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Incentive Spirometry Versus Massage Therapy on the Level of Shoulder Pain and Nausea among Post Laparoscopic Cholecystectomy Patients

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Acute cholecystitis is an inflammation of the gallbladder usually caused by gallstones obstructing the gallbladder neck or cystic duct (Adachi, Eguchi, & Muto, 2022). It is one of the most common surgical emergency presentations globally (Cirocchi et al., 2023). Cholecystectomy was well-known as the surgical care for cholecystitis and the preferred treatment for gallstone disease (Salem, Salah, Abdel-Hady & Abdallah, 2023). Earlier, open cholecystectomy was the gold standard for treatment of cholecystitis (Samee, Abaidullah, Afzal, Qammar, Iqbal, & Sharif, 2023). However, open cholecystectomy has been associated with a higher risk of surgical site infection (SSI) (Subhan, Riaz, Iqbal, Malik, Ali, & Shaikh, 2022).

Owing to open surgical procedures complications, the laparoscopic technique has now replaced the open technique in many common surgical procedures, including routine cholecystectomy. Laparoscopic cholecystectomy (LC) is clearly defined as a minimally invasive surgical procedure to remove an inflamed gallbladder resulting from symptomatic cholelithiasis, gallstone, gallbladder masses, or polyps (Mohammed, Rajab & Naif, 2023).

Laparoscopic cholecystectomy not only benefits the patient by reducing postoperative pain, discomfort, reducing intraabdominal adhesions, improving cosmetic results, shortening hospital stay and quickening return to usual activities, but it also benefits the surgeon by improving vision and access to the Calot's triangle (Singh, & Kaur, 2023). In spite of several blessings of laparoscopic surgical treatment, shoulder pain is considered one of early post laparoscopic symptoms. It seems to have a multifactorial mechanism, but the most reported theory is carbon

dioxide gas persistence between the right diaphragm and the hepatic dome that stays inside the abdominal cavity for some times. The surgeon injects CO2 gas into the peritoneum to increase the field of vision during cholecystectomy via laparoscopy, this gas causes stretching of the peritoneum and diaphragm, as well as excitation of the phrenic nerve and creation of shoulder pain (Bastamizad, Abbasi, Salari, & Jalali, 2023).

In other words, pain occurs in the scapula through stimulating the phrenic nerve, which originates from the third and fifth cervical nerves (C3-C5) and controls movement and provides sensation in the diaphragm (Imani, Nejati, Sepidkar, & Talebi-Ghane, 2023). Postoperative pain can lead to increase heart rate, high blood pressure, and consequently, increase cardiac workload, nausea, vomiting, and ileus (Sane, Sayyadi, Abbasivash, Rezaei, Azadfar, & Salimi, 2023).

During laparoscopy, the pneumoperitoneum can irritate the vagus nerve, leading to post-operative nausea and vomiting (PONV) which cause delayed discharge, dehydration, wound opening, pulmonary aspiration, patient dissatisfaction, and increased treatment costs. Approximately (50-75%)of patients develop PONV (Mohammed et al., 2023). Prevention and treatment of postoperative pain and control of complications such as nausea and vomiting play an important role in early mobility, improve the quality of surgery, and lead to patient satisfaction, early discharge, and reduce costs (Seyedsadeghi, Arabzadeh, Entezariasl, Shahbazzadegan, Dindar, & Isazadehfar, 2023).

Pharmacological and non-pharmacological applications are widely used to improve the quality of recovery after laparoscopic cholecystectomy (Mottahedi, Shamsi, Babani, Goli, & Rizevandi, 2023). Pain killers as opioids and nonsteroidal anti-inflammatory drugs have side effects such as respiratory depression, nausea,

itching, and bleeding which may affect patient's recovery (Weng, Cheng, & Li, 2023). Various drugs such as dopamine antagonists, and Dimenhydrinate are used for the prevention and treatment of nausea and vomiting, but each has advantages and disadvantages (Adibi, 2023).

Non-pharmacological nursing measures are cost effective, reduce pain, and analgesic drug dosage, improve patient's emotional control, and increase their functional capability (Hassan, Fathy, Mohamed, Ibrahim, & Hassan, 2023). Variant studies show that shoulder pain is less if the initial pressure of CO2 is maintained below normal levels**.** With the same approach, chest physiotherapy may have an impact on the mechanical movement of the chest wall and diaphragm. Multiple studies shows and report the dynamic movements of diaphragm and chest wall by cine magnetic resonance image, by stretching the alveoli and chest, the diaphragm's movements increase and contract downward. As a result, less CO2 is accumulated inside the abdominal cavity and result in the removal of CO2 (Bakr, Ayad, Abdelraouf, & Abosayed, 2023).

