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Kinesio®–taping after median sternotomy – an initial trial

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„Alles Wissen und alles
Vermehren unseres Wissens endet
nicht mit einem Schlusspunkt,
sondern mit einem Fragezeichen.“

Hermann Hesse

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Zusammenfassung

Die Schmerzbehandlung nach Herz-Thorax-Eingriffen via *medianer Sternotomie* ist für die Rehabilitation der Patienten essentiell. Auch wenn die Behandlung nach dem *WHO*-Stufenschema mit *Cyclooxygenase*-Hemmstoffen und *Opioidanalgetika* erfolgt, sind die Schmerzen und Schmerzmittelnebenwirkungen eine Herausforderung für die Behandler. Da Nebenwirkungen durch die Gabe von *Opioidanalgetika* vermieden werden sollen, kommt es in 60 % der Behandlungen zu einer Unterdosierung. Schmerzsensationen bei unzureichender *Analgesie* führen zu einer verlängerten *Rehabilitation*, da Patienten Bewegungen und Atemexkursionen einschränken. Eine zu geringe Dosierung der Schmerzmittel birgt die Gefahr von Thrombosen, Embolien, Lungenentzündungen und Herzinfarkten, wodurch Krankenhausaufenthalt und -kosten um ein Vielfaches steigen können.

Physiotherapeutische Maßnahmen und alternative Heilmethoden bieten die Möglichkeit, Schmerzen ohne Schmerzmittelnebenwirkungen zu therapieren. Zahlreiche Studien untersuchten die Wirksamkeit von Akupunktur, *TENS* und physiotherapeutischen Interventionen auf Schmerzen nach chirurgischen Eingriffen. Tapen zur Schmerzreduktion nach Herz-Thorax-Eingriffen ist weitgehend unerforscht. Lediglich eine Studie untersucht und zeigt die schmerzmindernden Effekte von Kinesio ® Tape nach *Lobectomie* durch *Thoracotomie* oder VATS.

Die hier vorliegende Studie untersucht die Effekte von Kinesio ® Taping nach Herz-Thorax-Eingriffen via *Sternotomie*. Zwischen September und November 2014 nahmen 39 Patienten im Alter von 66 ± 9 Jahren (m = 70 Jahre) an dieser prospektiv randomisierten Studie teil. Die Teilnehmer wurden in eine Intervention- und eine Keine-Intervention-Gruppe gelost. Probanden der Test-Gruppe wurden nach Verlassen der Intensivstation getapet. Täglich wurden in beiden Gruppen die folgenden Parameter erhoben: Schmerzintensität, Schmerzmittelverbrauch, subjektive Atmungsfähigkeit des Probanden, radiologische, *pulmonale* und mikrobiologische Auffälligkeiten, Antibiotikagabe und Nebenwirkungen des Tapes sowie die Dauer des Krankenhausaufenthaltes. Bei der Entlassung der Patienten wurde ihnen ein Abschlussfragebogen angeboten um die Patientenzufriedenheit zu ermitteln.

Getapete Patienten hatten signifikant niedrigere Schmerzwerte (2,14 ± 0,5, CI: 1,1; 3,13) als ungetapete Probanden (4,16 ± 0,6, CI: 2,92; 5,41, p = 0,01). Der Verbrauch von Opioid-Analgetika pro Proband war in der Versuchs-Gruppe signifikant geringer (1,2 ml ± 0,4 ml, CI: 0,40 ml; 2,01 ml) als in der Kontrollgruppe (3,1 ml ± 0,5 ml, CI: 2,0 ml; 4,2 ml, p = 0,01). Patienten, die mit Kinesio ® Tape behandelt wurden, schätzen ihre Atmungsfähigkeit signifikant besser ein, als Patienten, die keine Tape-Anwendung erfahren hatten ($p < 0,001$). Alle weiteren Parameter zeigten keine statistisch relevanten Unterschiede. Nebenwirkungen des Tapes traten nicht auf. Nach Beurteilung des Abschlussfragebogens zeigten Patienten der Test-Gruppe eine höhere Zufriedenheit als ungetapete Patienten.

Die positiven Effekte von alternativen Heilmethoden, die über die Haut angewendet werden, können anhand der *Gate-Control*-Theorie erklärt werden. So hemmen ankommende nicht-*nozizeptive* Reize aus peripheren Aα-Fasern und Aβ-Fasern die Weiterleitung von Schmerzreizen bis zu einem bestimmten Schmerzlevel. Nach seinem Erfinder geht die Wirkung des Tapes auf das Anheben der Haut und einen verminderten Druck auf Hautrezeptoren zurück. Die dauerhafte Reizung nicht-*nozizeptiver* Fasern durch das Tape könnte die geringere Schmerzintensität und die damit verbundenen positiven Effekte bei den Test-Personen erklären. Diese Ergebnisse gehen mit den positiven Resultaten der Anwendung von Tapes nach *laparoskopischer Cholezystektomie*, MKG-chirurgischen Eingriffen und nach *Lobektomie* einher.

Die Anwendung von *Tape* nach *Sternotomie* ist eine risikoarme, nicht-pharmakologische, kosteneffektive, vielversprechende Methode um die Atmung der Patienten zu verbessern und die Schmerzintensität und den Schmerzmittelverbrauch und somit das Auftreten von Schmerzmittelnebenwirkungen zu reduzieren.

Summary

After median sternotomy, the post-operative pain management is essential to the patients' rehabilitation and challenges medical staff. Following WHO guidelines, the pharmacological treatment of post-operative pain is the application of cyclooxygenase inhibitors and opioid pain medication. As pain medication can lead to severe side effects, the application of opioid analgesics is under-dosed in 60 % of the treatments. Patients with insufficient analgesia suffer from pain, which can lead to a prolonged rehabilitation, because patients restrict movements and breathing excursions of the chest. Under-dosed pain medication can lead to thrombosis, embolic events, pneumonia or myocardial infarctions, which increases hospital stay and costs.

Physiotherapeutic approaches and complementary medicine have the potential to reduce pain and side effects of pain medication. Numerous trials investigated the efficacy of acupuncture, TENS and physiotherapeutic interventions on post-operative pain. Taping as physiotherapeutic intervention to reduce pain after cardio-thoracic surgery is rarely investigated. Only one study examines the pain reducing effect of taping after *lobectomy* via *thoracotomy* or VATS.

This trial investigates the effects of Kinesio ® taping after cardio-thoracic surgery by median *sternotomy*.

Between September and November 2014, 39 patients aged 66 ± 9 years (m = 70 years), participated in this prospectively randomized trial. The participants were randomized into an intervention- or a no-intervention-group. Patients in the test group were taped after leaving intensive care. In both groups pain intensity, pain killer consumption, subjective estimation of breathing, radiologic, pulmonary and microbial abnormalities, the need for antibiotics, the length of hospital stay and side effects of the tapes were documented daily. At the day of hospital discharge, patients received a discharge questionnaire to evaluate 'patient satisfaction'.

Patients in the test group had significantly lower pain values (2.14 ± 0.5, CI: 1.1; 3.13) than patients in the control group (4.16 ± 0.6, CI: 2.92; 5.41, $p = 0.01$). The need for opioid analgesics per patient was significantly lower in taped patients (1.2 ml ± 0.4 ml, CI: 0.40 ml; 2.01 ml) than in untaped participants (3.1 ml ± 0.5 ml, CI: 2.0 ml; 4.2 ml, $p = 0.01$). Patients who received tape applications estimated their breathing ability significantly better than untaped patients ($p < 0.001$) did. The other investigated parameters did not reveal statistically significant differences. Adverse effects of the tape did not occur. In the discharge questionnaire, patients of the test group revealed a higher satisfaction than patients of the control group.

The efficiency of complementary methods applied to the skin can be explained by the Gate-Control-Theory. Afferent, not-nociceptive signals from Aα-fibers and Aβ-fibers diminish the transmission of pain-stimuli up to a certain pain level. The tapes' inventor proclaims that the tape lifts the skin and lowers the pressure on skin receptors, which releases a stimulus. The tapes' steady stimulation of not-nociceptive receptors in the skin could explain the lower pain values and positive effects in test patients in our trial. Our results go along with positive results of other trials. After *laparoscopic cholecystectomy*, mid-face and jaw surgery and after *lobectomy* taping revealed pain-diminishing results.

The application of tapes after *sternotomy* is a low-risk, non-pharmacological, cost-effective and promising method to improve the patients' breathing situation and to lower the pain, the need for pain medication and by this the occurrence of side effects caused by painkillers. Further trials with a greater number of probands are needed to prove our results.

Abbreviations

ASA	Acetylsalicylic-acid
ATP	adenosine triphosphate
CNS	central nervous system
COX	cyclooxygenase
CBT	cognitive behavioral therapy
CO_2	carbon dioxide
d	day
Fig.	Figure
g	gram
HPA	hypothalamic - pituitary – adrenal
MKG	Mund-Kiefer-Gesicht
mg	Milligramm
ml	Milliliter
NMDA	N-methyl-D-aspartate
Nn.	Nervi
NSAID	Nonsteroidal anti-inflammatory drugs
O_2	Oxygen
p	probability
PCA	patient controlled analgesia
PNS	peripheral nervous system
TENS	transcutaneous nerve stimulation
US	United States
VATS	video-assisted thoracoscopic surgery
WHO	World health Organisation

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Introduction

In 2015 925 200 people died in Germany. Among these 925 200 deaths 356 616 (39 %) were caused by cardio-vascular events and cardiac infarction (Statistisches Bundesamt (Destatis), 2017). Worldwide 56,4 million people died in 2015. 6.44 % of these deaths were caused by ischemic heart disease. During the last 15 years, the number of deaths caused by cardio-vascular events increased from 6,88 million deaths in 2000 to 8,76 million in 2015. Vascular diseases are the main cause of death in developed countries (WHO, 2017).

In the beginning of the 20th century, the need for treatment of cardio-vascular diseases was lower than these days. Medical progress aimed for the treatment of infectious diseases. As the incidence of infectious diseases decreased in the middle of the 20th century, cardio-thoracic surgery became a new center of attention (Jones, Podolsky and Greene, 2012). Today, heart disease is one of the main reasons for hospital stays in the US and cardiac surgeries are among the most frequently performed surgeries worldwide (Roger et al., 2012; Weisse, 2011).

Precondition for extensive surgeries is a sufficient anesthesia. Method of choice for cardio-thoracic surgery is total intravenous anesthesia (opioid combined with hypnotic) or balanced anesthesia (Opioid combined with volatile anesthetic) (Groesdonk and Larsen, 2016).

Surgical procedure

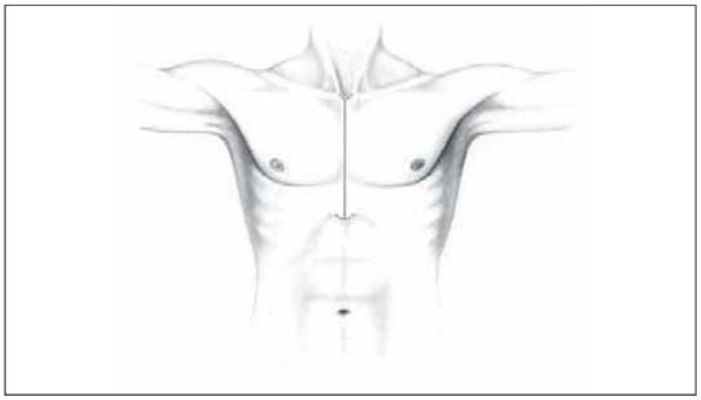

Fig. 1: **Transection for median sternotomy** from Schäfers and Aicher, 2011; printed with permission.

A common access for surgeries in the anterior mediastinum is the median sternotomy (Berchtold, Bruch and Trentz, 2008). Performing a median sternotomy begins with marking the sternal vertical midline (Fig. 1). The surgeon frees the *sternum* along this line. There is a low risk of injuring muscles while preparing the *sternum*, because muscles only attach to the lateral sternal areas. After freeing the *sternum*, the diaphragm is separated manually and the *sternum* is cut through vertically with an oscillating saw from caudal to cranial. The surgical access is hold open by a retractor, which presses the two pieces of the separated *sternum* aside and expands the thorax. This

procedure can lead to muscle contusions, overexpansion and rip fractures. After periosteal hemostasis, the indicated cardio-thoracic surgery can start (Schäfers and Aicher, 2011).

Innervation

The muscles of the thoracic wall are innervated by spinal nerves, the plexus *lumbalis* and *brachialis*. The intercostal nerves are *rami ventrales* of the thoracic spinal nerves (*Nn. thoracici*). The spinal cord is the link between peripheral nerves and the central nervous system. It ends *caudal* above the second lumbar vertebra and descents *cranial* into the *medulla oblongata.* Each spinal nerve belongs to a segment of the spinal cord. It has sensory (dorsal horn) and motoric (ventral horn) quality and unites at the f*oramen intervertebrale*. Afferent sensory stimuli from dermatomes and afferent visceral stimuli from organs and vessels reach the spinal cord via the *ganglion spinale* at the dorsal root. Within the spinal cord, the *tractus spinothalamicus* transmits information from the periphery to the CNS (Samandari and Mai, 2009). Motoric information is transmitted from the brain via the spinal cord, its anterior root and the corresponding spinal nerve to the corresponding muscles (Tortora and Derrickson, 2006).

Visceral afferent stimuli from compromised organs reach the spinal cord via the dorsal root. Probably, segmental visceral and sensory information converge in the spinal cord. The *tractus spinothalamicus* transmits these stimuli to the *thalamus*, where pain is perceived, but not the location of the painful stimulus. This convergence can sensitize convergent afferent fibers from the same segment of the spinal cord (central hyperexcitability), which can lead to referred pain in the corresponding *dermatome*. The painful areas are called Head zones (Klinke, Pape and Silbernagl, 2005; Huppelsberg and Walter, 2009).

Acute sternotomy pain

Post-operatively, pain after cardio-thoracic surgery is common. Immediately after surgery, patients suffer from acute pain at rest and while movement and coughing in several areas, for example, they have chest pain, leg pain, shoulder or back pain. The incidence of acute post-operative pain after sternotomy is high; pain is severe and described as burning, tender or numb (Lahtinen, Kokki and Hynynen, 2006). Acute pain or nociceptive pain is a bodys' protective function caused by injury or disease. Its duration is short, easy to treat by analgesics and self-limited (Campbell, 2007; Kehlet, Jensen and Woolf, 2006; Savage, Kirsh and Passik, 2008). After sternotomy, the majority of patients suffers from pain during

coughing, deep breathing and movement, but also at rest. Directly after surgery a patients pain is at highest level, but there are strong pain attacks one week after the operation. Pain location changes during the post-operative period from the incision site to the shoulders (Mazzeffi and Khelemsky, 2011; Lahtinen, Kokki and Hynynen, 2006).

