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VISUALIZATION, A STRATEGY FOR PATIENTS TO MANAGE PAIN

BY
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ENGLISH SUMMARY

The current practice of alleviating patients' pain during ablation of atrial fibrillation was not optimal and there was a need to study complementary methods that could support the pharmacological pain treatment. Radiofrequency ablation of atrial fibrillation is a relatively new treatment that can effectively eliminate physical symptoms in patients with severe symptoms. Ablation of atrial fibrillation is more complex than other ablation treatments and of longer duration, often 3-4 hours. The treatment may be accompanied by significant discomfort and pain, despite pharmacological analgesia. Visualization has been successfully used during other invasive procedures to manage pain and anxiety. By using non-pharmacological intervention in combination with conventional analgesics, potential side effects and overdose of strong pain medication could be avoided, thus increasing patient safety and well-being.
Pain stimulates the body's stress response and insufficiently treated pain and anxiety can cause discomfort, delayed wound healing, chronic pain and depression postoperatively, with prolonged hospitalization for the patients.

The overall purpose of this present dissertation was to examine the effectiveness, meaningfulness and the feasibility of an intervention, visualization used as an adjunct to usual analgesics to manage pain and anxiety during RF ablation of AF and other minimally invasive procedures.

A quasi-experimental study was conducted to test the effect of visualization and relaxation along with the usual pain medication to reduce pain and anxiety during the ablation of atrial fibrillation (Paper I).
To investigate patients' experiences and meanings of pain and anxiety when visualization was used to manage pain, a qualitative interview study was conducted with interviews of 14 patients from the intervention group in the quantitative study (Paper I) and analyzed by a qualitative inductive content analysis (Paper II). A systematic review (Paper III & IV) including ten studies was performed both in order to test the effect of hypnotic analgesia used in conjunction with usual analgesics to reduce procedural pain and anxiety during invasive procedures and also in order for these results to validate the findings in the quasi-experimental study.
Finally, the results from the quantitative (Paper I) and qualitative study (Paper II) were integrated into a mixed methods study (Paper V) with an explanatory sequential design in order to investigate the association between the patient's experience with visualization and the effect of visualization in relation to pain intensity, anxiety, amount of pain medication, procedure length and adverse events.
The main conclusions were:
Use of visualization together with the usual pain medication resulted in a statistically significant reduction in the use of pain medication (Fentanyl) in the intervention

group compared with the control group. During the procedure, patients expressed spontaneous pain significantly fewer times in the intervention group. However, there was no difference in the experience of pain intensity between the two groups and no difference was observed in measurements of anxiety, procedure length and the number of adverse events in the two groups.

Four categories were found in the analysis of the qualitative study: "Approach to visualization"; "Strategies for managing pain"; "Strategies for managing anxiety" and "Benefits of visualization". By analyzing across the four categories, two main themes were identified: "Stimulating Patients Own Resources" and "Being Satisfied without Complete Analgesia." Visualization was reported as a positive experience without serious side effects. Patients achieved pain relief by visualization and were supported in their own individual strategies for the management and control of pain and anxiety.

The results from the systematic review showed that hypnosis or visualization was effective in reducing the consumption of pain medication used during invasive procedures despite little effect on pain intensity and anxiety. The studies included were difficult to compare with regard to measurements and reporting results, which excluded a meta-analysis on several outcomes.

In the Mixed Methods study, three themes were identified: "Zero pain is not always the goal"; "Not a real procedure reduction, but a sense of time shrinkage" and "Importance of nurses' presence, visualization or not." Patients' own resources to cope with the pain were supported, but the pain intensity did not seem to be affected. The patients experienced the pain, but did not need to "go into the pain". It should therefore be questioned whether the effect of an intervention such as visualization should be measured in terms of pain intensity with a numerical rating scale. Although the patients did not experience severe anxiety during the procedure, they expressed that the close proximity of the staff was of major importance to the fact that they felt safe during the procedure. Despite a long treatment time, patients using visualization felt that they had experienced a short treatment time.

With the research methods used, visualization was found to be effective and meaningful for patients in pain management during ablation of atrial fibrillation. Furthermore, visualization appeared to be a feasible intervention that could be used in daily clinical practice without additional resources being required.

DANSK RESUME

Den nuværende praksis til lindring af patienters smerte under ablation af atrieflimren var ikke optimal og der var behov for at undersøge komplementære metoder der kunne understøtte den farmakologiske smerte-behandling. Radiofrekvent ablation af atrieflimren er en relativt ny behandling, som effektivt kan fjerne fysiske symptomer hos patienter med svære symptomer. Ablation af atrieflimren er mere kompleks end andre ablations behandlinger og af længere varighed ofte 3-4 timer. Behandlingen kan ledsages af betydeligt ubehag og smerte, på trods af farmakologisk analgesi. Visualisering eller hypnose har været brugt med succes under andre invasive procedurer til at håndtere smerte og angst. Ved at anvende en non-farmakologisk intervention sammen med sædvanlig smertestillende medicin kunne potentielle bivirkninger og overdosering af stærk smertemedicin undgås, og derved øge patienters sikkerhed og velbefindende.
Smerter stimulerer kroppens stressrespons og utilstrækkeligt behandlet smerte og angst kan forårsage ubehag, forsinket sårheling, kronisk smerte og depression postoperativt med forlænget hospitalsophold for patienterne.

Det overordnede formål med denne afhandling var at undersøge effekten, meningsfuldheden og anvendeligheden af en intervention, visualisering anvendt sammen med sædvanlig smertestillende medicin til håndtering af smerte og angst under radiofrekvent ablation af atrieflimren og andre invasive procedurer.

Et quasi-eksperimentelt studie blev gennemført for at teste effekten af visualisering og afslapning sammen med den sædvanlige smertestillende medicin til at reducere smerte og angst under ablation af atrieflimren (Artikel I). Til at undersøge patientens oplevelser og betydninger af smerte og angst når visualisering blev brugt til håndtering af smerte, blev en kvalitativ interview undersøgelse udført med interviews med 14 patienter fra interventionsgruppen i det kvantitative studie (Artikel I) og analyseret ud fra en kvalitativ induktiv indholdsanalyse (Artikel II). Et systematisk review (Artikel III & IV) med ti studier inkluderet blev udført med henblik på, dels at teste effekten af hypnotisk analgesi brugt sammen med sædvanlig smertestillende medicin til at reducere procedurale smerter og angst under invasive procedurer og dels for, at resultaterne herfra kunne validere resultater fra det quasi-eksperimentelle studie.

Endelig blev resultaterne fra det kvalitative og det kvantitative studie integreret i et mixed methods studie (Artikel V) med et ”explanatory sequential design” for at undersøge sammenhængen mellem patienternes oplevelse med visualisering og effekten af visualisering i forhold til smerteintensitet, angst, mængde af smertemedicin, procedurelængde og adverse events.

De vigtigste konklusioner var:

Anvendelse af visualisering sammen med den sædvanlige smertestillende medicin medførte en statistisk signifikant reduktion af forbruget af smertestillende medicin (Fentanyl) i interventionsgruppen sammenlignet med kontrolgruppen. Under proceduren udtrykte patienterne spontane smerter signifikant færre gange i interventionsgruppen. Derimod var der ingen forskel i oplevelsen af smerteintensiteten imellem de to grupper og ingen forskel blev observeret i oplevelsen af angst, procedurelængde og antallet af "adverse events" i de to grupper.

Fire kategorier fremkom i analysen ved det kvalitative studie: "Approach til visualisering"; "Strategier til håndtering af smerte"; "Strategier til håndtering af angst" og "Fordele ved visualisering". På tværs af de fire kategorier blev to overordnede temaer identificeret: "Stimulering af patienternes egne ressourcer" og "At være tilfreds uden fuldstændig analgesi". Visualisering blev rapporteret som en positiv oplevelse uden alvorlige bivirkninger. Patienterne opnåede smertelindring ved hjælp af visualisering og blev støttet i deres egne individuelle strategier til håndtering og kontrol af smerte og angst.

Resultaterne fra det systematiske review viste at hypnose eller visualisering var effektiv til at reducere forbruget af smertestillende medicin, der anvendes under invasive procedurer, på trods af ringe generel effekt på smerteintensitet og angst. De inkluderede undersøgelser var vanskelige at sammenligne med hensyn til målinger og rapporteringsresultater, som udelukkede en meta-analyse på flere outcomes.