In this respect, it is essential for surgical nurses to provide education on the proper usage of incentive spirometry to patients, as well as explain its significance and the positive impact of regular intervals on the recovery process. However, studies have found that the rates of teaching and applying deep breathing technique to patients via incentive spirometry are not at the desired level (Bulut & Karabulut, 2023).

Therapeutic massage is also one of the non-pharmacological interventions, it's the manipulation of the soft tissue of whole body areas to bring about generalized improvements in health. It is a non-invasive method with an easy application used to increase the quality of surgery (Mottahedi et al., 2023).

The effect of massage on pain is explained with the Gate Control Theory of Melzack. According to this theory, when massage is applied, the A-alpha and A-beta thick tactile fibers moving faster than the A-delta and C fine fibers that are involved in the transmission of the pain, prevent the impulses in the small-diameter fibers that carry the pain from reaching upper levels. The mechanoreceptors that are located in the center of the tactile fibers, which are mentioned in this theory, are found in the hands and feet (Sözen, & Karabulut, 2020).

Hand massage has been studied as a potential intervention to reduce postoperative nausea after laparoscopic cholecystectomy (Yaghoubinia, Abbasnia, & Zakerimoghadam, 2019). Therefore, the purpose of this study is to evaluate the effect of incentive spirometry versus massage therapy on post laparoscopic cholecystectomy patients in terms of their level of shoulder pain, and nausea.

Significance of the study

Cholecystitis is a common digestive health problem. Thousands of people develop symptoms of acute cholecystitis annually across the world (Fouad, Rezk, Saber, Khalifa, Ibraheim, & Ibraheim, 2022). It affects 1–4% of the western world population per year. Recently, cholecystectomy is the most common intra-abdominal operative interventions and was estimated to be about 500,000 annually in the USA (Doush, Abdelaziz, & Musaad, 2023). In the Middle East cholecystectomy is one of the most common operation performed in general surgical units. It represents up to 57% of major elective surgery and about 43% of emergency surgery (Farahat, Soltan, Shaheen, Hegazy, & Elghalban, 2021).

Laparoscopic cholecystectomy (LC) is one of the most commonly performed general surgical procedures worldwide, especially in Arab countries (Ali, Kadhim, & Khachian, 2023). While LC continues to evolve, postoperative pain remains a significant concern. Shoulder pain is among the early symptoms experienced after LC (Saremirad, Yazdimoghaddam, Dalili, & Rastaghi, 2022). Shoulder pain and discomfort can lead to a decrease in patient satisfaction ranging from 35% to 80% and may also result in prolonged hospital stays, increase healthcare costs, and a higher risk of complications (Park, 2020). Approximately 50-75% of patients develop a postoperative nausea and vomiting, with a resulting high management cost, delayed discharge and patient dissatisfaction (Mohammed et al., 2023).

Aim of the study

The aim of this study is to:

Evaluate the effect of incentive spirometry versus massage therapy on the level of shoulder pain, and nausea among post laparoscopic cholecystectomy patients.

Research hypotheses:

- **H1:** patients undergoing laparoscopic cholecystectomy surgery who utilize incentive spirometry or receive massage therapy will experience less shoulder pain, and nausea compared to those who receive routine care.
- **H2:** patients undergoing laparoscopic cholecystectomy surgery and utilize incentive spirometry will experience less shoulder pain, and nausea compared to those who receive massage therapy
- **H3:** patients undergoing laparoscopic cholecystectomy surgery who receive massage therapy will experience less shoulder pain, and nausea compared to those who utilize incentive spirometry.

Operational definition:

- **An incentive spirometry:** is a medical device that facilitate sustained, maximal inspiration (SMI) with incorporated visual indicators of performance. The device typically consists of a plastic chamber with a measurement indicator and a mouthpiece. The patient inhales through the mouthpiece, creating a flow of air that raises the measurement indicator. The technique involves taking 10 deep breaths every 2 hours for 12 hours. Specifically, the patient assumes a sitting position or half-sitting position, places the spirometry tube inside the mouth, inhales, holds his

breath for 3 seconds, and then exhales slowly through the mouth while removing the device (Zerang, Amouzeshi, & Barkhordari-Sharifabad, 2022).

