Preoperative respiratory therapy in patients undergoing surgery for lung cancer: A randomized controlled trial

ABSTRACT

Background: A preoperative respiratory therapy treatment was performed to analyze the effectiveness, with respect to postoperative air leak and pain, in patients undergoing surgery for lung cancer.

Objectives: To analyze air leakage and postoperative pain.

Material and Methods: Seventy one patients were studied, with a mean age of 62.58 years. Descriptive variables of gender, carcinogenic pathology, type of surgical incision and lung resection, use of glue and endostapler, and presence of adhesions were analyzed. Likewise, analysis of the quantitative variables of age, body mass index and forced expiratory volume in 1s Two homogeneous groups resulted. Differentiated, experimental group (EG) that performed preoperative respiratory therapy and control group (CG).

Results: There were statistically significant differences in favor of the EG with respect to postoperative air leak on days 1–2 during the performance of physio- therapy techniques, the food and during the performance of the exercises autono- mously. Furthermore, differences in air leakage were observed on days 2–4 during gait. The number of patients decreased to a greater extent in the EG. Regarding pain, there were statistically significant differences in the sample on days 1–4, with greater intensity of pain in the CG and after doing physiotherapy every day except the second.

Conclusions: Preoperative respiratory therapy in patients undergoing surgery for lung cancer was effective in reducing the number of patients who presented post- operative air leak and reducing pain in the EG.

KEYWORDS

Air leak; pain; pulmonary surgery; respiratory therapy.

INTRODUCTION

Lung cancer is the most frequent neoplasm and with the highest mortality rate in developed countries; it is the most commonly occurring cancer in men and the third most commonly occurring cancer in women (Bade & Dela Cruz, 2020). Prognosis is poor on a global level, with an overall 5 year survival rate of 15%. The main risk factor is tobacco, which has been shown to be the leading cause in 80%–90% of cases of lung cancers in men, and in 55%–80% of cases in women (Bray, 2018). Furthermore, suffering from chronic obstructive pulmonary disease increases the chances of developing lung cancer (Dai et al., 2017).

Currently, one of the main investigations into improve lung cancer survival is the early detection of the disease through imaging tests, such as computed tomography (Garrido et al., 2017) The most effective treatment is surgery, mainly performed in the early stages (Hoy et al., 2019). However, lung resection produces pathophysio- logical changes in patients, generating postoperative complications, including a postoperative air leak (PAL) and postoperative pain (Jimenez et al., 2018; Steffens et al., 2018). Persistent air leaks are a common problem, occurring spontaneously in pneumothorax but also after lung surgeries. If air leaks persist for more than 7 days, some- times the only solution is a reoperation. This complication prolongs the hospital stay and increases the socioeconomic cost of thoracic surgeries (Sakata et al., 2018).

There is an increased risk of PAL in the following cases: a low volume of air exhaled in the forced expiratory volume during the first second (FEV1); a low body mass index (BMI); in the presence of comorbidities such as other previous respiratory diseases or dia- betes; if previous lung surgeries had been performed; having fragile lung parenchyma; patients with lung adhesions or infections present; and in cases of previous steroid treatments and chemotherapy.

There is also an increased risk of PAL in surgical resections such as a superior lobectomy and bilobectomies, and if the pleural fissures are mishandled during the intervention (Burt & Shrager, 2015; Flandes Aldeyturriaga, 2015; Sebio et al., 2016).

Postoperative pain in thoracic surgery is one of the most intense and serious types, according to the scientific literature (Marshall, 2020). Patients experience pain from the intervention, which can increase due to immobility (Torres, 2003). Therefore, one of the main objectives to be treated by physical therapists is pain. Manual and instrumental, non-pharmacological means are used, and the importance of mobility and therapeutic exercise is increasingly being studied as measures for reducing and relieving pain through physical therapy (Arredondo-López et al., 2019; Morales & Lelis, 2018).

There is scientific evidence of the benefit of physical therapy in surgeries, both preoperative and postoperative, in order to reduce complications and the hospital stay (Ribeiro et al., 2016; Rivas-Perez & Nana-Sinkam, 2015; Sebio et al., 2016; Steffens et al., 2018; Vandenbos et al., 2017). Respiratory complications are the most frequent following thoracic interventions, which can be improved by respiratory therapy. An increasing number of studies are being con- ducted on prehabilitation and to discover which programs are most effective, although there is still little research in this field (Dezube et al., 2020; Licker & Navarro, 2020; Mahendran & Naidu, 2018).

This study's hypothesis was that preoperative respiratory ther- apy would decrease PAL and pain in patients undergoing lung cancer surgery. Therefore, our objective was to analyze the influence of preoperative respiratory therapy on the evolution of patients, con- cerning PAL and pain, following lung cancer surgery.

