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fordypning innen hjerte- og lungelidelser

Mastergradsoppgave MAFYS600

Frekvens av pusteøvelser etter åpen mageoperasjon
– en randomisert kontrollert pilot-studie

Tittel (norsk)

Frequency of breathing exercises after open abdominal surgery
– a randomized controlled pilot study

Tittel (engelsk)

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Frequency of breathing exercises after open abdominal surgery – a randomized controlled pilot study

Abstract

Background: Going through open abdominal surgery leads to temporary alterations in the respiratory system, both during surgery and in the following days. These changes have the potential of resulting in post-operative pulmonary complications, and patients are recommended doing breathing exercises daily to prevent this. However, there are no clear recommendations on how often these exercises should be carried out for best preventive effect.

Objective: The primary objective of this pilot study was to create a foundation for making clear recommendations about frequency of breathing exercises after open abdominal surgery to prevent post-operative pulmonary complications.

Method: A randomized controlled study was chosen as design in this pilot study. The test subjects were randomized into two intervention groups. One group was told to do breathing exercises three times a day, and the other group was told to do the exercises once every waking hour. The subjects went through pre-operative testing of lung function and peripheral oxygen saturation (SpO2). In addition, they were instructed in breathing exercises. The first four post-operative days the subjects got help with mobilization and the breathing exercises from a physical therapist. The physical therapist also registered any pulmonary complications, rate of mobilization, SpO2 and the number of days the subjects were hospitalized.

Results: 15 persons were randomized to the two groups. Three were excluded during the study period. The incidence of post-operative pulmonary complications was two out of five subjects in the tree-times-daily-group, and none out of seven in the once-hourly-group. In the three-times-daily-group median (range) length of hospital stay was 9 (6-16) days, and 15 (9-18) days in the other group. There was no difference of clinical relevance between the groups in measured SpO2. By the fourth post-operative day all the subjects in the three-times-daily-group, and six out of seven in the once-hourly-group were fully mobilized.

There were no statistical significant differences between the groups on any of the effect variables.

Conclusion: The results from this pilot study suggests that recommendations about doing breathing exercises as often as once hourly could be of benefit for patients going through open abdominal surgery. However, the power of the sample size in this study (n=12) is too small to conclude about the effects of the two interventions, and there is a need for similar studies of a considerably larger scale.

Sammendrag

Bakgrunn: Å gjennomgå åpen mageoperasjon fører til midlertidige forandringer i det respiratoriske systemet, både under operasjonen og de påfølgende dagene. Dette medfører fare for postoperative lungekomplikasjoner. For å forebygge forekomsten av slike komplikasjoner anbefales pasientene å gjennomføre pusteøvelser daglig under sykehusinnleggelsen. Det finnes imidlertid ingen klare retningslinjer for hvor ofte disse øvelsene bør utføres for best forebyggende effekt.

Hensikt: Studiens primære hensikt var å legge et grunnlag for å skape klare anbefalinger om hyppighet av pusteøvelser etter åpen mageoperasjon for å forebygge postoperative lungekomplikasjoner.

Metode: Som studiedesign ble det valgt å gjennomføre en randomisert kontrollert pilot-studie. Deltakerne i studien ble randomisert til to intervensjonsgrupper hvor den ene gruppen ble gitt i oppgave å gjøre pusteøvelser tre ganger daglig, mens den andre gruppen ble bedt om å gjennomføre øvelsene èn gang hver våkne time. Deltagerne gjennomgikk testing av lungefunksjon og perifer oksygenmetning (SpO2), samt fikk instruksjon i pusteøvelser pre-operativt. De fire første dagene etter operasjonen ble deltagerne fulgt opp av fysioterapeut med hjelp til øvelsene og mobilisering, og det ble gjort registrering av eventuelle lungekomplikasjoner, grad av mobilisering og SpO2. Antall sykehusdøgn ble også registrert.

Resultater: 15 personer ble randomisert til de to gruppene. Tre ble ekskludert underveis i studien. To av fem deltagere i tre-ganger-daglig-gruppen pådro seg lungekomplikasjoner i løpet av de fire første dagene etter operasjonen. I den andre gruppen på sju deltagere fikk ingen slike komplikasjoner. I tre-ganger-daglig-gruppen var median (range) antall sykehusdøgn 9 (6-16), og i den andre gruppen 15 (9-18). Det var ingen forskjell i SpO2 mellom de to gruppene som anses som klinisk relevant. Den fjerde postoperative dagen var alle deltagerne i tre-ganger-daglig-gruppen fullt mobilisert og selvstendig ved forflytning, mens tilsvarende tall for en-gang-i-timen-gruppen var seks av sju deltagere.
Det var likevel ingen statistisk signifikant forskjell mellom gruppene på noen av utfallsmålene.

Konklusjon: Resultatene fra denne pilotstudien tyder på at pasienter som gjennomgår åpen mageoperasjon kan ha større nytte av å utføre pusteøvelser så ofte som en gang i timen enn å gjøre det tre ganger daglig. Størrelsen på utvalget i studien (n=12) er imidlertid lite, og det er derfor ikke mulig å konkludere om effektene av de to intervensjonene.
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(in Norwegian)

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Terese Tveit Helland

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Abbreviations

In the paper the whole abbreviated term will be written the first time it is used, followed by the abbreviation in parentheses, e.g. Post-operative pulmonary complications (PPC). If the term is used later, only the abbreviation will be used.

ATS American Thorax Society

BMI Body mass index

CPAP Continuous positive airway pressure

FET Forced expiratory technique

FEV1 Forced expiratory volume in one second

FRC Functional residual capacity

FVC Forced vital capacity

IS Incentive spirometry

LAS Lower abdominal surgery

PEP Positive expiratory pressure

PPC Postoperative pulmonary complications

RCT Randomized controlled study

UAS Upper abdominal surgery

VC Vital capacity

Glossary

Atelectasis: lung tissue with collapsed alveolus without gas exchange (directly translated from Kåss, 1998, p.33)

Breathing exercises: general term for a variety of exercises aiming at affecting the respiratory system. Deep inspirations, forced expiratory technique (FET), and the use of devices such as the PEP-mask, incentive spirometry (IS) and continuous positive airway pressure (CPAP) are all examples of different methods.

Chest physical therapy, or Respiratory physical therapy: term used about field in physical therapy which focuses on interventions aiming to affect the respiratory system. It …"includes education, pain relief, accurately targeted mobilization, manual and mechanical techniques…" (Hough, 2001, p.147) and education and instructions in exercises the patient can perform on her/his own (Fagevik Olsen, 2005).

Closing capacity (CC): "the lung volume at which dependent airways begin to close, or cease to ventilate" (Macnaughton, 1994 in Denehy, 2008, p.405).

Continuous Positive Airway Pressure (CPAP): a device which delivers a constant flow of gas during both inspiration and expiration, through a facemask or a tube. The purpose of the method is to increase lung volumes and gas exchange by splinting open the airways (Hough, 2001, p.231).

Deep breathing: deep inspirations without the use of any devices. Can be combined with an end-inspiratory pause (directly translated from Antonsson et al., 2009)).

Forced expiratory technique (FET), or huffing: forced expiration without closing the glottis and can be performed at different lung volumes (directly translated from Antonsson et al., 2009))

Functional residual capacity (FRC): the lung volume at "the end of quiet exhalation…" (Hough, 2001, p.5).

Hypoxemia: "reduced oxygen in arterial blood" (Hough, 2001, p.12).

Incentive spirometry (IS): maximal inspiration with the use of a device that visualizes inspirational volume or flow (directly translated from Antonsson et al., 2009)

Open abdominal surgery: surgery involving an "…incision through the flank or, more generally, through any part of the abdominal wall" (Laparatomy, 2012). In medical terms: laparotomy (Denehy, 2008, p.409).

Positive expiratory pressure (PEP): positive pressure in the airways during expiration. Can be attained using devices such as the PEP-mask.

P-value: statistical term. This value indicates with which probability the differences between groups or the correlation between different variables are due to chance (Nortvedt et al., 2008, p.207).

Spo2: "oxygen saturation by pulse oximetry, equivalent to SaO2" (Hough, 2001, p.468)

Upper abdominal surgery (UAS): surgery which involves an incision above the umbilicus (Denehy, 2008, p.409).

Vital capacity (VC): "the volume of gas that can be exhaled after a full inspiration" (Hough, 2001).

1.0 Introduction

1.1 Post-operative pulmonary complications after abdominal surgery

All operations involving the abdominal viscera are called abdominal surgery (Denehy, 2008, p.409). There are several reasons for surgery of the abdomen; among the most common are resection of cancer in the colon or rectum, or conditions like diverticulitis and ulcerative colitis (Denehy, 2008, p.409).

There is a high incidence of post-operative pulmonary complications (PPC) in relation to open abdominal surgery (Örman & Westerdahl, 2010), up to 40% in studies from the last decade (Mackay, Ellis & Johnston, 2005).
Sputum retention, reduced lung volumes, ineffective cough and altered function of the respiratory muscles during and after surgery, with subsequent atelectasis are among the causes that seem related to the incidence of these complications (Pasquina et al., 2006 ; Denehy, 2008, p.403 ; Lumb, 2010 ; Antonsson et al., 2009).
As a consequence of PPC, patients have increased hospital morbidity, increased short- and long-term mortality, longer hospital stays and increased health-care costs (Pasquina et al., 2006 ; Canet et al., 2010 ; Smetana, Lawrence & Cornell, 2006). This is the case, especially for patients scoring high on pre-operative risk factors such as high age, obesity, functional dependence, people who smoke or have an obstructive pulmonary disease (Smetana, Lawrence & Cornell, 2006 ; Fagevik Olsen, 2006).
It is therefore of great interest, both for the patients and for the economy of the hospitals, to minimize the incidence of PPC. One of the interventions used for prevention of these complications is chest physical therapy.

Physical therapy at a local hospital

At the local hospital where I work all patients going through open abdominal surgery meet with the physical therapist pre-operatively and get therapy the early post-operative days. The aims for the physical therapist are to help the patient in preventing and treating PPC by counteracting the pulmonary changes that occur with surgery, as well as helping the patient improving his/her cardiopulmonary and physical function (Mackay, Ellis & Johnston, 2005 ; Fagevik Olsen, 2006 ; Antonsson et al., 2009).
Pre-operatively patients are informed about lung function alterations that occur during and after surgery, and are given recommendations about breathing exercises and early post-operative mobilization in relation to this. The patients practice the breathing exercises together with the physical therapist to

ensure correct performance, and they are also encouraged to do exercises for deep venous thrombosis prophylacsis.
Post-operatively patients are followed up by the physical therapist with breathing exercises according to the pre-operative information and the actual patients' post-operative status, and with help to general mobilization, from sitting and standing by the bed, to walking in the hallway.
The patients' respiratory and functional status is evaluated daily by the physical therapist and the treatment continues according to this. Therapy is ended when the patient is fully mobilized (self-reliant in ambulation and dressing and so on) and there is no sign of pulmonary complications needing treatment.

Which recommendations should the patients be given?

The first few days after surgery the patients are encouraged to do breathing exercises hourly. There have, however, been discussions about which exact recommendations to give to the patients. Research literature up till now has not provided any clear guidelines when it comes to optimal treatment dosage of breathing exercises for this population, and in three systematic review articles concerning abdominal surgery and physical therapy the authors have expressed a need for dosage studies (Örman & Westerdahl, 2010 ; Thomas, McIntosh & Dean, 1994 ; Antonsson et al., 2009).
Especially when it comes to the frequency by which the breathing exercises should be carried out, there is a lack of knowledge. Earlier studies use from once a day to once every waking hour as intervention frequency (Manzano et al., 2008 ; Ricksten, Bengtsson & Soderberg, 1986 ; Fagevik Olsen et al., 1997). Such a variety in studies has made it difficult for my colleagues and me to make exact recommendations to the patients. In addition it is observed that some patients do not follow the recommended dosage, but do the exercises with a lower frequency and must be reminded of it repeatedly. If patients could be recommended a lower frequency of these exercises it would present a smaller burden to her/him, and if a lower dosage was proven as effective as the current recommendations, then the quality of the performed exercises might possibly be higher.

Accordingly, there is a need for precise guidelines when it comes to the frequency of breathing exercises after open abdominal surgery, and this is both clinically relevant and requested by researchers. By testing the effect different frequency of these exercises have on relevant outcome measures, this could create a more solid foundation on which to base recommendations to the patients. And hopefully, this would be beneficial both for the patient, the therapist and the economy of the public health services.

1.2 Objective

The main objective of this pilot study was to lay a foundation which would enable giving clear recommendations concerning frequency of breathing exercises for patients going through open abdominal surgery, and to see if a pre-operative risk assessment would be a valuable tool for deciding which patients to prioritize in the clinical practice.

A secondary objective was to see if the design of this pilot study was appropriate for implementing in a study of a large scale.

1.3 Research question

Based on the primary objective of the study, the primary research questions in this paper are as follows:

> *Is there a difference in incidence of postoperative pulmonary complications when performing breathing exercises three times daily versus once every waking hour for patients going through open abdominal surgery?*
>
> *Is a pulmonary risk assessment beneficial pre-operatively?*

To answer these questions it will be relevant to also look at effect variables such as rate of mobilization and length of hospitalization, as these variables relate to incidence of post-operative pulmonary complications and to each other.

Based on the secondary objective of the study, the secondary research question is:

> *Is the project design adequate and viable in a large scale study?*

To answer this question it will be of relevance to investigate the test subjects' compliance to the given recommendations and to evaluate the current pilot study's usefulness and possible practical implications.

1.4 Areas of focus

This paper will focus on the respiratory interventions of physical therapy, which is breathing exercises and mobilization. This does not mean that other help or treatment from the physical therapist is not of relevance, e.g. exercises to enhance circulation, or treatment for pain or when functional limitations makes it necessary with assistance from the physical therapist. This is outside the objective of this paper, and will not be commented further.

The paper is written by a physical therapist. The topic is chest physical therapy for patients going through abdominal surgery. The focus will be on what is relevant for the physical therapist and the treatment given by her/him, and not on areas considered belonging to other professions, e.g. operation techniques and anesthesia.

The interventions in this project were interventions already being routinely used in this hospital. Other physical therapy techniques can also be beneficial, but I have decided to use positive expiratory pressure (PEP) breathing, the forced expiratory technique (FET) and cough. These are techniques often used routinely in Scandinavia for this patient group, and it is used in previous similar studies (Ricksten, Bengtsson & Soderberg, 1986 ; Fagevik Olsen et al., 1997 ; Örman & Westerdahl, 2010). Some of the other techniques will be mentioned in relation to studies on the effect of chest physical therapy and in the historical background, but except from this they will not be discussed further.

The theory presented and used in this paper is based on books about physical therapy with focus on respiration, and books about research method. In addition, I have searched databases like Medline, PubMed, Cinahl, Pedro and The Cochrane Library for articles relevant for the research questions. The searches included the free-text terms *physical therapy, respiratory physical therapy, chest physical therapy, breathing exercises, positive expiratory pressure, abdominal surgery, post-operative pulmonary complications.* These article's reference lists also uncovered some relevant articles which are used.

This paper is constructed with a theoretical background where abdominal surgery and the role of physical therapy in the post-operative days is presented, which will lead to a more detailed description of this project's relevance. I will then go through the method used in this study, the results and a discussion of these results and the method. The paper will end with a conclusion answering the research questions asked in the introduction chapter.

2.0 Theoretical background

2.1 Abdominal surgery

Abdominal surgery can be performed by laparascopy or laparatomy. Laparascopy involves the surgical procedure done using a camera and the operation instruments through small incisions in the abdominal cavity (Denehy, 2008, p.408). Laparatomy involves opening the abdominal cavity by a larger incision, either by upper abdominal surgery (UAS) with the incision above the umbilicus (Denehy, 2008, p.409) or by lower abdominal surgery (LAS) with the incision below the umbilicus.
In the local hospital where this study took place statistics from year 2010 shows that there were performed 24 UAS and 169 LAS that year. The UAS consisted of resections of the stomach, and the LAS consisted of colorectal resections (Mohn, 2012).

A great part of the abdominal operations are performed to remove cancer. In many Western countries colorectal cancer is the most common cause of cancer deaths among non-smokers (Denehy, 2008, p.409), and in the period 2005-2009 colorectal cancer was the second most frequent form of cancer for both men and women in Norway, following prostate cancer in men, and breast cancer in women (Kreftregisteret, 2011).
There were 5583 new cases of cancer in the digestive organs (total for both sexes) in Norway in 2009, 2405 of them cancer in the colon, 1219 in the rectum, rectosigmoideum or anus, 475 of them in the stomach and 152 in the small intestine (Kreftregisteret, 2011).
Other common reasons for abdominal surgery are, like mentioned earlier, diagnosis such as diverticulitis and ulcerative colitis (Denehy, 2008, p.409).