I Mixed methods studiet blev tre temaer identificeret: "Nul smerte er ikke altid målet"; "Ikke en reel procedure reduktion, men en følelse af "tids-krympning" og "Betydningen af sygeplejerskernes tilstedeværelse, visualisering eller ej". Patienternes egne ressourcer til at håndtere smerten blev understøttet men smerteintensiteten synes ikke påvirket. Patienterne oplevede smerten, men skulle ikke "gå ind i smerten". Der bør derfor stilles spørgsmålstegn ved om effekten af en intervention som visualisering bør måles på smerteintensitet med en numerisk "rating scale". Selv om patienterne ikke oplevede alvorlig angst under proceduren gav de udtryk for at personalets tætte tilstedeværelse havde stor betydning for, at de følte sig sikre under proceduren. Trods en reel lang behandlingstid, oplevede patienterne med visualisering en kort behandlingstid.

Med de anvendte forskningsmetoder blev visualisering fundet effektiv og meningsfuld for patienter i håndtering af smerte under ablation af atrieflimren. Yderligere viste visualisering sig som en gennemførlig intervention, der kan anvendes i daglig klinisk praksis uden yderligere ressourcer tilført.

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ABBREVIATIONS

AF: ATRIAL FIBRILLATION

CG: CONTROL GROUP

CI: CONFIDENCE INTERVALS

CATH. LAB.: CATHETERIZATION LABORATORY

DC CONVERSION: DIRECT CURRENT CONVERSION

FPS-R: FACES PAIN SCALE-REVISED

IG: INTERVENTION GROUP

IQR: INTER QUARTILE RANGE

JBI-MASTARI: JOANNA BRIGGS INSTITUTE META-ANALYSIS OF STATISTICS ASSESSMENT AND REVIEW INSTRUMENT

MMSE: MINI MENTAL EXAMINATION TEST

NRS: NUMERIC RATING SCALE

PRISMA: PREFERED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSIS

RF: RADIO FREQUENCY

RR: RISK RATIO

SCL-92: SYMPTOMS CHECKLIST 92

SD: STANDARD DEVIATION

STD. MEAN DIFFERENCE: STANDARDIZED MEAN DIFFERENCE

SUD: SUBJECTIVE UNITS OF DISCOMFORT SCALE

STAI: STATE TRAIT ANXIETY INVENTORY

VAS: VISUAL ANALOGUE SCALE

VRS: VERBAL RATING SCALE

CHAPTER 1. INTRODUCTION

Many patients undergo invasive procedures, which can be accompanied by considerable pain and anxiety (1-4). Pain contributes to the body's stress response and unrelieved pain and anxiety can cause discomfort, delayed wound healing, chronic pain and depression postoperatively with longer hospital stays for the patients (5) thus requiring effective and adequate pain management from health care staff (6).
The global "pain community" has declared access to adequate pain management to be a fundamental human right and failure to treat pain is considered poor medicine and unethical practice (7, 8).

In daily clinical practice at a cardiac catheterization laboratory it was often observed that patients undergoing radiofrequency (RF) ablation of atrial fibrillation (AF) experienced some degree of pain and anxiety during the procedure despite treatment with strong pain medication. Due to the risk of overdosing there was a limit to how much pain medication could be given. Pain is present during short treatment periods (lesion applications) and disappears in between these. Thus it can be challenging to control the pain medication so that the patients both get the medication needed for pain relief during the lesions but at the same time do not experience side effects. The current practice for alleviating patients' pain seemed inadequate and gave reason to look for non-pharmacological interventions that could support the pharmacological pain management during ablation of AF. By using a non-pharmacological adjunct together with usual pain medication, potential side effects from using additional strong pain medication could be avoided thereby increasing patients' safety and well-being (9).

This dissertation, "Visualization, a strategy to manage pain" focuses on pain management during radio frequency ablation of AF and other minimally invasive procedures, with particular focus on a non-pharmacological intervention, visualization, as an adjunct to pharmacological pain management as a strategy for reducing or manage procedural pain and anxiety.

The number of invasive procedures has increased over recent years. Diseases previously requiring surgery with general anesthesia are today often treated during an invasive procedure outside the operating theater under a light conscious sedation with intravenous sedatives and opioids (10, 11). This is a commonly used approach for management of acute procedural pain which, however, has potential side effects, especially when given in large doses (12).

There are several benefits from minimally invasive procedures compared to open surgery such as e.g. reduced tissue trauma; faster recovery and shorter hospital stay (13). However it can be difficult for patients to manage pain and anxiety during the

procedure when they are awake. Several factors can affect the level of pain and anxiety, e.g. local anesthetic injection may be painful, an experience of greater pain than expected during the procedure, monitor alarms, the low temperature in the procedure room, and unpacking instruments.

Patients' satisfaction with care has been found to be closely related to pain and pain management during their hospital stay, although satisfaction data must be interpreted with care because some patients report high satisfaction despite experiencing moderate to severe pain during their stay (14). However experiences with pain management do not only rely on pain relief but are also associated with the patients' expectations, preoperative anxiety or fear as well as medication side effects. Patient involvement and the quality of the patient-caregiver relationship are also factors influencing how patients perceive pain treatment during a procedure (15, 16).

Based on the clinical problem that patients undergoing ablation of AF in the Cardiac Cath. Lab could not be relieved of pain with pharmacological treatment alone, visualization was investigated as a possible method to relieve pain and anxiety. Thus the overall purpose of this present dissertation was to examine the effectiveness, meaningfulness and the feasibility of an intervention, visualization used as an adjunct to usual analgesics to manage pain and anxiety during RF ablation of AF and other minimally invasive procedures.

Quantitative and qualitative methodologies were used to investigate the effectiveness, meaningfulness and feasibility of visualization as an intervention to alleviate pain and anxiety. Integrating results from the quantitative and qualitative study in a mixed methods design was chosen to give a more comprehensive understanding of the complexity of the research problem. The research questions explored in this dissertation were therefore investigated by studies using both a quasi-experimental design; a qualitative interview design; a mixed methods design and finally a systematic review.

CHAPTER 2. BACKGROUND

2.1. PROCEDURAL PAIN

It is well known that interventional procedures can cause pain. However, with the knowledge of the supposed benefits of the procedure in mind, clinicians often assume that the pain is acceptable to the patients (17). Furthermore, patients cannot always express the extent of their discomfort during a procedure because the pain is a combination of subjective, sensorial and cultural experiences (18).

To provide appropriate pain management for patients going through painful procedures an understanding and knowledge of procedural pain and how the patients experience this pain is required. Data regarding short-term and long-term effects of procedural pain are limited, however, the effects of acute pain might be applied to procedural pain (19).

Acute pain is quite a composite condition, both dynamic and variable causing physiological and psychological distress and leading to increased demands on the organs in the body affecting cardiopulmonary function, inflammatory response, metabolic response and the immune system including wound healing (20, 21). Psychological distress with high levels of anxiety and fear are known to affect the stress response and it is well known that if the patients experience unpredictable painful episodes their anxiety or fear level rises (19, 22). Even very short intervals of acute pain can affect the body with long-term changes such as chronic pain and long-term psychological stress (5, 14).

Pain is a complex sensory, emotional and cognitive phenomenon that is experienced subjectively. A widely used definition from the American nurse Margo McCaffery states that: “pain is, whatever the experiencing person says it is, existing whenever and wherever the person say it does”(23), thereby emphasizing the subjective and individual perspective or dimension of pain, even though it is a broad definition. There are other definitions of pain (24, 25) but no unambiguous definition. However the International Association for the Study of Pain has described pain as, “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”. The emotional or affective component of pain has an evaluative dimension and the sensory component is more of a perception of the intensity of pain. The components of the pain experience are important in terms of pain assessment and how pain management is planned and carried out in relation to the specific pain (19).

Based on the definitions of pain, any procedure causing actual or potential tissue damage has the potential to cause pain to patients. No matter which procedure or

setting is involved, if the pain is not expected or treated appropriately the patients may experience many negative effects and a higher level of pain with future procedures (26). Patients could therefore experience procedural pain from the simplest procedures like venipunctures to highly invasive procedures such as RF ablation of AF or other cardiac procedures. However, it cannot be predicted whether a procedure will be with or without pain, because it depends on many factors such as gender, age, diagnosis, culture and cognitive level, and study results differ regarding these factors (19).

The pain system is a multi-stringency sensing system where information about tissue damage is communicated to the brain via many systems and where multiple areas of the brain participate. This activation of many brain areas is probably responsible for the complex and highly nuanced experiences of pain and the same structures also participate in the pain control (27).

A recent study with patients satisfaction questionnaires (n=101) after RF ablation of AF showed that 67% of the patients experienced pain during the procedure and often both more - and stronger pain than expected (28). Another study with 80 patients concluded that the majority of the patients experienced pain during RF ablation of AF even when given strong pain medication. Furthermore, they found that women experienced more pain than men during the procedure (29). Generally very few studies have investigated patients' experienced pain during ablation of AF but those conducted support the observations done at our department (28, 29) .