- **Massage Therapy,** refers to specific massage techniques which include Kneading-Friction-Petrissage techniques. These techniques involve manipulating the muscles and soft tissues in specific ways. ***Petrissage Massage,*** applying direct pressure slowly and rhythmically with the fingertips. ***Friction Massage,*** rubbing in small areas in a circle while pressing the area with the front of the fingertips or the front of the palm. ***Kneading Massage,*** is similar to twisting and changes the compression direction in succession (Mottahedi et al., 2023).

Method

Study Design:

A quasi-experimental research design will be utilized to carry out this study. It is a suitable design which attempts to compare three groups by applying interventions to two groups and comparing with a control group (Polit & Beck, 2020).

Setting:

This study will be conducted in the Gastrointestinal Surgery Center, at Mansoura University. Where patients undergo laparoscopic cholecystectomy.

Subjects:

Sample technique:

A purposive sample of 96 patients undergoing laparoscopic cholecystectomy surgery, experiencing shoulder pain and nausea, the study participants will be divided into three matched groups: Incentive spirometry group (A) , Massage therapy group (B)and control group (C) in the above-mentioned settings and fulfilling the following criteria:

Inclusion criteria:

- Both sexes.
- Patients aged between 20 to 60 years.
- Patients having the ability to communicate.
- Willing to participate in the study.

Exclusion criteria:

- Patients who had postoperative bleeding.

- Patients who had postoperative hemodynamic disorders (severe elevation or reduction of blood pressure and shock).
- Patients who had postoperative complications requiring mechanical ventilation.
- Patients who had respiratory aspiration.
- Patients who had a history of drug abuse.
- Patients who had previous shoulder pain chronicity
- Uncooperative patients or patients unable to understand how to use the incentive spirometry device properly.
- Patients whose surgery converted from laparoscopic to open surgery

Sample size calculation:

The sample size was calculated using research software (https://clincalc.com) based on a previous study done by **(Bastamizad et al., 2023),** that noticed a pronounced improvement in the intervention groups in the three measurements by mean± SD, of (4.5 ± 1.3, 3.5 ± 1.2, and 2.55 ± 1.2) and (4.5 ± 1.4, 3.6 ± 1.3, and 2.4 ± 1.3) compared to (4.7 ± 1.2, 4 ± 1.4, and 3.6 ± 1.3) in the control group. At Power (1-β error probability) = 0.80 and α error probability = 0.05. So, final sample size is 96 (32 patients in each group).

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * (1 + \frac{1}{k})} + z_{1-\beta} * \sqrt{p_1 * q_1 + (\frac{p_2 * q_2}{k})} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.32 * 0.68 * (1 + \frac{1}{1})} + 0.84 * \sqrt{0.48 * 0.52 + (\frac{0.16 * 0.84}{1})} \right\}^2 / 0.32^2$$

Formula of calculating sample size

Tools of data collection:

Two tools will be used to collect data pertinent to the study:

Tool I: A structured Interview Questionnaire:

This tool will be developed by the researcher after reviewing relevant literature. It will include the following 2 part:

Part 1: Patient's Demographic Data:

This part will be used to address the personal data of the patients; it will include the patient's age, gender, marital status, level of education, occupation,…..

Part 2: Health Relevant Data:

This part will focus on the patient's medical history, history of previous surgery, vital signs, smoking, weight, height, body mass index, total length of stay…..

Tool II: visual analog scale (VAS):

To investigate the severity of shoulder pain and level of nausea experienced by the patient. Patients are able to self-report their level of pain and nausea using this scale. The severity of pain and nausea will be recorded four times by the participants (before the intervention as well 4, 8 and 12 hours following the intervention). This instrument will be provided to the patient to mark a point on the line that best represents their level of shoulder pain and nausea experienced. They will be asked to assign a separate score for the sensation of shoulder pain as well as for the level of nausea. Then, based on the stated number, the severity of pain and nausea will be documented.

Scoring system:

- For measuring the intensity of pain adopted from **(Ghai et al. 2015).** The VAS instrument is a 10-cm ruler on which one side shows "no pain = 0" and other side shows " worst possible pain= 10". Its total score ranges from 0 to 10 where:
  - Score (0) = *No pain*
  - Score (1-3) = *Mild*
  - Score (4-6) = *Moderate*
  - Score (7-10) = *Severe pain*.
- For measuring the level of nausea adopted from **(Boogaerts, Vanacker, Seidel, Albert, & Bardiau, 2000)**. The VAS instrument is a 10-cm ruler on which one side shows "no nausea = 0" and other side shows " severe nausea = 10". Its total score ranges from 0 to 10 where:
  - Score (0) = *No nausea*
  - Score (1-3) = *Mild*
  - Score (4-6) = *Moderate*
  - Score (7-10) = *Severe nausea*.