In the same hospital a multimodal program called “enhanced recovery after surgery (ERAS)” was introduced in year 2000 through a research project and was continued after the end of the study. This program is used for patients going through colorectal surgery and involves in-depth preoperative information to the patients, a specific dosage of nutrition, fluids, opiates and anesthesia, and early mobilization (Fearon et al., 2005 in Mohn et al., 2009, p.156). The goal of this program is an accelerated recovery with a shorter hospital stay, and is shown to give good results compared to traditional care (Mohn et al., 2009).

2.2 Effect of surgery on respiratory function

During and after surgery all patients will have an altered respiratory function. Several respiratory changes follow as a result of general anesthesia, administration of drugs, post-operative pain, recumbency and immobility (Denehy, 2008, p.403). All forms of surgery involving general anesthesia affects the respiratory system negatively, although open surgeries have the greatest impact compared to laparascopic surgery, and of them especially upper abdominal surgery (UAS) and surgery of the thorax (Fagevik Olsen, 2006).

Surgery with general anesthesia leads to reduced lung volumes, such as a decrease in vital capacity (VC) and in functional residual capacity (FRC) (Roukema, Carol & Prins, 1988). These lung volumes continue to decline the first two post-operative days, but usually returns to normal values within 5-10 days after surgery (Lumb, 2010, p. 348 ; Denehy, 2008, p.404). FRC changes with body position; it is reduced in supine position because gravity pushes the abdominal contents and the diaphragm cephalad (Denehy, 2008, p.404), and it is largest in standing position when the abdominal contents are pushed downwards and makes room for a larger lung volume. FRC normally decreases 500-1000 ml from the standing to the supine position (Denehy, 2008).
The reduced FRC is of great clinical importance post-operatively; the surgical procedure and recumbency the days after surgery together with possible increases in closing capacity can lead to arterial hypoxemia and increases the risk of atelectasis and PPC (Denehy, 2008, p.405 ; Fagevik Olsen et al., 1997). A shallow and rapid pattern of breathing post-operatively is also a cause of reduced lung volumes and atelectasis (Orfanos, Ellis & Johnston, 1999 ; Fagevik Olsen, 2006).

Atelectasis is found in the most dependent part of the lungs in 90% of healthy individuals going through general anesthesia with muscle paralysis, and this also lasts post-operatively (Duggan & Kavanagh, 2005 ; Lumb, 2010, p.348). Atelectasis leads to decreases in lung compliance and increased alveolar dead space, which means that blood passes through airless parts of the lungs, and the oxygenation of the blood is impaired (Lumb, 2010, p.348 ; Hough, 2001 ; Fagevik Olsen, 2006). The majority of persons going through surgery in the thorax or abdomen therefore develop hypoxemia, which often lasts for two to five days post-operatively (Duggan & Kavanagh, 2005 ; Kehlet, 1997 ; Antonsson et al., 2009 ; Denehy, 2008, p.405).

Lung function testing after surgery also shows reduced values, especially if the patient is not satisfactorily pain-relieved (Lumb, 2010, p.348 ; Fagevik Olsen, 2005).

The strength of the respiratory muscles is significantly reduced post-operatively; the diaphragm is affected by anesthesia, phrenic nerve dysfunction and the surgical procedure, and the excursion of this muscle is reduced after abdominal surgery, lasting up to one week post-operatively for UAS (Forgiarini Junior et al., 2009 ; Denehy, 2008, p.405 ; Pasquina et al., 2006 ; Roukema, Carol & Prins, 1988). Research on the mechanisms behind this dysfunction is inconclusive, and the exact consequences are not yet clear, but several researchers points at its obvious impact on risk for PPC (Lumb, 2010, p.348 ; Denehy, 2008, p.406 ; Pasquina et al., 2006).

Sputum retention in the airways occurs in many patients during surgery, as a result of general anesthesia, the tracheal tube, mechanical ventilation, ineffective cough and reduced lung volumes. This can last also post-operatively (Lumb, 2010, p.349 ; Denehy, 2008, p.405).

The mechanism behind development of PPC is explained in different ways. Denehy (2008, p.406), Lumb (2010, p.349) and Antonsson et al. (2009) explain that sputum retention together with reduced FRC, atelectasis, hypoxemia, diaphragmatic dysfunction and ineffective cough probably are the causes of development of PPC.
According to Pasquina et al. (2006), the functional disturbance of the respiratory muscles after surgery plays the key role in the development of PPC.
An animal study from 2004 (van Kaam et al.) showed that atelectasis promoted bacterial growth because of reduced functional surfactant and reduced function of macrophages in the alveolus in ventilated piglets. If this is the case with humans it could explain the risk of getting pneumonia after development of atelectasis (van Kaam et al., 2004).

Other possible factors leading to PPC are prolonged intubation, abdominal distension, post-operative pain, nasogastric tube and analgesics, together with immobilization (Denehy, 2008, p.406)

In summary; the post-operative period is characterized of physiological changes to both the lung tissue and the respiratory muscles in all persons going through general anesthesia. A combination of reduced lung volumes, atelectasis, reduced strength of the respiratory muscles and sputum retention seem to lead to the development of pulmonary complications post-operatively.

2.3 Post-operative pulmonary complications

Post-operative pulmonary complications are the greatest cause of mortality and morbidity after abdominal surgery. This leads to prolonged hospital stays and increased hospital expenses (Forgiarini Junior et al., 2009 ; Canet et al., 2010).

The incidence of post-operative pulmonary complications (PPC) after abdominal surgery varies depending on the definition used. In studies before the 90s the incidence is reported to be as high as 88% (Mackay & Ellis, 2002). In more recent studies the incidence is lower, but still varied; from 5-10% (Canet et al., 2010), up to 23% (Brooks-Brunn, 1997) and even 43% (Mackay, Ellis & Johnston, 2005). There exists no Norwegian national register for complications after abdominal surgery. However, in the previously mentioned ERAS-study the researchers found an incidence of pneumonia in 6% of the 98 test subjects (Mohn et al., 2009).

Common for studies using the term PPC and defining it, is the presence of two or more positive respiratory findings. The four most common findings are (1) a temperature over 38 degrees Celsius, (2) a change in sputum color or volume compared with pre-operative status, (3) alterations in auscultation findings and (4) alterations on chest radiographs consistent with collapse or consolidation (Mackay & Ellis, 2002 ; Chumillas et al., 1998). In addition Fagevik Olsen et al. (1997) use a SpO2 below 92% as a definition on PPC.

Another way of defining PPC has been to divide it in specific types of PPC, such as atelectasis, pneumonia, bronchospasm, bronchitis and respiratory failure (Roukema, Carol & Prins, 1988 ; Brooks-Brunn, 1997 ; Conde & Lawrence, 2008). These specific types will then need to be defined in each study.

2.4 Predictors of post-operative pulmonary complications after abdominal surgery

When undergoing surgery there are several factors that contribute to an increased risk of developing PPC. This leads to differences in the need for, and effect of, physical therapy post-operatively and can help in directing which patients to prioritize (Fagevik Olsen, 2005 ; Denehy, 2008, p.406).

In a review-article from 2005 (Fagevik Olsen) the following are listed as some of the major contributing factors leading to PPC in surgery (not just abdominal surgery); (1) age > 55 years, (2) smoking, (3) obesity (Body Mass Index > 30), (4) obstructive pulmonary diseases, (5) operation site close to the diaphragm, (6) duration of surgery and anesthesia, (7) post-operative immobilization and (8) pain.

Several researchers have performed multivariate analysis of possible risk factors contributing to PPC, with the aim of finding the factors that leads to the greatest risk and consequently, which patients need close follow-up.

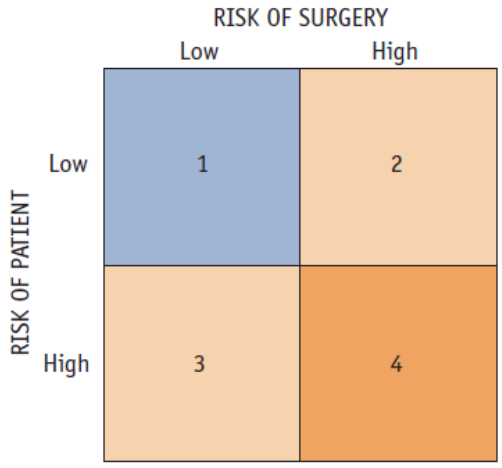
Hall et al.'s (1991b) analysis lead to the conclusion that a combination of an American Society of Anaesthesiologists (ASA) score >1 and age >59 years identified 88% of the patients with PPC after open abdominal surgery, and this is suggested as a simple tool for categorizing in high or low risk for this population. The ASA-score is a classification tool used to predict patient risk from anesthesia, and classifies patients into five groups, from healthy (class 1) to moribund (class 5) (Denehy, 2008, p.407 ; Hall et al., 1991b).

Canet et al.s (2010) analysis resulted in a risk index based on seven factors; (1) age, (2) pre-operative So2, (3) respiratory infections the last month, (4) pre-operative anemia, (5) site of the surgical incision, (6) duration of the surgery, and (7) if the operation was an emergency procedure.

More comprehensive risk indexes have also been developed, where factors like neurological status, need for blood transfusions and blood urea nitrogen level are included (Arozullah et al., 2001).

A more practical way of evaluating the amount of physical therapy needed to prevent PPC can be using a theoretical model presented by Fagevik Olsen (2005). This model takes into consideration the risk of the patient, such as if he/she smokes or not, and the risk of the surgery, such as if the patient is going through upper or lower abdominal surgery. Combining these two creates four quadrants which each tell us about the need of physical therapy in relation to surgery (figure 2.1). For instance, a patient considered to fit quadrant 4 is in great need of physical therapy, whereas one in quadrant 1 might not need any prophylactic physical therapy at all (Fagevik Olsen, 2005).

Figure 2.1: Theoretical model for defining the amount of physical therapy needed in relation with surgery.



Copied from Fagevik Olsen, 2005, p. 312

Other risk factors mentioned in the literature is ineffective cough, inactivity pre-operatively, intubation, impaired cognitive function pre-operatively and postoperative atelectasis lasting longer than normal (Smetana, Lawrence & Cornell, 2006 ; Brooks-Brunn, 1997 ; McAlister et al., 2005).

2.5 Historical review of physiotherapy after surgery

Post-operative chest physical therapy with breathing exercises has been used since the early 1900s to prevent PPC for surgical patients (Fagevik Olsen, 2005 ; Pasquina et al., 2006). Deep breathing exercises were first described in an article from Great Britain in 1915 as treatment for patients with war injuries involving damage to the pleura, lung and diaphragm (Macmahon, 1915, in Fagevik Olsen, 2005, p.309). Since then different techniques have been developed, at first passive, manual techniques such as percussion, vibrations, shaking and clapping on the thorax, where the patient was dependent on the physical therapist's help (Antonsson et al., 2009 ; Fagevik Olsen, 2005).

More recently, active techniques which can be carried out by the patients themselves are being used, often with the use of mechanical breathing devices such as incentive spirometry (IS), positive expiratory pressure (PEP) and continuous positive airway pressure (CPAP) (Pasquina et al., 2006 ; Antonsson et al., 2009 ; Fagevik Olsen, 2005). Techniques without breathing devices are also widely used, e.g. deep breaths, sustained maximal inspirations and FET (Chumillas et al., 1998).

Traditional care after surgery previously involved bed rest, and although early mobilization proved beneficial in studies, it was considered controversial for many years (Kehlet, 1997). Early mobilization is now a key factor after every surgical intervention.

2.6 The importance of positioning in chest physical therapy

Hough wrote that "…no physiotherapy treatment should be carried out without consideration of the position in which it is performed…" (Hough, 2001, p.149) and continued to describe the changes in functional residual capacity (FRC) which happens with different positions.
In a study of from 2004 (Zafiropoulos, Alison & McCarren) on patients in the intensive care unit, the subjects increased their tidal volumes, breathing frequencies and minute ventilation significantly when changing from the supine to the standing position. The sitting position also increases FRC and tidal volumes compared to lying in bed, but less than the standing position (Hough, 2001 ; Zafiropoulos, Alison & McCarren, 2004).
For these reasons positioning is crucial in respiratory care, and must be taken into consideration when doing breathing exercises.

2.7 Positive expiratory pressure

By breathing out against a resistance a person can attain positive expiratory pressure (PEP) in his/her airways. This technique is used in chest physical therapy after surgery, with a PEP-mask or a mouthpiece to increase FRC and tidal volumes, decrease atelectasis and mobilize secretions (Örman & Westerdahl, 2010 ; Astra Tech Healthcare, 2010).

Falk et al. (1984) claimed there is enough evidence to state that PEP has an effect on peripheral airways and on the collateral channels between alveolus and that this leads to air getting behind the secretions and in this way "leads" it up. But in Örman og Westerdahl's (2010) review it is stated that there is a lack of knowledge about what PEP-breathing actually leads to, but that "an increased functional residual capacity is considered essential" (p. 261). This statement is supported by Myers (2007) who writes that the theoretical benefit of PEP is to mobilize secretions by either stenting the airways and by this preventing collapse of them, or by increasing collateral ventilation or increasing FRC, leading to increased intrathoracic pressure behind the secretions.

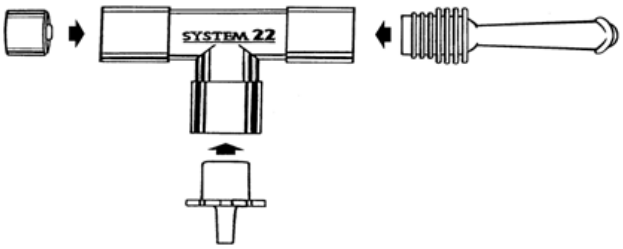
PEP-breathing was developed in Denmark in the 1970s (Myers, 2007) and was described in an article by Falk et al in 1984, and quickly became a widespread treatment in Scandinavia, Europe, and Canada (Sehlin et al., 2007).

The original PEP-apparatus consists of a facemask with a one-way valve (figure 2.2). A resistor is fitted to the valve, and a manometer can be inserted in the system to measure and adjust the actual pressure attained (Falk et al., 1984 ; Astra Tech Healthcare, 2010) (figure 2.4). A mouthpiece can be used instead of the mask (figure 2.3).

Figure 2.2: The PEP-mask

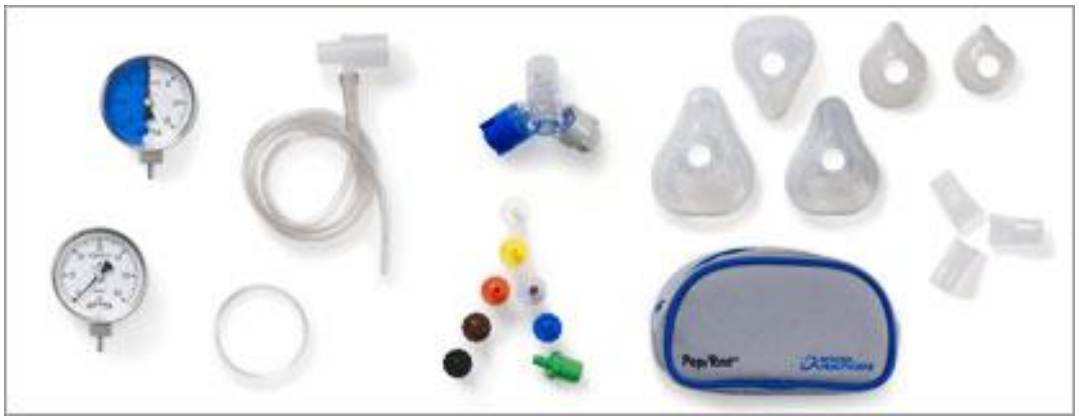
Picture copied from the brouchure "Bedre for hvert åndedrag" on www.astratech.no

Figure 2.3: The PEP-system with mouthpiece



Picture copied from www.normed.no

Figure 2.4: The PEP-system with masks, manometer and resistors



Picture copied from the brouchure "Bedre for hvert åndedrag" on www.astratech.no

The patient should perform 10-20 breaths with the PEP-device (Myers, 2007), and during PEP-breathing pressure should be 10-20 cmH2O in the middle part of the expiration phase (Falk & Andersen, 1991 inPryor & Prasad, 2008, p.151). The pressure produced under PEP-breathing is dependent on the resistor's size, the patient's expiratory flow and on the performance of the maneuver

(Örman & Westerdahl, 2010). The expiration phase should be three times as long as the inspiration phase (Myers, 2007).

