exercise on shoulder pain for patients after LC. The researcher used this clinical trial to minimize shoulder pain for patients. Strategies to reduce shoulder pain include exercise and vibration devices

Methods

Study Design

A Simple, Randomized Clinical Trial for patients who suffer from shoulder pain as a result of inflating the abdomen with carbon dioxide gas during laparoscopic cholecystectomy. It started from November 13th to June 31st, 2023.

Study Setting

The study was carried out at the surgical wards of AL-Kindi and Baghdad Teaching Hospital.

Sample and Sampling

A simple random sampling (probability) sampling technique that is non probability (purposive) of 70 patients with shoulder pain following LC in the surgical ward was selected to achieve the objective of the study. According to the Slovin's formula (Ellen, 2012), total population (targete patients) =120; $n = \text{sample size } 92; n = N / [1 + (N) (E)2]; n = 92.3; n = 92$ patients as criteria.

Procedure Explanation

The seventy patients were randomly divided into two groups. The data collection technique used was personal interviews by the researcher with the patient after two hours of the patient's rest and recovery from the effects of anesthesia after the operation while lying in

the surgical ward bed. Then, the data was collected for the two groups (intervention and control) for the pre-test to measure the pain level using the numerical pain scale. After that, the vibration maneuver and exercise were applied to patients with shoulder pain after cholecystectomy. The post-test was also conducted for the two groups as figure 1.

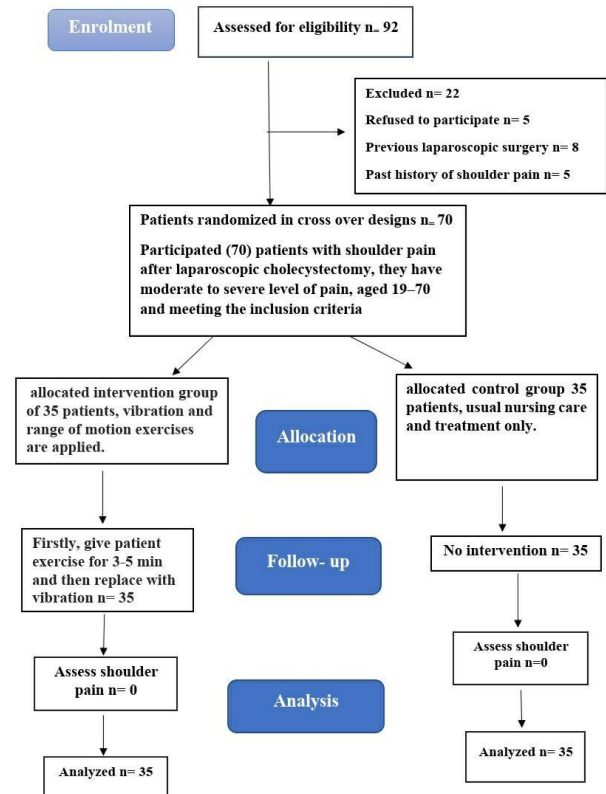


Figure 1. CONSORT Diagram

Before beginning the intervention, the researcher first evaluates the patient's shoulder pain using A numerical pain scale contains ten scores and four ratings: no pain, mild, moderate, and severe. 0 represented no pain, 1-3 represented mild pain, 4-6 represented moderate pain, and 7-10 represented severe pain. Afterwards, stander shoulder exercise is given for the shoulder for 3-5 minutes. After waiting 30 minutes, the researcher evaluates the patient's shoulder pain once more.

Finally, the patient is given vibration using a vibration device hyper press local vibrating massager USA used for adults only and can be used on dry and clean skin surfaces of the body (10). It works by pressing and gently moving it on the skin for 60

seconds, without pain or discomfort at a level of 30–40 Hz for 3-5 minutes. Pain was measured two hours after the vibration intervention was performed with the device on the patient, and the pain was also monitored for two days after the experiment. The pain measurement was repeated at two hours for two days after the intervention.

Data Collection and the study Questionnaire

Part I: This part consists of patients’ sociodemographic characteristics by interview using questions such as age, gender, and chronic disease.

Part II: Numerical pain scale to measure shoulder pain after LC. The researcher used the numeric rating pain scale (NRS), which consists of four ratings (no pain, mild, moderate, severe), and scoring (from 0-10). The items of the questionnaire were scored as 0 for no pain, 1–3 for mild pain, 4–6 for moderate pain, and 7–10 for severe pain.