Optimal pain management in the perioperative setting is thus an important focus in order for the patient to achieve a successful recovery and to avoid a prolonged stay at the hospital, with increased costs for society (14). Furthermore comprehensive pain assessment is required, because a detailed understanding of the assessment together with the management of the acute pain is important to prevent chronic pain and to achieve the patients' satisfaction (7, 30-33). In order to increase both physical and psychosocial patient outcomes for procedure comfort, a plan for management of the procedure pain should be developed with both pharmacological and non-pharmacological interventions. The patient should be involved in its development (17, 32).

Acute pain may be controlled with adequate short term pharmacologic treatment, using either non-opioid analgesics or opioid analgesics – or in combination depending on the type of pain. Using these drugs, however, confers a risk of side effects with cardiovascular and respiratory influence or depression, nausea, vomiting and over-sedation even in dosages usually well tolerated. The risks of medically induced over-sedation have to be weighed against the risks of uncontrolled discomfort. Therefore optimal pain relief often requires combining a variety of medications and possibly including a supplement of a non-pharmacological therapy (34, 35).

Non-pharmacological therapies have proven to be important in relieving acute pain and have gained acceptance in clinical settings as a supplement to the pain medication used during invasive medical or minor surgery procedures (36, 37). Examples of non-pharmacological interventions used to reduce procedural pain include hypnosis or visualization, relaxation techniques, meditation, massage, music therapy or music used as distraction or relaxation (38-42). Visualization or hypnosis has been used in a wide range of clinically controlled studies to reduce pain and anxiety during various painful procedures (2, 4, 38, 43-45). The strength of existing research on the subject is still limited but fortunately increasing.

A growing demand for alternative treatment supplements from patients could be one of the reasons why more hospitals offer these treatments. Moreover non-pharmacological interventions are often quite easy to administer and have fewer side effects than pharmacological analgesics (46). To the best of our knowledge the effect of visualization used during RF ablation of AF has not yet been investigated.

2.1.1. CLINICAL PAIN ASSESSMENT

Pain is a subjective experience or feeling, and it is a challenge to translate this experience into an objective measure because it is difficult to find methods to transfer a multidimensional patient perception into an objective one-dimensional measurement or scale which can be communicated or documented. Indeed there has been criticism of how pain is measured and whether pain measuring instruments are useful when they translate patients' experiences into a single number (47, 48). Despite this, both from a treatment perspective and from a research perspective, there is a need to describe the patient's pain as well as changes to it in order to determine if a pain treatment works. Moreover, it is important that it is the patient who measures and reports the pain as several studies have shown that health professionals measure the patient's pain as being significantly lower than the patients themselves do (49, 50). Furthermore it was shown that patients feel safer and less burdened if they were asked about their pain and felt that using a rating scale for assessment facilitated communication of pain with the health care professionals (51, 52).

Acute pain during procedures varies over time, hence repeated assessment of its intensity and quality over time is necessary to make adjustments to the pain treatment. To achieve effective pain management, valid and reliable pain assessment tools are essential, including measurement tools appropriate to the specific population, culture, situation, type of pain, and setting (31, 53).

The most commonly used measurement tools during medical procedures and research settings are the Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), Verbal rating Scale (VRS) and the Faces Pain Scale-Revised (FPS-R). Each of these measurements reliability and validity across many populations are supported by evidence and they have been found to detect changes in pain intensity. However the NRS and VAS might be first choices for specifically sensitive and

responsive pain intensity measurements (54-56). In fact the NRS has been found to be slightly more responsive than VAS in some studies and furthermore may be preferred over VAS by patients and many clinicians in different clinical and research setting because of its simplicity and easy administration and scoring (56, 57).
However, the main criticism of VAS and NRS is that they are one-dimensional measuring instruments used to assess acute pain which is multi-dimensional. This indicates that patients not only rate their pain intensity but also describe other components of the pain, e.g. the emotional component (47, 48). Empirical evidence has been drawn from a number of studies with an acceptance of a divisibility of pain into sensory and affective components but at the same time with speculation as to how these components are synthesized in the perception of pain (58).

2.2. ANXIETY IN THE PRE- AND PERIOPERATIVE SETTING

It is known that anxiety can worsen pain during medical procedures and after surgery (59, 60) where patients with a high level of preoperative anxiety perceive more pain during the medical procedure than patients with a moderate level of anxiety (61).
Acute stress and high levels of anxiety are seen in patients admitted for surgery or invasive procedures. It is a commonly known phenomenon and accepted as a normal reaction for patients pre- and perioperatively. There is also an increasing interest in how anxiety can affect the outcome of the invasive and surgical procedures (62, 63). The prevalence of preoperative anxiety has been shown between 11-80% depending on the method used for measurement and the type of surgery. The highest prevalence was found where standardized measuring tools were used, perhaps because ordinary questioning ignores some patients with preoperative anxiety (63-65). The pre- and perioperative period represent an unpredictable and potentially dangerous threat for some patients and a certain level of anxiety is a common reaction to this. Nevertheless, it is known that a high pre- and perioperative anxiety level causes patho-physiological effects such as tachycardia, arrhythmias, high blood pressure and experience of more pain post-operatively. Moreover increased anxiety level pre- or perioperatively can increase the experience of nausea, fatigue and depression and may prevent or delay healing postoperatively. All of these symptoms may adversely affect the results of an invasive procedure and can contribute to prolonged and expensive hospital stays for the patient (66).

Anxiety is caused by a number of factors varying from concerns about the imminent invasive procedure, fear of pain, the possible anesthesia, having blood transfusion, a fear of needles, loss of control or fear of dying. The patient's previous experience with surgery or medical procedures and experiences from other family members or friends are factors that can influence his or her anxiety level. Moreover anxiety is a subjective feeling that can be influenced by age, gender and ability to cope with

stressful experiences (65). Thus it can be difficult for staff to identify and characterize the pre- or perioperative fear or anxiety (67).

In a large study with more than 700 patients waiting for various surgery procedures (68) it was found that the in-hospital waiting period preceding surgery was the patients' greatest concern. Furthermore three different dimensions of various fear were shown: 1) the fear of the unknown, 2) the fear of feeling ill, and 3) the fear for one's life. This fear might continue during the procedure if the patient is awake and undergoes the procedure in local anesthesia.

Studies often differentiate between fear and anxiety by the fact that an object is identified for fear, whereas one often cannot be identified for anxiety (69, 70). However, when measuring fear or anxiety pre- and perioperatively distinguishing between the two concepts is often not done because many of their characteristics may coincide (71). In the literature, the concepts are often also very broadly defined.

Patients' anxiety in the pre- or perioperative setting can be managed by both conventional pharmacological and non-pharmacological interventions; however health care professionals typically use pharmacological medication such as sedatives as these are easy to apply and effective, even though these drugs can cause serious side effects and might require extended monitoring (72, 73).

A systematic review reported that many non-pharmacological strategies to reduce pre- and perioperative anxiety have been tried (66). From this review the most successful interventions were education and music therapy, but the authors suggested other interventions be investigated.

Visualization or hypnosis, another non-pharmacological intervention has been shown to reduce distress during invasive or surgical procedures. Several studies have proven the effect of visualization or hypnosis as an adjunct to usual care or sedatives (73, 74). In addition it has been concluded that adjunctive hypnosis treatment provided beneficial outcomes for patients with both low and high levels of anxiety but that the latter had the most to gain (74).

2.2.1. ASSESMENT OF ANXIETY IN THE PERIOPERATIVE SETTING

Although there are benefits as described above from going through an invasive procedure compared to open surgery, patients often perceive and express anxiety and pain that exceeds their coping strategies. They might experience a loss of control when in the procedure room (75). It is therefore essential to identify the patient's pre- and perioperative anxiety with a validated and useful tool, capable of measuring anxiety levels (11). By using accurate measurements on the patient's anxiety level before and during the procedure, effective and supportive anxiety-suppressive interventions can be initiated. Therefore, the choice of instruments is of

great importance (12). The question is whether the tool allows health staff to identify exactly what the patients feel at the particular time when the suspected anxiety is measured.

The State Trait Anxiety Inventory (STAI) or visual analog scale (VAS) has been used in a number of studies to measure preoperative anxiety (62, 64, 76).

In a study of preoperative anxiety with 32 women undergoing elective breast surgery, a significant correlation was found between three measuring instruments STAI, VAS and Symptom Checklist 92 (SCL-92)(64). The authors concluded that all three instruments measured something essential in the phenomenon of pre-operative anxiety, but recommended using SCL-92, because it was validated in a Danish background population (77). However, SCL-92 cannot be used to measure anxiety during the procedure, due to the fact that it takes about 10-15 minutes to complete it. The SCL-92 will therefore be more suitable for measuring preoperative anxiety or baseline anxiety prior to the procedure and VAS or NRS for use during the procedure.