In addition to these instructions, the quality of the maneuver is also of great importance; the patient should sit comfortably with arms resting on a table, and take a deep, sustained breaths (not to total lung capacity) (Falk et al., 1984 ; Örman & Westerdahl, 2010). The expiration should be slightly active (Myers, 2007).

In Scandinavia chest physical therapy with PEP is often routinely prescribed after surgery (Örman & Westerdahl, 2010), this is also the case in the hospital where I work. It should be noted that in this hospital the PEP mouthpiece with a resistor is used instead of the mask, and the patient is instructed in exhaling through the mouthpiece.

2.8 Effects of breathing exercises post-operatively

Breathing exercises is a general term for a great variety of methods and techniques used by physical therapists in the field of chest physical therapy.
Irrespective of the method used, the goals of the breathing exercises are the same; to increase lung volumes, mobilize secretions, improve bloodgas levels, improve ventilation distribution, increase gas exchange and thereby preventing PPC (Chumillas et al., 1998 ; Antonsson et al., 2009).

Interventions used in the studies presented in this chapter are PEP, IS, FET, deep breaths and CPAP. In addition, in one new study (Kulkarni et al., 2010) the intervention consists of using a device (Powerbreathe®) for strength training of the inspiratory muscles.

There have been published several systematic reviews the last decade, looking at the effect of chest physical therapy after abdominal surgery and surgery in general. Summaries and systematic reviews are at the higher end of the scale compared to primary studies when it comes to the reliability of the article, and should be emphasized (Nortvedt et al., 2008, p.44). These will therefore be presented first.

Conde and Lawrence (2008) summed up research about prevention of PPCs after abdominal and cardiac surgery. Concerning chest physical therapy they concluded that there is some evidence that to prevent PPCs, some sort of breathing exercises are beneficial compared to no intervention. This is supported in another systematic review (Lawrence, Cornell & Smetana, 2006) about prevention of PPC after non-

thoracical surgery. Thomas, McIntosh and Dean's systematic review (1994) on different types of breathing exercises after abdominal surgery also agrees with this, and concludes that incentive spirometry (IS) and deep breathing exercises were better than not doing any exercises, but there was not found any differences between the methods tested.
But Conde and Lawrence continue by writing that although the use of breathing techniques in relation to surgery is universal, there is not good enough evidence to claim they are better than early mobilization. Pasquina et al (2006) supports this in their systematic review on respiratory physical therapy after abdominal surgery, and additionally state that "… the routine use of respiratory physiotherapy after abdominal surgery does not seem to be justified (p.1887)"
Common for these four systematic reviews is that they all report of low methodological quality of their included studies; no blinding, inadequate randomization procedures and small sample sizes.

The effects of positive expiratory pressure (PEP) after abdominal and thoracic surgery were evaluated in a systematic review from 2010 (Örman & Westerdahl). With the exception of Ricksten, Bengtsson and Soderberg's (1986) study (see later paragraph in this chapter) the use of PEP compared to other breathing techniques or in addition to usual physical therapy treatment demonstrated no additional effect. There was not found any studies with an untreated control group. The authors suggest that breathing exercises without any form of device might have the same effect post-operatively, but there is yet no research on this.

Studies on IS have also systematically reviewed several times, the latest being a Cochrane review (Guimarães Michele et al., 2009). The authors concluded with no statistically significant effect of IS in the prevention of PPCs. They too, claim the methodological quality of the trials they included were only moderate.

Many primary studies were published in the 80s and 90s which looked at the effects of chest physical therapy after abdominal surgery.
Few studies have an untreated control-group, but two which do are the once of Roukema, Carol and Prins (1988) and Fagevik Olsen et al (1997);

Roukema, Carol and Prins (1988) demonstrated a reduction of PPCs when patients received chest physical therapy. The intervention group got a wide selection of different breathing exercises pre-and post-operatively. The authors reported of an incidence of clinically important PPCs on 4% in the intervention group compared to 35% in the untreated control group.

In 1997 Fagevik Olsen et al published an RCT where 368 patients going through open abdominal surgery were randomized to a treatment group or an untreated control group. The subjects in the treatment group received chest physical therapy which included instructions in doing 30 deep breaths, huffing and coughing hourly, and they also got information about early mobilization. High-risk patients were in addition given a PEP-mask to use post-operatively. The results of the study showed that subjects in the treatment group had significantly fewer PPCs, higher SpO2 and were mobilized earlier than the patients in the control group.

Most studies have compared different types of intervention with each other;
Among these were Ricksten, Bengtsson and Soderberg (1986) who compared the effect of CPAP, PEP-mask and IS post-operatively. The participants in the study used the devices for 30 consecutive breaths once every waking hour the three first postoperative days. The PEP mask was better than IS. The study showed that the use of PEP mask or CPAP was more effective on preservation of oxygenation and lung volumes and on prevention of atelectasis than the IS was.

In Chumilla et als RCT from 1998 40 participants followed a respiratory rehabilitation protocol, whereas the control group (n=41) did not. The protocol consisted of instructions about forced expiratory technique, cough, chest expansion exercises, diaphragmatic mobilization, maximal sustained inspiration and early mobilization. The exercises were performed for 10 minutes every two hours the first postoperative days, and for 10-15 minutes four times daily the subsequent days. There was found no statistical significant difference in SpO2 value, spirometric values or the incidence of PPC between the two groups. But there was found significant differences in radiological alterations, with a higher number of alterations in the control group. There was a 12% lower incidence of PPC in the rehabilitation group compared with the control group, and the authors claim that this, and a beneficial odds ratio suggests that respiratory rehabilitation is beneficial and protects against PPCs, especially in moderate- and high-risk cases.

Mackay, Ellis and Johnston's did a trial in 2005 where they examined if breathing exercises in addition to early mobilization lead to fewer PPCs than early mobilization alone. The breathing exercises consisted of three deep inspirations with end-inspiratory hold for three seconds. This was repeated twice every waking hour. The authors found no significant reduction in the incidence of PPCs when adding the breathing exercises to the mobilization program. They claim this confirmed their hypothesis that it

could be the mobilization and change in position that follows with chest physical therapy, and not the actual breathing exercises that lead to the positive effect on PPCs seen in earlier studies.

In a more recent study (Manzano et al., 2008) physical therapy after upper abdominal surgery showed no significant effect on SpO2 or lung function testing compared to the control group. In this study the participants did passive exercises, deep breathing exercises and exercises for expansion of the thorax 30 minutes a day. The control group did not get any physical therapy.

Inspiratory muscle strength training pre-operatively was the intervention in a study by Kulkarni et al (2010). The researchers found an increased inspiratory strength after a training period and post-operatively compared to other interventions like breathing exercises and IS. The sample size was too small to conclude with an effect on PPCs, but the authors speculate that strength training of the respiratory muscles might prevent post-operative fatigue and the subsequent risk of PPC.

Other positive effects of chest physiotherapy reported have been reduced length of stay in the high dependency unit (Westwood et al., 2007) with the use of IS.

There are many studies on the effect of breathing exercises after open abdominal surgery, and the results differ between them. In some studies breathing exercises leads to clear, positive physiological and clinical effects, in other studies specific groups of patients seem to have greater advantage of such exercises than other patient groups. On the contrary, in yet other studies the researchers conclude that there is no use in breathing exercises at all for this population. No specific method seems to be better than the others, but it seems breathing exercises of some sort is better than no exercises for prevention of PPC.

Örman og Westerdahl (2010) suggest the reason for lack of effects of breathing exercises could be that the performance of the exercises is not done with sufficient quality. Instructions on how to perform the breathing exercises must be described more detailed.

2.9 Frequency of breathing exercises postoperatively

In 2009 the Association of Swedish Physical therapy published Swedish guidelines for chest physical therapy after abdominal- and thoracic surgery (Antonsson et al., 2009). The purpose of this publication was to create treatment recommendations for physical therapists working with this patient group by

gathering research evidence in combination with comments from a group of experienced physical therapists (an expert group).
These guidelines recommend for all patients in the post-operative days after open abdominal to change position in bed and mobilize out of bed as often as their condition allows it. 30 deep inspirations every hour during the daytime is also recommended. If needed, treatment should be intensified, by PEP or external positive pressure (e.g. CPAP).
In the guidelines the authors point out that there is no consensus when it comes to duration and intensity of the different methods of treatment, and that there is a considerable need for research within this field.

Thomas, McIntosh and Dean (1994) called for the same in their systematic review. The authors found no dosage studies in their literature search, and wrote "…the lack of strong positive evidence may be attributed to the fact that there was an insufficient dosage of treatment (p.12)".

Örman and Westerdahl (2010) supported this statement, and claimed that the optimal treatment duration and frequency is not yet found. They suggested that the lack of positive effects of the PEP-breathing in their review could be due to treatment dosages that were not optimal.

As described previous about effects of breathing exercises the frequency by which these exercises are carried out varies widely. In some studies the exercises are done once a day (Manzano et al., 2008), in others twice to six times a day (Denehy et al., 2001), whereas in other studies they are done hourly (Ricksten, Bengtsson & Soderberg, 1986 ; Fagevik Olsen et al., 1997 ; Mackay, Ellis & Johnston, 2005). In addition, the dosage of treatment in the different studies seems almost random, with no information on theoretical reasoning or evidence-based background.
However, there is one study that holds this; Orfanos, Ellis and Johnston (1999) found that deep breathing exercises lead to an increase in tidal volume and minute volume which was only temporary. As early as five minutes after performing the exercises, tidal volumes returned to almost resting level. This suggests a high frequency of exercises dosage of exercises would be necessary to obtain the positive effects of them during the day.

Except from the mentioned reviews and some few articles (Denehy et al., 2001) dosage of treatment is seldom a theme of discussion in the research done on patients going through abdominal surgery.

According to the studies described in this section, and the previously described need in the local hospital for clear recommendations, studies on frequency of breathing exercises post-operatively is of great relevance.

2.10 Methodological background

This section explains the methodological concepts used later in this paper.

2.10.1 Designing an effect study

When the aim of a study is to test the effect of an intervention, such as in this study, a randomized controlled study (RCT) is the design which by many is considered being the gold standard (Polit & Beck, 2008, p.250). The design is experimental, has an intervention- and a control-group and involves a randomization procedure (Domholdt, 2000, p.116).

The fact that the design is experimental makes it possible to evaluate the difference between the groups on outcome measures that were chosen before the study began (Kampmann & Christensen, 1996). Randomization means that subjects are assigned into the intervention- and control group at random, so that the chance of being placed in the intervention group(s) is the same as being in the control group(s) (Polit & Beck, 2008, p.254). As long as the groups are equal at study start, the randomization makes it possible to claim that differences in outcome measures happened because of the intervention (Kampmann & Christensen, 1996).

The randomization should preferably be carried out blinded (Kampmann & Christensen, 1996). Blinding, which means concealment of the group allocation (Polit & Beck, 2008, p.259), can apply to the subjects, those administering the intervention, those doing the measurements and those analyzing the results. The objective of blinding is to ensure that the researchers' or the subjects' knowledge of group allocation does not in any way affect the results (Skovlund & Vatn, 2004).

The term *population* is the group to whom one wishes to generalize the findings in the study; it is the group of people that we are interested in, the ones the research question was aiming for (Domholdt, 2000, p.96 ; Bjørndal & Hofoss, 1996, p. 15). Studying every subject in the whole population is often difficult, and a *sample* is therefore often chosen. The sample is then the actual subjects being studied, and should be representative of the population (Bjørndal & Hofoss, 1996, p.15).

In the planning phase of a study, a *power analysis* helps the researcher to design a study that has the ability to detect a real difference when it exists (Domholdt, 2000, p.297). Calculating power often

means taking into consideration the variability one can expect to see within the groups being studied, the between-group difference that would be of clinical importance and the sample size. The sample size is the factor which is most often controllable, and by using the other two factors the sample size which will give the study power can be estimated (Domholdt, 2000, p.297).

Carrying out a pilot study before the start of a larger study can be advantageous. The objective of this could be to see if the study design is appropriate or to test the study procedure in practice (Dirksen & Jørgensen, 1996 ; Skovlund & Vatn, 2004) with a few persons similar two those meant to participate in the larger study (Domholdt, 2000, p.430).

Research validity is of great importance when designing or analyzing a study. With this term we mean how useful and believable the results from a study are (Domholdt, 2000, p.77). Three types of research validity will be mentioned here; *construct validity,* which means to what degree the outcome variable reflects the variable we really want to study (that we cannot measure directly), *internal validity,* which focuses on whether the results we get are actually caused by the intervention, and *external validity,* which means to which people in which settings the results of the study can be generalized (Domholdt, 2000, p.77 ; Benestad & Laake, 2004).

2.10.2 Measuring effect of chest physical therapy after surgery

According to Domholdt measurement is "…the systematic process by which things are differentiated (Domholdt, 2000, p.222)", which means it is performed by following given guidelines or rules.
A variety of outcome measures are used in studies on chest physical therapy after surgery. Of the most common are arterial blood gases, pulmonary function measured by spirometry and atelectasis measured by evaluation of chest roentgenograms (Örman & Westerdahl, 2010).
In addition, other outcome measures which have been considered relevant are post-operative complications, pain, use of bronchodilators, antibiotics and oxygen, temperature, auscultation findings, pulse, quantity and degree of mobilization, dyspnea, cough, expectoration, peripheral oxygen saturation, alveolar-arteriolar oxygen difference, subjective experiences and time to removal of chest tube (Fagevik Olsen et al., 1997 ; Mackay, Ellis & Johnston, 2005 ; Örman & Westerdahl, 2010).
Mackay and Ellis (2002) also points at length of stay and use of staffing resources as relevant clinical outcomes for physical therapists.
In two review articles the authors state a need for the observation period to be longer than in previous studies where subjects have been followed just the first post-operative days (Pasquina et al., 2006 ;

Örman & Westerdahl, 2010). An observation period till discharge from hospital, as well as long-term evaluation is suggested.

In deciding which outcome measurements to use it is crucial that they are both *reliable* and *valid*; as free from measurement errors as possible, and appropriate to test the phenomenon we actually want to study (Domholdt, 2000, p.77 and p.231).

Measurement reliability consists of several components; *instrument reliability*, which tells us about the instruments accuracy and repeatability, *intrarater reliability*, which tells us about the repeatability one researcher has between repeated tests of the exact same set of response, *interrater reliability*, which tells us about the repeatability between different researchers testing the exact same set of response, and *intrasubject reliability*, which tells us about the possible variability in the subject's performance from test to test.
Reliability can be measured with a *correlation coefficient*, and if this is 1.0, it indicates that the association between repeated measures is perfect (Domholdt, 2000, p.231).
Measurement validity is the meaningfulness and usefulness of the results we get from the specific measurements; it is related to the utility of the results (Domholdt, 2000, p.77).

2.10.3 Statistics

Statistics can be descriptive, meaning we describe the data, or it can be inferential, meaning we make conclusions about the population (Polit & Beck, 2008).
Description of data can be done by describing central tendency, such as the mean or median, and variability of the data material, such as the range or standard deviation (SD) (Polit & Beck, 2008, p.556).
When using inferential statistics we evaluate and analyze data and use this to draw conclusions based on a sample of the population (Polit & Beck, 2008, p.583).

Using inferential statistics to analyze the data from a study involves choosing the appropriate statistical test. To do this there are some factors that need to be known; what level of measurement the test is for, how many groups are involved in the study, if the design is paired or unpaired, and if the test is parametric or not (Kampmann & Christensen, 1996).
When the same subjects are tested under different circumstances the design of the study is called paired, whereas an unpaired design involves two (or more) groups who get different interventions (Kampmann

& Christensen, 1996). The analysis of the first type of design is done with paired tests after the end of the study to see if there are any statistical differences between the means e..g. before and after a given treatment, whereas unpaired tests are used to test for differences in the means of different intervention groups (Christensen & Dirksen, 1996)

One of the assumptions behind a parametric test is a normal distribution of the data. When analyzing small samples the data seldom follows this distribution and non-parametric tests is then appropriate (Christensen & Dirksen, 1996).

Statistical significant differences is often assumed when $p < 0.05$ or < 0.01. This means that we accept that a true null hypothesis (no difference) would be wrongly rejected with a probability of 0.05 or 0.01, respectively (Polit & Beck, 2008, p.588).