Chronic sternotomy pain

After sternotomy the prevalence of chronic post-sternotomy pain is high (da Costa et al., 2015). Chronic pain is not linked to an injury or acute disease, has no function and reduces the patients' quality of life. It can persist for months or years, even when the injury or disease is cured (Beubler, 2012). Chronic pain occurs in between 11 % and 56 % of patients after sternotomy and seems to depend on specific factors. Young age, overweight, gender, sex, pre-operative pain, genetics and psychosocial preconditions are pre-operative factors, which can support the development of chronic post-operative pain. Intra-operative factors can be the surgical technique itself, duration, incision size and localization, tissue handling, nerve injury or internal mammary artery harvesting. Post-operative factors could be acute post-operative pain and the post-operative analgesic technique and dose. Patients suffering from chronic post-operative pain often describe burning pain, spontaneous pain sensations, dysesthesia, hypersensitivity and allodynia, hyperalgesia, hyperpathia (Kehlet, Jensen and Woolf, 2006; Lahtinen, Kokki and Hynynen, 2006; Mazzeffi and Khelemsky, 2011).

Etiology, pathophysiology and other causes for post-operative pain

The cause for post-operative pain is the surgery itself. Acute pain after cardio-thoracic surgery is myofascial and inflammatory pain. Among other reasons, it can be initiated by the incision, rib traction, (healing) rib fractures, nerve injury, bedding during surgery, muscle sparring, joint dislocation, pleural or chest wall lesions, chest- and mediastinal tubes, and the inflammation during healing (Gottschalk, Cohen, Yang and Ochroch, 2006; Woolf and Chong, 1993; Benedetti et al., 1998; Mac et al., 2005; Mazzeffi and Khelemsky, 2011).

Nociceptive pain after cardio-thoracic surgery is caused by the tissue damage during surgery. Tissue damage initiates a healing process. This healing process, and the corresponding inflammation, are the main reasons for post-operative pain. Inflammatory mediators and ions, as sodium, potassium, calcium, bradykinin, histamine, substance P,

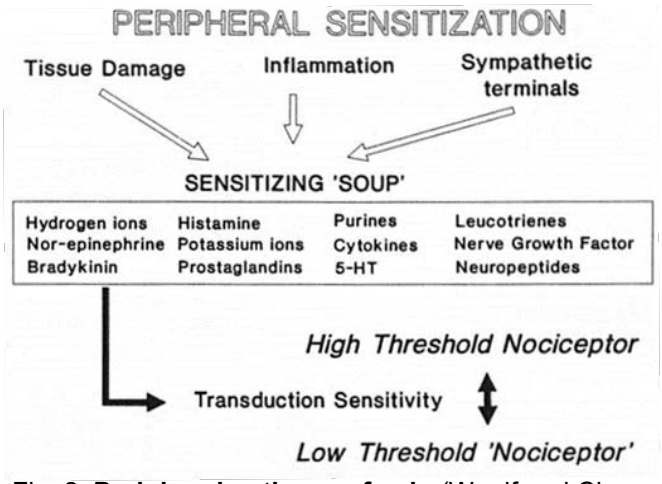

Fig. 2: **Peripheral pathway of pain** (Woolf und Chong 1993; printed with permission)

ATP, 5-hydroxytryptamine, nitric oxide, leukotrienes and prostanoids are released. Phospholipids are released when cell walls are damaged. These are split in arachidonic acids by phospholipase A_2. Cyclooxygenase-1 and -2 splits arachidonic acid into prostaglandin H, which can be converted to prostaglandin-I_2 and E_2 (Burgis, 2008). These mediators activate peripheral nociceptive neurons (peripheral sensitization). Other mediators activate indirect mechanisms. The area around the incision becomes hypersensitive (hyperalgesia) to external and internal stimuli, leading to a general hypersensitivity (secondary hyperalgesia) (Fig. 2). A higher number of incoming pain signals activate spinal and supra-spinal neurons (central sensitization), causing a central hypersensitivity. The spinal cord receives incoming pain signals from A-delta- and C-fibers. Incoming signals reach the dorsal horn and are transmitted via the *tractus spinothalamicus* to brain stem, thalamus and cortex (Mazzeffi and Khelemsky, 2011). *Substantia gelatinosa* in the ventral horn of the spinal cord provokes an adverse-effect reflex. Via *tractus spinathalamicus* pain signals are transmitted to the *reticular formation,* which causes a vegetative reaction. The *hypothalamus* provokes an endocrine reaction. Pain identification takes place in the *thalamus* (what?), the limbic system (how?), the *gyrus postcentralis* (where). The *cortex* transmits information to the cerebellum, where a defense action is induced (Huppelsberg and Walter, 2009).

Usually this process is reversible, but long central sensitisation can lead to irreversible modification of nociceptive structures (chronic post-operative pain) (Fig. 3). Short painful stimuli can cause a central sensitisation which is 10 to 200 times longer than the primary provocation.

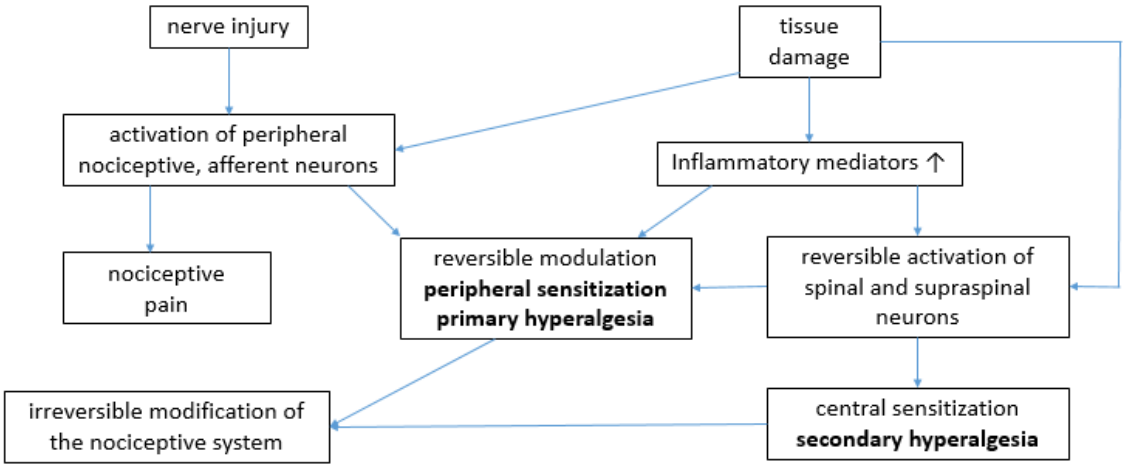

Fig. 3: **Chronification of pain** (modified from Schnabel and Pogatzki-Zahn, 2010)

In many cases, chronic post-operative-pain is neuropathic pain, caused be nerve injury during surgery and the healing of injured nerves. New nerve endings and the over-expression of sodium and calcium channels in the incision area can also lead to irritations. Nerve lesion can lead to a transformation of afferent neurons, the inhibitory system and the CNS, so that central and peripheral neurons have a higher excitability and indolent stimuli induce pain perception. (Schnabel and Pogatzki-Zahn, 2010; Woolf and Chong, 1993; Mazzeffi and Khelemsky, 2011).

Consequences of pain

Acute and chronic pain can have personal and social consequences for patients and their relatives. It reduces the quality of life and can end up in disability, sleep disturbances, depression and unemployment. A lower physical and mental health status implements high costs for the patient himself and for the social and health care system as longer post-operative hospital stays and frequent consultations are common (da Costa et al., 2015; Wells, Pasero and McCaffery, 2008; Mazzeffi and Khelemsky, 2011).

Acute pain causes stress, which leads to a stimulation of the hypothalamic - pituitary – adrenal axis, leading to a higher expression of cortisol. Wound healing can be limited and the patients can be more vulnerable to infections because cortisol can inhibit the immune system. Stress also activates the sympathetic system, resulting in unwanted pulmonary and cardiovascular effects, as increasing heart rates, cardiac arrhythmia, blood pressure, stroke volumes, a higher myocardial oxygen demand, an increased respiratory rate and increased rates or wound infections. It reduces myocardial supply and facilitates myocardial ischemia.

Edema, stroke, deep vein thrombosis, pulmonary embolus and angina pectoris are the result of hypercoagulability, a higher peripheral resistance and immobility caused by pain. Furthermore, pain has endocrine and gastro – intestinal effects. The activation of the HPA –axis changes metabolism from anabolic to catabolic. Insulin production decreases and blood sugar levels rise. An increased smooth muscle sphincter tone and higher amounts of intestinal secrets combined with low gastro – intestinal motility and delayed gastric emptying increase the risk for ileus (Wells, Pasero and McCaffery, 2008; Tetzlaff, 2004; Mazzeffi and Khelemsky, 2011). Pain sensations while breathing inhibit the patients' ventilation. Insufficient breathing and coughing results in retention of fluid, atelectasis, hypoxia and lung infection. Unwanted pulmonary complications especially happen during the first three post-operative days (Becker et al., 2007; Mazzeffi and Khelemsky, 2011).

Mechanics of breathing – Pathology after sternotomy

While exhalation at rest is mainly passive, inhalation is an active process. At rest, the major muscle for inhalation is the diaphragm. During inspiration, it moves downward and the thorax becomes wider, which expands the lungs. *Mm. scaleni* and *Mm. intercartilaginei* support inhalation and the *Mm. intercostales externi* stabilise the thorax. This causes a negative pressure inwardly and air flows into the lungs. During exhalation elastic fibers of the lung retract passively and no respiratory work is needed (Becker, Schönhofer and Burchardi, 2005; Klinke, Pape and Silbernagl, 2005). Respiratory neurons are located in the *medulla oblongata*. These neurons receive information from the CNS and the body to regulate respiration appropriate to the oxygen need. Respiratory stimuli are the Hering-Breuer-reflex (prevents lung from over-expansion), coughing reflex, distinct reflexes of respiratory muscles, changes in temperature, emotions, pain, changes in blood pressure, hormonal stimuli, information from mechanoreceptors from the musculoskeletal system, changes in arterial O_2- and CO_2-partial pressure and arterial pH value. Peripheral chemoreceptors (*Glomerula carotica* and *aortica*) transmit information on arterial partial pressures and the pH value to respiratory neurons in the CNS. An increased arterial CO_2 partial pressure, pH value below 7.4 and a decreased O_2 partial pressure stimulate respiration (Klinke, Pape and Silbernagl, 2005).

After sternotomy, the transmission of force from thorax to lung is limited. Pain disables respiration and the thorax is unstable after surgery. Pathologies can occur in all

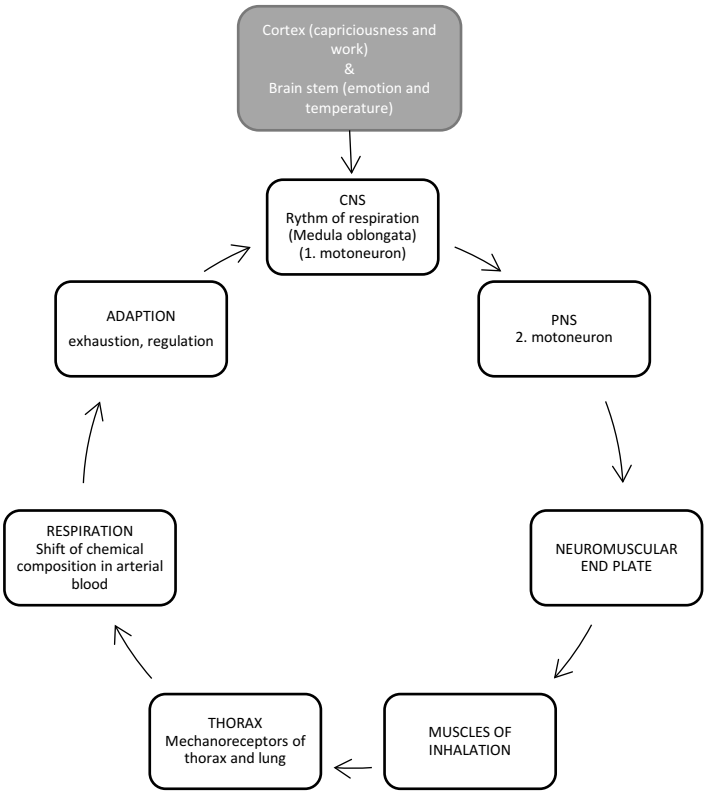

Fig. 4: **The Respiratory Pump:** Transmission of information during respiratory regulation CNS: central nervous system; PNS: peripheral nervous system (modified from Klinke, Pape and Silbernagl, 2005 with information from Pfeifer, 2012; printed with permission).

processes of transmission of force and information (Fig. 4). Sternotomy rarely injures muscles, because they are attached in the lateral part of the *sternum* (Schäfers and Aicher, 2011). However, pain caused by contusions and over-expanded muscles, rib fractures and nerve lesions of the phrenic nerve can limit respiration (Mazzeffi and Khelemsky, 2011). The phrenic nerve supplies the diaphragm, which is the most important muscle for inhalation. If there is a restriction of diaphragm or other muscles contributing to inhalation, myogenic respiratory pump failure is possible (Kabitz, 2014). Pain caused by the injured tissues can make patients adopt a relieving posture, causing a restricted inhalation. Bedding, general anesthesia and artificial respiration during surgery induce a decrease of residual capacity of 20 %. Functional residual capacity falls below the level of closing capacity and atelectasis occur (Rossaint, Nollert, Werner and Zwißler, 2012; Hedenstierna, 2003). Surgeries via ventral access, cause pleural effusions. Fluid retentions in the pleural cavity increase the pressure and the lungs' expansibility is limited. This causes a higher alveolar pressure, which increases the breathing resistance and makes breathing more difficult (Gekle et al., 2010; Kabitz, 2014).

Pain therapy

To avoid central hyperexcitability after surgery, it is important to treat post-operatively as early as possible (Woolf and Chong, 1993). Acute post-operative pain is mainly short-lived and retreats when injured tissue is healing (Campbell, 2007; Kehlet, Jensen and Woolf, 2006; Savage, Kirsh and Passik, 2008). Sufficient pain therapy should provide adequate pain control and should be offered continuously to assure constant relief. Pain levels should be assessed frequently to prevent adverse outcomes. Therefore, adequate pain therapy needs to maintain functional ability and psychological well-being. As a consequence it should improve patients' quality of life and reduce cost of care (Wells, Pasero and McCaffery, 2008).

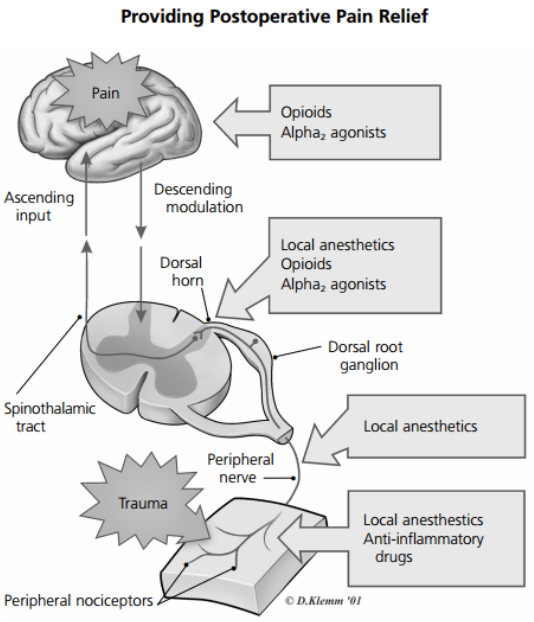

Fig. 5: **"Providing Postoperative Pain Relief"** (Gottschalk and Smith, 2001; printed with permission). Hypnotics, tranquillizer, narcotics and antidepressants affect the CNS. Central analgesics, as weak- strong opioids suppress the transmission of stimuli between the spinal cord and the brain. Local anesthesia blocks the transmission of pain stimuli in peripheral nerves and peripheral anesthetics affect peripheral pain receptors.