2.3. ATRIAL FIBRILLATION

Atrial fibrillation (AF) is the most common type of cardiac arrhythmia diagnosed in clinical practice, with an estimated prevalence of 1-2% in the general population and with a lower prevalence in women. Globally the estimated prevalence of AF was 33.5 million in 2010 (78). The prevalence of AF is expected to double in the next decades, progressing with age thus becoming an increasing medical and economic challenge for the health system globally (79). The number of patients with AF in Europe is estimated to increase by 120,000-215,000 annually, reaching 14–17 million in 2030 (80).

AF is associated with poor quality of life, increased hospitalization, with a 5-fold greater risk of stroke, a 3-fold greater risk of heart failure and a doubling of mortality (81). Patients with AF are often living with a number of symptoms, frequently with a limited physical function and an impaired health status characterized by psychological distress (82, 83). In addition patients with AF often have limited knowledge about their disease, how to treat their disease, and how to manage their symptoms in a safe way (84).

AF is based on presentation and duration divided in the following types (79):

- Paroxysmal AF – Episodes of AF - self terminating, often within 48 hours but can continue up to 7 days.
- Persistent AF – Lasts longer than 7 days. Episodes of AF terminated by electrical or medical cardio version are included as persistent AF.

- Long-standing persistent AF – Episodes of AF have lasted ≥ 1 year when it is decided to adopt a rhythm control strategy.
- Permanent AF – Exist if the presence of the AF is accepted by the patient and the physician and a rhythm control strategy not attempted.

The purpose of the management of AF is to alleviate AF symptoms by re-establishing sinus rhythm and to prevent complications. Stroke prevention with anticoagulant treatment is one of the essential elements in the management of AF (79).
Two main strategies are available to manage AF, respectively rate and rhythm control strategies, where the rate control treatment with anti-arrhythmic drugs is given to all patients with symptomatic AF or AF with fast ventricular action.
Rhythm control includes a cardio version (medical and/or electrical), anti-arrhythmic treatment and pulmonary vein isolation, RF ablation or Cryo ablation. The main purpose is symptom reduction (79, 85). A recent systematic review showed that catheter ablation had a better effect in inhibiting recurrence of AF compared to medical treatment in patients with paroxysmal or persistent AF (86).

2.4. RADIOFREQUENCY ABLATION OF ATRIAL FIBRILLATION

RF catheter ablation of AF is a relatively new but well established treatment with an increasing number of procedures being performed worldwide (87). The primary goal of RF ablation is to relieve the patients' symptoms and to improve their quality of life. The catheter ablation is proven to be quite effective in managing paroxysmal and persistent AF, thus about 75% of patients with paroxysmal AF achieve durable maintenance of sinus rhythm (87, 88). RF ablation is superior to medical therapy for prevention of recurrence of atrial arrhythmias, both short and long term regardless of AF type (89).
The RF ablation consists of point-by-point radiofrequency lesions encircling each of the pulmonary veins' ostias. The RF ablation procedure can last several hours with numerous applications of different durations up to three to four minutes with breaks in between (87).
It often causes varying degrees of pain and discomfort to the patients despite pharmacological analgesia. The pain is strongly related to the lesions (29, 90). The procedure can be performed under general anesthesia or in a light conscious sedation according to patient characteristics, experience, and protocols of the different institutions. Unfortunately there is no gold standard for pain management in this group of patients (91). In most hospitals in Denmark the ablation of AF is performed under local anesthesia, with a light conscious sedation with Fentanyl or Morphine, together with Midazolam, administered by trained nurses.
Although many patients have great success with the RF ablation, it has been found that patients who have undergone ablation of AF reported negative experiences, particularly during and immediately after the ablation procedure. The experiences were mainly related to having more pain than expected, being more awake than

expected or related to the result of inadequate provision of peri-procedural analgesia and sedation (28).

2.5. VISUALIZATION AS A PAIN MANAGEMENT STRATEGY DURING PAINFUL MEDICAL PROCEDURES

The growing need and interest in non-pharmacological treatments has sparked an increasing interest in visualization as an adjunct to pharmacological treatments helping patients coping with both acute and chronic pain and anxiety(38).

Several definitions of visualization or hypnosis have been suggested over time, but professionals have disagreed on the true meaning of hypnosis mainly because the nature and mechanisms underlying the effects of hypnosis are not yet fully understood. Hypnosis could be linked to cortical and physiological incidents (45, 92).The definition used in a dissertation from 1994 from "the Society of Psychological Hypnosis" stated that hypnosis can be a procedure during which one person (e.g. a patient) is guided by another (e.g. the nurse) to respond to suggestions for changes in subjective experience, (e.g. pain and anxiety), alterations in perception, sensation, emotion, thought or behavior (93). Thus hypnosis is a form of self-hypnosis, but can be guided by another person (94).
Over the years the definition was criticized for not containing the word "state", that the definition was a mixture of both a definition and a description of normal hypnotic experiences and that the definition contained some of the areas where hypnosis could work and not others. This led to a revised definition published in 2015 (92). In this new definition hypnosis or visualization was defined as "a state of consciousness involving focused attention and reduced peripheral awareness characterized by an enhanced capacity for response to suggestion" Hypnotic induction was defined as, "A procedure designed to induce hypnosis". The new definition aimed at distinguishing between hypnosis (the product) and procedures that are planned to lead to hypnosis.

In our studies we have preferred the term "visualization" instead of "hypnosis". However when reporting studies in which the term hypnosis was used we have used the same term. Even though patients are more open minded to alternative techniques now than years ago, some may distrust the term hypnosis because they might have had previous experiences with e.g. stage hypnosis. When patients are undergoing ablation of AF, they may suffer from preoperative anxiety or a sense of insecurity where a term such as hypnosis may contribute to further uncertainty because of previous experiences. Furthermore, we share an opinion with many other professionals, that it is the process of the intervention, visualization, used in the studies which is important rather than the label term (95, 96).

When using visualization as hypnotic analgesia in the treatment of pain or anxiety prior to or during a painful procedure, it can be explained as a technique for

diverting attention from pain and anxiety and a state of attentive and receptive concentration that allows patients to explore their own abilities to cope with a painful and distressing situation (97). Typically there are five stages when using hypnosis or visualization: Setting the stage and building rapport; Lower breathing and improving relaxation; Suggestions for a deeper relaxation and the hypnotic state, to enter trance; Suggestions for pain relief or anxiety management and reorientation (45).

There is a great deal of individual variability in how visualization works and in responsiveness to hypnotic suggestions and hypnosis is not effective in all people. Hypnotizability or hypnotic susceptibility can be explained by a subject's response to suggestions or hypnosis (92) and measured by a standardized tool specifically developed for the terms (98, 99).

In recent years, more research studies of better quality have been conducted on hypnosis used together with the usual pain medication to reduce acute pain and anxiety during painful procedures. In particular, in radiological invasive procedures, larger studies have demonstrated effects (2, 4, 43, 44). In addition, the effect of hypnosis on pain, consumption of pain medication, procedure time and several other outcomes has been investigated among other things in connection with dental procedures, labors, painful dermatological procedures, pregnancy termination, electromyography and others, with an effect of hypnosis on several parameters (3, 100-103). Very few studies have been conducted within cardiology invasive procedures and these are older and of questionable quality and with outcomes of a more technical nature (104, 105). To our knowledge no studies have been published where visualization or hypnosis has been used as an adjunct to usual analgesia to reduce pain in cardiology electrophysiological procedures.

New imaging technology such as PET and MRI scanning can provide researchers with a better understanding of which parts of the brain are affected by hypnotic analgesia, under the influence of pain. A complete understanding of the underlying neural mechanism of pain and hypnosis will help in the creation of post-hypnotic suggestions aimed at the individual's pain (45, 106).

2.5.1.PATIENTS EXPERIENCES OF VISUALIZATION USED AS PAIN REDUCTION DURING INVASIVE PROCEDURES.

Evidence of patients' subjective experiences using visualization for pain reduction during painful invasive procedures and how they manage pain by using it might be a very valuable aid before visualization is used in clinical practice, helping the staff to improve pain assessment and management. Several studies have shown that clinical management of pain does not always correlates with the patients' experiences although pain is one of the main sources of suffering when patients are undergoing medical procedures (28, 107).