MATERIAL AND METHODS

Scope of this study

This randomized controlled clinical trial was carried out at the Uni- versity Hospital Gregorio Marañón. The study was approved by the Ethics Committee, in May 28, 2014. And was conducted between September 2014 and July 2016. All participants provided written consent.

Study inclusion and exclusion criteria

The inclusion criteria were: intervention with pulmonary resection for lung cancer; use of a digital chest drain system; having a para- vertebral catheter placed to manage postoperative pain; not suffering from cognitive impairment; and speaking in Spanish.

The exclusion criteria were: hemodynamic instability in the perioperative period; admission to the intensive care unit (ICU); and patients who presented serious complications (paralytic ileus) during the immediate postoperative period requiring surgical reintervention.

Procedures performed

The patients recruited by the thoracic surgeons were randomized through a table of random numbers, using the Epidat 4.2 program, based on which the groups were assigned. Subsequently, the sur- geons referred the subjects to the rehabilitation service for preop- erative evaluation and treatment.

All patients had a consultation with the rehabilitation physician, which consisted of an assessment and information provided on the techniques to be performed in the postoperative period. The importance of performing respiratory exercises was explained to the patients and a guide was given to them with the techniques to continue their practice at home independently until the intervention. The group that only performed this practice was assigned to the control group (CG). Another group, in addition to the consultation, was referred to the physical therapist and was assigned to the experimental group (EG). The EG carried out five respiratory therapy sessions, in a row, from Monday to Friday, and the booklet was given to them with information on the techniques performed and the physiotherapist's advice for the intervention. The patients were trained in physical therapy techniques: directed breathing (DB), incentive spirometry (IS), expiratory flow increase (EFI), wound pro- tection in coughing, a combination of physical therapy and aerosol therapy, and mobilization of the upper limb.

All patients must be operated within 4 weeks of a cancer diag- nosis. In those weeks, they had to consult with the physiatrist, anesthesiologist and physiotherapist.

Thoracic surgery was performed by video-assisted thoracoscopy or open thoracotomy, depending on the surgeon's preference or taking into account the technical needs of each case. At the end of the surgery, a single chest tube was placed in the pleural space and connected to the Medela suction device® (Medela AG, Thopaz, Switzerland), programming a suction pressure of −20 cm H_2O. The thoracic drain was removed once there was a prolonged absence of PAL for 12 h and when the pleural drain output was less than 300– 400 ml.

Sociodemographic data and clinical variables were recorded (age, gender, BMI and FEV1) along with the intervention variables once it was over (incision, resection, use of laser, use of aerostatic surgical sealants, use of endostapler, presence of adhesions). All patients left the operating room with a paravertebral catheter placed for post- surgical analgesia. Pain management was performed mainly by continuous epidural perfusion with ropivacaine and sufentanil. Alternatively, locally-placed catheters with ropivacaine were used. As a supplement, patients received intravenous morphine, oral non- steroidal anti-inflammatory drugs and paracetamol for as long as needed.

After surgery, the existence of a PAL was recorded daily, before starting physical therapy and after each physical therapy technique (DB, EFI, IS and cough), once a day, by the lead researcher. The collaborating researchers also observed and recorded whether or not there was a PAL in one meal a day, with the patient walking and performing the exercises independently. Pain before and after the physical therapy session was also quantified and recorded by the leading physical therapist researcher in all patients.

The PAL was measured by observing the digital chest drainage screen that each patient had. In this study, the drain system used was the Thopaz Medela® digital system. It is a digital drain, which quantifies the PAL in milliliters/minute; it also sets the suction pressure to be carried out by the medical team. Recent studies support the claim that PAL could be better managed. This study used to quantify the PAL present in each patient when performing each physical therapy technique and each activity (Doi & Maniwa, 2018; Satoshi Muto & Hiroyuki Suzuki, 2017).

The PAL records were taken from the first postoperative day until the drain was removed.

The pain was quantified through the Visual Analogue Pain Scale (VAPS). This scale consists of a 10 cm horizontal line, at the ends of which are the extreme expressions of a symptom. On the left end is the absence of the symptom or a lower intensity, and on the right the highest intensity. The patient is asked to mark the number that represents their pain from 0 to 10, with 0 being no pain and 10 being the worst pain. It is a valid and reliable scale (Vicente Herrero et al., 2018). The minimal clinically important difference was set at 1.1 points (Mintken et al., 2009).

Sample size calculation

To calculate the necessary sample size, and given the originality of this study, a pilot study was previously carried out with 10 partici- pants, in order to estimate the effect of preoperative respiratory therapy on the PAL; the calculation was made with the GRANMO sample size calculator (version 7.12, IMIM), accepting an alpha risk of 0.05 and a beta risk of 0.2 (power of 80%), determining that 34 pa- tients would be required in each group.