Before starting the analysis of the data it is important to decide which subjects we wish to include. One strategy is to use an *intention to treat-analysis* which includes all randomized subjects, whether they have followed the prescribed treatment or intervention or not (Skovlund & Vatn, 2004). This analysis is used to prevent systematic bias.

3.0 Materials and methods

3.1 Design

To answer the research questions in this pilot study a randomized controlled trial (RCT) was chosen as design.

3.2 Recruitment of participants

All patients going through elective abdominal surgery at this hospital are asked to meet to a medical preoperative examination one or several weeks before surgery. This control is performed by an anesthesiologist and a nurse. After the examination the nurse asked eligible patients to participate in the study and gave them an information sheet to read through. They then either accepted or refused participation immediately or brought the information back home and gave an answer the day before surgery. The nurse did not have any other role in the study.
All patients were referred to the physical therapist, with information on whether they wanted to participate in the study or not. Those willing to participate signed an informed consent (appendix 1).

3.3 Power analysis

A power analysis was not conducted before this study, but in two similar studies 22 and 50 patients were stated as giving a statistical power of 80% (Manzano et al., 2008 ; Mackay, Ellis & Johnston, 2005), whereas most studies on this subject have a larger sample size. The two studies used the same effect variables as in this study; post-operative pulmonary complications, number of hospital days, degree of mobilization, spirometric values and SpO2 and the results from their power analysis is therefore assumed being transferable to this project.
Due to the limited time for data-collection in this project, the goal in this project was to include 20 patients, although a greater number would be preferred.

3.4 Randomization procedure

The participants were randomized either to the three times daily-group (3TD-group) or to the once hourly – group (1H-group). In this study randomization was performed by the subjects drawing one of 20 prepared sealed opaque envelopes containing group allocation. This was done at the pre-operative

consultation for each subject. The envelopes were prepared by two physical therapists not involved in the study.

3.5 Blinding

Blinding was difficult in this study due to lack of staff resources, which led to the same person being responsible for pre- and post-operative testing, randomization procedure, instructions to the patients and analysis of the data. Some of the post-operative testing was done by physical therapists other than the researcher, in these cases the physical therapists were blinded to group allocation, but this was not consistently carried out.

The intervention consisted of a program of active exercises, so the nature of the intervention itself made it impossible to blind the subjects, they were all aware of which intervention they got.

3.6 Population and Sample

In this study the population is defined as all women and men older than18 years going through elective open abdominal surgery in a local hospital in Norway.

The sample in this study consists of all women and men older than 18 years going through elective abdominal surgery in the local hospital in the period 1.Oktober 2011 – 31.March 2012 and who met the entry criteria.

3.7 Entry criteria

The following were the inclusion criteria:

- Persons going through elective open abdominal surgery with a midline incision
- Age > 18 years
- The patient was able to understand informed consent and the instructions given
- The surgery performed was a primary surgery
- The person was available for testing pre-operatively
- The person was able to walk 30 meters (with or without the use of a walking aid)

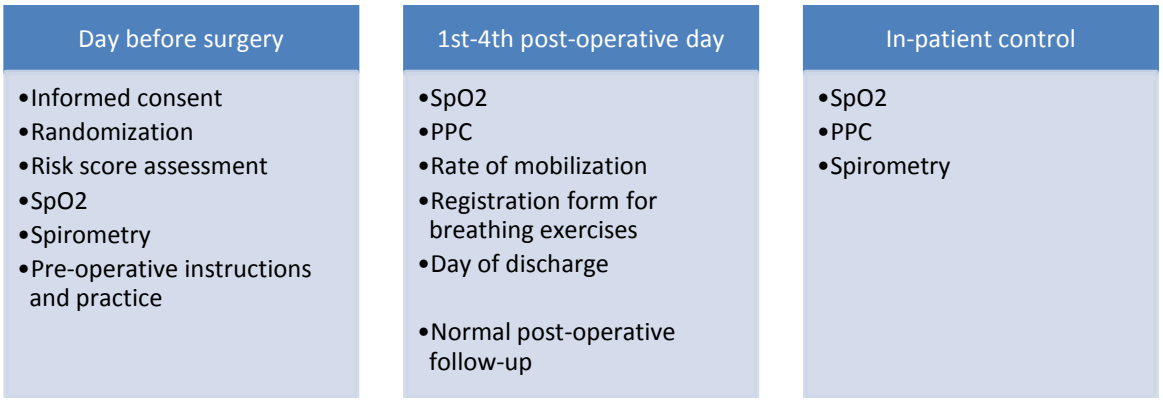
The following were the exclusion criteria:

- The patient were in need of a ventilator directly after surgery
- The patient was diagnosed with postoperative pulmonary complications before the initiation of the breathing exercises
- Acute intraoperative or postoperative non-respiratory incident that affected respiration
- Reoperation during the first four postoperative days
- The surgery performed was a secondary surgery, during the same hospitalization as the primary surgery
- Laparascopic surgery
- Surgery for abdominal aortic aneurysm

3.8 Test procedures

After inclusion in the study the patients were all followed up according to the test procedures. This is presented in figure 3.1 and explained in more detail below.

Figure 3.1: Course of the test procedures



PPC: Post-operative pulmonary complications

3.8.1 Baseline

All subjects had a consultation with the physical therapist pre-operatively, between 1 and 4 p.m. There they went through an examination including lung function testing, questions about pulmonary history and smoking and a measurement of height, weight and SpO2 (appendix 2). From this data the subjects were given the pulmonary risk score.

The subjects were then randomized to one of the two groups and instructed in breathing exercises and practiced this with the physical therapist. They were also informed about exercises for thrombosis prophylacsis and the importance of mobilization after surgery. They received an information sheet with this information and a form for registration of the breathing exercises they were to perform post-operatively. For details on the intervention for the two groups, see section 3.9.

3.8.2 1st -4th post-operative day

The patients were followed up by daily measurements of SpO2, PPC and rate of mobilization day 1, 2, 3 and 4 post-operatively. The measurements were done between 8 and 10 a.m., preferably before the first breathing exercises and mobilization that day. No measurements were done Sundays since there were no physical therapists at work that day.
The physical therapist also helped the patient with breathing exercises and mobilization once daily. When PPCs occurred the physical therapy intervention was intensified with recommendations about breathing exercises every waking hour and if considered necessary, other treatment techniques and/or several physical therapy treatments daily.

3.8.3 At discharge from hospital

The length of hospitalization was registered the day the patient left the hospital. The form for registration of the breathing exercises was retrieved from the patient before she/he left.

3.8.4 Out-patient control

Patients going through abdominal surgery were/are routinely asked to meet at an out-patient clinic about a month after surgery for a post-operative follow-up with the surgeon. Those subjects participating in this project received a phone call in advance of the control and were asked to meet at a physical therapy control the same day. This control consisted of lung function testing, measurement of SpO2 and questions about occurrence of pulmonary complications since leaving the hospital.
The testing was performed between 1 and 4 p.m., as with the pre-operative testing.

3.9 Intervention

3.9.1 The three times daily-group (3TD-group):

The subjects were told to perform breathing exercises three times a day as long as they were in the hospital, also on the weekends. The breathing exercises consisted of three series of 10-15 breaths with the PEP-device with a mouthpiece, and they were instructed in doing the PEP-breathing with slight active expiration, and with a larger inspiration volume than normal. A manometer was used to measure expiratory pressure under the training pre-operatively, and the patients were given an individually adjusted resistor which gave a pressure of 10-20 cmH2O in the middle part of the expiration phase.
In between the series of PEP-breathing they were told to do the forced expiratory technique (FET) and coughing. The exercises should be carried out in a comfortable position, preferably in the seated position in a chair or in bed.
The subjects were also instructed in exercises for deep venous thrombosis prophylacsis (active ankle plantar- and dorsiflexion), and were encouraged to early mobilization and frequent change of position in bed and out of bed.
It was recommended to start the exercise program as soon as they woke up from the anesthesia, the day of the surgery. No other physical therapy treatments than these mentioned above were given to any of the subjects if not specified.

3.9.2 The once hourly -group (1H-group)

The subjects in the 1H-group were instructed in the same exercises as the 3TD-group, but were told to do the breathing exercises once every waking hour. Except from this, the group was treated the exact same way as the other group, both pre- and post-operatively.

3.10 Measurements

This section presents the outcome measures used in this study and how data were collected.
Strengths and weaknesses of the chosen outcome measures are discussed in chapter 5.2.3.

3.10.1 Post-operative pulmonary complications

In this study post-operative pulmonary complications (PPC) is considered the main outcome measure. PPC is defined as one of the following:

- Atelectasis: verified by chest X-ray, and not present prior to surgery
- Pneumonia: the patient is treated with antibiotics for a suspected pneumonia

- Peripheral oxygen saturation < 90%

The definition is based on definitions used in earlier research as described in section 2.3 and on discussions with an anesthesiologist, a chief surgeon at the Department of Gastro Surgery and chief physician at the Department of Thoracic Medicine (all working at the same hospital as the study was performed).

Registration of PPC was done daily by measuring SpO2, by dialog with the subjects' nurse and physician, and by reading the patients' medical records.

3.10.2 Pulmonary function tests

Spirometry measures the mechanics of breathing, and how a person breathes volumes of air in an out as a function of time (Domholdt, 2000, p.267 ; Miller et al., 2005).

Pulmonary function tests were conducted using the criteria in the ATS/ERS "Standardisation of spirometry" document (Miller et al., 2005) with Sensormedics vitalograph spirometre (Vitalograph ® 2120, Vmax Spectra Software version 11-1) (figure 3.2). Calibration was done daily before testing began.

The following variables were recorded: Forced Vital Capacity (FVC) and Forced Expiratory Volume in one second (FEV1), measured in milliliters and as percentage of the reference value, and the ratio FEV1/FVC.

Figure 3.2: The equipment used for pulmonary function tests

The spirometry testing was administered by a physical therapist. A chief physician (K.S.) at the Department of thoracic medicine in the same hospital was present under three of the tests. The rest of the spirometry tests were overseen and approved by the same physician. Analysis of all the spirometry tests was done by the physician and physical therapist together.

3.10.3 Peripheral oxygen saturation (SpO2)

A non-invasive pulse oxymeter measures the saturation of hemoglobin with oxygen in arterial blood, by transcutaneous examination of the hemoglobin's color spectrum (Singh & Hudson, 2008 ; Lumb, 2010, p.210).

Oxygen saturation (SpO2) is related to arterial oxygenation, and is for this reason considered useful for measuring physiological function of the respiratory system (Domholdt, 2000, p.267). An SpO2 > 95% is considered normal (Hough, 2001, p.11).

SpO2 was measured with Nellcor N-20PA handhold pulse oxymeter (figure 3.3). The apparatus was calibrated before the study period began by an engineer working at the Department for Medical equipment at the hospital.

Figure 3.3 Pulse oxymeter

Picture copied from www.nellcor.com

Measurement of SpO2 was done after the patient had been sitting up resting for 10 minutes without oxygen treatment. The subject's position was considered important due to the possible effect of changes in FRC and other respiratory parameters on SpO2. The test was stopped if SpO2 dropped under 85%. With unstable patients were they could not be disconnected from the oxygen, SpO2 was registered as 89%, which was assumed being the highest level without oxygen (Fagevik Olsen et al., 1997).

3.10.4 Rate of mobilization

Rate of mobilization was measured using the mobility indicators described in Mackay, Ellis and Johnston's study (2005).

The inter- and intrareliability of these mobility indicators was tested (Mackay & Ellis, 2002), and measured with a correlation coefficient called Kappa (Domholdt, 2000, p.350). The intrarater reliability was found to have kappa values from 0,65 to 0,87, which according to the authors demonstrated substantial intrarater reliability (one researcher was tested). When testing interrater reliability, kappa values of 0,4-0,87 were found, which means a moderate to substantial strength of reliability (three researchers were tested).

In this previous study indicator 1 was defined as first day sitting on the side of the bed, whereas in this pilot-study it is defined as first day sitting out of bed. The reason for this was that according to the procedures in the local hospital the goal the first post-operative day is for the patient to sit on the side of the bed.

The mobility indicators in this study were:

1) first day sitting on the side of the bed
2) first day walking (with or without assistance, including walking on the spot)
3) first day walking 30 meters without assistance (with or without a walking aid)

Registration of mobilization was done in the morning, at the same time as registering SpO2.

3.10.5 Length of hospitalization

Length of hospitalization was measured as number of days counted from the day of surgery to the day the patient left the hospital.

3.10.6 Compliance to the recommendations given by the physical therapist

The subjects were given a registration form where they registered how often they did the breathing exercises (Appendix 3).

3.10.7 Pulmonary risk score

A pulmonary risk score schema was used to calculate pulmonary risk score (table 3.1 and appendix 4). This was published by Chumillas et al.(1998) and was a revised version of a more comprehensive preoperative evaluation form published in 1988 (Torrington & Henderson).

Torrington and Henderson tested this risk score schema on 345 patients and found that the patients with a low risk score more often got fever and had abnormal findings on x-ray than patients in the moderate- to –high risk groups. The need of higher level of respiratory therapy services also increased with risk groups, as well as higher costs.

Table 3.1: Pulmonary risk score

Parameters	Score
Spirometry*	
FVC <50%	1
FEV_1/FVC	
65% to 75%	1
50% to 65%	2
<50%	3
Age ≥65 yrs	1
BMI >25%	1
Abdominal surgery, supraumbilical	2
Pulmonary history*	
Antecedents	1
Cough and expectoration	1
Smoker	1

* Cumulative score: Spirometry, 0–4; pulmonary history, 0–3.

Copied from Chumillas et al, 1998, p.6.

The minimum score was 0 and maximum was 11 (low, 0-3; moderate, 4-6; high >7). Because of the limited sample size in this study the moderate and high risk subjects were assigned to the same category; a moderate to high risk – category.
In the risk score calculation supraumbilical is the same as upper abdominal surgery. Subjects were given one point in the antecendents question if they had chronic obstructive pulmonary disease (COPD), asthma, pneumonia, bronchitis or other disease or infection affecting the lungs. They were given one point if they had cough or expectoration at the current moment. Current smokers were also given one point. These definitions are the same as used in Torrington and Henderson's original scheme.

For calculation of the pulmonary risk score the following data were collected:
Pre-operatively the subjects were asked about current smoking and pulmonary history. Height and weight were measured. Information concerning medical history, pre-operative and intra-operative procedures was retrieved from the patient's medical records.
Two chief surgeons at the Departement of Gastro Surgery at the same hospital read through the operation reports of all the subjects in the study and reported to the physical therapist which surgical incision each of the patients had had, since this was not always self-explanatory from the operation report. This risk group categorization did not influence the subjects' allocation to intervention group, but was used in the analysis of the data.

3.11 Ethical considerations

Ethical approval was granted for inclusion of 200 subjects before the start of the project by the Komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest) 31.08.2011 (Committee for medical and health professional research ethics) and with case number 2011/1261 (appendix 5).
Each subject was given an identification code at inclusion in the study. Each subject's data were put in a statistical program, but only the identification code was used there, and not any data that could possibly make the individual subject recognizable. A namelist connected the identification code and the subjects' name, personal number and other personal data. The list with identification code and name of the subjects was kept separate from the data registered in the statistical program. All the data were kept in a locked cupboard, and after ending the project all data were shredded.
All subjects had to give their written informed consent to be included in this study (appendix 1).
In this project I have chosen to test the effect of an intervention which is already used routinely. No new interventions are introduced, but there is a difference in the prescribed dosage. Except from the possible increased stress from the spirometry test and the form to register how often the breathing exercises were done, there were no known disadvantages of participating in the project. None of the measurements could be of harm to the patients.

3.12 Statistical analysis

The statistical analysis was performed using the program PASW® statistics 18 for Windows. Statistical tables and figures were made using the same program, as well as Microsoft® Office Excell 2010.

Descriptive statistics were used to present the data material in the study. Continuous variables, such as age, height and weight, will be expressed as median with range, whereas categorical and ordinal variables, such as smoker/non-smoker and pulmonary risk score, will be presented as frequency and percentage.

Inferential statistics were used to test differences between the groups, both differences in demographic and clinical characteristics pre-operatively, and differences in outcome variables post-operatively.
Due to the small total sample size in this study, an assumption of normal distribution of variables cannot be made here, and non-parametric tests were chosen (Christensen & Dirksen, 1996 ; Polit & Beck, 2008, p.591). The design of this study was unpaired, which meant unpaired tests had to be used.