However, only a few studies were identified investigating patients' views of or satisfaction with visualization or hypnosis when used for pain management from a

literature review (108, 109). One study (108) with 152 women from the intervention group of a randomized controlled trial investigating hypnosis for managing pain and anxiety during pregnancy terminating procedure were asked following the procedure for which of the three hypnosis strategies they used during the procedure: "imagining of a secure place", "out of body experience" and "a focal analgesia strategy with numbness of hands and / or abdomen". The study showed that 71% of the women asked used the imagining of a secure place, but also used the out of body experience, in total 42% and 39% used focal analgesia. After a month all patients from the CG and the IG in the randomized controlled study (100) were asked to mark their likes or dislikes of the procedure. Furthermore patients from the IG were asked if they would recommend hypnosis to a friend undergoing a similar procedure and whether they would participate again in a similar hypnosis study. Ninety seven percent of the respondents affirmed that they would recommend hypnosis to a friend and all but one of the women asked in the hypnosis group were satisfied with their hypnosis experience. More than 98% of the participants in both groups were willing to participate in a similar study with hypnosis as an adjunct to usual pain.
The other study (109), including 30 participants with chronic pain investigated patients' satisfaction with hypnosis when using hypnosis in managing pain. The patients were contacted by telephone and asked structured questions. In this study a high level of treatment satisfaction was found despite the patients not achieving complete pain relief. Furthermore the patients reported several benefits, both pain-related and non-pain related.

2.6. SUMMARY AND RATIONALE FOR THE PRESENT DISSERTATION

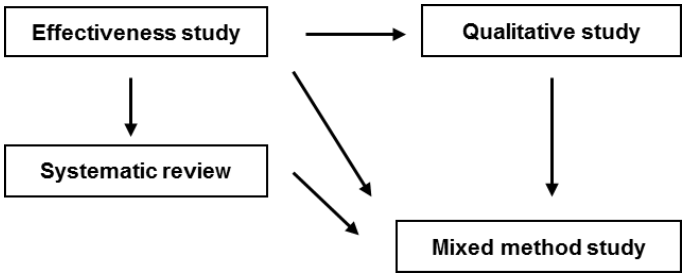
Thus the current practice for relieving patients' pain seemed inadequate using pharmacological treatment alone when undergoing ablation of AF and gave reason to look for non-pharmacological interventions that could support the pharmacological pain management.
Ideally patients' values along with clinical expertise together with research evidence should guide a change in clinical practice when a new routine is to be started (110). First of all, it is necessary that strong evidence be available. Thus the intervention investigated has to be found effective and useful in more studies. In addition patients must find the intervention meaningful and finally the staff must be adequately trained to have expertise in providing the intervention (111, 112). The intervention has to be found effective, meaningful and feasible before implementation can be effectuated (113).

The research questions in the present dissertation were therefore investigated in four studies structured as illustrated below. Figure 1.To test the effectiveness of the intervention, a quantitative, quasi-experimental study with a control group was conducted and to explore the meaningfulness of visualization a qualitative interview study was carried out with interviews of participants from the intervention group

(IG) of the quantitative study. The intervention's feasibility was investigated by carrying out the quantitative study (114) in daily routine practice with a trained staff from the ablation team and by exploring whether the intervention was useful for the patients. The effectiveness study and the qualitative study were planned at the same time. The systematic review was conducted subsequently in order to gain insight into whether the results in the quantitative study could be supported in other studies. Furthermore, the systematic review could also validate the results in the quantitative study. Finally the mixed method study was carried out. Results from the quantitative and qualitative studies were integrated in order to achieve a better understanding of the association between the patient's perception of using visualization and the effects of visualization on pain, pain intensity, spontaneously expressed pain and anxiety as well as pain medication used during the ablation.

To the best of our knowledge no one has previously reported the use of visualization to reduce pain during RF ablation of AF. Hence there is a scientific relevance of this PhD dissertation. Additionally, previously conducted systematic reviews on the use of hypnosis in painful procedures had wider aims and purposes such as childbirth, open surgery and dental treatments in different populations or with only randomized controlled trial included or with a mix of patients in general anesthesia and in conscious sedation (38, 115, 116). The results from these could not be used to specifically assess if visualization had an effect in term of pain reduction in minimally invasive procedures where the patients are conscious. Furthermore a systematic review modified to minimally invasive procedures could provide recommendations to practitioners regarding the use of the intervention and help identify areas for future research currently not covered scientifically.

Figure1. Trial design with the four studies included in the dissertation



CHAPTER 3. AIM

The overall purpose of this present dissertation was to examine the effectiveness, meaningfulness and the feasibility of an intervention; visualization used as an adjunct to usual analgesics to manage pain and anxiety during RF ablation of AF and other minimally invasive procedures.

Paper I: To test the hypothesis that relaxation and visualization performed in patients during RF ablation of AF, combined with structured attentive behavior from the staff, could reduce the patient's perception of pain; (1) pain intensity, (2) spontaneously expressed pain, (3) the consumption of analgesics, and reduce anxiety and procedure length - as well as the number of adverse events that required extra attention from the staff.

Paper II: To investigate patients' experiences with visualization in relation to pain and anxiety during an intervention, consisting of visualization when going through an ablation of AF.

Paper III and paper IV

To identify, appraise and synthesize the best available evidence on the effectiveness of clinical hypnotic analgesia in the management of procedural pain, in adults 18 years and older undergoing minimally invasive procedures.

Paper V: To examine patients' experiences with the effect of visualization during ablation of atrial fibrillation and its association with pain intensity, anxiety, pain medication and procedure length

CHAPTER 4. PAPERS

1. Norgaard MW, Larsen B, Darmer MR, Werner A, Abrahamsen R, Pedersen PU. Visualization and attentive behavior for pain reduction during radiofrequency ablation of atrial fibrillation. Pacing Clin Electrophysiol. 2013 Feb; 36(2):203-13.

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3. Norgaard MW, Pedersen PU. Systematic review protocol, "The effectiveness of clinical hypnotic analgesia in the management of procedural pain in minimally invasive procedures, a systematic review protocol. JBI Database of Systematic Reviews and Implementation Reports. 12(2):82-90, February 2014.

4. Nørgaard MW, Håkonsen, SJ, Bjerrum M, Pedersen PU. Effectiveness of clinical hypnotic analgesia in the management of procedural pain in minimally invasive procedures, a systematic review and meta-analysis, Submitted.

5. Nørgaard MW, Pedersen PU, Bjerrum M. Understanding how patients use visualization during ablation of atrial fibrillation in reducing their experience of pain, anxiety, consumptions of pain medication and procedure length: integrating quantitative and qualitative results. Applied Nursing research, February 2018, 39: 229-40.

CHAPTER 5. METHODS

5.1. THE INTERVENTION TRIAL (PAPER I)

5.1.1. DESIGN

To test the effect of visualization used as pain reduction during RF ablation of AF a quasi-experimental design was chosen, in the form of a clinical controlled study, which means that it was a design without randomization, but with a CG (117). The study was a practice-oriented design and because the staff was required to change attitudes toward patients in the IG, a temporal separation of the CG and the IG was made. It was not possible to use neither randomization of patients or blinding of the intervention in the study because of the nature of the intervention.

The patients in the CG received usual information and nursing care during the ablation of AF. Patients in the IG were guided in relaxation and visualization according to a manual by a procedure nurse from the ablation team. (Appendix A) All staff provided structured attentive behavior to the patient while in the procedure room. The structured attentive behavior is specified in a manual as eight key points in standardized attentive behaviors, adapted from Lang et al (2) (Appendix B). Table 1 shows the differences in the procedures between the CG and the IG outlined within the red square. In all other aspects the procedures in two groups were similar.

The analgesics (Fentanyl and Midazolam) were given in relation to an instruction in the department. To assure that patients in IG and the CG had the same access to medication, the patient was equipped with a push button and alerted the nurse by pushing the button, when they needed more analgesics (114). Rules for overruling the patient's request of analgesics were agreed on by the procedure staff before this study and used in previous similar studies (4, 43, 74). The rules were as follows: Analgesics were withheld if the systolic blood pressure fell below 90 mm Hg. saturation fell below 90% despite oxygen therapy or if the patient developed slurred speech or became difficult to arouse. Analgesic was administered without the patient's request for reasons of safety such as when blood pressure rose de novo to more than 180 mm Hg and was not normalized with fast acting blood pressure medication or if the patient expressed discomfort or restlessness.

Table 1.The differences between the procedures provided in the CG and IG(114)

	Control	**Intervention**
Informed consent obtained in outpatient Clinic	Yes	Yes
Mini Mental State Examination test in outpatient Clinic	Yes	Yes

Symptom Checklist 92 immediately before the ablation	Yes	Yes
Offered an information meeting prior to the ablation	Yes	Yes
Offered Premedication prior to the ablation	Yes	Yes
Offered music during the ablation	Yes	Yes
Responsible Care nurse is specially trained in techniques of relaxation and visualization, and structured attentive behavior	No	Yes
Structured attentive behavior by the staff during ablation	No	Yes
The patient is introduced to relaxation and visualization on the procedure table - instructed by a manual	No	Yes
Patients equipped with push-button for analgesics request	Yes	Yes
Analgesics given to the patients upon request according to instruction	Yes	Yes

5.1.2. POPULATION AND RECRUITMENT

All adult patients referred for RF ablation of AF were invited for participation.