Statistical analysis

A descriptive analysis was carried out for all independent variables. The qualitative variables are described with frequencies and per- centages for each of their categories and the quantitative variables with the mean and standard deviation (SD). The corresponding 95% confidence intervals were also calculated. To study the distribution, the Kolmogorov-Smirnov test of non-parametric variables was per-formed, with $p > 0.05$ to determine the homogeneity of the sample.

To study the relationship between dichotomous Yes/No respi- ratory therapy qualitative variables and the Yes/No PAL variable, the Chi-square test was calculated. To study the relationship between Yes/No pain and respiratory therapy quantitative and qualitative variables, the Student's T-test and the Mann-Whitney U test were used.

For all analyses, a two-sided p value < 0.05 was considered statistically significant. All analyzes were performed with IBM SPSS Statistics 24 (IBM Corporation).

RESULTS

Seventy-one patients of the 72 initially recruited were analyzed, one was excluded (pneumonectomy, no digital drain). Two homogeneous groups resulted; the CG and the EG. In the CG, 35 patients completed the study and in the intervention group 36 patients completed, as shown in Figure 1.

The baseline characteristics (demographic and preoperative clin- ical variables) of both groups are presented in Table 1. There were no statistically significant differences between the groups with respect to the demographic and preoperative clinical variables: age, gender, BMI and preoperative FEV1. Regarding the characteristics of the surgery, both groups were also homogeneous. A greater number of large sur- gical incisions were made, 50 patients (70.4%); a greater number of large resections, 18 patients (25.4%); laser was used only a few times, six patients (8.5%); sealants and an endostapler were used in most cases, 45 patients (63.3%) and 54 patients (76%); and the presence of pulmonary adhesions occurred in 28 patients (39.4%) (Table 2).

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Figure 1. CONSORT diagram of results

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Table 1. Sociodemographic and clinical profiles characteristics of the intervention and control groups

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Table 2. Surgery characteristics in the intervention and control groups

3 Postoperative air leak results

All EG patients who had undergone preoperative respiratory therapy were able to perform all respiratory therapy techniques (DB, IS, EFI and cough) postoperatively from day one; compared to the CG where only 3%–8.6% were able to perform respiratory therapy maneuvers on the first day.

In all the patients in the sample, the PAL gradually resolved, the thoracic drain was then removed, and the study was completed. The percentage of patients with PAL in the EG was lower compared to the CG, on each day of the study. On the second day in the EG, 58.4% of patients did not have a PAL or a thoracic drain, compared to the CG where 60% did have a chest drain since the PAL persisted. On the 7th day, 100% of the EG had finished the study, while in the CG only 77.8% had finished (Figure 2). Statistically significant differences ($p < 0.05$) were obtained in the presence of a PAL on days 1 and 2, with a greater number of patients with PAL in the CG, where $p < 0.001$ on day 1 at rest, and $p = 0.022$ on day 2. For the PAL while performing DB, $p < 0.001$ on day 1 and $p = 0.008$ on day 2. Per- forming the IS technique, the PAL on day 1 was statistically signifi- cant, in addition to being higher in the CG, where $p < 0.001$ on day 1 and $p = 0.047$ on day 2. When patients performed the EFI technique, we found similar values for p, with $p < 0.001$ on day 1 and $p = 0.022$ on day 2. We found differences in the cough, with $p = 0.001$ on day 1 and $p = 0.047$ on day 2.

When performing the exercise independently, we found statis- tically significant differences in the first 3 days. In the EG, between 8.3% and 13.9% of the subjects had a PAL, compared to 25.7% and 37.1% in the CG. PAL on day 1 and 2 was 0.017, and on day 3 it was 0.018.

------ insert Figure 2 here ------

Figure 2. Patients with PAL, control group (CG) and intervention group (IG) during the 7 days

Pain results

Regarding pain, pain levels were lower in the EG before and after respiratory therapy than the CG, throughout the observation period. In the EG, there was a clinical difference in pain intensity starting on postoperative day 3. An increase in pain perception was observed in the CG compared to the EG, both in the baseline level before per- forming the respiratory therapy maneuvers and after performing the respiratory therapy techniques. The pain perception results are shown before and after performing respiratory therapy. There were statistically significant differences before respiratory therapy be- tween the two groups, on days 3.5 and 7, with less pain in the EG, where $p = 0.008$ on day 3, $p = 0.028$ on day 5 and $p = 0.005$ on day 7. After physical therapy, the pain was less in the EG, with statistically significant differences on all days of the study, except the second day.

DISCUSSION

Our results have shown that preoperative respiratory therapy in patients undergoing surgery for lung cancer was effective in reducing the number of patients who had a postoperative air leak.