For ordinal and continuous variables, such as age, height and weight pre-operatively and length of hospitalization or SpO2 post-operatively, an exact Mann Whitney U test was performed. This test is suitable for an unpaired design, and is non-parametric (Christensen & Dirksen, 1996).
The exact chi-quadrat test was used for categorical variables such as smoker/non-smoker pre-operatively and PPC/not-PPC post-operatively. This test is also unpaired and non-parametric and is appropriate when the cell sizes ($n<5$) or the total sample size is as small as in this study ($n<30$) (Polit & Beck, 2008, p.600).

Incidence of PPC and rate of mobilization was presented in bar charts to show distribution of subjects to the different categories, whereas SpO2 and the subjects' compliance to the interventions were presented using boxplots, to show the variability of the test scores.

Statistically significant differences were assumed when $p < 0.05$.

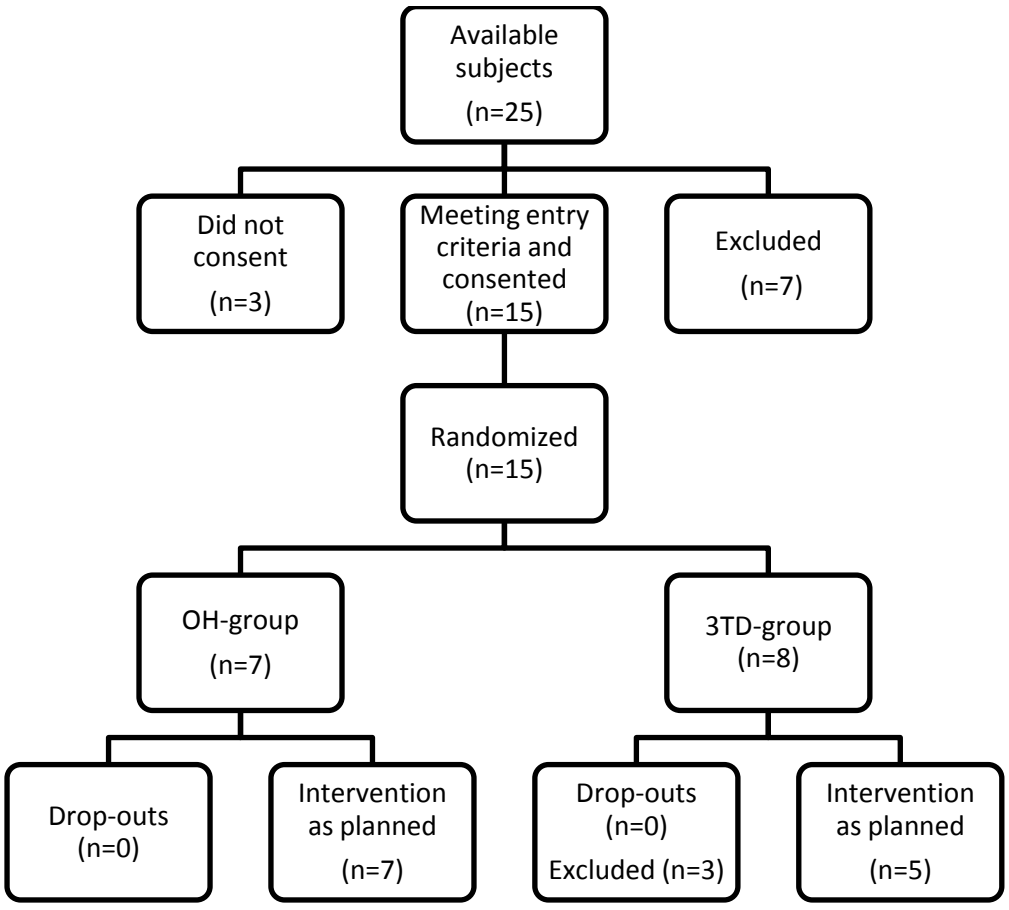
The analysis of the data was conducted on an intention-to-treat basis for those who finished the whole study period. This means that e.g. those in the once hourly-group who only did the breathing exercises one or three times a day were still analyzed in the group they originally belonged to.

4.0 Results

4.1 Subjects

The study included a consecutive series of 12 patients that completed the study, six women and six men, aged 38 to 80 (median 67,5) years undergoing elective open abdominal surgery in a gastroenterological unit at a local hospital. All available patients admitted between 1.October 2011 and 31. March 2012 were assessed, with 18 meeting the entry criteria. Three did not consent. The 15 other subjects gave informed written consent and were tested pre-operatively. Three participants were excluded during the study period, all of them belonging to the three times daily-group (3TD-group). Two of these subjects had laparascopic procedures, despite being scheduled for a laparotomy. One other patient was diagnosed with a PPC as soon as he woke up from surgery, before initiation of the breathing exercise program and was therefore excluded. There were no drop-outs during the post-operative period. The flow of subjects through the study is shown in Figure 4.1.

Figure 4.1: The flow of subjects through the study



3TD group: Three times daily-group. 1H group: Once hourly-group.

Table 4.1: Demographic and clinical characteristics of the participants, totals and in the two different groups.

	Total (n=12)	Three times daily-group (n=5)	Once hourly - group (n=7)	p-value
Sex[1], females	6 (50 %)	2 (40 %)	4 (57.1 %)	1
Age[2], years	67.5 (38-80)	63 (38-78)	74 (51-80)	0.362
Height[2], m	1.70 (1.6-1.8)	1.7 (1.7-1.8)	1.7 (1.6-1.8)	0.404
Weight, kg	70.5 (50-107)	71 (64-107)	69 (50-86)	0.138
BMI[2], kg/m²	24.3 (18.4-36.6)	23.2 (21.9-36.6)	24.3 (18.4-26.3)	1
Smokers[1]	4 (33.3 %)	2 (40%)	2 (28.6 %)	1
SpO2[2], %	98 (96-100)	98 (96-100)	98 (97-100)	0.688
FVC[2], liters	3.6 (2.8-5.5)	3.7 (3-4.6)	3.2 (2.8-5.5)	0.432
FVC[2] %	109 (72-148)	104 (90-116)	117 (72-148)	0.343
FEV1[2], liters	2.7 (2.1-4.2)	3.2 (2.2-3.5)	2.4 (2.1-4.2)	0.343
FEV1[2]%	100.5 (75-137)	100 (85-121)	112 (75-137)	0.639
Risk score[1]				0,417
Low	11 (91.7 %)	4 (80 %)	7 (100 %)	
Moderate-to-high	1 (8.3 %)	1 (20 %)	0	
ASA-score[1]				0,697
1	3 (25 %)	2 (40 %)	1 (14.9 %)	
2	6 (50 %)	2 (40 %)	4 (57.1 %)	
3	3 (25 %)	1 (20 %)	2 (28.6 %)	
4	0	0	0	

[1] Count (percent).[2] Median (Range). BMI:body mass index (kg/m²).

There were no significant differences in demographic or clinical variables between the two intervention groups at baseline. The 3TD–group had a higher median weight and BMI, but this difference was not statistically significant.

The FVC and FEV1 of all subjects were normal, except from the values from one man in the once hourly-group (1H-group), who had a FVC of 72% and a FEV1 of 75% of the reference value. The presumable reason for his low values was difficulties in performing the procedure correctly, which was obvious when interpreting the flow-volume curves from the test.

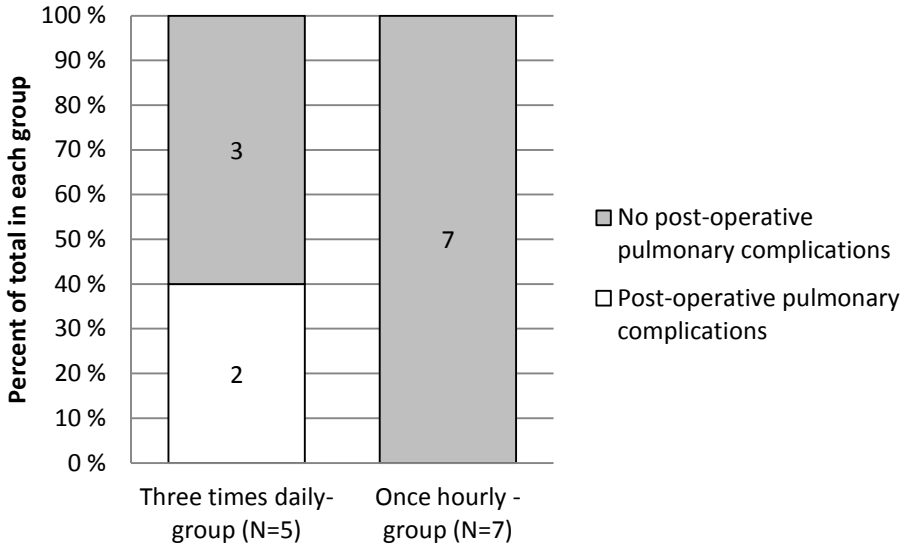
One patient in the 3TD –group went through upper abdominal surgery (UAS). That, combined with a high age and his pulmonary history lead to categorization to moderate-to-high pulmonary risk pre-

operatively. The other 11 had lower abdominal surgery and were all categorized to low pulmonary risk. There was no significant difference on the pulmonary risk variable either.
The most common surgical procedures in this study were resection of the rectum and resection of segments of the colon, and the most frequent diagnosis were cancer of the rectum and/or colon, followed by ulcerative colitis.

4.2 Incidence of post-operative pulmonary complications

The overall incidence of PPC in this study was 16.7 %. Two women in the 3TD-group developed PPC, whereas none in the once hourly-group did, however these differences were not statistically significant (p=0.152). This is presented in figure 4.2.
Of the two subjects with PPC one person started with antibiotic treatment on indication of pneumonia on the third post-operative day, and x-ray on the fourth day showed atelectasis basodorsalt on the right lung. The other person was given antibiotics from the fourth day for the same reason.
Concerning pre-operative demographic and clinical characteristics for these women one of them was < 40 years of age, the other > 70, and they had a BMI of 35 and 23, respectively. Both women reported coughing and expectoration the last days. None of them were smokers. They both went through lower abdominal surgery, had normal spirometric values and an SpO2 >97% pre-operatively and were categorized to the low pulmonary risk-group pre-operatively.

Figure 4.2: Incidence of post-operative pulmonary complications



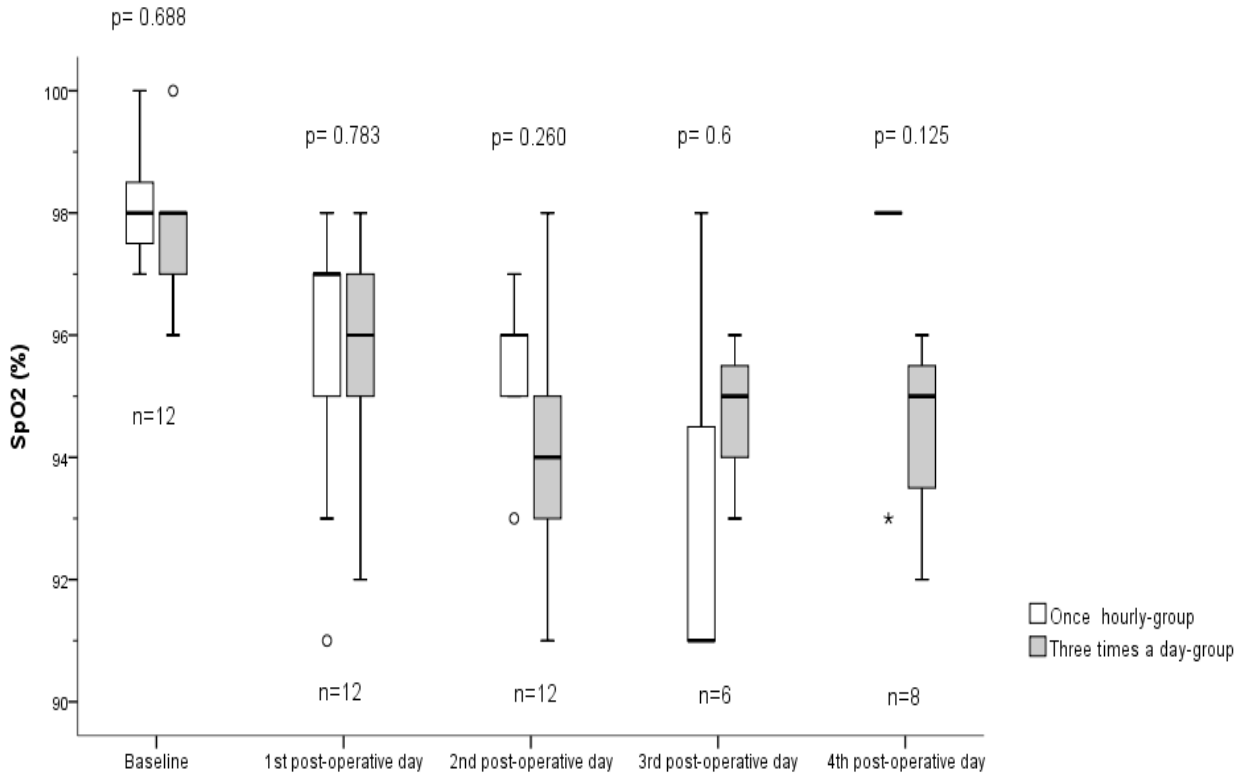
Incidence of post-operative pulmonary complications during the first four postoperative days.
Values on columns describes number of subjects in the different categories.

4.3 Peripheral oxygen saturation (SpO2)

In both groups there was a decrease in SpO2 post-operatively (figure 4.3). Median was slightly higher in the 1H-group all post-operative days except from day 3, but there was no statistical difference between the two groups on any of the days.

Due to no physical therapists on work Sundays to do measurements there was quite a few missing values on this variable on the 3rd and 4th post-operative day. Values are based on six subjects day three, and eight subjects on day four. The measurements on the other days are based on all included subjects (12 persons).

Figure 4.3: Peripheral oxygen saturation pre- and post-operatively



SpO2 at baseline and the first four post-operative days. The dark line on each column symbolizes the median.

4.4 Days in hospital

The median (range) number of days in hospital was 11.5 (6-18) for all the subjects. In the 1H-group median was 9 days, and their values ranged from 6-16 days. In the 3TD-group the subjects stayed 15 days in hospital, and these subjects' values ranged from 9-18 days.

There was no statistical difference between the groups (p=0.12).

The two women who developed a PPC had a length of stay on 9 and 17 days.

4.5 Rate of mobilization

All subjects in this study reached mobility indicator 1 and 2 on the first post-operative day. There are only variations between subjects concerning reaching indicator 3. By day four, all but one woman from the 1H-group had met the criteria of indicator 3. There were no statistical differences between the groups (p=1 on all indicators).

Figure 4.4: Rate of mobilization

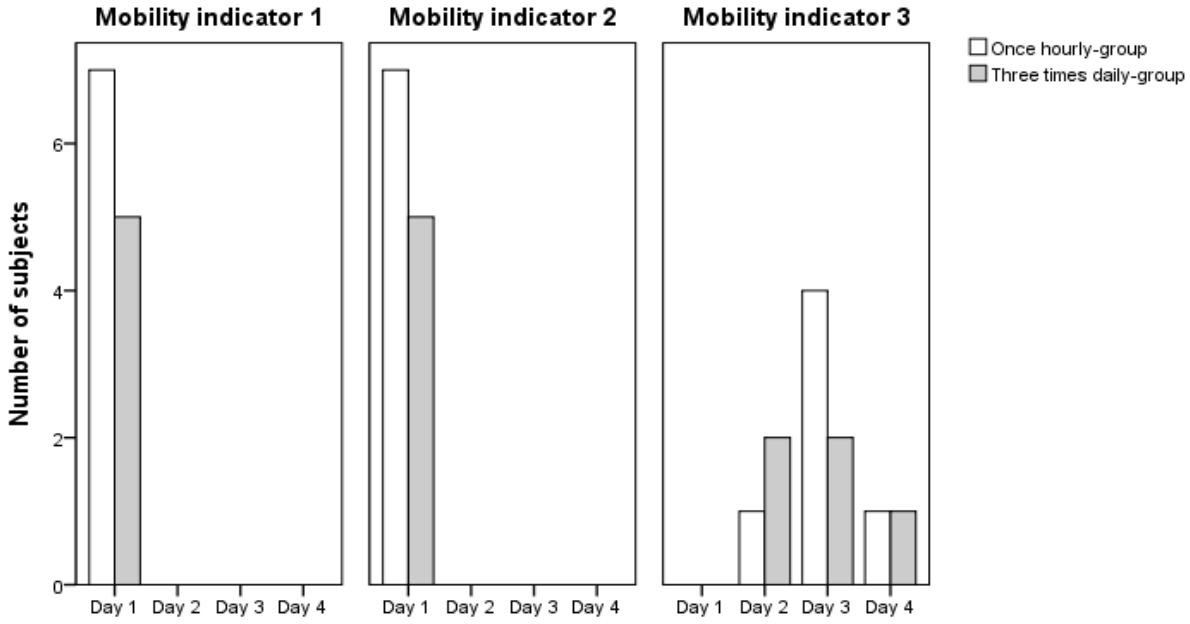


Illustration of which day the three different mobility indicators were reached.