Inclusion criteria: Adult patients who were able and willing to give written informed consent were recruited.

Exclusion criteria: Patients with severe chronic obstructive pulmonary disease; a Mini Mental State Examination test (MMSE) score lower than 26; patients who were diagnosed with psychosis or other serious mental illnesses; intolerance of Fentanyl or Midazolam; patients who did not understand and speak Danish; patients who were affected by Midazolam after a transesophageal electrocardiography and finally patients who were undergoing the ablation of AF under general anesthesia.

The patients were consecutively enrolled in the CG between December 2009 and May 2010, and in the IG between December 2010 and June 2011. The training of the staff in the manual for visualization and structured attentive behavior proceeded in between conducting the CG and IG.

Patients were included into the trial during their initial consultation in the outpatient clinic prior to the ablation of AF. Before the inclusion the patients were assessed for their eligibility to participate in the study with screening for cognitive dysfunction with Mini Mental State Examinations test (MMSE) which is well-tested in screening for this condition. This instrument has been validated in a Danish population (118, 119). It consists of 20 items with a maximum score of 30 points. We have used the limit of 26 points for participating in the study as in previous similar studies (2). The usual threshold for abnormal MMSE test is 24-26 points.

5.1.3. OUTCOME MEASURES

The outcomes were:

1. Pain: Pain intensity; Spontaneously expressed pain outside the scheduled measurements; Total amount of analgesic (Fentanyl and Midazolam) used during the procedure
2. Anxiety
3. The procedure length
4. The number of adverse events

The patients scored the pain intensity experienced on a validated NRS (120) from zero to ten every15 minutes and after potentially painful experiences: 1) when local anesthetic was administered in the groins, 2) by insertion of the sheath, 3) when initial RF lesion started. Furthermore, the patients were instructed to express their spontaneously experienced pain outside the 15-minute intervals and whenever patients expressed pain they were asked to score their pain intensity on NRS. This was important because lesion delivered could occur outside the scheduled measurements, thus the patients feel the pain only when the lesions are delivered and have no pain in between the lesions. Total dosage of injected Fentanyl, and injected Midazolam (if used) was measured, both pr kg./pt and in total/pt.

The anxiety experienced was scored on a validated NRS (64) from zero to ten every 15 minutes and after potential painful experiences.
Before entering the procedure room, the patient scored the baseline anxiety on a validated instrument Symptom Checklist (SCL-92)(64, 77) which consists of nine subscales, with 92 statements in total. In this study two subscales were used: Anxiety and Phobic anxiety, with a total of 17 questions. SCL-92 is a self-reporting questionnaire, assessing the patients' anxiety state within the last seven days. SCL-92 has been translated into Danish (77)(Appendix C).

Elements from the Aldrete score, a commonly used scoring system used to safely discharge patients from recovery rooms (121, 122) were used to define adverse events which could occur during the ablation of AF. The total numbers of adverse events were counted during the procedures in the CG and the IG, which were all

episodes during the procedure where extra attention was needed from staff in connection with restoring hemodynamic or respiratory stability and defined as: (A) Fluctuations in systolic blood pressure greater than 50 mm Hg with a single measurement greater than 180 mm Hg or less than 105 mm Hg, unless it tended towards a more normal value from an initial hypertension, (B) Vasovagal episodes, (C) De novo diastolic hypertension of more than 95 mm Hg, (D) Cardiac arrhythmias, (E) Tachycardia (heart rate > 100 when in sinus rhythm), (F) De novo bradycardia (heart rate <50), (G) Persistent chest pain between RF applications (lesions), (H) Respiratory disturbances, for example dyspnea or tachypnea and (I) Oxygen to maintain oxygen saturation > than 90% (114). The patients were monitored with standard hospital equipment and the nurses recorded the adverse events according to the objective definitions from the monitoring equipment during the procedure.

5.1.4. DATA ANALYSIS

A statistical power analysis estimated the required sample size to be 70 patients in each group. The size of the respective CG and IG was calculated based on results in the study by Lang et al.(2) A reduction in adverse events was used. When the risk for type 1 error was set to 5%, the risk of type 2 errors was set to 20% and it was expected that 25% of patients in the CG would experience an adverse event compared to 12% in IG. Seventy patients were required in each group. Because of an expected dropout rate of up to 15%, 81 patients had to be included in each of the CG and IG(114).

Data were analyzed using the statistical program SPSS 18 (SPSS Inc., Chicago, IL, USA). If data were normally distributed and measured on a ratio-interval scale, an unpaired t-test was used to test differences between the two groups. If data were not normally distributed or measured on an ordinal scaled level, a Mann-Whitney rank sum test was used. The mean values and standard deviation (SD) were presented. Fisher's exact Chi-square test was used to test for differences between groups for data measured on the nominal scaled level. Data were analyzed according to the intention-to-treat principle and the level of significance was set to $P < 0.05$.

5.1.5. ETHICAL CONSIDERATIONS

The patients gave written informed consent after receiving oral and written information by the project manager or project assistant 1–2 days before the ablation treatment at the outpatient clinic. Patients were assured that their anonymity was protected and that they could withdraw from the study at any time. The recommendations of the Declaration of Helsinki II was followed (123). The study was approved by the Regional Ethics Committee (j.nr. H-3-2009-111), the National Agency for Data Security (J.nr.2007-58-0015) and was registered at the Clinical Trials. Gov. J.nr. NCTO1162811).

5.2. THE QUALITATIVE INTERVIEW STUDY (PAPER II)

5.2.1. STUDY DESIGN

The aim of the qualitative study was to investigate patients' experiences with visualization in relation to pain and anxiety during an intervention, consisting of visualization when going through ablation of AF (124). A qualitative inductive research design, based on a descriptive explorative approach, with semi-structured open- ended individually interviews as a method was chosen (117, 125, 126) .

5.2.2. POPULATION, RECRUITMENT AND SETTINGS

The study was carried out at a University Hospital in a cardiology department. The individual face-to face interviews took place the day after the ablation either in the patient's room or in the hallway in the cardiology ward and lasted 15 minutes on average.
Fourteen participants, eleven men and three women, aged 39–77 years (mean 55.79) were included in the study. A purposive sample strategy was used to include knowledgeable and articulate participants (117) selected to reflect the participants in the IG from the quantitative study (114) and representative regarding age, gender, type of AF, type of ablation, patients undergoing their first ablation procedure and those undergoing a re-do procedure. Table 2. Finally both patients with positive and negative comments about the intervention.

Table 2 Demographic and clinical data of the 14 interviewed participants (127)

Participant	Gender	Age, years	Type AF	No of previous ablations
1	Male	54	Parox	3
2	Male	53	Long Standing Persis	0
3	Male	39	Parox	0
4	Male	57	Parox	0
5	Male	45	Parox	0
6	Male	54	Parox	0
7	Female	67	Parox	2
8	Female	46	Persis	1
9	Male	63	Parox	0
10	Male	46	Parox	0
11	Female	59	Parox	0

12	Male	74	Parox	0
13	Male	62	Long standing persis	0
14	Male	59	Parox	0

Parox= Paroxysmal AF; Persis= persistent AF

5.2.3. DATACOLLECTION

A semi-structured interview guide with the following themes to be explored: "pain experience", "experience with fear and anxiety", "experience with the use of visualization", "the importance of being guided in visualization during ablation of AF" and "anything else?) (Appendix D) was used. The interview was initiated with a wide open question, "Please tell me how you experienced going through ablation of AF yesterday?" and ended with the question: "Is there anything else in terms of visualization you want to comment on?" The interview guide was subsequently used to structure the dialogue during the interview thus to ensure consistency but if necessary additional questions out of script were asked to get deeper details of the participants' answers. Before commencing the interviews, two pilot interviews were conducted in which the interview guide was tested and subsequently customized. The interviews were conducted from December 2010 until June 2011. After fourteen interviews; data saturation was reached with no more new knowledge added from the interviews, and making further interview unnecessary (117, 128). The interviews were conducted by the primary investigator (MWN), who was not part of the clinical intervention but had a thorough knowledge of the research field. All interviews were recorded and fully transcribed afterwards by either a secretary or the primary investigator.