The transmission of pain signals can be interrupted at different levels of the pain pathway (Fig. 5). Opioid- and non – opioid analgesics have central and peripheral pain–relieving effects. Local anesthetics inhibit peripheral pain receptors by locking up voltage gated sodium channels. Electric stimulation and transmission of pain signals are prevented. NSAIDs prohibit sensitization of receptors by inhibiting the synthesis of prostaglandins.

Psychotropic drugs lead to central inhibition of pain. (Burgis, 2008; Gottschalk and Smith, 2001).

WHO analgesic ladder

The WHO analgesic ladder recommends a specific treatment for different pain intensities (see Table 1).

Mild to moderate peripheral or visceral pain should be treated with cyclooxygenase-inhibitors. Depending on the localization, antiphlogistic cyclooxygenase inhibitors combined with weak opioids can be used for the treatment of strong peripheral pain and

antipyretic cyclooxygenase inhibitors and spasmolytic are medication for strong visceral pain.

Strong opioids in combination with neuroleptic, spasmolytic or antidepressant drugs are indicated when very strong pain or tumor pain occurs (Burgis, 2008; Wells, Pasero and McCaffery, 2008).

Step	Therapy
Step I	
Mild to moderate peripheral or visceral pain	Monotherapy: cyclooxygenase-inhibitors (ASA, paracetamol, flupirtin, nefopam)
Step II	
Strong peripheral or visceral pain	
IIa peripheral pain	Antiphlogistic cyclooxygenase inhibitors and weak opioid
IIb visceral pain	Antipyretic cyclooxygenase inhibitors and spasmolytic
Step III	
Very strong pain, tumor pain	Strong opioid and neuroleptic, spasmolytic or antidepressant

Table 1: **WHO analgesic ladder.** (Burgis, 2008) WHO: World Health Organisation

Non – opioid analgesics

Among non – opioid analgesics there are antipyretic – antiphlogistic drugs and non-antiphlogostic – antipyretic drugs (see Table 2). Besides selective cyclooxygenase-2-inhibitors, antipyretic – antiphlogistic agents have an acidic pH and cumulate in inflamed tissues. By inhibiting COX 1 or 2 they block prostaglandin synthesis and the mediation of temperature rise and stimulation of nociceptors. So, COX – inhibitors are pain-relieving, anti-inflammatory and anti-pyretic drugs. They are also called non-steroidal-anti-inflammatory drugs (NSAIDs).

Non-antiphlogistic-antipyretic agents' pH is neutral or alkaline. They do not cumulate in inflamed tissues and there is no anti-inflammatory effect (Burgis, 2008).

Agent	Mode of action	effect	Side effect	indication
Acetylsalicylic acid	Irreversible and unspecific inhibition of COX-1and -2 COX-1-selective	*Analgesic*, *anti-inflammatory, antipyretic*	Platelet aggregation inhibition *Gastrointestinal* side effects Hypersensitivity reactions Uric acid retention	Head ache
Diclofenac	Selective inhibition of COX-2	*Anti-inflammatory, analgesic*	*Gastrointestinal* side effects Cardio-vascular side effects	Inflammatory rheumatic illness
Ibuprofen	Unspecific inhibition of COX-1 and -2	*Antiphlogistic, analgesic*	*Gastrointestinal* side effects	Tooth ache
Metamiziol	Unspecific inhibition of COX-1 and-2	*Analgesic, anti-pyretic*	*Gastrointestinal* side effects	Tumor-pain
Paracetamol	Unclear, inhibition of prostaglandin release in the spinal cord and CNS	*Analgesic, antipyretic*	*Hepatotoxic*	fever and mild pain

Table 2: **Non-opioid analgesics** (Burgis, 2008)

After sternotomy intravenous paracetamol (1g in 6 hours), diclofenac rectal (100mg in 18 hours), can reduce a patients' pain and opioid pain killer consumption (Mazzeffi and Khelemsky, 2011).

Opioid analgesics

Opioid analgesics affect the opioid receptors, which are principally located in the central nervous system. A distinction is drawn between δ-, κ- and μ-receptors. All of these receptors mediate an analgesic effect. Stimulation of μ-receptors can lead to addiction and additionally mediates euphoria, respiratory depression, obstipation. Agonistic stimulation of κ-receptors can lead to sedation, miosis and depressiveness. Excitation of δ-receptors can make patients hallucinate or dysphoric.

Opioid receptors are G-protein coupled receptors. Stimulation by agonists activate a G-inhibitory protein .Cellular, potassium channels are opened and calcium channels are closed, when opioid receptors are activated. The release of neurotransmitter and sensitivity of neurons are reduced so that pain perception is inhibited (Al-Hasani and Bruchas, 2011).

Opioid analgesics are graded in weak, strong and very strong opioids. Tilidine and codeine are weak opioids, strong analgesics are piritramide, morphine or oxycodone. Fentanyl is an example for a very strong opioid.

The highest density of opioid receptors is located in the CNS, but a low density of receptors is also distributed in the entire body. According to their distribution, opioid analgesics can have central and peripheral effects. Stimulation of central dopaminergic neurons can go along with euphoria. Inhibition of afferent neurons in the reticular formation can lead to sedation. Inhibition of the cough center and baroreceptors (*medulla oblongata*) mediate a reduced cough reflex and reduced blood pressure.

Stimulation of the *area postrema* (vomit centre) can bring nausea and vomiting. Opioid analgesics also manipulate the respiratory center. Sensitivity to CO_2 is reduced, which can lead to respiratory depression.

Peripheral effects can be a retarded emptying of stomach, obstipation and urinary retention (Burgis, 2008).

Trials have shown that patient-controlled-anesthesia is superior to nurse-controlled-anesthesia. “There does not appear to be a clinically significant difference in efficacy among opioids, and current evidence does not support the use of basal infusions in addition to bolus doses. When selecting a particular opioid analgesic, the drugs’ potential adverse effects should be considered first; but if multiple drugs are appropriate, cost should be a secondary consideration because there is a large variation in cost among drugs” (Mazzeffi and Khelemsky, 2011).

Economic impact of opioid side effects

Post-operative complications can cause a multiplication of hospital cost (Nelson and Dries, 1986; Mokhtari et al., 2008; Oderda et al., 2003; Kessler, Shah, Gruschkus and Raju, 2013). Opioid side effects can lead to a 55 % longer hospitalization, "47% higher costs of care, 36% increased risk of 30-day readmission, and 3.4 times higher risk of inpatient mortality" (Kessler, Shah, Gruschkus and Raju, 2013). Forty-seven percent higher costs of care meant $6721 per patient in 2013 (Kessler, Shah, Gruschkus and Raju, 2013).

Antidepressants and anti-epileptic drugs

Antidepressants, as amitriptyline or trazodone, are used alone or in combination with non-opioid analgesics or analgesics. Low doses inhibit reuptake of inhibitory neurotransmitters as noradrenaline, dopamine and serotonin. These neurotransmitters stay longer in the synaptic gap and inhibit pain transmission in the spinal cord and can reduce the use of opioid analgesics and their side effects (Beubler, 2012; Burgis, 2008).

Carbamazepine, clonazepam or phenytoin are anti-epileptic drugs. They are used when convulsive pain attacks occur. Anticonvulsants inhibit the increased transmission of stimuli in nociceptive neurons and reduce neuropathic pain (Beubler, 2012).

In pain management after cardio vascular surgery via sternotomy gabapentin (1.2 mg preoperatively and 600 mg postoperatively) can reduce the need for opioid pain medication and the patients pain (Mazzeffi and Khelemsky, 2011).

Interventional procedures

Procedures like peripheral, regional nerve blockade, chemical neurolysis or epidural anesthesia are surgical interventions that are used when pharmacological means alone bring no sufficient pain relief (Bause et al., 2011).

Seven percent of anesthesiologists use thoracic epidural anesthesia after cardiac surgery as the risk of an epidural hematoma is present. Nevertheless, it can reduce post-operative pain, cardiac arrhythmia, depression and pulmonary complications. Paravertebral anesthesia, intercostal nerve blocks and local and continuous wound infiltration can lead to a reduced need for opioid drugs and to lower pain values (Mazzeffi and Khelemsky, 2011).

Multimodal analgesia

To reduce side effects of pain medication and to improve analgesia, a combination of preventive analgesic techniques can be used in post-operative pain management. Opioid painkillers are the main pain medication in post-operative pain therapy. They can be combined with other non-opioid drugs, as NSAIDs, COX-2 inhibitors, NMDA agonists (ketamine, magnesium), Alpha-2 adrenergic agonists (anticonvulsants as pregabalin), glucocorticoids and antidepressants. Alternatively or additionally local anesthetic wound infiltrations can be used pre- or preoperatively to reduce pain by the incision (Beubler, 2012; Buvanendran and Kroin, 2009; Gottschalk, Cohen, Yang and Ochroch, 2006; Gottschalk and Smith, 2001). In thoracic surgeries, cryoanalgesia seems to be a safe adjuvant method to reduce post-operative pain and opioid adverse effects in combination with patient controlled analgesia (PCA) (Sepsas et al., 2013). Interventional procedures can also be used together with opioid analgesics, to reduce patients pains and opioid consumption (Bause et al., 2011).

Physical approach

In sports medicine, physical approaches are common for the treatment of pain by traumata or muscle tension. In post-operative pain management, opioid side effects need to be avoided and complementary methods become more popular. One non-pharmacological method for pain management is transcutaneous nerve stimulation (TENS). As the name suggests, cutaneous receptors are influenced by electrical stimuli. These stimuli are transmitted to the spinal cord by large myelinated nerve fibers. The incoming stimuli can counter pain signals from A-delta- and C fibers, what finally reduces the pain stimulus transmitted to supraspinal structures. After sternotomy, the adjunct use of TENS can reduce pain and the need for pain medication. The evidence if TENS can improve pulmonary function is divergent (Mazzeffi and Khelemsky, 2011; Sbruzzi et al., 2012).

Another adjunct method in post-operative pain management is (electro) acupuncture. Needles are placed on trigger points in the skin. The needles can be stimulated by electric impulses which leads to a discharge of endogenous opioids. This can then reduce pain, opioid consumption and opioid side effects and consequently improve pulmonary function after sternotomy (Mazzeffi and Khelemsky, 2011; Sun, Gan, Dubose and Habib, 2008; Colak, Kavakli, Kilinc and Rahman, 2010).

Early physiotherapeutic and osteopathic treatments after cardio-thoracic surgery, like breathing exercises, mobilisation exercises and manual therapy are safe and feasible methods

to improve patients' situation after heart surgery. The consequences are less pain and a better pulmonary function with higher inspiratory volumes and less atelectasis, as well as a shorter hospital stay (Racca et al., 2016; Westerdahl et al., 2005).

Besides other complementary techniques ,"trigger point injections are […] [a] commonly practiced pain interventional technique for symptomatic relief" (Wong and Wong, 2012). Therapists identify trigger points via palpation. Hardened areas can be considered as potential trigger points. During palpation, pressure on trigger points provokes pain. This pain can cause central hypersensitivity and an intensification of pain perception in the affected area. Not only non-invasive techniques are used for the treatment of trigger points. Injections of local anesthetics are used to relief the pain. Similar to acupuncture, dry needling is also possible (Wong and Wong, 2012).

A common treatment in sports medicine, especially for sport injuries, is medical taping (Kalron and Bar-Sela, 2013). Taping practitioners state that taping improves blood- and lymphatic flow as well as tissue healing. Thus, it is supposed to reduce inflammation and pain. Depending on the indication, different application types can be chosen. After surgery, applications for the treatment of lymph edema and/or hematoma should provide relief. Therefore, patients' skin needs to be stretched and the tape is attached without tension. Retraction of the skin leads to a lifting effect on the epidermis of the taped area. The tissue is extended. Thus, lymphatic vessels, arterioles and venules in the subcutis are also extended and lymphatic valves are opened. Tape, which stays on the skin for several days, stabilizes the epidermis. This leads to friction between cells in epidermis, dermis and subcutis. Movement between cells induces connective tissue loosening and facilitates lymphatic flow. Edema and protein accumulation are removed more easily (Kumbrink, 2016; Lee, Bergan and Rockson, 2011). Recent studies show the efficacy of taping after surgery. Taping improves pain, swelling, mouth opening and the quality of life after mid-face surgery (Ristow et al., 2014). After cholecystectomy, taping reduces pain, pain killer consumption and the time needed for a 100 m walk test (Krajczy, Bogacz, Luniewski and Szczegielniak, 2012). Patients after lobectomy for lung cancer reported less pain and significant lower pain values on day 5 and 8 after surgery and significant less persistent pain after 30 days (Imperatori et al., 2016).

Psychological approach

Patients, who are informed about post-surgical procedures, behaviour and pain pre-operatively, feel less insecure post-operatively. Although, or just because they ask for more pain medication, patients who are informed pre-surgically receive better healing results (Mazzeffi and Khelemsky, 2011; Snowdon, Haines and Skinner, 2014).

Another psychological approach in pain therapy is cognitive behavioural therapy (CBT). CBT aims to break through the circle in which pain causes fear, depression and bad thoughts, which can even increase the pain, leading to more fear and depression. Patients learn to estimate their situation realistically and how to replace bad by good thoughts. Positive affirmation ("I'm good, I will get through this") can provide relief so and relapse prevention techniques are important. They help patients to stay positive in difficult situations, when pain becomes stronger. Relaxation exercises, as progressive muscle relaxation, stretching and breathing techniques can support CBT and show the patients how to maintain control over their bodies.

Autogenic training helps pain-suffering patients to reduce their pain by imagination. Patients imagine that their pain decreases, because the cause changes or disappears, or they imagine their pain not to be intensive but warm.

Mobilization is important for rehabilitation. Physical activity as a pain therapy only helps when there are enough substantial breaks in between. Too many activities can cause even more pain, but if patients perform short exercises with frequent breaks, their pain-free active intervals become longer and their pain diminishes.

Operant- behavioral therapy can be combined with CBT. Patients are supposed to live their normal daily routines and so ignore the pain. Relatives are asked not to take over unpleasant work and to treat their ill family member as normal as possible.

In addition, patients who suffer from pain for a long period can learn biofeedback in multiple sessions. They learn how to control "heart rate, muscle tension and galvanic skin response" (Songer, 2005) and thereby control their body and pain.

Two more cognitive techniques to reduce pain are hypnosis and meditation. In meditation, patients concentrate on the moment and their body (mindful meditation), on a certain word or stimulus (concentration meditation) or on a sound or mantra, without forcing themselves to concentrate. By these different techniques, body and mind can relax and the pain is shielded. Yoga is a form of movement meditation, which also helps to relax.