4.6 Compliance to the recommendations

The registration of sessions of breathing exercises showed that the 1H-group had a median (range) of 21.5 (3-49) sessions. For the 3TD-group the number of sessions during the first four post-operative days were 12 (8-12).

Data on this variable was missing on two subjects, one subject from each of the intervention groups. One subject left the hospital without returning the form to the researcher, and this was not possible to

retrieve later. The other subject was a woman diagnosed with PPC on the second post-operative day. From this day the physical therapy treatment intensified and the exercises were done more frequent. She did not remember how often she had done the exercises, and her data are therefore missing.

The other woman who got PPC in this study performed 12 sessions of breathing exercises during the first four post-operative days.

Figure 4.5: Compliance to the breathing exercises recommendations

Number of total sessions* with breathing exercises performed during the first four post-operative days in the two intervention groups. The dark line in the two columns symbolizes the median.
*One breathing exercises session consisted of 3 series of 10-15 breaths with the PEP-device.

4.7 Outpatient clinic control

A long-term evaluation was planned in this study, at the out-patient clinic follow-up. Unfortunately, this was impossible to carry out. The subjects were scheduled for control at the surgical out-patient clinic at the hospital and due to long travelling distance for some of the patients the out-patient control in this study was planned coordinated with this one. But for different reasons this data collection was difficult to carry out; the responsible physical therapist was not at work on all the control days, one patient refused doing the spirometric test again and some patients were never scheduled for a control at the surgical out-patient clinic.

4.8 Other post-operative complications

In addition to pulmonary complications some of the subjects experienced other complications after surgery that could have impacted upon their length of stay and given them mobility restrictions.
Allocated to the 1H-group were two subjects with severe nausea post-operatively and one subject going through reoperation after day four due to anastomotic leakage. They had a length of hospitalization on 12, 12 and 16 days, respectively.
In the 3TD-group one subject had stomach pain and an infection in the laparotomy wound, and one other subject went through a reoperation after day four because of need of re-suture of the laparotomy wound. These two subjects were hospitalized for 15 and 18 days, respectively.

5.0 Discussion

In this chapter I will start by discussing the results of this pilot study, before a discussion around the research method, the outcome measures and statistics will be presented.

5.1 Discussion of results

Many studies have looked at the effect of chest physical therapy on incidence of post-operative pulmonary complications (PPC). These earlier studies have compared different interventions to each other, or to an untreated control group. The aim of these studies has been to find the most effective technique or device, or to see if there is any need in chest physical therapy at all. However, there has been a lack of dosage studies. This current pilot study is a contribution to this research field, as it focuses on a topic suggested by several authors to be of great clinical relevance.

5.1.1 Answer to the primary research questions

The primary research questions of this study were:

> *Is there a difference in incidence of postoperative pulmonary complications when performing breathing exercises three times daily versus once every waking hour for patients going through open abdominal surgery?*
>
> *Is a pulmonary risk assessment beneficial pre-operatively?*

Incidence of post-operative pulmonary complications

Studies on chest physical therapy interventions for this population have reported varied incidence of PPC after intervention; from 6% - 17% (Fagevik Olsen, 1997, Denehy, 2001, Chumillas 1998, Hall, 1996, mackay 2005, westwood, 2007)

In this pilot study two women developed PPC, which corresponds to 40 percent of the subjects in the three times daily-group (3TD-group), or 17% of the whole study sample. Taking in to consideration the small sample size, especially in the 3TD-group, we cannot assume that this would be the representative for the whole population as only one person amounts to a great percentage of the sample, and this is most likely the reason why the incidence is higher than in studies with comparable subjects and interventions.

Considering the pre-operative characteristics of these two women one was >70 years of age, the other had a BMI of 35, and they both reported cough and expectoration the last days before surgery. Except from this, they did not score positively on any other possible risk factors which were registered.
The fact that both subjects were categorized to the low pulmonary risk-group pre-operatively is interesting. Possible causes are that the outcome measure (pulmonary risk score) used was not suitable for its purpose, that the intervention they received was less beneficial than that of the 1H-group, or again; that the sample size was so small that the results of the study were confounded by random events. There is a possibility that the extra attention from the physical therapist may have led to a better compliance to the recommendations and consequently, a lower incidence of PPC than what is the case in the clinical setting (Polit & Beck, 2008, 264.).

The chosen definition of PPC and the risk categorization measure used in this study is discussed in chapter 5.2.3.

Rate of mobilization

Mackay and Ellis' study from 2002 included 60 patients going through open abdominal surgery (OAS). In that study 34 subjects had still not met mobility indicator three (the patient could walk 30 meters independently) by day five. Six of these had impaired mobility at the time of admission, but still those results are very different from the results in this current study, where all but one were independent by day four.
Also in the study by Mackay et al (2005) of 50 high-risk patients 25 out of the 50 subjects had still not met indicator three by day five. It is of importance that all the subjects in those two studies went through upper abdominal surgery, whereas in this current study only one did, and the rest had lower abdominal surgery. This could affect the rate of complications and need for health care, but still, the subjects in this study were quickly mobilized compared to these two previous studies.
Fagevik Olsen et al (1997) reported that the patients in their treatment and control group were fully mobilised after a mean (SD) of 1.8 (0.9) and 2.4 (2.9) days, respectively. Those results are more similar to the once in this pilot study.
This current study did not register the quantity of mobilization, which can be of great importance for the results. Browning, Denehy and Scholes (2007) demonstrated a relationship between "uptime", length of hospital stay and PPC after upper abdominal surgery; their results showed that the once with more "uptime" had a shorter length of stay and fewer PPCs.

Hospital days

In this project the median (range) length of stay was 9 (6-16) in the 1H-group and 15 (9-18) in the 3TD-group.

In Mackay et als study (2005) equivalent numbers were 13 (5-23) and 10 (6-21) whereas the study by Mackay and Ellis (2002) found a median of 18 and 14.5 (no range mentioned).

Fagevik Olsen et al (1997) found a mean (SD) duration of hospital stay on 8.8 (4.5) in the treatment group and 9 (5.1) in the control group (no median mentioned) in their study. In the ERAS-study carried out at this local hospital/the university hospital the median hospital stay was four days. This is considerable lower than the numbers found in this current study. It is also of interest that the principles from the ERAS-study were implemented after the study, and is in current use. One possible reason could be that after the end of a project, resources and focus on the given interventions and principles might not be as great as during a study.

In this study the two women with PPC had a stay of 9 and 17 days in the hospital. Due to few patients in this project, an analysis of the correlation between incidence of PPC and hospital days was not possible to carry out. But other researchers have done this; one study (Brooks-Brunn, 1997) with 400 patients compared the length of hospital stay for patients who developed PPC and those who did not. A statistical difference between the groups was found; the PPC-group had a mean length of stay 9.4 ± 5.6, and the non-PPC group had a stay of 6.9 ± 4.8 days. In Denehy et als (2001) study with 57 patients, the analysis of the data showed a statistical difference between patients with and without PPC; 13 (12-19) and 11 (6-25) (median with range), respectively.

Also McAlister et al (2005) did a study with 1055 subjects and found statistical differences in mean length of stay between those with a PPC (27.9 days) and those without (4.5 days).

These studies also demonstrates a relationship between the two variables; PPC and hospital stay, and how important reducing incidence of PPC is to reduce number of days in hospital, and subsequently limit the increased costs.

Economic variations between hospitals, departments in hospitals and patient groups makes it difficult to define a specific price on one hospital day, but it is estimated to be from 3000 to 5000 NOK (Helse- og omsorgsdepartementet, 2012). It is then self-explanatory that with the high number of abdominal surgeries performed every year prolonged hospitalizations due to post-operative complications is substantial and it is of great importance to lower these.

In summery; in this study there are no statistical differences between the intervention groups on any of the effect variables. A closer look at the actual findings suggests there is a tendency for fewer PPCs and shorter hospitalization in the group with the highest frequency of breathing exercises.
These are, at least, interesting results, which suggests a large-scale study would be of interest.

The role of physical therapy in the surgical department

The fact that some studies show no positive effect of chest physical therapy on incidence of PPC or length of hospitalization, and that some systematic reviews does not support routine use of breathing exercises post-operatively, does not necessarily mean that chest physiotherapy is not possibly advantageous for this population. The negative results could be caused by the use of an ineffective method or technique, or like both Thomas, McIntosh and Dean (1994) and Örman and Westerdahl (2010) suggests, an insufficient treatment dosage.
In designing this study I looked after well-documented interventions in earlier studies. These were difficult to find, as most studies only have very brief descriptions of their interventions, (e.g. Hall et al., 1991a ; Denehy et al., 2001) and lack information of, for instance, the position they were performed in and which exact instructions the patients were given. This also makes it difficult to use the results from some of the studies, because the actual intervention studied is unclear to the reader.
On the other hand, results from high-quality studies, e.g. clinical guidelines or systematic reviews, showing little or no effects of chest physical therapy should act as a reminder of being critical to continuing doing the things the way they "always have been done" and replacing this with an evidence-based practice with high quality.

Prioritizing high-risk patients?

As hospitals and their departments are under a constant pressure to tighten budgets and cut down on staff resources, physical therapy is one of the groups risking cuts in staff if it cannot be proven invaluable in post-operative care. The importance of justifying the health care costs they are responsible for is central. If physical therapy after surgery does not lead to fewer complications, faster rehabilitation, fewer hospital days and lower costs, it cannot be claimed that physical therapy is necessary for these patients. And if doing breathing exercises after surgery has no effect, then we should not burden the patients with the extra effort it leads to, and the use of the physical therapist's expertise and time cannot be justified.

Studies from the 90s and the last decade have drawn attention to prioritizing patients that have a high risk of acquiring PPC and really is in need of help and will benefit the most from chest physical therapy

(Fagevik Olsen, 2005 ; Chumillas et al., 1998 ; Mackay, Ellis & Johnston, 2005). This means using fewer resources on the low-risk patients and to avoid indiscriminate use of chest physical therapy (Chumillas et al., 1998). If we found a way of prioritizing high-risk patients it would probably also be easier to justify the use of resources on these, because clinical research would most likely show more positive effects than if all patients were treated.

At the local hospital where this project was carried out, physical therapy is not provided for patients going through laparascopy. These patients get a brochure, much like the one used in this study, from the nurse pre-operatively, and are helped with mobilization by a nurse post-operatively.
All patients going through open abdominal surgery currently receive chest physical therapy. If, like newer research suggests, one should only prioritize the high-risk patients, an approach like the laparascopy procedure for those categorized as low-risk could be an alternative.

Finding a useful risk-assessment tool would then be important (see chapter 5.2.3).

The focus on high-risk patients is substantial in research articles. However, Fagevik Olsen et al (1997) found a significant reduction of PPC also in the low-risk patients going through abdominal surgery; of their low-risk patients four of 132 patients (3 %) in the intervention group developed a PPC, whereas 32 of 153 patients (21%) in the control group did ($p<0.001$). The authors concluded that all patients going through major abdominal surgery should receive chest physical therapy pre-operatively, but especially the high-risk patients. This could be considered a contribution to the one-sided focus on the high-risk patients, even though it is outnumbered by articles stating the opposite.

Are breathing exercises enough?

In this study I have focused on breathing exercises, but there is one other treatment of great importance for the pulmonary changes following surgery; ambulation. All the subjects in this study were told about the importance of mobilization out of bed and were encouraged to frequent mobilization. Both the patient's position, the amount of activity and the intensity with which it is performed is of importance. Mackay, Ellis and Johnston (2005) suggest that much of the positive effects seen from chest physical therapy could be confounded by the effects of changing position and mobilization. In their study there was no significant difference between a group doing deep breathing exercises in addition to mobilization and the group doing mobilization alone (Mackay, Ellis & Johnston, 2005). But if this is the case, if there is no difference in incidence of PPC, is it then no use in doing breathing exercises post-operatively? Yes, according to the results in a different study (Orfanos, Ellis & Johnston, 1999) deep

breathing exercises lead to a greater increase in tidal volume than did ambulation. And the increased tidal volume is one of the wanted effects of physical therapy, to prevent and treat atelectasis, and thereby prevent the development of PPC.
A combination of these two interventions seems to be most beneficial.

5.1.2 Answer to the secondary research question

The secondary research question of this study was:

Is the project design adequate and viable in a large scale study?

This study was a pilot study, what Domholdt called a "dress-rehearsal" for designing a possibly larger study (Domholdt, 2000, p.430). The goal was to include 20 persons in this pilot study, but due to limited time and staff only 12 were finally included, consented and went through the study.
As pointed out earlier; the sample size in this study is small and this makes it impossible to generalize the results to the whole population. But as a pilot study it still is valuable and a helpful background for a subsequent larger scale study which can hopefully give clear results.

Compliance to recommendations

In designing a study with an intervention the subjects' compliance to the intervention is essential. If persons are assigned to a group to test the effect of an intervention it is crucial to know if they really performed what they were assigned to. If not, the effects seen after the intervention period might possibly be due to other factors and the validity of the study is threatened.
According to the results in this study, the subjects in the 3TD-group followed the recommendations they got, whereas in the other group there was a great difference between the subjects concerning compliance to the intervention. The median in the 1H-group was 21.5 sessions the first four post-operative days, but this group's registered values had a range of 3-49, reflecting the great variation between the subjects. One of the subjects in this group actually only did the exercises three times; less than any of the other subjects, independent of group allocation.
In addition, like mentioned earlier, there is a possibility that compliance is even lower in real life, as the knowledge of participating in a study could lead to an altering of actions (Polit & Beck, 2008, p.264), for instance higher compliance (Mackay, Ellis & Johnston, 2005). The awareness of this will be of importance when discussing the results of a possible larger study, and when implicating them to clinical practice.

Based on these compliance results it seems the planned high-dose intervention was difficult to achieve. It is impossible to make a conclusion whether or not doing breathing exercises once every waking hour leads to wanted effects, because in fact very few of the test subjects actually performed this intervention. If the sample size was substantially larger we could make conclusions about effects of *giving these recommendations*, but with a compliance as low as here, we could not make conclusions about the effects of actually following the prescribed dosage.

One other study (Ricksten, Bengtsson & Soderberg, 1986) has registered the frequency of chest physical therapy sessions. In that study the participants were told to do breathing exercises, 30 breaths with different devices (Triflo, PEP-mask, CPAP) every hour, comparable to this current study. The frequency was registered by a nurse or the patient himself. The authors found that on the day of surgery the PEP-group had a mean of 5.6 sessions, and a mean of 10.8, 10.4, and 7 sessions on the first, second and third post-operative day, respectively. Compared to this current study the subjects in Ricksten, Bengtsson and Soderberg's study had a considerably greater compliance; a mean of about 28 sessions the first three post-operative days. The reason for this is not known. It could be the patients had a closer follow-up by the physical therapist or nurse, but this is not explained clearly enough in that trial to decide.

Even though most subjects in the 1H-group did not perform the recommended frequency of breathing exercise sessions, they still did the exercises almost twice as often as subjects in the other group. If, in a larger study, the results of the study showed that those in an 1H-group had less PPC and shorter length of stay than the 3TD-group (like in this pilot study) a recommendation of exercises once hourly could be beneficial even though the compliance was not optimal.
We do not know what the case would be if these participants were told to do exercises only five or six times a day; would they follow these recommendations, or would they also in this case do substantially less? It seems three sessions a day were achievable for most subjects, and maybe the participants found the other frequency to be more stressful, or that it was not possible to achieve because of nausea or many medical procedures the first days, and so they gave up doing it as frequent? Or they might not have faith in the intervention and found it useless?
Maybe a closer teamwork between physical therapists, nurses and physicians, would be necessary to improve the compliance and possibly reduce incidence of PPCs? Another alternative is letting the patient take responsibility for her/his own health and just provide information of the importance of exercises as well as instructions pre-operatively.

The compliance to recommendations should be included if the study was done in large scale.

Should a large scaly study be designed differently?

I would claim, after going through literature on this area and carrying out this pilot study, that it would be of great clinical relevance to perform a large scale study concerning the frequency by which breathing exercises should be carried out.