5.2.3. DATA ANALYSIS

Qualitative inductive content analysis was used to analyzing the 14 transcribed interviews (129-131). Using this method the interview material was analyzed in four phases: 1.The interviews were read through several times to obtain a complete understanding of the content and codes were inductively identified and transformed into categories; 2.The interviews were organized by these categories; 3. The descriptive level, meaningful patterns were deduced from the categorized data describing the main elements of how the participants experienced visualization in relation to pain and anxiety when used as an adjunct to usual pain medication during ablation of AF and 4. The explanatory level: The categorized data were then interpreted by a comparative analysis and how they interconnected was investigated in order to sort patterns of regularities and variations to gain new information so participants' experiences of visualization in relation to pain and anxiety during

ablation of AF when visualization was used as an adjunct to usual pain management could be described (129-131). The categories inductively derived from the interviews are presented in the results section together with the overarching themes. (Table 7, page 44).The themes are identified from an analysis across categories and constitute the theoretical explanation in relation to the purpose of the study, which should give an understanding of how patients' experienced visualization in reducing pain and anxiety during ablation of AF.
The analysis was primarily carried out by the primary investigator but to maximize the reliability of the study, the outlines of the analysis were discussed with two other researchers (PUP and MB)(131, 132).

5.3. THE SYSTEMATIC REVIEW (PAPER III & IV)

To identify, assess and synthesize the best available evidence on the effectiveness of clinical hypnotic analgesia in the management of procedural pain in adults (18 years and older) undergoing minimally invasive procedures, a systematic review was conducted.

5.3.1. REVIEW DESIGN

The systematic review of effectiveness was conducted using Joanna Brigg's Institute approach (133, 134) with the following steps in the research process: formulating a review question; defining inclusion and exclusion criteria; locating studies through searching; selecting studies for inclusion; assessing the quality of studies; extracting data; analyzing and synthesizing the relevant studies; presenting results and interpreting the results, which requires that a protocol must be published first and followed strictly throughout the process of conducting the review. Likewise two reviewers are required during the process. According to the requirements from Joanna Briggs Institute the systematic review was based on a peer-reviewed, published protocol to ensure a rigorous and transparent method (Paper III in this dissertation) (135) and two reviewers participated in the development of the review.

5.3.2. POPULATION, TYPES OF INTERVENTIONS, COMPARATORS AND OUTCOMES

The research question was formulated based on the following mnemonic PICO criteria: the population; intervention; comparator and outcomes.

Population: Adult patients (18 years and over) who had undergone minimally invasive procedures that caused significant acute pain as assessed by medical professionals or by patient self-report. A minimally invasive procedure was defined as a procedure less invasive than open surgery but carried out for the same purpose and where penetration of tissue or invasion of a body orifice is required (136).

Types of intervention (s): Studies that evaluated clinical hypnotic analgesia as an adjunct to usual analgesia used just before and/or/ during a minimally invasive procedure and had usual care or standard care with usual analgesia for comparison were considered for inclusion in the review, where hypnosis had to be provided in a face-to face setting or as a pre-recorded tape or CD without limits of the length of the intervention.

Types of comparator: Usual analgesic

Types of outcomes: Studies that primarily included the following outcome measure: Patient rated procedural pain intensity. In addition the outcomes: the amount of pain medication (analgesia) used during the procedure; patient rated anxiety, procedure length and observer rated adverse events have been analyzed.
Validated scores and scales were used for assessing the outcomes pain and anxiety.

Types of studies: Any experimental study design including randomized controlled trials and non-randomized controlled trials were considered for inclusion.

5.3.4. DATA COLLECTION

A three step literature search strategy was developed to find both published and grey literature (133) with an initial limited search in MEDLINE via PubMed and CINAHL. The second search was conducted across all relevant included databases and finally a third search was carried out in the reference lists of all identified reports and papers for additional studies.

No data limits were used in this review and only studies published in English, Danish, Swedish and Norwegian were considered for inclusion.

The literature search was conducted with the following keywords: Pain intensity **or** pain management or anxiety **or** fear **or** acute pain **or** invasive medical procedure pain **or** pain **AND** Clinical hypnosis **or** hypnosis **or** visualisation **or** visualization **or** guided imagery **or** clinical hypnotic relaxation **or** hypnotic analgesia **or** imagery psychotherapy **or** relaxation **or** analgesia **or** patient controlled **or** adjunctive hypnosis **AND** Surgical procedures **or** minimally invasive **or** invasive procedures **or** medical procedures.

The following databases were searched together with a research librarian for published literature: MEDLINE via PubMed, CINAHL, Scopus, Swemed+ and PsycINFO . Deviations from the search strategy in the protocol are described in the systematic review report.

The search for grey literature was conducted in the following databases and web sites: Mednar; ProQuest dissertations and theses (for international dissertations and

theses); Google Scholar; Trip database; National Institute of Health's (NIH) Clinical Trials Databases (Host: http://www.clinicaltrials.gov); American Society of Clinical Hypnosis (ASCH) (Host: http://www.asch.net/); The American Board of Medical Hypnosis (ABMH) (Host: http://www.abmedhyp.net/); The American Society of Clinical and Experimental hypnosis (SCEH) (Host: http://www.sceh.us/) and the International Society of Hypnosis (ISH) (Host: http://www.ishhypnosis.org/).

5.3.5. SELECTION OF STUDIES

All papers identified in the search were screened by title and abstract by the primary reviewer (MWN) to exclude irrelevant studies. The abstracts which met the inclusion criteria were subsequently assessed by two reviewers (MWN and PUP) independently and, subsequently, full text papers considered potentially relevant for inclusion was screened against the inclusion criteria.

5.3.6. ASSESSMENT AND DATA EXTRACTION

The assessment for methodological validity of the studies selected for inclusion was carried out by two independent reviewers using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI)(133). If there were disagreements between the reviewers, they were solved by discussion. Two other independent reviewers were involved in evaluating a study conducted by the original reviewers.

5.3.7 DATA SYNTHESIS

The studies were grouped according the different outcome measures, pain intensity, anxiety, consumption of pain medication, procedure length and adverse events and results were presented in meta-analyses forest plot and narrative summaries. When studies were sufficiently similar, data was pooled in a meta-analysis using the review Manager Version 5.3 software (Copenhagen: The Nordic Cochrane Centre, Cochrane). Because we expected between-study heterogeneity we performed the meta-analyses using a random effect model on the outcomes, procedure length with seven studies included and adverse events with seven studies included.
The assessment of heterogeneity was tested statistically by using Tau^2 and Chi^2 tests. I^2 test was used to quantify the inconsistency (137).

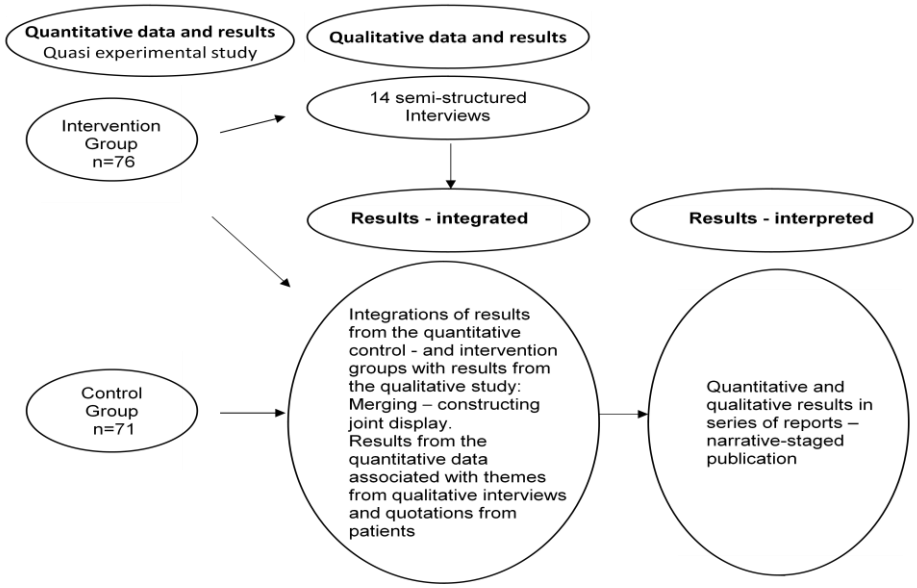
5.4. THE MIXED METHODS STUDY (PAPER V)

5.4.1. STUDY DESIGN

Patients' experiences with the effect of visualization during ablation

of AF and its association with pain intensity, anxiety, pain medication and procedure length were examined in a mixed method explanatory sequential study design, which means that data was collected and analyzed in a quantitative phase first and subsequently a qualitative phase was conducted and analyzed. The mixed method study(138) included thus a quasi-experimental study with a CG with 71 participants and an IG with 76 participants included (Paper I)(114) and a qualitative interview study (Paper II)(127) with 14 interviews with participants from the IG from the quantitative study. The results from both studies were integrated by merging and constructing joint display, in a follow-up joint display (139-141) where the results from the qualitative study was used to explain the results from the quantitative study. Figure2.In line with the mixed method design each of the studies included had their own aims.