Another related method is hypnosis. Here patients learn that their pain is not too painful. This suggestion stays real for the patient even after hypnosis has ended. Patients can also learn self-hypnosis, which can help when pain becomes stronger (Songer, 2005).

Aims of the trial

Post-operative pain management is the main factor for patient rehabilitation, and chest pain can lead to weak coughing and breathing and so chest infection, as pneumonia (mortality 27 %). On average it can develop "4 days after cardiac surgery" (Brockmann and Klein, 2018, a sufficient dosing of pain medication is obligatory (Weissman, 2004). Additionally, early mobilization is desirable. Analgesia should be satisfactory and side effects need to be minimized. Overdosed opioid pain killers can bring undesirable effects, but under-dosed pain medication might also be reason for complications (Ramsay, 2000). As outlined above, too high doses of opioid analgesics can lead to unwanted side effects like "nausea, vomiting, constipation, sedation, respiratory depression, and addiction. To mitigate and avoid these negative effects, it has been shown that in 60 % of postoperative cases, patients are under-dosed with pain medication […]" (Brockmann and Klein, 2018). Under-dosed pain killers can lead to complications, as increasing heart rates, cardiac arrhythmia, blood pressure, stroke volumes, a higher myocardial oxygen demand, an increased respiratory rate, pneumonia or wound infections, because patients still suffer from pain (Gottschalk, Cohen, Yang and Ochroch, 2006; Kessler, Shah, Gruschkus and Raju, 2013; Tan, Law and Gan, 2015; Wells, Pasero and McCaffery, 2008; Tetzlaff, 2004; Mazzeffi and Khelemsky, 2011; Becker et al., 2007).

Although modern types of anesthesia are available, pain management after heart-thorax-surgery remains a challenge in post-operative care. Rising numbers of surgeries in this sector, which are linked to the modern way of life, increase the need for an improved pain management. Complementary methods, as acupuncture, TENS, hypnosis or physical therapy, can help patients who suffer from post-operative pain after heart-thorax-surgery (Colak, Kavakli, Kilinc and Rahman, 2010; Rao, 2006; Sun, Gan, Dubose and Habib, 2008; Sbruzzi et al., 2012; Mazzeffi and Khelemsky, 2011; Racca et al., 2016; Westerdahl et al., 2005). Only a few trials deal with pain-diminishing effects of taping after surgery (Krajczy, Bogacz, Luniewski and Szczegielniak, 2012; Ristow et al., 2014). If heart-thorax surgeries are considered as an iatrogenic trauma, which is similar to sports trauma (rib fractures, muscle sparing, over-expanded joints and tissues), the use of tape in post-operative pain

management becomes more likely. There is only one study, treating the effects of taping after thorax-surgery. It reveals significant lower pain values und less persistent pain (Imperatori et al., 2016).

The following initial trial deals with the pain-diminishing effects of taping after heart-thorax-surgery by sternotomy.

Patients and Methods

Between September 2014 and December 2014, a prospective randomized, controlled study was performed in the Department of Cardiovascular Surgery of the University Hospital of Duesseldorf to investigate if medical taping influences patients' pain perception after median sternotomy. Regardless of the cardiac diagnosis, the inclusion criterion for this study was a planned surgery with access via median sternotomy. As medical tapes were used, patients with hypersensitivity to acrylic glue and patients having atrophic skin, psoriasis or eczema within the region to be taped were excluded from the trial. Furthermore, patients with severe infections, patients under radiation or chemotherapy and relapsing patients could not participate in the study.

As the trial was initiated as a single center initial study, no power calculation was performed and the maximum number was set to 50.

The final sample consists of 39 subjects, who were introduced to the trial pre-operatively. After discharge from intensive care to intermediate care, they were asked for their approval once more. All patients included gave verbal and written consent. The sample of the study consisted of 6 (15 %) female and 33 (85 %) male persons who were between 47 and 81 years old. The average age was 66 ± 9 years and the median age was 70 years. Nobody had to be excluded from the trial. Average hospital stay was 10.5 days. Patients who were transferred to other hospitals, were excluded from this calculation.

Before including patients into the trial, detailed medical history of the patients was taken. Age, gender, previously identified illnesses and the cardiac diagnosis were documented. No significant differences between the two groups were observed (Table 3).

The participants had different cardio-thoracic indications for surgery (Table 3). Bypass- and valvular surgeries were their prevailing indication. Thirteen percent of the patients suffered from aortic valvular stenosis, 77 % had coronary heart disease and one person had an aneurysm, a paravalvular abscess, aortic valve insufficiency, mitral valve calcification or a sternal dehiscence from a prior surgery.

		Tape	no Tape
number (n)		23	16
mean age (median)		66 ± 9 (65)	67 ± 8 (70.5)
Gender	Female	5 (22 %)	1 (5 %)
	Male	18 (78 %)	15 (95 %)
Aortic valve stenosis		2 (9 %)	3 (19 %)
Coronary heart disease		20 (87 %)	10 (63 %)
Sternal dehiscence		1 (4 %)	0 (0 %)
Aneurysm		0 (0 %)	1 (6 %)
Paravalvular abscess		0 (0 %)	1 (6 %)
Mitral valve calcification		0 (0 %)	1 (6 %)
Aortic valve insufficiency		0 (0 %)	1 (6 %)

Table 3: **Indications for surgery** (As some patients had multiple indications the total does not meet 100 %) (modified from Brockmann and Klein, 2018; printed with permission).

Medical history was documented by including patients into the trial. As the patients' ability to breathe was one of the investigated parameters, participants were asked if they had had pulmonary dysfunctions prior to the present situation. In the test group 5 patients had had such problems like bronchial asthma, previous pneumonia, bronchitis or obstructive lung diseases. In the control group there were 2 patients who had suffered from a disturbed pulmonary function (Fig. 6).

To avoid potential hypersensitive reactions to the tape, allergies were documented. Nobody had to be excluded, because of hypersensitive reactions to adhesive bandages. Seven patients in the test group had other hypersensitivities and in the control group there were three allergic participants.

As diabetes, coagulation dysfunction and lymphatic diseases might influence wound healing these illnesses were recorded (Fig. 6). Nine participants taped and six untaped suffered from diabetes. Thirteen patients in the test group and 10 in the control group mentioned they had high blood pressure. Fourteen test-patients and 7 patients of the control

group had a coagulation dysfunction, partly due to corresponding medication. Two participants in each group suffered from lymphatic diseases. Prior cardio-thoracic surgeries

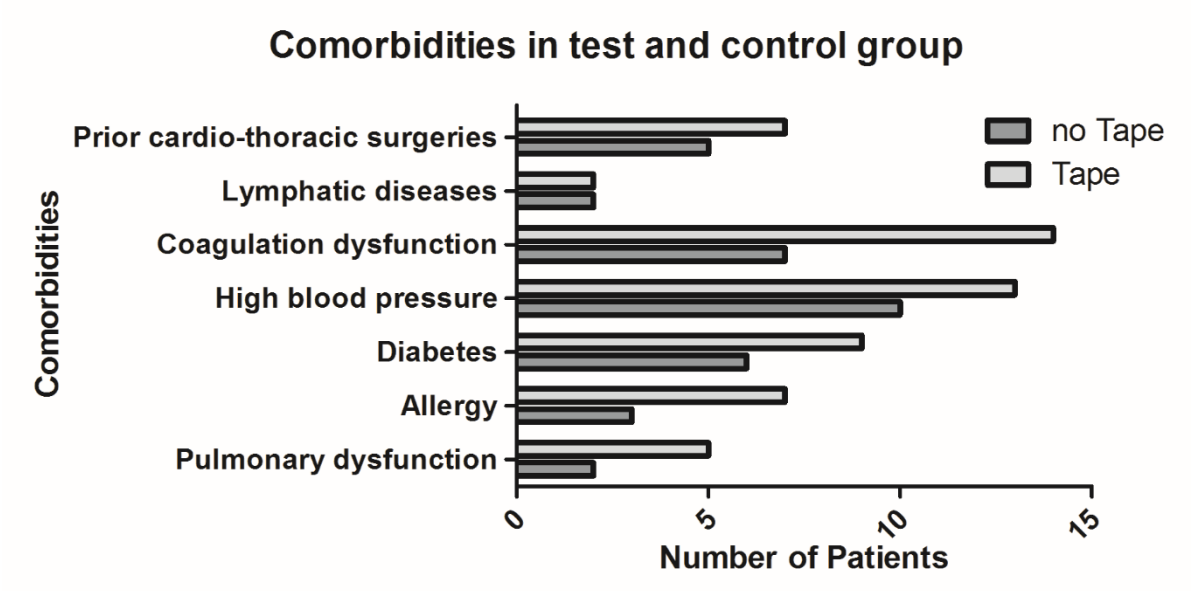

Fig. 6: **Medical History**

also belonged to the medical history questionnaire. Seven participants in the test-group and five patients in the control group had had cardio-thoracic surgeries before.

IBM SPSS Statistics Version 21.0 and GraphPad Prism 5 were used to perform all statistical analysis. Text processing was performed by Microsoft Office Word 2007. Literature was managed with Citavi 4.

Continuous variables are presented as mean values ± standard errors of the mean and confidence intervals. For normally distributed parameters the students' t-test was used to evaluate differences between the two groups. Not normally distributed parameters were evaluated with the Mann Whitney U test. The Fisher-test was performed for nominal parameters. The significance level was set to 0.05.

The randomization was performed by Microsoft Excel. Using the function "random number" a list of 25 times value "0" = no Tape and 25 times value "1" = Tape was randomized. The new sequence of "0" and "1" presented the order in which patients belonged to the test or control group. "The random sequence was transferred to file cards which were placed in envelopes. By including a patient in the trial, the corresponding envelope was opened" (Brockmann and Klein, 2018).

"The study was submitted to the ethical review committee of the Heinrich Heine University Duesseldorf and has been accepted (trial number: 4730R, Registration

ID: 014072701). The German Clinical Trials Register number is DRKS00006753" (Brockmann and Klein, 2018).

All data collection was performed anonymized and data protection orders were met.

A schedular patient file was used to perform daily data collection. After extubation and release from intensive care, patients were asked and taped (patients from the test group) for the first time. Data collection consisted of a daily interview and the documentation of the need of pain medication until hospital discharge.

Fig. 7: **Pain scale:** An English equivalent of the used visual rating scale (Wong-Baker FACES Foundation, 2017; printed with permission).

The patient file included a consent form, a data privacy statement, patients' medical history (Attachment 1.1) and a discharge questionnaire per patient (Attachment 1.2 and 1.3). Pain intensity (by means of a visual pain scale; 0 = no pain – 10 = worst imaginable pain) (Fig.7), the need for pain medication (piritramide and paracetamol), the need for antibiotics (usually Piperacillin/Tazobactam), patients' ability to breathe (by means of a respirometer patients should decide whether their ability to breathe is impaired or normal), the length of hospital stay, pulmonary and radiologic abnormalities (pleural infusions, lung infiltration), microbial abnormalities (e.g. MRSA, VRE), impaired wound healing and adverse effects of tape use were documented daily.

The discharge questionnaire (Attachment 1.2, 1.3) was offered after completing data collection on the day of hospital discharge. It provided the opportunity to rate the medical treatment, the pain experience, the treatment with the tape and previous experiences with tape applications.

Interventions

In 1979 its inventor Dr. Kenzo Kase used Kinesio® Tape for the first time. Kase proclaims that the tape reduces pain, restores muscle function, supports joint and improves the healing of hematomas and lymph edemas. By lifting the upper layers of the skin, blood- and lymph-

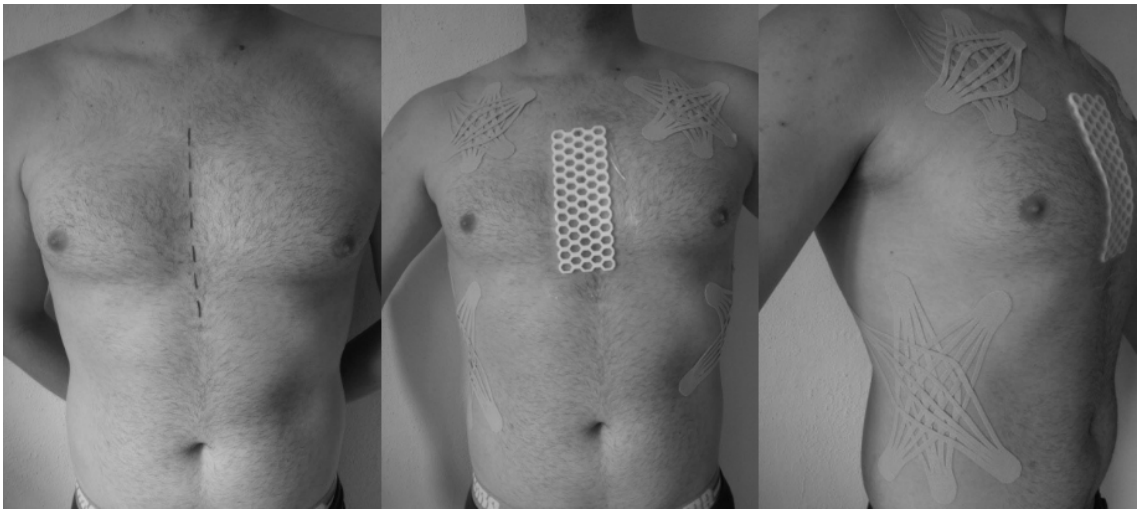

Fig. 8: **Tape applications on the patient's body** (Brockmann and Klein, 2018; printed with permission).

flow can be improved. Skin receptors shall be stimulated. Kinesio® Tape has similar characteristics to human skin. Its expansibility is 55-60 % and it consists of cotton, placed in elastic polymer-fibers. Acrylic glue, which is activated by warmth, makes the tape stick to the skin. It easily dries and is permeable to liquids (Kalron and Bar-Sela, 2013; Kase, Kase and Wallis, 2013). "After leaving intensive care, participants in the treatment group were taped with skin-colored Kinesio® Tex Gold Fingerprint Tape, 25 mm x 5 m" (Brockmann and Klein, 2018).