In a pilot study like this there was not enough time or resources to establish good routines, whereas in subsequent larger study things would hopefully run more smoothly, after adjusting factors which are weaknesses or threats to the quality of this study.

By doing this pilot study I have realized there are changes needed to be done to ensure doing a trial with high methodological quality and such making it clinically relevant for this given population.

Following is a list of factors which are considered necessary, or at least beneficial, to change if a larger study was to be carried out, these will be described in detail in chapter 5.2;

A clear definition of post-operative pulmonary complications would be essential. Cluster randomization would be preferred, as well as blinding of the researchers if necessary resources were available. To test the effect up against an untreated control-group would give valuable information on effect of the breathing exercises compared to natural variations in untreated patients, although ethical considerations would have to be made concerning holding back on treatment which most likely has beneficial effects.

A pulmonary risk score would be useful in a larger study, but the one used in this study was not optimal for that purpose, and a simpler alternative with relevant risk indicators would have to be found. A long-term evaluation was intended to perform in this pilot study, and finding effective procedures for this would be advantageous in a future study.

In addition, a tool to measure the patients' opinion on the dosage and effect of the treatment would also be relevant.

More resources would be necessary, creating the possibility for more researchers or assistants to partake. If this was the case the study would not be so vulnerable for absence or unforeseen event e.g. if one physical therapist was on sick-leave, or there was a meeting the nurse had to attend.

More resources could also allow an increased study time-span to include subjects, possibly with the use of patients in several hospitals (multicenter study).

A larger study would enable using statistical methods meant for a greater number of subjects, and could give a better chance of detecting statistical differences. This is described in the following paragraph.

Statistics

If the sample size was larger the chance for a normal distribution of the data material would be greater. A test for normality with a graphical presentation of the data in a histogram for the different variables would be appropriate to check this (Christensen & Dirksen, 1996). Given it was not, finding an appropriate method of transforming the variables to make it normal would be an option. With a normal distribution of the data, parametric tests could be used (Christensen & Dirksen, 1996). Unpaired tests would still be correct, since the purpose was to test for differences between the two intervention groups. To test differences between the groups' pre-operative data and post-operative outcomes suitable tests would be unpaired t-tests for continuous (age, height, BMI) and ordinal (pulmonary risk score) data and the chi-square test for categorical data (smoker/non-smoker, sex) (Polit & Beck, 2008, p.592 ; Christensen & Dirksen, 1996).

In addition to the tests done in this pilot study it would be of interest, if the sample size was larger, to test if there was a correlation between the actual number of breathing exercises the subjects performed and the incidence of PPC.

5.2 Discussion of method

5.2.1 The study design

The aim of this study was to test the effect of an intervention, and an RCT is then considered being the gold standard, the most powerful method for testing effect (Polit & Beck, 2008, p.263). The strength of this design is that differences seen between the groups can be ascribed the differences in the intervention, as all other factors possibly affecting the results are equal between the two groups (Kampmann & Christensen, 1996).

But experiments, which the RCT is, have been criticized for being artificial and reductionistic (Polit & Beck, 2008, p.264). In clinical practice one will most often, to some degree, customize the physical therapy treatment to fit the individual patient. This can be based on the patient's age, severity of illness or need for motivational help. In an experimental study there is no room for this, e.g. in this study the tests and instructions post-operatively were done between 8 and 10 a.m., whereas for some subjects who struggled with nausea or who was in the middle of dressing or eating breakfast, the afternoon would have been a better time of day for meeting with the physical therapist. In this way this design leads to an artificial way of communicating with the patients, because in real life, the physical therapist would adjust the timing of the treatment which could lead to a more effective treatment session.

Experiments are reductionistic in that they focus only on what is decided in beforehand of the study, and constrains human experience (Polit & Beck, 2008, p.264). This study design gave no possibility for e.g.

asking the patients if they found the treatment meaningful and how this affected their motivation for doing the exercises. However, this was outside the scope of this study.
By using an experimental design we also risk missing the causal explanation *why* there is a connection between variables (Polit & Beck, 2008, p.264), e.g. *why* do patients who are recommended doing exercises once every waking hour have a lower incidence of PPC than those in the other group? Or *why* the compliance to the recommendations is lower in one group compared to the other? By choosing an experimental design in this study we only get the answer to the question *is* there any difference in effect?

In this study the randomization procedure was done by the subjects drawing one out of twenty envelopes which contained the group allocation. It was not possible for the responsible researcher to affect the randomization in any way, as the envelopes were prepared by persons not involved in the study. This strengthens the internal validity of the study (Domholdt, 2000, p.85).
But by using this randomization method there was a risk that the size of the intervention groups would be very different, e.g. the ten first subjects were assigned to one group, and only two to the other group. An alternative randomization procedure could have been beneficial to ensure an equal distribution of subjects to the two groups; cluster randomization, where one randomly assigns clusters (or groups) of individuals to the different intervention groups (Kampmann & Christensen, 1996). In the case of this current study, the clusters would have to be quite small, e.g. 3-4 subjects to ensure that there would be subjects in both groups.
In addition, this procedure could help in preventing "contamination of treatments", a clouding of the results, if groups of patients who entered the hospital e.g. during the same month were randomly assigned to the same intervention group (Polit & Beck, 2008, p.258). If subjects from different intervention groups in this study talked to each other about their intervention and expectations in the hallway, this could affect the results. This would be prevented if they were randomized as described here.

A weakness of this study is that it was not blinded. This could have biased the results of the study, by the subjects' or the researcher's awareness of group allocation (Polit & Beck, 2008, p.260). Even as I did not intend to affect the results in any way, I might, in some way, have implied to the subjects my beliefs in the different interventions. And the patients in one group might have a greater confidence in one of the interventions, than what the other group had, risking expectancy bias (Polit & Beck, 2008, p.260) and by this being a threat to the study's internal validity (Domholdt, 2000, p.88). The possible disappointment of not being assigned to the other group could have led to lower compliance to the

intervention, or lower motivation for early mobilization. If this was the case, this would affect the results. Blinding is not always possible, like here, where the interventions were active exercises, and where the ethical committee (REK) required that the different interventions where described in the informed consent scheme.

One way of solving blinding of the researcher would be to have more researchers or assistants available, so that different persons were responsible for the randomization procedure, the pre-operative testing, the post-operative follow-up and the analysis of the data material.

One of the study's strengths is that it describes the intervention in detail, both the quantity of the exercises and the qualitative performance of them. The position by which the exercises are performed is also described, which minimizes the chance of the results being confounded by the respiratory effects of change in position (Mackay, 2005). This detailed description makes it possible to copy the intervention in a subsequent larger study.

There was no untreated control-group in this study, which can be a weakness because we will not know if the results we get are caused by the treatment or by other conditions (Kampmann & Christensen, 1996). On the other hand, the objective of this study was to look at differences between different dosages of the same treatment, and we can assume that natural variations in the patients' health or other factors affecting the results were present in both groups. For ethical reasons an untreated control group was not included here; earlier studies with an untreated control group have shown good results of chest physical therapy (Fagevik Olsen et al., 1997 ; Roukema, Carol & Prins, 1988). In addition, it is current practice that all patients going through open abdominal surgery at the local hospital receive physical therapy. This means that if including an untreated control-group we would hold back on routine treatment which most likely was beneficial for the patients.
With two very different treatments, such as e.g. exercises once every waking hour compared to a non-intervention control group, the chance is, the results would have differed more from each other (Polit & Beck, 2008, p.252) and we would see clearer results, at least in a large scale study.

The fact that no physical therapists work Sundays at the local hospital, lead to a considerable amount of missing values. Since most surgeries were performed in the middle of the week these values where missing on the third and fourth postoperative day. With such a substantial percentage of missing information, like measurement of SpO2 on day three and four (figure 4.3), valuable information is lost. This will most likely affect the results, especially in a small study like this.

Ethical considerations

There is a possibility that subjects that had not decided about participation before the day of admission could feel pressured into participating in the study, since the physical therapist responsible for the project was the one that met them that day and asked them for an answer. This possibility was supposed to be reduced by help from a nurse requesting the patients' participation at the pre-operative control, but some of the patients needed time to think this over and therefore this was the result.

The full pre-operative clinical profiles of the subjects in this study who developed a PPC, as well as the subject categorized in the moderate-to-high pulmonary risk would be of interest, but due to the small sample size there was a risk patients participating in the study could be recognized by themselves or others if reading this paper, and only parts of their profiles which were considered important for answering the research questions is therefore presented.

5.2.2 Sample and subjects

12 persons were included in this pilot-study, and the small sample size is probably the most important weakness of this trial. The plan was to include 20 persons, but this was unfortunately not achieved. An even greater sample size, with at least 50 test subjects, as stated in chapter 3.3. on power analysis, would be desirable in a subsequent study.

There were no statistical differences pre-operatively between the two groups' demographic characteristics or in the given risk-factors for PPC. This could be due to the small sample size (a type 2-error, see chapter 5.2.4), but having a closer look at the numbers in table 4.1 it appears there were no clinically important differences either.

The higher median and range values on weight and BMI seen in the 3TD-group could be due to a greater percentage of men in this group than the other. As mentioned in chapter 4.1 one person in the 1H-group performed below reference values on the spirometric test, which makes the number of this group look inferior to the other group's number. Except from this person, all other subjects had normal FVC and FEV1 values.

Based on these considerations we can assume the two groups were equal at baseline on variables that could affect the results, which contributes positively on the internal validity of the study.

Possible differences between the groups at baseline would most likely be reduced with a larger sample size.

Was the sample in this study representative for the whole population? In this study the subjects were recruited successively, all patients who went through an open abdominal surgery and qualified for inclusion according to the preset criteria were asked to participate, there was no selection of particular patients, and the sample is therefore considered representative for the population.
However, some of the entry criteria excluded patients that might make the sample and population differ from each other. e.g. one person was excluded due to the need for a wheelchair for mobilizing. Mackay and Ellis (2002) claim that many research papers select less complicated cases and that their sample is not representative of the actual population. In their study the researchers included aged, frail and ill people, as well as people who died after surgery. The entry criteria in this current study were set to make it possible to do standardized measurements and give all subjects the planned intervention, but this might have led to exclusion of people that had a greater risk of getting a PPC, and may also have benefitted greatly of the breathing exercises. This, in turn, could mean that study sample deviates some from the population and could be a threat to the external validity of the study (Benestad & Laake, 2004).

Results from other studies (Chumillas et al., 1998) show that high-risk patients (patients with risk of getting PPC) are those in greatest need of, and with the greatest benefit of chest physical therapy. The limited time and the limited number of high-risk patients at this local hospital did not allow for inclusion of only high-risk patients, although this would be ideal. If the sample consisted of only high-risk patients we might expect a higher incidence of PPC, and a greater difference in the treatment effects than in a study like this which also included low risk patients.

The population here was limited to only patients in this local hospital. It is possible that the results could be generalized to a larger population, e.g. other local hospitals in Norway, or possibly even university hospitals. But which surgical procedures are performed in different hospitals was not known, and this, in addition to the possibly higher risk-profiles of persons going through surgery in the large hospitals compared to the local hospital, made it difficult to generalize the results to hospitals like those. Consequently, the population in this study did not include other hospitals.

5.2.3 Outcome measures

Postoperative pulmonary complications

The need of a clear, validated definition on post-operative pulmonary complications (PPC) is crucial in studies like this. Different definitions have been presented earlier in this paper, and nearly all articles

used as theoretical background in this paper describes a need for one universally accepted definition (Pasquina et al., 2006).
The definition used in this study was based on criteria accessible to the physical therapist in the given local hospital and they were considered clinically important by physicians with experience with this population. Defining PPC was not depending on the researcher's subjective assessment of e.g. auscultation, but relied on observations done by the radiologist, the physician's decision to prescribe antibiotics and the measurement of SpO2.
Mackay, Ellis and Johnston (2005) claim that their definition included criteria that can be assessed objectively; fever, auscultation changes, chest x-ray and increase in amount and/or color of sputum compared to what the patient reports is usual for him/her. These are also measures used in many of the studies defining PPC (Mackay & Ellis, 2002 ; Smetana, Lawrence & Cornell, 2006), including studies with a large data material (Brooks-Brunn, 1997 ; Hall et al., 1991b) and systematic reviews (Conde & Lawrence, 2008). For that reason I will have a closer look at these outcome measures – are they really suitable for defining PPC?

In the first few post-operative days fever (body temperature>38°C) is common and it is usually caused by the tissue trauma of the surgery and resolves spontaneously, according to a recently published literature review (Weed & Baddour, 2012). Pneumonia could be the reason of fever, but it could also relate to many other conditions (Weed & Baddour, 2012).
Atelectasis, which can be found in 90% of patients after surgery, might neither be a sufficient measure to define PPC. As atelectasis is transient and resolves without any intervention in many patients, using interpretation of chest x-rays might not be as relevant either (Hall et al., 1991b) and could falsely lead to a high incidence of PPC. This could be the case also in this study, which have atelectasis as one of the criteria.
If a definition has atelectasis and fever as the only criteria, as is the case in e.g. Brooks-Brunn (1997), the chance is many patients are diagnosed with PPC without it having any clinical relevance.
Lung auscultation with a stetoscope is a widely used tool, for both doctors and physical therapists. But using it to diagnose pneumonia might not be optimal; in a literature review from 2007 (Saeed) on lung auscultation as an indicator of pneumonia the author found five relevant studies, and concluded with limited diagnostic efficacy and a high interrater variability. The reliability of this outcome measure depends on the kind of stethoscope used, the surroundings (quiet/noisy) and the experience of the examiner (Saeed, 2007).
Alone, these outcome measures are not sufficient, but a combination of them and possibly, other measures, might be appropriate.

The definition used in this paper consists of some of the measures discussed here, as well as SpO2, which is discussed in the next paragraph. The fact that relevant measures to test the actual condition of the post-operative course of the patient is so uncertain, makes the definition of PPC a threat to the construct validity of this and other studies (Domholdt, 2000, p.88).

I will not try to come up with a new definition here, as this is something which clearly is much debated, without it resulting in a widely used, clear definition. But deciding on a definition in each study, one which is clearly defined, and which tells of clinically relevant complications will be important in future research.

SpO2

Pulse oxymetry is an easy, non-invasive way of measuring the hemoglobin's saturation of oxygen, but the measurement tool has limitations; it becomes unreliable when SpO2 is <50%, the patient wears nailpolish or when systolic blood pressure < 80 mmhg and peripheral circulation is reduced.
Using a pulseoxymeter does not provide information about underventilation or about a possible damaging level of CO2 in the blood, so direct arterial Po2 by a blood test is the first choice when oxygenation is critical (Singh & Hudson, 2008 ; Lumb, 2010, p.210).
Here, pulse oxymetry was used as a criterion in the definition of PPC. There were no extreme values measured. But total accuracy cannot be guaranteed, according to the above mentioned limitations.
A strength of this study is that the patient's position and external oxygen supply under measurement is described in detail. If measurement is done independent of position, one risks a higher FRC and better premises for oxygenation of the blood in sitting or standing position than in the supine position.

Spirometry

Spirometry was tested as part of the pulmonary risk score. It was performed following the standardization statement of ATS/ERS (Miller et al., 2005) to ensure test-reliability. One weakness of the spirometry testing was that the physical therapist administering the tests did not have long experience with this apparatus. To avoid this affecting the test-scores, and for ensuring correct analysis of the tests, chief physician K.S. went through all tests together with the physical therapist.
According to Miller et al. spirometry is "…invaluable as a screening test of general respiratory health (Miller et al., 2005, p.320)." But the utility of performing spirometry before abdominal surgery is debatable. Whereas Torrington and Henderson (1988) claim pulmonary function testing is one of the key factors for predicting risk of post-operative complications, others have found spirometry to have no predictive value (Zibrak, O'Donnell & Marton, 1990 ; Roukema, Carol & Prins, 1988). In Roukema,

Carol and Prins's study (1988) study of patients going through upper abdominal surgery there was no difference in incidence of PPC between those with normal spirometric values and those with abnormal values.
Zibrak, O'Donnell and Marton (1990) did a literature review and found no measureable benefit of testing spirometry before UAS to predict risk of pneumonia, prolonged hospitalization or death post-operatively. A clinical assessment of respiratory status is considered more important (Hall et al., 1991b). On the other hand, pulmonary function testing, together with clinical history, could give an answer to if the patient has a pulmonary diagnosis, e.g. chronic obstructive pulmonary disease (COPD) if there is suspicions of this, which is stated as risk factors in some studies (Smetana, Lawrence & Cornell, 2006 ; Fagevik Olsen, 2005). But the routine use of pre-operative spirometric testing cannot be justified. Spirometric values were not tested post-operatively, due to already well-documented decreases in FVC and FEV1 after abdominal surgery (Fagevik Olsen et al., 1997 ; Forgiarini Junior et al., 2009 ; Chumillas et al., 1998).