The EG was in the hospital for fewer days than the CG. On day 7, there were no longer any patients with PAL in the EG; in the CG on day 7 there were still eight patients with PAL. The number of days in hospital was not collected.

The practice of respiratory therapy in thoracic surgery is per- formed routinely in the postoperative phase (Brocki et al., 2016; Sommer et al., 2018). This study analyzed whether preoperative respiratory therapy could improve complications regarding PAL and pain. By comparing two homogeneous groups in terms of socio- demographic, clinical and surgical variables, it was shown that pre- operative respiratory therapy led to a decrease in PAL and pain.

Some authors confirm that preoperative therapy would be useful in reducing postoperative complications (Brocki et al., 2016; Sommer et al., 2016; Sommer et al., 2018). However, there are no other studies linking PAL and preoperative physical therapy used in this research, with this type of technique reducing the chances of suffering from PAL. The presence of pulmonary adhesions favors PAL, with their presence being scarce in the sample studied (Simón Adiego et al., 2011).

Preoperative respiratory therapy in this study allowed the EG patients to perform all physical therapy techniques and all activities from the second day. On the first day, only 1 patient in this group did not eat or do the exercises independently, 58.3% did not walk, compared to 80% of the CG. Furthermore, some patients in the CG did not do any techniques or activities until the fourth day. There- fore, the importance of preoperative physical therapy is demon- strated, as in other studies conducted by Sebio García et al. (Sebio Garcia et al., 2016) and Sánchez-Lorente et al. (Sanchez-Lorente et al., 2018).

The preoperative and postoperative respiratory therapy pro- gram was based on other programs reviewed in the scientific liter- ature such as those conducted by Giménez et al. (Gimenez et al., 2004), Pryor (1993), or in accordance with the guidelines of scientific societies (López Fernández & Vilaró Casamitjana, 2014). In the scientific literature, there are studies where the physical therapy only includes manual techniques, such as those conducted by Giménez et al. (Gimenez et al., 2004) and Sebio García et al. (Sebio Garcia et al., 2016), and others that only include the IS technique, such as the research conducted by Narayanan et al. (Narayanan et al., 2016). In recent years, respiratory therapy programs with aerobic training exercises have been carried out in different pathologies with good results, such as the research conducted by Cavalheri et al. (Cavalheri & Granger, 2017) or Piraux et al. (Piraux et al., 2018), or others like Katsura et al. who have looked at the training of the respiratory musculature with instrumental aids in the postoperative period (Katsura et al., 2015), or even high intensity training programs such as that by Sanchez-Lorente et al. (2018). But the latter needs 6–8 weeks of training, which is too much time. Usually, patients with lung cancer should be operated on within 4 weeks from the disease diagnosis, at least at the hospital of study.

Regarding pain, there are other studies relating pain and post- operative physical therapy with good results, such as those con- ducted by Vandenbos et al. (2017), Aréchiga-Ornelas et al. (Aréchiga- Ornelas et al., 2011) and Arranz-Álvarez et al. (Arranz Álvarez et al., 1999). In this study, preoperative respiratory therapy was also beneficial for pain management.

The EG had less pain than the CG, before and after physical therapy, with statistically significant differences on days 3, 5 and 7; before physical therapy ($p = 0.008$ on day 3, $p = 0.028$ on day 5 and $p = 0.005$ on day 7). And less pain in the EG after physical therapy on every day of the study, except the second day; (p = 0.035 on day 1, p = 0.007 on day 3, p = 0.016 on day 4, p = 0.028 on day 5, p = 0.020 on day 6 and p = 0.005 on day 7). In the EG, clinical differences were also observed in pain intensity from the fourth day. In the studies by Pouwels et al. (2015), this decrease in pain is associated with a higher quality of life and comfort in patients.

Knowledge of the postoperative period that comes from receiving information in the preoperative period reduces the anxiety levels in patients, according to studies such as that conducted by Gordillo et al. (Gordillo et al., 2011).

Implications for the practice of physiotherapy

Prehabilitation in surgery is more and more studied, but its perfor- mance is not applied enough. Our results improve the knowledge gap in the area of preoperative physiotherapy. The area of preoperative and postoperative respiratory therapy is commonly performed in hospitals by physiotherapists. Our data show that preoperative res- piratory therapy reduces postoperative air leakage. Physical thera- pists can use this information to justify their intervention to other health professionals and decision makers.

The preoperative period improves the quality of life of patients and reduces sócio-economic costs.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

This study was approved by the Research Ethics Committee from the General University Hospital of Gregorio Marañón (approval code: 185/14).

PATIENT CONSENT STATEMENT

All participants signed an informed consent form.

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