Fan-like drainage tapes were applicated in a star-shaped form below the clavicles and on the lateral thorax. The tape applications were chosen as big as the clinical dressing allowed (Attachment 2.1, 2.2, 2.3, 2.4). "The tape was not sterile, so they could not be placed over existing bandages or wounds. The application pressure did not exceed 2 g and the tapes were attached without any extensions. [Applicating the tape started with attaching the upper anchor on the patients' body. After this, the tape was separated from its base and placed on the [patient's] skin, without attaching it

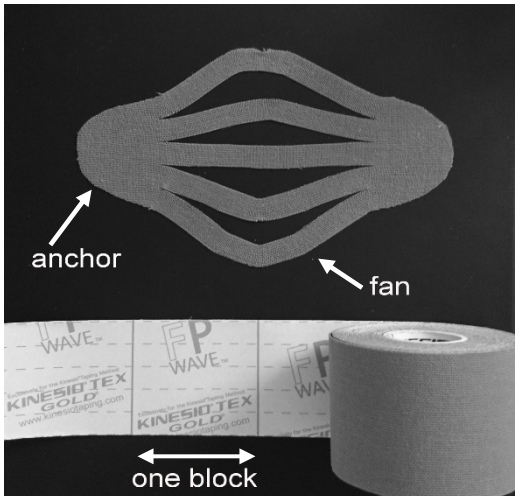

Fig. 9: **The tape**

to the skin. By this action, the initial tension of the tapes was loosened. After attaching the lower anchor to the skin, the thin parts of the fan were pulled apart and attached to the skin in a fan-shaped manner (Fig. 8, 9).] The tape was gently rubbed as the acrylic glue is activated by warmth. Tape was replaced [according to need and then] stayed on the patient's bodies until discharge. The taping technique was developed in cooperation with the Kinesio® Taping Association" (Brockmann and Klein, 2018). Applicating the tape took approximately 15 minutes.

According to the free skin space and the patient's body size, tapes measured between two or three and a half blocks below the clavicles. On the lateral thorax they were between three and a half and five and a half blocks (Fig. 9).

Kinesio Tex Gold™ FingerPrint tape (skin-colored) (GKT15014) was used for the tape applications. The tape was delivered on rolls (2.5cm x 5m). Manufacturers' data indicate that the tape consists of 100 % cotton, it is free of latex and water-resistant. The tapes were cut with a Kinesio® pro scissors. The patient's ability to breathe was tested by means of a respirometer MEDIFLO duo (pharma central number: 4183368).

Results

Pain values

In both groups, the lowest pain value was 0; the highest pain value was 9 in the treatment group and 10 in the control group. Taped participants had a mean pain value of 2.3 ± 0.2 [CI: 1.1; 3.13] and untaped patients had a mean value of 3.6 ± 0.4 [CI: 2.92; 5.41] during postoperative hospitalization. The students't-test shows a significant statistical difference between the two groups ($p < 0.012$). Outcomes in pain value measurements are shown

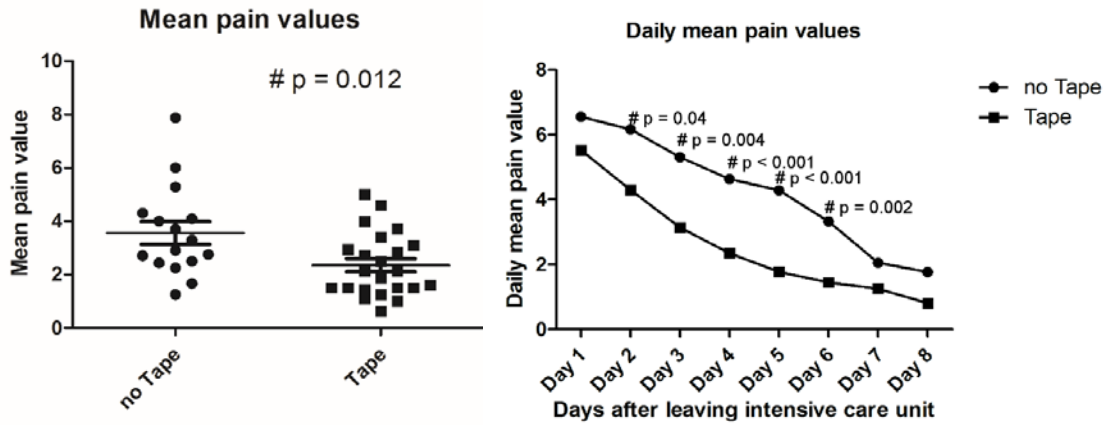

Fig. 10: **Pain values in tape and control group.** p: probability

in Fig. 10. When comparing the daily mean pain values of the two groups, there were significant differences between test and control group on day 2 (Tape: 4.3 ± 0.5; no tape: 6.2 ± 0.7, p=0.04), day (Tape: 3.1 ± 0.4; no tape: 5.3 ± 0.6, p=0.004), day 4 (Tape: 2.4 ± 0.3; no tape: 4.8 ± 0.6, p=0.001)),day 5 (Tape: 1.8 ± 0.3; no tape: 4.4 ± 0.6, p=0.001)) and day6 (Tape: 1.5 ± 0.3: no tape: 3.4 ± 0.5, p=0.002).

Analgesic consumption - Piritramide

In the treatment group, patients needed significantly lower mean daily doses of piritramide (1.4 ml ± 0.3 ml; CI: 0.4 ml; 2.1 ml) than in the control group (3.1 ml ± 0.6 ml; CI: 2.0 ml; 4.2 ml) (p = 0.018). As piritramide is administered intravenously, 15 mg piritramide are

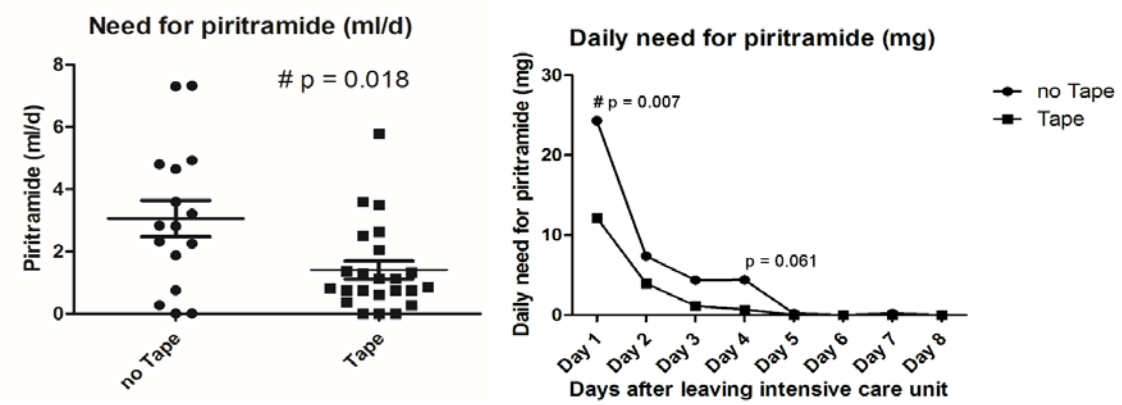

Fig. 11: **Need for piritramide in tape and control group.** p: probability; ml: milliliter; mg: milligram; d: day

diluted in 10 ml physiologic salt solution (1 ml solution contains 1.5 mg piritramide). Therefore, taped patients needed 2.1 mg ± 0.45 mg piritramide per day and untapped patients had a need of 4.65 mg ± 0.9 mg piritramide per day. Analgesic treatment outcomes for piritramide are shown in Fig. 11. Comparing the daily need for piritramide of the two groups, there were significant differences between taped and non-taped group on day 1 (Tape: 12.15 ± 2.4 mg; no tape: 24.3 ± 3.45 mg, p=0.007) and significant by trend on day 4 (Tape: 0.72 ± 0.35 mg; no tape: 4.35 ± 1.77 mg, p=0.061).

Analgesic consumption - Paracetamol

Patients of the treatment group needed lower mean daily doses of paracetamol (1.0 g ± 0.1 g;

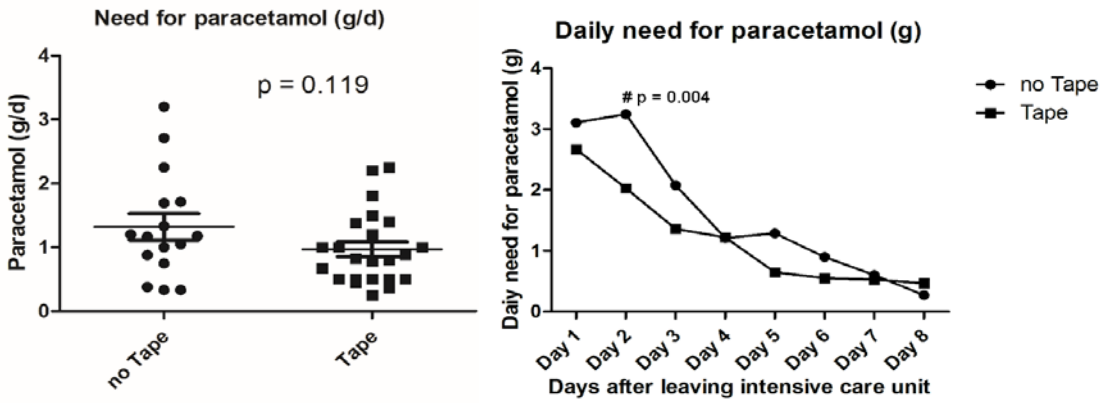

Fig. 12: **Need for paracetamol in test and control group.** g: gram; d: day; p: probability

CI: 0.6 g; 1.6 g) than patients from the control group (1.3 g ± 0.2 g; CI: 0.8 g; 2.0 g) (p = 0.119). On day two, the comparison of the daily need for paracetamol, shows significant differences between test and control group (p = 0.004). Analgesic treatment outcomes for paracetamol are depicted in Fig. 12.

Safety and feasibility

Taping could easily be performed for all study subjects. On average taping per patient took between 10 and 20 minutes, and adverse effects of the tape were not observed in any patient.

Subjective evaluation of breathing

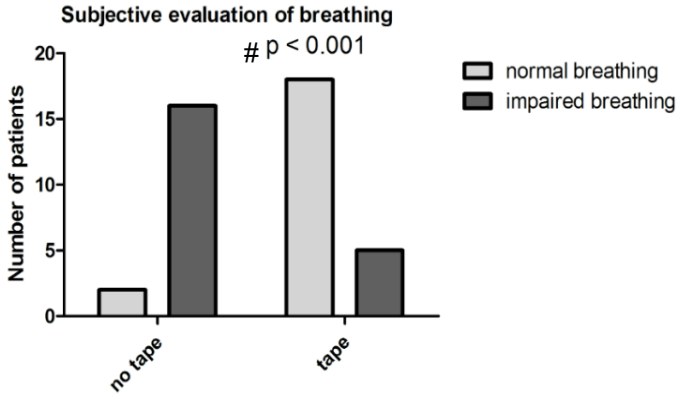

Fig. 13: **Subjective evaluation of breathing** (Brockmann and Klein, 2018; printed with permission). p: probability

Highly significant differences between test and control group (p < 0.001) in the patients' ability to breathe were observed. Fourteen patients out of the control group (n = 16) did not

defined their respiration as normal while 18 taped patients (n = 23) described their pulmonary function as regular (Fig. 13).

Other parameters

During daily documentation, radiologic and microbial abnormalities were observed and the two groups were compared. There were no statistically relevant differences between the tape group and the control group. The antibiotic consumption of taped and untaped participants showed no statistical differences, as well. The comparison of lung infiltration in test and control group revealed that 5 out of 16 untaped patients and 3 out of 23 taped patients had a lung infiltration ($p = 0.24$). Test patients' hospital stay took 11 ± 1 days [CI: 9.17 days; 11.83 days] and untaped participants stayed for 10 ± 1 days [CI: 8.74 days; 11.78 days]. The comparison of the length of hospital stay in the two groups showed no statistically significant difference.

Only one participant taped suffered wound healing disorders, whereas no infection occurred. In the no-tape-group, no case of impaired wound healing was observed. There was no statistical difference between the two groups. No adverse effects of tape use, for example local skin reaction or impaired mobility, could be observed.

Reduction of hematoma

During the daily visits, the taping practitioner noticed that hematomas were more rapidly reduced in taped areas than on untaped skin. Fig. 14 shows the reduction of a hematoma on the lateral thorax within one day. The left picture shows the tape. The right picture shows the hematoma after removing it one day later for examination purposes.

Fig. 14: **Reduction of hematoma after one day**

Discharge questionnaire

In the test group one person refused to fill out the questionnaire. The overall judgement for the medical treatment was good or very good in both groups. Thirty-seven-point-five percent (n = 6) of the untaped patients and 27 % (n = 6) of the test patients rated the treatment ‘very good’. Ten control patients (63.5 %) and 13 taped patients (59 %) chose the judgement ‘good’. Two taped participants estimated the treatment ‘satisfying’ and one person in the test group rated it ‘fair’. Patients in both groups could also estimate how strong the influence of the post-operative treatment was. Eighteen percent (n = 4) in the test group and 12.5 % (n = 2) in the control group stated that the post-operative treatment did not influence them. Eleven taped patients (50 %) and 6 untaped patients (37.5 %) recognized a very slight influence. Three participants in each group felt a slight influence of the post-operative medical treatment and 18 % of the patients (n = 4) in the test group and 19 % of the patients in the control group (n = 3) rated the influence as ‘moderate’. One person of the untaped group stated a strong or very strong influence of the post-operative medical treatment.

The tape applications were estimated ‘very good’ by 27 % of the taped participants. ‘Good’ was chosen by 46 % of the test patients and 9% rated the tape application ‘satisfying’. Nobody in the test group rated the tape applications ‘fair’, ‘poor’ or ‘unsatisfactory'.

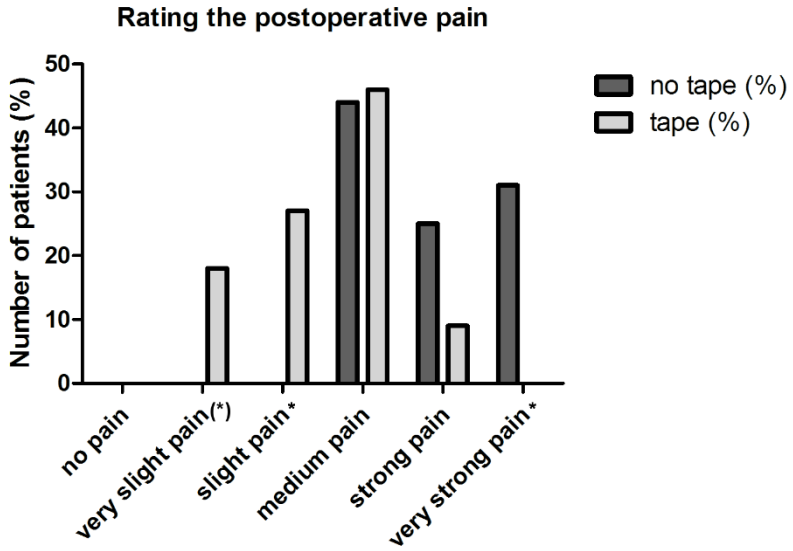

Fig. 15: **Post-operative pain**: Evaluation of the post-operative pain in the discharge questionnaire. * = statistical significant difference between the groups (Brockmann and Klein; 2018 printed with permission).

“Considering the overall postoperative pain, […] no patient reported very strong pain [in the treatment group]. Thirty-one percent of the participants […] [of] the control group estimated their postoperative pain [as ‘very strong’]. Nine percent of the taped [patients] and 25% of the untaped patients valued the pain as [‘strong]. Forty-six percent of the patients in the treatment group and 44% of the participants […] [of] the control group judged

the postoperative pain [‘moderate]. Twenty-seven percent of the taped patients valued their postoperative pain as [‘slight’] […] and […] [none of the] untaped participants said they had [‘slight pain’]. […] [None of] the untaped patients estimated the postoperative pain as [‘very slight’], and 18% of the patients […] [of] the treatment group chose the option [‘very slight pain’]. No patient reported having no pain at all. The distribution of pain values is depicted in Figure [15]. These results display a statistically significant difference between test and control group for the judgements [‘very slight pain’] (p=0.075), [‘slight pain’] (p=0.023) and [‘very strong pain’] (p=0.004)” (Brockmann and Klein, 2018). Regarding the influence of the tape, 86 percent of the participants were not influenced at all. Fourteen percent were slightly influenced by the tape applications, one person felt a strong (positive) influence.