Rate of mobilization

Considering the rate of mobilization in this study, it seems there was no need for differentiating between so many levels, as all subjects reached mobility indicator 2 on the first day. A possibly more meaningful and simpler measure of mobility would be to register when the patient was fully mobilized, e.g. could walk 30 meters without help, or was able to walk one floor of stairs. This also seems more relevant for the length of hospital stay, as fully mobilized patients often are ready for leaving hospital at this stage.

Pulmonary risk score

The pulmonary risk score used in this study was originally used in Torrington and Henderson (1988). In choosing a way of assessing post-operative risk for pulmonary complications in this study, it was of importance that the assessment could be carried out by the physical therapist, considering the limited staff resources available. Many of the suggested risk assessment tools presented in other articles depends on results from blood samples, or tests or analyzes which are only carried out by nurses or physicians, something which was not possible here.
Considering the previously discussed debate around routine pulmonary function testing, it seems this part of the risk score could have been left out. The remaining factors in the schema are factors also described in later studies as risk factors (Brooks-Brunn, 1997 ; Arozullah et al., 2001 ; Fagevik Olsen et al., 1997). Leaving the spirometry out of the risk score also makes it a tool that is simpler and takes less time to complete.

Using a risk calculation like this presupposes that the different factors used in the schema have clear definitions (e.g. smoker, pulmonary antecendents), which was not the case with this used in Torrington and Henderson and Chumillas et al's articles. Without it, the reliability of this measurement tool is low and threatens the internal validity of the study, which definitely is the case with this pulmonary risk score.

A model developed by Fagevik Olsen for deciding the amount of physical therapy prescribed for each patient was presented in the theoretical background. This model might be more useful in clinical practice than in a research project, as using it in research would mean that these different quadrants would have to be well-defined with strict criteria. In addition to, or as a part of a tool like this, individual adaption to each patient is important. This means that also psychological factors like the patient's motivation and cognitive status should be considered important for deciding both pre- and post-operative follow-up.

5.2.4 Statistics

The data of this study is plotted to PASW manually, by one person, which means there is a risk of mistakes in the data registering. However, the data material is not so large and all numbers have been controlled twice.
Since there were few subjects in this study, there was a risk that only one person with extreme values, so-called *outliers* (Domholdt, 2000, p.434), would skew the data distribution. Median (range) was by this reason chosen as the measure of central tendency, as it is insensitive to extremes (Polit & Beck, 2008, p.563)

The small sample size in this study makes it difficult to draw any absolute conclusion on effect and it cannot be claimed that the results from these 12 subjects is applicable for the whole population.
With a small sample size there is a risk of making what is called a type 2 mistake; that the statistical tests tell us there is no effect of the intervention when in fact there is (false negative) (Skovlund & Vatn, 2004). With few subjects the power of the tests are weak, and even clinical important effects might not be discovered (Pasquina et al., 2006 ; Skovlund & Vatn, 2004).

The analysis of the data in this study was done on an intention-to-treat basis. Although there were no drop-outs in this study the intention-to-treat principle was important; it led to all of the subjects in the 1H-group being analyzed in that group, despite the fact that some of them did the exercises much less

frequent and in practice got the intervention of the other group. The choice to include all test subjects' data in the analysis, and not exclude any may have reduced possible positive effects of the intervention with the highest frequency because the subjects did not follow the recommendations they were given. But using the intention-to-treat principle is a strength of this study because it gives a realistic result, and makes it clinically relevant.

5.3 Practical implications

Carrying out an evidence-based practice means combining knowledge retrieved from research, from experience and from the patient. Additionally, all clinical practice is acted out in a context, which means that we have to take into consideration culture, economics, politics and the practical conditions in the environment we work in (Nortvedt et al., 2008, p.14). When looking at implementation of new knowledge, these are all factor we need to address.

This pilot study revealed there was a tendency for fewer PPCs and shorter hospitalization in the group which was recommended the highest frequency of breathing exercises, that is, once hourly. I would claim existing routines should not be changed based on a study this small. But the pilot study can still be useful, mainly as an invitation to designing a larger study, but also useful for clinical practice; it substantiates the current recommendations given to the patients at this local hospital. And the fact that compliance was so low tells us this is something we need to be aware of in our consultations with patients, and maybe bring up when meeting with each patient?

The previous experiences we have as therapists and the knowledge each patient holds can help us choosing the correct way of addressing patients and making individually adjusted treatments for each of them, at the same time as maintaining the recommendations research prompt us to. This could mean talking to the patient in a specific way (e.g. formal versus informal), making sure the patient has an electrically adjusted bed so she/he can mobilize her/himself or making agreements with the patient's husband/wife to help the spouse remembering the exercises or help in mobilization.

This study could not give a clear answer to whether a risk evaluation should be performed in each patient before initiation of physical therapy. But based on previous research presented in this paper's theoretical background, and on the economics of the public health service, I would suggest this being considered in near future at this hospital. As the physical therapy treatments have changed from passive to more active the last decades there is a greater opportunity for the patients themselves to take responsibility over his/her postoperative rehabilitation. And so they should; this would free resources for patients needing them more.

Finding forums to present the results from a pilot study like this would also be important; in this way we can increase other health professionals' awareness of the relationship between pulmonary alterations and complications, hospitalization and costs and what research says about the possibilities of reducing these. This will hopefully lead to a closer teamwork where everyone pulls in the same direction, and both the patients and the hospital will profit.
I have planned to present this study at the Physical therapy Department for my colleagues, at the Gastro Surgical ward for the nurses and doctors there, and I am also hoping to present it for the board of directors in the hospital.

5.3 Future work

There has been a lack of dosage studies in research on chest physical therapy. In the future large, randomized, controlled studies are needed to test the effects of different frequencies of breathing exercises. The studies will need to have detailed descriptions of their interventions, and registration of compliance would be beneficial.
Another aspect of dosage is the number of repetitions performed in each exercise session and the intensity with which the exercises are carried out. Future research should focus also on this, and together with studies on frequency, make it possible to give concrete advice to the patients about optimal dosage.

The role of breathing exercises versus mobilization in post-operative care was mentioned in this paper. The objective of this pilot study did not allow further investigation of it, but studies looking at this would be of great relevance, both to reduce the strain on the patient with many different methods and to possibly reduce time spent on methods with little effect.

Another suggestion for future trials would be to compare simple deep breathing to breathing exercises with devices like the PEP-mask/mouthpiece. If taking deep breaths is as effective as the other methods, large economical expenses could be saved.

A great amount of trials have been performed previously, but there is still a need to answer questions concerning chest physical therapy in relation to open abdominal surgery. High quality will be essential in such studies.

6.0 Conclusions

The results from this pilot study suggests that recommendations about doing breathing exercises as often as once hourly could be of benefit for patients going through open abdominal surgery. However, the power of the sample size in this study (n=12) is too small to conclude about the effects of the two interventions, and there is a need for further research in studies of a considerably larger scale. In addition, compliance to the recommendations given was low in the once-hourly group, which means the effects of actually performing the prescribed dosage are not known.

Due to the small sample size and few high-risk patients in this study it was not possible to draw a conclusion about whether a risk evaluation before surgery would be beneficial. Previous research has advocated a categorization of patients with high and low pulmonary risk as a tool for determining which treatment is most suitable for each patient. This could be relevant in this local hospital if a suitable assessment tool was found.

A larger study focusing on frequency of breathing exercises is considered valuable to clinical practice.

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Helse Fonna

Forespørsel om deltakelse i forskningsprosjektet

"Fysioterapi etter åpen mageoperasjon"

Bakgrunn og hensikt
Som et ledd i en Mastergradsutdanning ved Høgskolen i Bergen gjennomføres en studie for å se nærmere på fysioterapibehandling i forbindelse med åpen mageoperasjon. Du blir spurt om å delta i denne studien fordi du skal gjennomgå en slik operasjon.
Slik praksis er i dag får alle som gjennomgår åpen mageoperasjon oppfølging av fysioterapeut på sykehuset. Fysioterapeuten gir anbefalinger om, og hjelp til, pusteøvelser og aktivitet i dagene etter operasjonen. I dette prosjektet vil fokus være på hvordan pusteøvelser kan bidra til å forhindre lungekomplikasjoner, som for eksempel lungebetennelse, etter operasjon. Hensikten med prosjektet vil være å danne et grunnlag for best mulige anbefalinger for personer som skal gjennom mageoperasjon.

Hva innebærer studien?
Alle som gjennomgår mageoperasjon blir automatisk henvist til, og får oppfølging av fysioterapeut. Som deltager i studien vil du, i tillegg til vanlig rutine, bli bedt om å gjennomføre en pusteprøve (spirometri) dagen før operasjonen, samt i forbindelse med poliklinisk kontroll i etterkant av operasjonen. Pusteprøven gjøres i fysioterapirommet like ved avdelingen.
Deltagerne i studien vil bli tilfeldig fordelt i to grupper, hvor de vil utføre forskjellig frekvens av pusteøvelser etter operasjonen for å undersøke om dette gir noen forskjeller i lungekomplikasjoner.
Du vil også få utdelt et skjema hvor du skal krysse av hvor ofte du gjør pusteøvelsene de fire første dagene etter operasjonen.
Oppfølging av fysioterapeut vil bli som følger:

- Dagen før operasjon:
  Samtale med fysioterapeut og gjennomføring av pusteprøve
- De fire første dagene etter operasjon:
  Daglig oppfølging av fysioterapeut med gjennomgang av pusteøvelser, samt hjelp til å komme i aktivitet.
- Ved poliklinisk etterkontroll:
  Gjennomføring av pusteprøve

Du vil få oppfølging av fysioterapeut så lenge du vurderes til å ha behov for det, også utover de fire første dagene.

Mulige fordeler og ulemper
Du vil følges opp av fysioterapeut som ved normal rutine før og etter operasjonen. Ekstra undersøkelse utover dette vil være pusteprøve. Det er ingen kjente fordeler eller ulemper ved å delta i studien.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Når studien er avsluttet vil personalia om deg bli slettet.
Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Terese Tveit Helland, tlf: 975 74 995.

Dette prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest) den 31.08.2011 med saksnummer 2011/1261.

Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel A – *Personvern, biobank, økonomi og forsikring.*

Samtykkeerklæring følger etter kapittel A

Kapittel A - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg i forbindelse med studien er din alder, høyde, vekt, samt eventuelle risikofaktorer for å få lungekomplikasjoner etter operasjonen (lungesykdom, hjertesykdom, røyking). Dette hentes fra din innkomstjournal ved sykehuset, i tillegg til at du vil bli spurt om det av fysioterapeuten dagen før operasjon.
Lungekomplikasjoner og antall dager du ligger på sykehuset vil dokumenteres i studien. Opplysninger om dette hentes fra din journal, eller ved samtale med legen/sykepleier.
De fire første dagene etter operasjonen vil det også måles mengde oksygen i blodet ditt (oksygenmetning), samt noteres ned hvor langt du er kommet i forhold til aktivitet (sitte, stå, gå).
Oksygennivået i blodet ditt testes ved å sette en måler/klype på fingeren din. Dette er helt smertefritt.
Resultatet fra pusteprøven din vil også bli brukt i studien.
Alle som får innsyn har taushetsplikt.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi
Det er ingen økonomiske interessekonflikter knyttet til studien.

Informasjon om utfallet av studien
Prosjektet vil bli presentert som masteroppgave ved Høgskolen i Bergen.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien ”fysioterapi etter åpen mageoperasjon”

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Helse Fonna

Registreringsskjema pre-og postoperativt

Fylles ut av fysioterapeuten

Risiko for postoperative lungekomplikasjoner: Moderat/Høy ___ Lav___
ASA-score: ___

Preoperativ test:

Dato/Tidspunkt: _____

FVC	%forventet	FEV1	%forventet	FEV1/FVC	%forventet	PEF	%forventet	SpO2

1.-4. postoperative dag:

Dag	Dato	SpO2	Lungekomplikasjoner	Mobiliseringsnivå
1				
2				
3				
4				

Sykehusdøgn: ___

Poliklinisk kontroll:

Dato/Tidspunkt: _____

FVC	%forventet	FEV1	%forventet	FEV1/FVC	%forventet	PEF	%forventet	SpO2

Lungekomplikasjoner:

Helse Fonna

Registreringsskjema : pusteøvelser

Dag	Antall økter
Dag 1 etter operasjon	
Dag 2 etter operasjon	
Dag 3 etter operasjon	
Dag 4 etter operasjon	

Sett en strek per økt med pusteøvelser du har gjennomført
En økt = 10-15 repetisjoner x 3 serier

Lever skjemaet til fysioterapeuten før du reiser hjem.

Preoperativ risiko score for lungekomplikasjoner

Parametre		Score	
Spirometri*:	FVC < 50%	1	
	FEV1/FVC 65-75%	1	
	FEV1/FVC 50-65%	2	
	FEV1/FVC < 50%	3	
Alder ≥ 65 år		1	
BMI > 25%		1	
Abdominal kirurgi, øvre snitt		2	
Historie lunge*:	Tidligere lungehendelse**	1	
	Hoste og ekspektorat	1	
	Røyker nå	1	
Samlet score (maks 11 poeng)			

*Samlet score: spirometri: 0-4; sykehistorie lunge: 0-3.
**Pneumoni, bronkitt, astma, KOLS

Legg sammen poengene og sett sirkel rundt risikonivå i tabellen under:

0-3 poeng	Lav risiko
4-6 poeng	Moderat risiko
≥ 7 poeng	Høy risiko

Oversatt fra: Chumillas, S., Ponce, J.L., Delgado, F., Viciano, V. og Mateu, M. (1998) *Prevention of Postoperative Pulmonary Complications Through Respiratory Rehabilitation: A controlled Clinical Study.* Archives of Physical Medical Rehabilitation, 79, s.5-9.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Camilla Gjerstad	55978499	31.08.2011	2011/1261/REK vest
			Deres dato:	
			15.06.2011	

Vår referanse må oppgis ved alle henvendelser

Ola Drange Røksund
odro@helse-bergen.no
Barneklinikken

2011/1261 Fysioterapi etter åpen mageoperasjon

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk i møtet 18.08.2011.

Prosjektomtale (revidert av REK):
REK Vest anser Helse Fonna HF som forskningsansvarlig for prosjektet. Hensikten med dette masterprosjektet er å undersøke hvordan det å gjøre øvelser tre ganger daglig versus hver time påvirker antall lungekomplikasjoner, antall sykehusdøgn, pusteprøve (spirometri) og grad av mobilisering hos pasienter etter åpen mageoperasjon. To randomiserte grupper med pasienter vil utføre forskjellig frekvens av postoperativ lungefysioterapi. Totalt vil 200 forskningsdeltakere bli inkludert.

Forskningsetisk vurdering

Komiteen har ingen innvendinger mot gjennomføringen av prosjektet.

REK ber om deltakerne informeres om at det vil bli foretatt randomisering og at de to randomiserte gruppene vil utføre forskjellig frekvens av lungefysioterapi etter operasjon for å undersøke om dette gir forskjeller i lungekomplikasjoner.
Noen mindre feil/unøyaktigheter i informasjonsskrivet bes korrigert – se vedlegg.

REK legger til grunn at personidentifiserbare opplysninger vil bli slettet/anonymisert så snart det ikke lenger er behov for ytterligere oppbevaring og senest ved prosjektslutt 30.06.2013.

Vedtak
Prosjektet godkjennes på betingelse av at ovennevnte vilkår tas til følge.

Prosjektet skal sende sluttmelding til REK Vest på fastsatt skjema via saksportalen SPREK senest et halvt år etter prosjektslutt.Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.
Vi ber om at alle henvendelser sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no .Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen,

Jon Lekven (sign.)
komitéleder

Camilla Gjerstad
rådgiver

Kopi til: post@helse-fonna.no

De regionale komiteene for medisinsk og helsefaglig forskningsetikk foretar sin forskningsetiske vurdering med hjemmel i helseforskningsloven § 11, jfr. forskningsetikkloven § 4. REK Vest forutsetter at dette vedtaket blir forelagt den forskningsansvarlige til orientering. Se helseforskningsloven § 6, jfr. § 4 bokstav e.

Saksbehandlingen følger forvaltningsloven. Komiteenes vedtak etter forskningsetikklovens § 4 kan påklages (jfr. forvaltningsloven § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes REK Vest (jfr. forvaltningsloven § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. forvaltningsloven § 29).