Data collection process:

Phase I: The Preparatory phase:

- Administrative stage:

- An Ethical approval will be obtained from the Research Scientific Ethical Committee of the Faculty of Nursing, Mansoura University.
- An official letter to carry out the study will be submitted from the faculty of Nursing, Mansoura University to the director of the Gastrointestinal Surgery Center, at Mansoura University.

- An official written permission to carry out the study will be obtained from the director of Gastrointestinal Surgery Center, at Mansoura University, to obtain his approval to conduct the study after an explanation of the purpose of the study.
- The researcher will meet the head nurse of the Gastrointestinal Surgery Center and the coordination of the study process will be conducted among nursing staff.

- Tools development:

- **Tool I: A structured Interview Questionnaire:** (Patient's demographic data and health-relevant data) will be developed by the researcher based on a review of related literature.

- Validity of the study tools:

- Content validity of the study tools will be assessed and revised by a panel of five experts in the field of Medical-Surgical Nursing. It will be revised for its clarity, content, a sequence of items and relevance or irrelevance of content to measure the extent to which the scores represent the variables they intended to measure. suggestion of the jury members will be followed.

- Reliability of the study tools:

- It will be measured to evaluate whether all items on the study tools measure the same variable over time and how well the study items fit together conceptually. The internal consistency of the study tools will be tested by means of the Cronbach's alpha coefficient test.

- Training course:

- The researcher will undergo a training course on how to perform kneading-friction-petrissage correctly in order to ensure effective technique.

Phase II: The Operational phase:

- pilot study:

- A pilot study will be carried out on 10% of the study sample (10) to ensure the feasibility, clarity, relevance, comprehensiveness, free of mistakes and applicability of the study tools, to allow necessary adjustment before conducting large scale study, to estimate the time needed to fill the questionnaire sheet. It will be excluded from the study sample.

- Filed work:

- The researcher will start by introducing herself to the patients and giving them a brief idea about the aim of the study.
- The framework of the study will be carried out in four stages, that will start from the postoperative phase, consciousness recovery, and ultimately reaching a point where patients are capable of responding to nursing instructions as the following:

1. ***Assessment phase;*** using all study tools to ensure that all patients fulfill the inclusion criteria

2. ***Planning phase;*** Based on the findings of assessment phase, patients who match sampling criteria & who accept to participate in the study will be divided into three equal groups, the incentive spirometry group (A) for which a spirometry device will be utilized, the massage therapy group (B) for which a kneading-friction-petrissage technique will be performed and control group (C) who will receive hospital routine care

3. ***Implementation phase;*** Patients in the incentive spirometry group (A) will be instructed in a clear and simplified manner on how to use the incentive spirometer correctly. This includes understanding the purpose of the

technique and the proper technique for effective use which involve taking 10 deep breath via the incentive spirometry every 2 hours for 12 hours. And next, patients will be asked to redemonstrate the usage of the spirometry, so that the researcher could confirm correct application of the training; patients in the massage therapy group (B), kneading-friction-petrissage technique will be explained in a clear and simplified manner, taking into consideration their health condition, the massage will be performed at regular intervals of 4, 8, and 12 hour after the surgery; patients in the control group (C); will receive only the hospital routine care.

4. ***Evaluation phase:*** This phase aims to evaluate the effect of an incentive spirometry versus massage therapy on the level of shoulder pain, and nausea at 4, 8 and 12 hours following the intervention in the two experimental groups and comparing with the control group

Ethical consideration and human rights:

All relevant possible aspects will be considered. A written consent will be obtained from each patient enrolled in the study after providing comprehensive information about the nature of the study, aim, benefits, risks, compensation, and alternative treatment. The researcher will emphasize that participation is absolutely voluntary. Participants will be informed that they have the right to refuse to participate in the study and withdrawn at any time and the refusal to participate in the study will not affect their care. Anonymity, privacy, safety, and confidentiality will be assured throughout the whole study.

Statistical Analysis

The collected data will be coded, tabulated, and analyzed using Statistical Package for the Social Science (SPSS) program version 22. Appropriate statistical tests will be used.

Results

Data collection will be presented in tables, graphs, and figures.

Discussion

The results of this study will be discussed in the light of relevant, similar studies nationally and internationally.

Conclusion and Recommendations

Appropriate conclusion and recommendations will be drawn based upon the study findings and discussion.

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