In the test group, three patients had had prior experience with tape applications. Their prior experiences were estimated ‘good’ (2 participants) or ‘very good’ (1 person).

Discussion

In cardio-thoracic surgery, the access via median sternotomy is common in practice. Severe to moderate pain is normal after this intervention. The dimension of the iatrogenic trauma leads to a complex genesis of pain. Opening the thorax, hurts the skin, bones and expands the ribcage. Overextension of muscles, compressions and rib fractures can provoke post-operative pain and bedding during and after surgery can evoke tensions in the thorax and increases the patients’ malaise (Lahtinen, Kokki and Hynynen, 2006; Mazzeffi and Khelemsky, 2011).

For the patients’ rehabilitation, including low post-operative pain levels, an exactable quality of life, psychological comfort, without (or with few) functional limitations, low rehabilitation costs and a short hospital stay, form an essential standardized pain management. Continuous pain relief assumes that an adequate pain control is offered all around the clock and that patients can act their part in the pain management by rating the pain control and asking for pain medication. In post-operative care, modern anesthetic techniques are used to reduce patients’ pain after cardio-thoracic surgery (Mazzeffi and Khelemsky, 2011; Wells, Pasero and McCaffery, 2008).

In post-operative care, the administration of opioid analgesics is common, because they abate pain reliably. Opioid analgesics can be administered intravenously by the medical staff or by a pain pump. Here, patients can decide, when they need a dose of pain medication. The maximum is limited as well, but it is offered at any time and patients are more

independent from the medical staff. However, opioid drugs cannot be administered limitless. Opioid adverse effects like dizziness, nausea, allergic reactions, *ileus*, impaired kidney function, sedation, impaired coordination and respiratory depression can delay rehabilitation and extend hospital stay and costs. Due to the indicated adverse effects, the administration of opioids needs to restricted and additive painkillers and techniques need to be taken in consideration. Non-opioid drugs, like paracetamol, ibuprofen, diclofenac or voltaren can be administered additionally. In this trial, patients maintained paracetamol, which is removed by the liver and cannot be taken limitless, as well. In fear of severe side effects, opioid analgesics are often under-dosed, so that patients suffer from pain and its complications, like thrombosis, emboli, pneumonia, stroke or cardiac infarction (Kessler, Shah, Gruschkus and Raju, 2013; Mazzeffi and Khelemsky, 2011). Recent investigations show, that not only opioid analgesics can lead to adverse outcomes after cardiac surgery. "All nonaspirin NSAIDs should be utilized with extreme caution, especially in patients with cardiovascular disease" (Ross, Elgendy and Bavry, 2017). The administration of NSAIDs, especially combined with aspirin can lead to severe adverse events, as stroke, cardio-vascular complications and a higher cardiac mortality (Ross, Elgendy and Bavry, 2017). "Furthermore, […] NSAID use, particularly in patients being treated with antithrombotic therapy, may confer an increased risk of bleeding events" (Ross, Elgendy and Bavry, 2017).

Post-operative care faces the problem of severe side effects of under- or over-dosed pain medication. Adequate pain control cannot be achieved with pain medication alone (Mokhtari et al., 2008; Nelson and Dries, 1986; Oderda et al., 2003; Sbruzzi et al., 2012) „The need for complementary methods without pharmacological risk is paramount" (Brockmann and Klein, 2018. Complementary methods like physiotherapy, TENS, acupuncture and medical taping can have a positive influence post-operative pain (Rao, 2006; Sekine et al., 2005; Snowdon, Haines and Skinner, 2014; Colak, Kavakli, Kilinc and Rahman, 2010; Imperatori et al., 2016; Sbruzzi et al., 2012; Maimer et al., 2013; Lima et al., 2011).

Iatrogenic traumata after cardio-thoracic surgery are similar to those, which are treated in orthopedics, sports medicine and physiotherapy. Many injuries are muscle- or fiber over-extensions, contusions, tensions or broken bones. Complementary techniques are often used additionally to pharmacological techniques in pain therapy in these sectors. Especially tape applications are used more frequently than in other sectors. Tape applications are discussed controversially in actual literature. Whereas some authors could not discover any measurable effects by the tapes, others could prove the efficacy of the tapes. In many recent

trials probands are healthy adults and the comparison to impaired subjects is not reasonable (Kalron and Bar-Sela, 2013; Serra et al., 2015; Halski et al., 2015). Besides, the application of tapes is always dependent on one essential variable, - the practitioner taping his patient.

In this prospective randomized trial, patients who received Kinesio® tape applications additionally to the usual post-operative treatment, had less acute post-operative pain and a lower opioid pain medication consumption, "especially during the first 4 to 6 days after leaving intensive care" (Brockmann and Klein, 2018). They had better breathing conditions and a lower incidence of lung infiltrations (13 %, n = 3 versus 31 %, n = 5) than patients not treated with Kinesio® tape. The final discharge questionnaire revealed that patients did not feel disturbed by the tape applications, since the minority of the patients realised an influence of the tape during their recovery. Untaped patients were less satisfied and expressed higher pain values than patients who received tape applications (Brockmann and Klein, 2018).

As the traumata in heart surgery and orthopedics can be very similar, it is obvious, that the same techniques can be used to reduce the patients' pain. In cardo-thoracic surgery, pain-reducing techniques comprise a variety of pharmacological and adjuvant techniques.

However, only one recent trial investigates the effects of taping after thoracic surgery. The research group including Imperatori et al. could show that taped patients have a significant pain reduction after lobectomy via VATS or thoracotomy. "As the incidence of persistent pain in post-thoracotomy-patients is higher than in patients after sternotomy, they could also show a significant reduction on the postoperative pain after 30 days" (Brockmann and Klein, 2018).

There are two other trials investigating the efficacy of medical taping after different surgery. After mid face surgery, taped patients had significantly better conditions than those untaped. Ristow et al. could show, that taping after mid-face surgery improves the patients' quality of life and has a significant effect on mouth opening and swelling (Ristow et al., 2014)**.** Another trial provides evidence, that taping after laparoscopic cholecystectomy has a significant effect on the patients' post-operative pain perception and analgesic consumption (Krajczy, Bogacz, Luniewski and Szczegielniak, 2012). These examples suggest that "[tape] applications as additional treatment can satisfy all requirements of post-operative pain management, mentioned [above]." (Brockmann and Klein) Different trials investigate the pain reducing effect of medial taping, but the influence on the lymphatic system and the neurologic effects remain inconclusive (Kalron and Bar-Sela, 2013; Krajczy, Bogacz, Luniewski and Szczegielniak, 2012; Ristow et al., 2014). Nevertheless, as our photo-

documentation (Fig. 14) proves, hematoma is reduced more rapidly under taped skin, what supports the theory of a higher lymphatic activity under the taped areas.

The pain-reducing influence of tape applications can be explained by the gate-control-theory. In 1965, Melzack and Wall described the gate-control-theory and the inhibition of the transmission of pain stimuli. Their theory hypotheses that incoming pain signals in the spinal cord can be reduced by the stimulation of receptors in the skin and their transmission to the CNS (Melzack and Wall, 1965). Tape applications are supposed to have another receptor-associated mechanism. Kenzo Kase, the creator of the tape, describes its skin-lifting effect, leading to a reduced pressure on dermal receptors and thus a reduction of pain. Aligned MR images could demonstrate that taped skin areas and the region around the tape are directly deformed by tape applications. In the different areas below and next to the tape, the skin and the connective tissue below the skin are lifted and lengthened, but also pressed and shortened. Depending on the examined location, the deformations differed. It is remarkable, that there were deformations in the surrounding muscles, caused by local myofascial loads, probably induced by the tape application (Pamuk and Yucesoy, 2015). Dermal mechanoreceptors are supposed to be taking part in pain inhibition, when being stimulated by skin deformation (Kase, Wallis and Kase, 2013; Pamuk and Yucesoy, 2015; Hotta, Schmidt, Uchida and Watanabe, 2010).

After sternotomy, the transmission of information for respiration can be impaired in all parts of regulation (Fig. 3). Opening the rib cage can irritate thoracic muscles and mechanoreceptors, what can lead to a disturbed respiration and impaired breathing.

The tapes in our trial covered parts of the respiratory muscles. The big star-shaped tapes on the lateral chest covered the external intercostal muscles and the *M. serratus anterior*. The smaller star-shaped tapes below the clavicles were placed in parts of the *M. pectoralis major and minor.* Referring to the results of Pamuk and Yucesoy, it can be possible, that the tapes affected the respiratory muscles and the thoracic mechanoreceptors, leading to better breathing conditions and less pain in the tape group.

Facilitated blood flow and an improved circulation of lymphatic fluid are expected taping effects. These enhance wound healing (Shim, Lee and Lee, 2003; Skirven, Osterman, Fedorczyk and Amadio, 2011) and a faster reduction of hematoma under taped skin shown in Fig. 14.

On day one and two after attaching the tapes, the pain reducing effect and the reduced need for pain medication in the test group is remarkable. An early reduction of pain is desirable. Therefore, patients should be taped as early after surgery as possible, preferably

in the operation room. In care after cardio-thoracic surgery, post-operative pneumonia is feared. On average it occurs on day 4 after cardio-thoracic surgery (Weissman, 2004) and results in a mortality rate of 27 %. The mortality of post-operative pneumonia, combined with ventricular failure is almost twice as high (51 %). As lung infiltrations increase the risk of post-operative pneumonia, "a lower incidence of pneumonia and lung infiltration would be desirable" (Brockmann and Klein, 2018). Pneumonia is caused be external pathogens, which need to be eliminated from the lungs. In our trial taped patients had a lower incidence of lung infiltrations, lower pain values and better breathing conditions. Probably, patients with lower pain values can remove pathogens more easily from their lungs by coughing and breathing, because their respiration and their thoracic mobility is not impaired by pain sensations. This theory indicates that tape applications can reduce the incidence of post-operative pneumonia. Thus, an early treatment with tapes after surgery is even more important.

Trusting the MRI analysis (Pamuk and Yucesoy, 2015) the application of a placebo tape without causing any deformation is impossible. Nevertheless, a placebo effect in taped patients cannot be excluded, but it is implausible, because taped patients declared they did not feel a strong influence of the tape. Although a placebo effect must be taken into consideration, the pain relieving effects of tape applications could be investigated in other trials mentioned above (Ristow et al., 2014; Krajczy, Bogacz, Luniewski and Szczegielniak, 2012; Imperatori et al., 2016), and they are similar to our pain-reducing and painkiller-decreasing investigations in the test group. It is interesting that patients of the tape group estimated the medical treatment worse than patients of the control group, even if they expressed less pain. It is possible, taped patients got more attention from the taping therapist than from the medical staff, so that they had a more negative impression of the medical treatment.

Many patients suffer from adverse effects by patches (Widman, Oostman and Storrs, 2008), but the material of the tapes did not induce dermal irritation in our study. As this trial was an initial trial and the primary goal was to test the safety and feasibility of taping in daily hospital care, the application of tapes after cardio-thoracic surgery has been proved to be feasible and safe for patients and medical staff.

The use of tapes after cardio-thoracic surgery also seems to be economically advantageous. The total need for opioid painkillers among taped patients was significantly lower than among untaped patients, so the costs for analgesics are lower in the test group. One milligram of the used pain medication piritramide costs about € 0.11 (Dieterich et al.,

2012). Patients not treated with Kinesio® tape, on average needed 20 mg more piritramide than those provided with tape. The cost of this tape treatment are about, € 1.30, compared to € 2.22 for piritramide. “Besides directly therapy-related cost savings, Kinesio taping may reduce the incidence of opioid-associated adverse events, and maybe even the length of hospital stay” (Brockmann and Klein, 2018). Although the results were not statistically significant, patients in the test group had a one-day shorter hospital stay than patients in the control group. This one day of hospitalization amounted to $ 2,311 in the United States of America in 2012, whereas the charges for surgical hospital stays increased since 2003 from $ 17,300 to $ 21,200. In comparison to medical ($ 8,500) or maternal hospital stays ($ 4,300), they were highest for surgical patients in 2012 (Moore, Levit and Elixhauser, 2014; Weiss and Elixhauser, 2014). Further trials need to prove the link between post-operative taping and shorter hospital stays. If the application of tapes after surgery can accelerate the patients’ rehabilitation, over $ 2000 per patient and day can be saved. In this context, the costs created by opioid side effects need to be taken into consideration. Side effects of opioid analgesics can cause a 55 % longer hospital stay, “47% higher costs of care [$6721 per patient in 2013], 36% increased risk of 30-day readmission, and 3.4 times higher risk of inpatient mortality” (Kessler, Shah, Gruschkus and Raju, 2013). As our results suggest that the application of Kinesio® tape can reduce the need for opioid and non-opioid analgesics, side effects caused by these painkillers, it is obvious that tape applications could also diminish pain medication side effects and their costs. A further trial, with a larger number of patients is essential to approve our results.

As the trial was an initial one, it has several limitations, which need to be eliminated in a further study. The results would be more meaningful with a higher number of participants. Furthermore, the examination of parameters was on a subjective level. In a subsequent trial patients’ breathing conditions can be tested by means of a spirometer. Medical staff was responsible for the administration of pain medication. On demand, patients received a dose of paracetamol or piritramide. The administration of either paracetamol or piritramide can also influence the results. Patient-controlled pain medication with one painkiller by means of a pain pump would make the results more reliable. It would be interesting to find out, if taped patients have a lower incidence of persistent pain, which is also common after sternotomy (Kalso, Mennander, Tasmuth and Nilsson, 2001).

Conclusion

The question, if Kinesio® tape applications can really improve patients' situation or are just fashionable these days (Kalron and Bar-Sela, 2013) cannot be answered by this initial trial. Objective facts show that pain is one big challenge in today's post-operative hospital care and the usage of modern analgesic techniques is limited by their side effects and risks (Kessler, Shah, Gruschkus and Raju, 2013). It is obvious that alternatives are badly needed. Especially, since Ross et al. could reveal the dangers of NSAIDs, which were not supposed to be dangerous and are therefore, are frequently used to reduce the application of opioids (Mazzeffi and Khelemsky, 2011; Ross, Elgendy and Bavry, 2017). Even though this initial trial included only a small patient cohort and the investigated parameters were partly the patients' subjective estimations. The results suggest that patients in the test group benefited from the tape applications. The existence of a placebo effect remains inconclusive, but in medical care, success should be the most important criterion and whatever is capable of improving a patient's situation is worthwhile trying.