The data were collected through the use of a questionnaire by means direct interviews with patients from December 14, 2022, until February 14, 2023. Study participants were interviewed and informed about the study's purposes and objectives, and demographic data were collected from all participants. The researcher got permission

Results

Table 1. Socio-demographical characteristics of the study and control groups (n=70)

Variable	Groups	Study group		Control group	
		F.	%	F.	%
Age	19-28	4	11.4	9	25.7
	29-38	14	40	11	31.4
	39-48	6	17.1	6	17.1
	49-58	3	8.6	5	14.4
	59-over	8	22.9	4	11.4
	Mean ± SD	42.85± 13.69		38.2±13.55	
sex	Male	14	40	17	48.6
	Female	21	60	18	51.4
Comorbidity diseases	Yes	18	51.4	18	51.4
	No	17	48.6	17	48.6

F= Frequency, %= percentage, Mean± Standard Deviation

from all participants to record their responses and saved those responses for data analysis.

Ethical Consideration

The researcher distributed an informed consent sheet to all patients with shoulder pain after LC in order to obtain their permission to participate in the study. In addition, they were informed that they could withdraw from the research, refuse to answer a specific question, or participate in the intervention at any time.

The study protocol was reviewed and approved by the Ethics Committee of Baghdad University of collage of nursing, Bagdad, Iraq (approval code: 428, 28-11-2022).

The study was registered for Clinical Trial Register at <https://www.irct.ir/> reference number (IRCT Code: IRCT202303100576 72N1). Date of enrolment:2023-03-30. Under the guidance of principles of the World Medical Association Declaration of Helsinki

Statistical Analysis

Statistical Package for Social Sciences (SPSS) version 24.0 is used to analyze the data. The following statistical data analysis techniques (frequency, percentage, mean of score, and paired t-test) were used to analyze and evaluate the study's findings.

Table (1) presented that mean age of the study group was 42.85 years old while the mean age for the control group was 38.2 years old. In relation to sex, most of the study group were females with (60%) and in the control group was (51.4%). A similar percentage (51.4%) of the study group and the control group suffer from comorbidity diseases.

Table 2. Differences of Pre and Posttest Pain Scores for the Study and Control groups

Score	N	Mean	t	df	P.value
Pretest and Post-exercise pain (Study Group)	35	9 6.68	18.059	34	0.001*
Pretest and Post-vibration pain (Study Group)	35	9 4.05	29.92	34	0.001*
Pretest Pain score (study and control groups)	35	9 8.9	.255	34	0.8
Pain score post vibration (study group) and pain score Posttest (control group)	35	1.68 2.94	-14.71	34	0.001*

N= number, M= mean of score, SD= standard deviation, NS =non-significant at P>0.05, S= significant at P<0.05.

In table (2), the study group showed highly significant differences in pain level between pretest and post-exercise at P value =0.001, as well as a highly significant difference in pain level between pretest and post-vibration at P value =0.001. While no significant difference between pretest pain score of both study and control groups at P=.8, the results showed a highly significant difference (P =.000) between the study group's post-vibration pain score and the control group's retest score.

Discussion

The findings of the present study indicate that in this study, half of the study group was female. and this result is supported that a prospective double-blind randomized controlled trial. A total of 100 patients were undergoing LC, of which about 50% were female. gallbladder diseases occur more frequently in women than men ⁽¹⁷⁾.

Another supported that the pulmonary recruitment maneuver (exerted as manual ventilation of the lung with a positive pressure of 40 cmH₂O) on shoulder pain after a gynecologic laparoscopy operation in a double-blind trial. They reported that shoulder pain severity was significantly lower at 12, 24, and 48 hours after surgery in the intervention group compared to the control group ⁽¹⁸⁾.

The study findings reported that the effects of vibration and the administration of a cold gel bag on patients receiving intravenous catheterization's pain level. In an experimental

study in a university hospital in Turkey, one hundred patients participated in the study, which was divided into two groups: study and control. The mean score of the pain of the patients was 1.04 in the study group and 5.32 in the control group (P =.001) ⁽¹⁹⁾.

A prospective study design asserted that one hundred patients of the study sample. The result showed that more than half of the study sample (71%) had mild to moderate pain, which means a significant positive statistical correlation lowering right shoulder pain with normal saline in the intraperitoneal (p value = 0.01) ⁽²⁰⁾.

The study was conducted on a semi-experimental design with a pretest/post-test control group design. participated in 102 patients who had elective laparoscopic cholecystectomy in the research hospital in Istanbul, the pain levels (10 minutes before and after positioning) and SPO₂ levels (1, 5, and 10 minutes before and after positioning—

total 6 times) of the patients were measured using a visual analog scale and pulse oximetry, respectively.

Conclusion

The study found a statistically significant difference in shoulder pain patients before and after vibration application and exercise. Both vibration and exercises had a positive effect to minimize patients' shoulder pain, but vibration had a significant and obvious role in relieving shoulder pain.

Recommendations

The vibration had a positive effect on relieving shoulder pain after laparoscopic cholecystectomy. Advise patients to apply vibration and exercises for post-laparoscopic cholecystectomy.

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