The application of tapes is easy and does not require any special qualification. Learning the baseline techniques enables trained laymen to use tapes correctly. If medical staff feels unable to applicate the tapes, physiotherapists will be able to do this. This study show, that the application of tapes in post-operative care is safe and feasible for patients and hospital staff.

If further trials with a larger patient cohort can confirm our results, the application of tapes can be an easy and economically advantageous technique to support patients' rehabilitation after cardio-thoracic surgery, by improving their respiration, reducing pain, and painkiller consumption. The tapes do not contain pain medication like, for example morphine patches, so the risk of pharmacological side effects does not exist. The risk of allergic reactions to the tape remains. Thus, patients with allergies to acrylic glue and dermatosis in the taping area should not be taped. The incidence of impaired wound healings in the test group was not significantly higher than in the control group, but the preventions of infections caused by tape applications has priority. It is desirable to work with sterile tapes as an additional treatment to routine post-operative treatment and the administration of non-opioid and opioid analgesics in daily hospital care. As to our results, the application of tapes can ease the pain and is safe and feasible for hospital employees and patients.

This initial study was created to investigate the safety and feasibility of taping for patients and staff in daily hospital routine. The positive influence of the tapes on patients

after cardio-thoracic surgery via sternotomy needs to be confirmed in secondary trials with a larger patient cohort.

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Annexe

Attachment 1 Patient file

Universitätsklinikum Düsseldorf

HEINRICH HEINE UNIVERSITÄT DÜSSELDORF

Klinik für Kardiovaskuläre Chirurgie

Universitätsklinikum Düsseldorf · Moorenstr. 5 · D-40225 Düsseldorf

Notfall-Hotline
0151-14235659

An den Studienteilnehmer/die
Studienteilnehmerin der Studie:

Einfluss von Kinesio Taping auf den

Heilungsprozess nach Sternotomie

Ansprechpartner	Mein Zeichen	Durchwahl	E-Mail	Datum
Prof. Dr. med. H.M. Klein		17411	kleinhm@med.uni-duesseldorf.de	06.09.2014

Sehr geehrter Patient, sehr geehrte Patientin,
es folgt der Aufklärungsbogen zur klinischen Studie

Einfluss von Kinesio Taping auf den Heilungsprozess nach Sternotomie

Hintergrund der Studie:
Die Schmerztherapie nach Herz-Thorax-Operationen ist essentiell für eine schnelle Rehabilitation der betroffenen Patienten. Die Therapie mit Schmerzmitteln stellt die heutige Standartbehandlung dar. Um die Situation der Patienten nach einem Eingriff zu verbessern, können zusätzlich alternative Heilmethoden eingesetzt werden. Moderne Studien konnten belegen, dass postoperative Beschwerden durch Akupunktur und Tens (transkutane elektrischen Nervenstimulation) behandelt werden können. Eine weitere Methode ist das Tapen. Sie ist bereits in der Orthopädie und Physiotherapie etabliert. Hierbei werden Tapes auf die Haut aufgebracht. Kinesio-Taping ist eine Methode, die die natürlichen Heilungsprozesse des Körpers unterstützen soll. Es soll den Lymphfluss, Durchblutung und Heilung unterstützen und Entzündungen und Schmerzen reduzieren.

Grund zur Durchführung:
Der Ansatz der geplanten Studie ist, die Situation der Patienten nach Herz-Thorax-Eingriffen zu verbessern, da trotz moderner Behandlungsmethoden und schmerzstillender Medikamente häufig Schmerzen und Komplikationen auftreten. Erste Versuche geben Hinweise auf verbesserte Therapiemöglichkeiten unter Hinzunahme des Kinesio Tapes. Ziel und Zweck der Studie sind die Wirksamkeit einer zusätzlichen Therapie mittels der Taping-Methode zu untersuchen um ggfs. neue Therapieschemata zu entwickeln.

Konzept:
In einem ersten Versuch sollen 50 Patienten an der Uniklinik Düsseldorf an der Studie teilnehmen. Die zu untersuchenden Patienten sollen ungeachtet der Diagnose im Zustand nach Sternotomie nach der Verlegung von der Intensivstation mit den Kinesio Tapes behandelt werden, damit Patienten mit Komplikationen schon vor dem Tapen ausgeschlossen werden können. Geschlecht und Alter

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spielen eine untergeordnete Rolle. Patienten mit reduziertem Allgemeinzustand und schwerwiegenden Begleiterkrankungen werden ausgeschlossen.
Die Teilnehmer werden auf zwei Gruppen verteilt. Beide Gruppen erhalten die Standartbehandlung nach der Operation, eine der beiden Gruppen wird zusätzlich mit Kinesio Tapes behandelt. Nach der Datenerhebung soll ermittelt werden, ob Unterschiede im Heilungsprozess zwischen getapeten und ungetapeten Patienten vorhanden sind. Nach dem Klinikaufenthalt werden die Patienten zunächst bei Entlassung untersucht und gebeten eine Rückmeldung per Fragebogen abzugeben. Um eine zufällige Verteilung der Probanden zu gewährleisten, wird den Probanden eine Referenznummer zugeordnet und mit dieser eine Zufallstabelle mittels Excel erzeugt.

Durchführung:
Die Studie wird im Rahmen der Versorgung der teilnehmenden Patienten durchgeführt. Nach dem chirurgischen Eingriff werden den jeweiligen Teilnehmern entsprechenden Kinesio Tapes unterhalb des Schlüsselbeins und auf den seitlichen Rippenbögen angelegt. Diese betreffen nicht das Wundgebiet. In den folgenden Tagen werden die Schmerzintensitäten der Teilnehmer mittels einer Schmerzskala festgehalten. Außerdem wird der Schmerzmittelverbrauch dokumentiert. Wundheilungsstörungen und andere Komplikationen werden routinemäßig erfasst und zur Auswertung herangezogen. Zusätzlich sollen Lungenfunktionstests durchgeführt werden. Außerdem sollen radiologische Auffälligkeiten, der mikrobiologische Befund und die Notwendigkeit einer Antibiotikagabe ausgewertet werden.

Risiken und Nebenwirkungen:

Das Tape besteht aus Baumwolle und elastischen Fasern, die über eine Acrylkleberschicht auf der Haut haften. Es ist Latexfrei und enthält keinerlei Medikamenten. Da das Tape bei der geplanten Anlage ohne erhöhte Spannung auf die Haut aufgebracht wird, besteht kein Risiko einer Schädigung von Gewebe oder Blutgefäßen. Hautreizungen können entstehen, wenn man das Tape schnell, ruckartig von der Haut entfernt. Nach Kinesio Taping Association Empfehlung soll das Tape unter leichtem Druck von der Haut abgezogen werden, sodass kein Trauma entsteht und Hautreizungen weitestgehend vermieden werden.

Bekannte Komplikationen bei der Anwendung von Kinesio-Tape sind die oben beschriebenen Hautreaktionen. Beim Auftreten einer allergiebedingten Hautreizung können die angelegten Streifen sofort entfernt werden. Bei Patienten, die blutverdünnenden Medikamente einnehmen kann es bei erhöhter Spannung des Tapes zu Quadelbildung, Juckreiz und punktuellen Einblutungen kommen. Das Auftreten der Hautreaktionen bei diesen Patienten ist jedoch wissenschaftlich nicht erfasst. Gleiche oder ähnliche Reaktionen wurden auch bei Patienten, die keine blutverdünnenden Medikamente einnehmen, beobachtet. Mögliche Komplikationen durch die gleichzeitige Gabe von blutverdünnenden Mitteln können ausgeschlossen werden, da diese erst ab einer sehr stark herabgesetzten Blutgerinnung (INR von 3,5) eintreten und das Tape ohne Spannung aufgebracht wird.
Patienten mit verstärkter Körperbehaarung sollten im Vorfeld des Tapens im zu behandelnden Bereich rasiert werden um Schmerzen beim Entfernen des Tapes, durch das herausziehen der Haare, zu vermeiden.

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Alternative Therapie

Falls Patienten kein Interesse an der Teilnahme der oben beschriebenen Studie haben, erhalten sie die Standart-Therapie mit Schmerzmitteln.

Notfalladresse bei unerwünschten Ereignissen während der Studie sowie Name und Adresse des Prüfarztes:

Notfallhotline: 0151-14235659 24h Erreichbarkeit

Herr Prof. Dr. med. Michael Klein
Klinik für kardiovaskuläre Chirurgie
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Hinweis auf Versicherung

Da durch diese adjuvante Therapie eine eigenständige Komplikation nicht zu erwarten ist, ist ein zusätzlicher Versicherungsschutz nicht notwendig.

Hinweis auf Freiwilligkeit, Nicht-Teilnahme und jederzeitige Möglichkeit des Widerrufs ohne Angabe von Gründen und ohne Nachteile für die weitere Behandlung

Die Teilnahme an dieser klinischen Prüfung ist freiwillig. Jeder Teilnehmer hat das Recht, seine Einwilligung jederzeit und ohne Angaben von Gründen diese Zustimmung widerrufen, ohne dass sich dieser Entschluss nachteilig auf die spätere Behandlung auswirken wird.

Bestätigung der Vertraulichkeit

Die persönlichen Daten der Teilnehmer werden in verschlüsselter Form gespeichert. Sie werden vertraulich behandelt und einer Weitergabe erfolgt nur in anonymisierter Form.
Die Auflagen des Datenschutzgesetztes werden zu keiner Zeit verletzt.

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Datenschutzerklärung

- Einfluss von KinesioTaping auf den Heilungsprozess nach Sternotomie -

Mir ist bekannt und ich bin einverstanden, dass bei dieser Studie personenbezogene Daten, insbesondere medizinische Befunde, über mich erhoben, gespeichert und ausgewertet werden sollen. Die Verwendung der Angaben über meine Gesundheit erfolgt nach gesetzlichen Bestimmungen und setzt vor der Teilnahme an der Studie folgende freiwillig abgegebene Einwilligungserklärung voraus, d. h. ohne die nachfolgende Einwilligung kann ich nicht an der Studie teilnehmen.

Einwilligungserklärung zum Datenschutz

1) Ich erkläre mich damit einverstanden, dass im Rahmen dieser Studie erhobene Daten, insbesondere Angaben über meine Gesundheit, erhoben, in Papierform oder auf elektronischen Datenträgern in der**Klinik für kardiovaskuläre Chirurgie, Geb. 12.46, Moorenstraße 5, 40225 Düsseldorf**und gespeichert werden. Soweit erforderlich, dürfen die erhobenen Daten pseudonymisiert (verschlüsselt) weitergegeben.

2) Ich bin darüber aufgeklärt worden, dass ich meine Einwilligung in die Aufzeichnung, Speicherung und Verwendung meiner Daten jederzeit widerrufen kann. Bei einem Widerruf werden meine Daten unverzüglich gelöscht.

3) Ich erkläre mich damit einverstanden, dass meine Daten nach Beendigung oder Abbruch der Studie 10 Jahre aufbewahrt werden Danach werden meine personenbezogenen Daten gelöscht, soweit dem nicht gesetzliche, satzungsgemäße oder vertragliche Aufbewahrungsfristen entgegenstehen.

Name Studienteilnehmer/gesetzlicher Vertreter in Druckbuchstaben, Datum, Unterschrift

Patienteneinverständniserklärung zur klinischen Studie:

Einfluss von Kinesio Taping auf den Heilungsprozess nach Sternotomie

Patientenaufkleber/Patientencode

Ich, ...(Name des Patienten)....., wurde von meinem Arzt über Wesen, Bedeutung und Tragweite der klinischen Prüfung mit dem o.g. Titel aufgeklärt.

Ich habe den Aufklärungstext gelesen und verstanden. Ich hatte die Möglichkeit, Fragen zu stellen, und habe die Antworten verstanden und akzeptiere sie. Mein Arzt hat mich über die mit der Teilnahme an der Studie verbundenen Risiken und den möglichen Nutzen informiert.

Ich hatte ausreichend Zeit mich zur Teilnahme an dieser Studie zu entscheiden und weiß, dass die Teilnahme an dieser klinischen Prüfung freiwillig ist. Ich weiß, dass ich jederzeit und ohne Angaben von Gründen diese Zustimmung widerrufen kann, ohne dass sich dieser Entschluss nachteilig auf die spätere Behandlung durch meinen Arzt auswirken wird.

Mir ist bekannt, dass meine persönlichen Daten in verschlüsselter Form gespeichert werden.

Ich habe eine Kopie der Patienteninformation und dieser Einwilligungserklärung erhalten. Ich erkläre hiermit meine freiwillige Teilnahme an dieser klinischen Studie.

Ort und Datum Unterschrift des Patienten

Ort und Datum Unterschrift des aufklärenden Arztes

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Pat.Nr._____

1. Aufnahme in die Studie

Pat.-Initialen _____(Vorname/Nachname)

Geb.-Datum _____(Tag/Monat/Jahr)

Geschlecht M W

Klinik Universitätsklinikum Düsseldorf
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Für die unmittelbare Behandlung verantwortliche(r) Arzt/Ärztin

---

Für die Studie verantwortliche(r) Arzt/Ärztin

Diagnose

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Pat.Nr._____

Checkliste

Folgende Bedingungen sind erfüllt:

- Das geplante Operationsverfahren ist die Sternotomie
- Keine weiteren Risikoerkrankungen sind bekannt (Diabetes, Infektionen, Radiatio-Patienten, adipöse Patienten und Rezidivpatienten, Pergamenthaut, Schuppenflechte und wunde und nässende Hautauschläge im geplanten Tapingbereich)
- Keine bekannte Allergie gegen Acrylkleber
- Schriftliches Einverständnis zur Teilnahme an der Studie und zur Speicherung und Weitergabe der persönlichen Daten im Rahmendes Protokolls liegt vor
- Alter >/= 18 Jahre
- Kooperationsbereitschaft des Patienten
- Erreichbarkeit des Patienten für Behandlung und nachträgliche Befragung

Unterschrift _____

Aufnahme in die Studie ja nein

Pat.Nr.

Datum _____

Unterschrift Studienkoordination_____

Kontaktadresse

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E-Mail: kleinhm@med.uni-düsseldorf.de
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Pat.Nr._____

2. Ersterhebung präoperativ

1. Patientendaten

Pat.Nr. _____
Pat.-Initialen _____
Geb.-Datum _____
Geschlecht M W
Aufnahmedatum in die Klinik _____

2. Daten zur Operation/Diagnose

Diagnose _____
Operationsmethode _____

3. Klinische Angaben

Relevante Begleiterkrankungen	Ja	nein	Wenn „Ja", welche?
Lungenfunktionsstörungen			
Allergien			
Diabetes			
Hypertonie			
Gerinnungsstörungen			
Lymphatische Erkrankungen			
Bisherige Herz-Thorax-Operationen			
Sonstiges			

Datum _____

Unterschrift (Arzt/Ärztin) _____

3

Datenerhebungsbogen
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3. Erhebungsbogen zur Dokumentation der Schmerzintensität

Angabe der subjektiven Schmerzempfindung des Patienten auf einer Skala von 0-10.
(0 = keine Schmerzen, 10 = der größte vorstellbare Schmerz)

Tag	Wert auf der Schmerzskala	Datum	Unterschrift
Präoperativ			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

4

Datenerhebungsbogen
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4. Erhebungsbogen zur Ermittlung des Schmerzmittelverbrauches

Schmerzmittel: _____

(1 = 0mg-50mg; 2 = 50mg-100mg; 3 = 100mg-150mg; 4 = 150mg-200mg)

Tag	Schmerzmittelverbrauch	Datum	Unterschrift
Präoperativ			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			

5

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Pat.Nr._____

5. Erhebungsbogen zum Lungenfunktionstest

Tag	Lungenfunktion		Datum	Unterschrift
	Normal	eingeschränkt		
Präoperativ				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

6

Datenerhebungsbogen
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Klinik für Kardiovaskuläre Chirurgie
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40225 Düsseldorf

Zeitpunkt: Während des Klinikaufenthaltes in der Klinik für Kardiovaskuläre Chirurgie

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6. Erhebungsbogen zur Ermittlung von Wundheilungsstörungen

Tag	Wundheilungsstörungen		Datum	Unterschrift
	Ja	nein		
Präoperativ				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				

7

Datenerhebungsbogen
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7. Erhebungsbogen zur Ermittlung von pulmonale Komplikationen

Tag	Pulmonale Komplikationen					Datum	Unterschrift
	Ja				nein		
	Pleuraerguss	Lungeninfiltration					
		Re.	Li.	Bds.			
Präoperativ							
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							

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8. Erhebungsbogen zur Ermittlung von radiologische Auffälligkeiten

Tag	Radiologische Auffälligkeiten		Datum	Unterschrift	Auffälligkeit (entfällt bei nein)
	Ja	nein			
Präoperativ					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

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Datenerhebungsbogen
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9. Erhebungsbogen zur Ermittlung von positiven mikrobiellen Befunden

Tag	Pos. Mikrobieller Befund		Datum	Unterschrift	Befund (entfällt bei nein)
	Ja	nein			
Präoperativ					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

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Datenerhebungsbogen
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10. Erhebungsbogen zur Ermittlung von zusätzlicher Antibiotikagabe

Tag	Antibiotikagabe		Datum	Unterschrift	Antibiotikum (entfällt bei nein)
	Ja	nein			
Präoperativ					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					

11

Datenerhebungsbogen
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11. Dokumentation von unerwünschten Ereignissen bei Studienpatienten

Unerwünschtes Ereignis	**Anfangsdatum**	**Enddatum**	**Schweregrad** 1= mild 2=moderat 3=schwerwiegend 4=lebensbedrohlich 5= Tod	**Zusammenhang mit der Studie** 1= gesichert 2= wahrscheinlich 3= möglich 4= unwahrscheinlich 5= nicht zu beurteile	**Klassifikation als SAE**		**Datum und HZ Prüfer**
					Ja	nein	

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Erhebungsbogen zur Entlassung

Entlassung regelrecht an Tag x nach Operation (nach 8-14 Tagen postoperativ)	Entlassung nicht regelrecht an Tag y nach Operation	Grund für nicht regelrechte Entlassung	Datum	Unterschrift
X =	Y =			

Entlassung in die Rehabilitation	Entlassung nach Hause	Entlassung in eine andere Klinik	Datum	Unterschrift

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Attachment 1.1 **Patient file**

Datenerhebungsbogen
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Qualitätsfragebogen für Patienten

1. Wie empfanden Sie die Behandlung? sehr gut ☐ gut ☐ befriedigend ☐ ausreichend ☐ mangelhaft ☐ schlecht ☐

2. Wie empfanden Sie die Behandlung mit dem Kinesio-Tape?
sehr gut ☐ gut ☐ befriedigend ☐ ausreichend ☐ mangelhaft ☐ schlecht ☐

3. Wie stark waren Ihre Schmerzen? keine Schmerzen ☐ Sehr gering ☐ leicht ☐ mittel ☐ stark ☐ sehr stark ☐

4. Wie stark wurden Sie durch die postoperative Behandlung beeinflusst?
Gar nicht ☐ Sehr gering ☐ leicht ☐ mittel ☐ stark ☐ sehr stark ☐

5. Wie stark wurden Sie durch das Tape beeinflusst?
Gar nicht ☐ Sehr gering ☐ leicht ☐ mittel ☐ stark ☐ sehr stark ☐

6. Haben Sie vor der Teilnahme an der Studie Erfahrungen mit Taping gemacht?
Ja ☐ Nein ☐

7. Bei „Ja" wie waren Ihre Erfahrungen mit Taping vor der Teilnahme an der Studie?
sehr gut ☐ gut ☐ befriedigend ☐ ausreichend ☐ mangelhaft ☐ schlecht ☐

Vielen Dank für Ihre Teilnahme

Attachment 1.2 **Discharge questionnaire in the tape group**

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Qualitätsfragebogen für Patienten

1. Wie empfanden Sie die Behandlung? ☐ sehr gut ☐ gut ☐ befriedigend ☐ ausreichend ☐ mangelhaft ☐ schlecht

2. Wie stark waren Ihre Schmerzen? keine Schmerzen Sehr gering leicht mittel stark sehr stark
   ☐ ☐ ☐ ☐ ☐ ☐

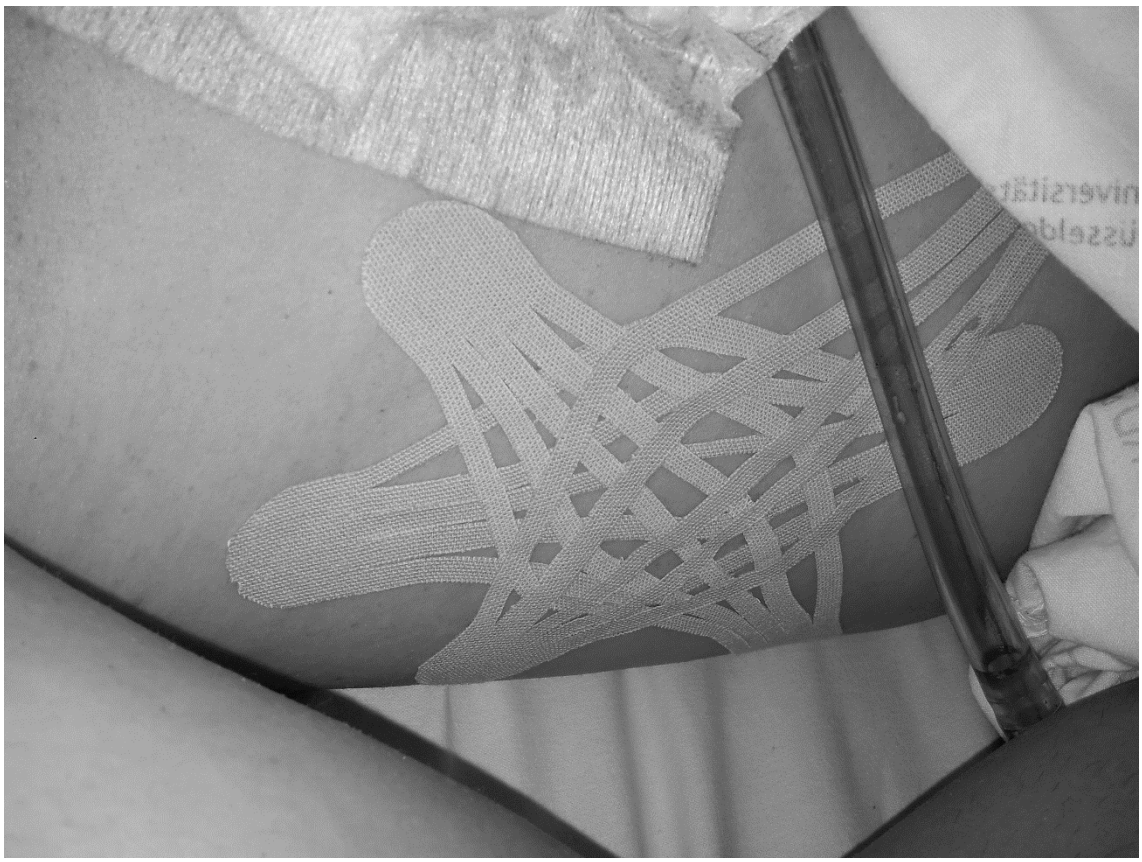
3. Wie stark wurden Sie durch die postoperative Behandlung beeinflusst?
   Gar nicht Sehr gering leicht mittel stark sehr stark
   ☐ ☐ ☐ ☐ ☐ ☐

Vielen Dank für Ihre Teilnahme

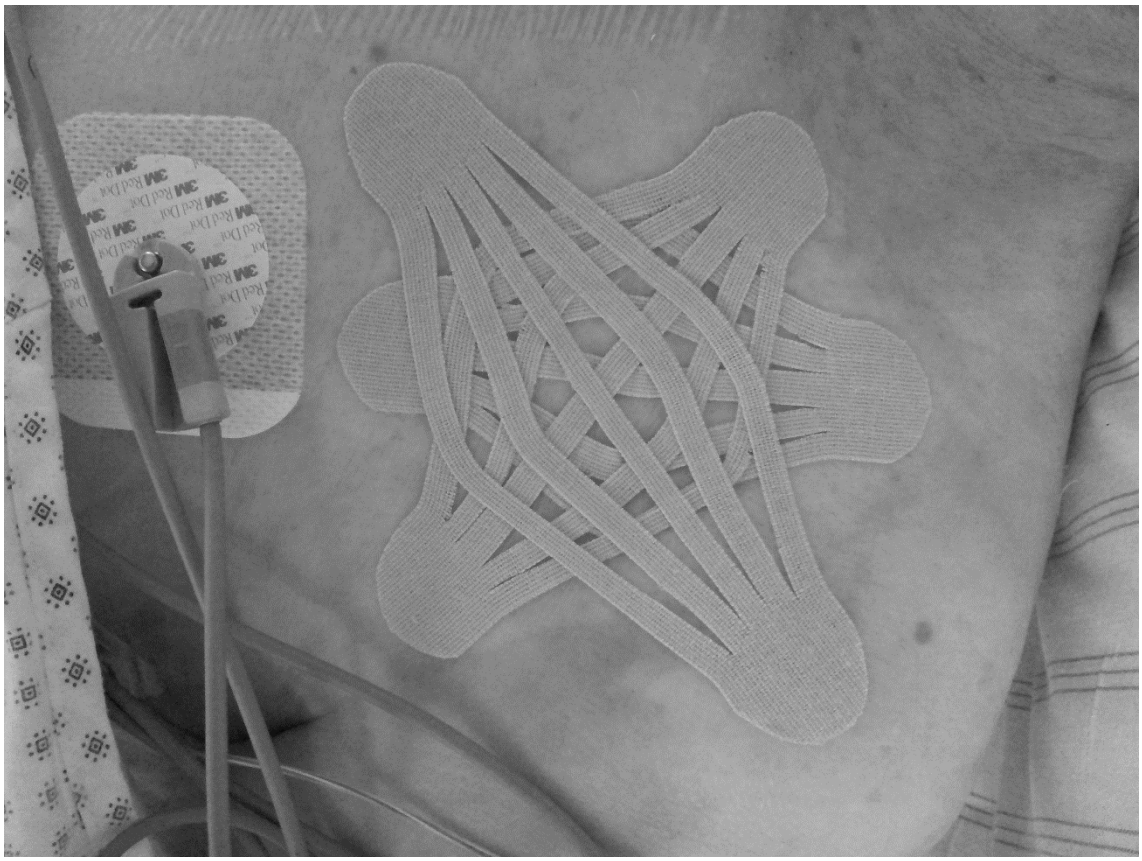
Attachment 1.3 **Discharge questionnaire in the no-tape group**

Attachment 2 Fotos

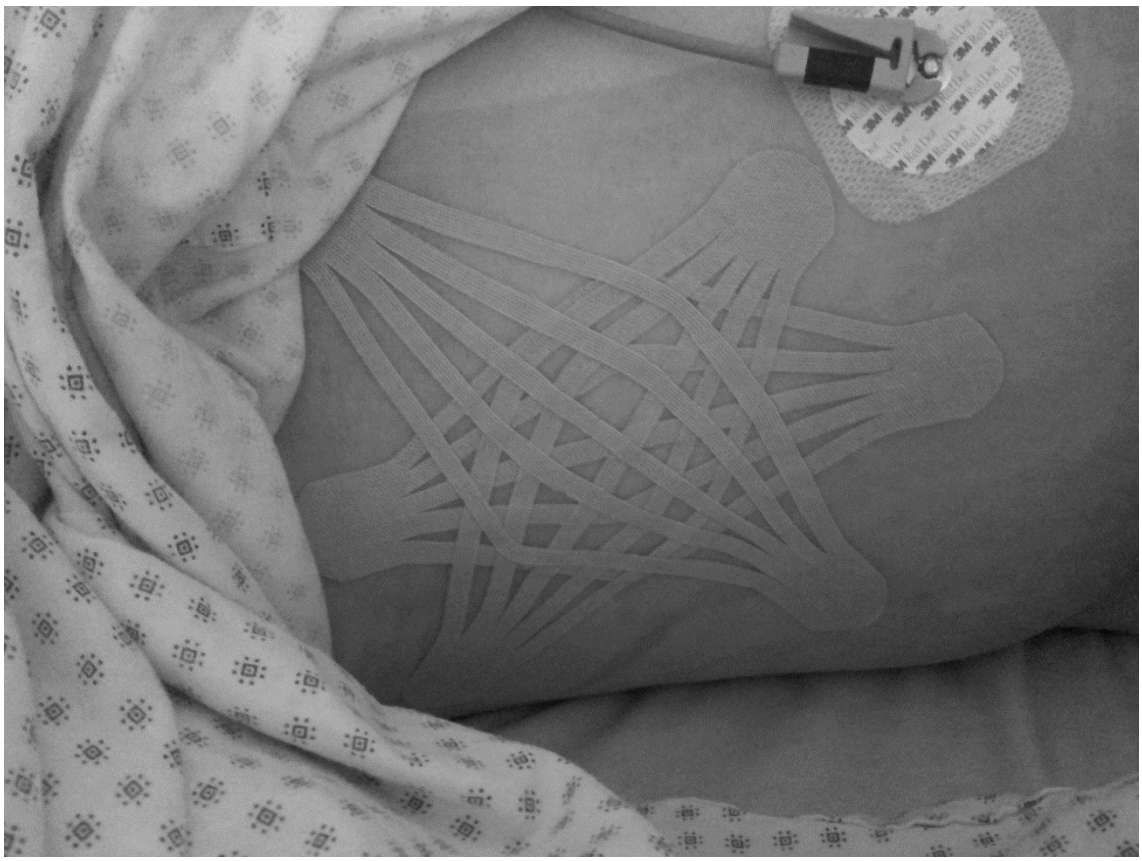
Attachment 2.1 **Infraclavicular tape application**



Attachment 2.2 **Tape application at the lateral thorax**



Attachment 2.3 **Infraclavicular tape application**



Attachment 2.4 **Tape application at the lateral thorax**

Danksagung

An dieser Stelle möchte ich mich bei den Menschen bedanken, die mir während der Anfertigung meiner Doktorarbeit zur Seite standen.

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