Figure 2 Visual model for the used mixed-methods sequential explanatory design (138)



5.4.2. POPULATION, RECRUITMENT AND SETTINGS

Participants were recruited from December 2009 to July 2011. Adult patients who were referred to RF ablation of AF and who were able and willing to sign an informed consent were invited to participate in the quasi-experimental study (114). In the qualitative study (127) fourteen patients (18% of the IG) who had undergone

an ablation of AF and had participated in the IG in the quasi-experimental study were invited to participate.

Both studies were conducted in a university hospital. The quasi-experimental study was carried out in a cardiac cath. lab. and the qualitative study was carried out in a cardiology ward in the same hospital.

5.4.3. INTEGRATION AND DATA ANALYSIS

The integration of the results from the quantitative and qualitative studies took place in the analytical and interpretative stage of the mixed methods study (142) thus the results (the outcomes: patient reported NRS rated pain-intensity; the number of spontaneous expressed pain; patient reported NRS rated anxiety; the amount of pain medication used during the procedure and the procedure length from the quasi-experimental study (Paper I) (114) and results (categories and themes with quotations from the participants) from the qualitative study (Paper II) (127) were integrated through joint displays, in follow up joint displays. Four categories and two themes that emerged from the analysis of the qualitative interviews were used in the explanation of the results from the quantitative data. The integration of results from the two studies is presented in a visual model (Table 11, page 54) with results from Paper I in one column, results from Paper II in a second column, and information about how the qualitative results (Paper II) was used to explain results in the quantitative results (Paper I) in a third column.

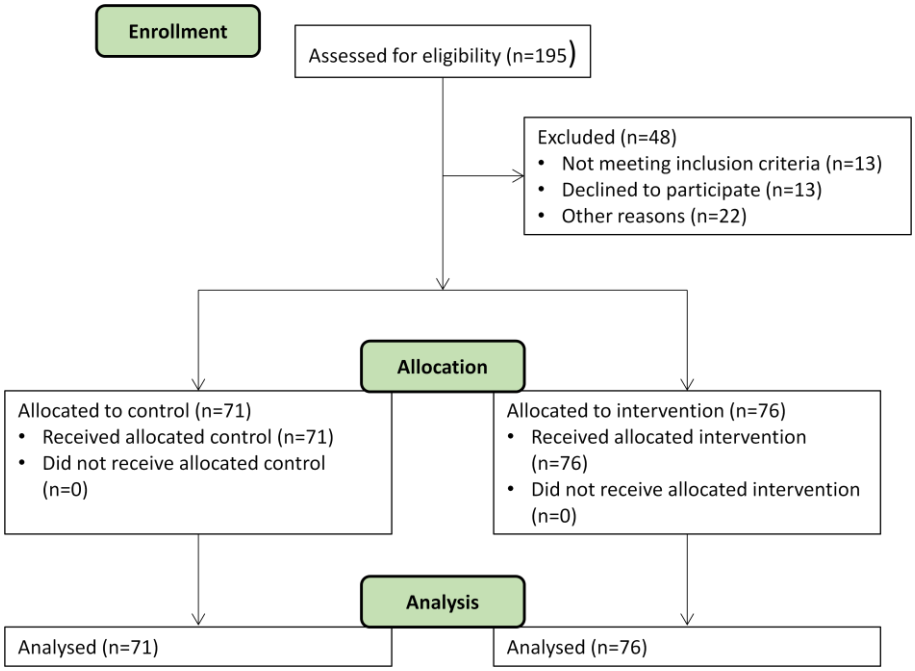
Data collection in this mixed method study was initially performed by the first author (MWN) and subsequently discussed with two experienced researchers (PUP and MB) so that a sufficient and relevant data collection to answer the research question could be carried out. All three researchers did the analysis and interpretation with the three themes derived.

CHAPTER 6. RESULTS

6.1. RESULTS FROM THE QUANTITATIVE STUDY (PAPER I)

In this study 147 participants were included between December 2009 and July 2011 with 71 participants in the CG and 76 in the IG. One hundred and ninety five patients in total were assessed for eligibility. Figure 3

Figure 3. Flowchart of non- participants and participants in the intervention study



The two groups in this study were similar regarding the demographic factors surveyed, except from the type of AF and whether they were DC converted or not after the procedure. Table 3.

The number of patients with paroxysmal AF was significantly greater in the IG and the number of patients with longstanding persistent significantly fewer in the IG compared to the CG with a significantly greater part being converted with direct current (DC) in the CG. Due to their being more patients with persistent AF in the CG, more patients in this group needed cardio version compared to the IG. It is often more difficult to treat patients with persistent AF than paroxysmal AF and more patients with a persistent AF need cardio version with either medication or DC cardio version after the procedure (143-145).

Table 3: Patients' demographic and clinical characteristics (114).

N=147	Control group n=71	Intervention group n=76	P Value
Sex, male %	66	71	0.595
Age, mean ±SD (yrs)	59.5±9.8	59.9±8.1	0.792
Weight, mean± SD (Kg)	87.4±17.3	84.2±17.5	0.274
MMSE mean ± SD	28.9±0.9	28.7±	0.465
Participated in the Information Session (%)	34	39	0.607
Previous Ablation (%)	46	41	NS
Stereotaxis%/ablation Frontier %	92/8	95/5	0.523
Listening to Music during procedure %	93	97	0.263
Paroxysmal AF % Persistent AF % Long standing persistent AF %	52 13 35	74 17 9	0.01
DC converted %	56	36	0.013
Baseline anxiety SCL-92 measured	0.44±0.38	0.43±047	0.888

6.1.1. OUTCOME MEASURES PAIN

Patients scored their perceived pain intensity on a NRS rating scale every 15 minutes during the procedure and after painful episodes and no statistically significant differences in terms of perceived pain intensity were found at any time during the procedure between the CG and the IG Table 4.

Table 4: Perceived pain intensity and anxiety, NRS score, CG and IG

		PAIN				ANXIETY			
Time min.	**Control Intervention**	**N**	**Mean**	**SD**	**P value**	**N**	**Mean**	**SD**	**P value**
0	CG IG	71 75	.00 .12	.0 .5	.031	70 75	1,84 2.03	2.4 2.1	.623

15	CG IG	70 75	2.90 2.57	3.1 3.0	.519	69 74	.68 1.04	1.4 2.8	.330
30	CG IG	69 75	2.22 2.11	2.9 3.0	.822	68 75	.53 .61	1.1 1.6	.720
45	CG IG	65 73	1.68 1.53	2.7 2.3	.737	64 73	.48 .48	1.0 1.3	.981
60	CG IG	59 65	1.68 1.31	2.8 2.3	.415	59 64	.44 .22	1.2 1.0	.261
75	CG IG	53 53	.75 1.19	1.8 2.1	.255	53 53	.47 .21	1.3 0.8	.295
90	CG IG	39 40	.41 .48	1.3 1.6	.843	39 39	.21 .26	0.9 1.3	.837
105	CG IG	21 23	.38 .61	1.4 1.4	.593	20 23	.30 .13	1.1 0.3	.497
120	CG IG	10 11	.60 .45	1.4 1.0	.784	10 11	.10 .09	0.3 0.3	.947

SD= Standard Deviation

However, it was found that patients spontaneously reported pain outside the fixed 15 minutes interval significantly fewer times in the IG compared to the CG, but with no significant difference in the level of pain intensity when the patients reported pain. Table 5. Furthermore no difference was found with relations to pain between the groups for patients going through their first ablation of AF and those going through a re-do ablation. In the IG, patients received statistically significantly less pain medication compared to the patients in the CG. Table 5

Table 5 Patients spontaneously expressed pain and the total amount of pain medication used pr patient and per kilogram

	Control group n=71	**Intervention group n= 76**	**P Value**
Number of times patient expressed pain (mean ± SD)	2.8 ± 1.8	1.4± 1.2	0.0008
Fentanyl µg (mean ± SD) (total)	292.3±107	220±93	< 0.0001

Fentanyl µg (mean ± SD) pr KG	3.4 ± 1.4	2.6± 1.0	< 0.0001

6.1.2. OUTCOME MEASURES, ANXIETY

No statistically significant difference between groups was observed in perceived anxiety measured at NRS at any time during the procedure. Table 4. Furthermore, in baseline anxiety measured at SCL-92 prior to entering the procedure room no statistical difference was observed (CG: 0.44±0.38; IG: 0.43±0.47, p= 0.888).

However, there was found a difference in perceived anxiety in the CG between patients undergoing ablation for the first time compared to patients going through a re-do procedure (NRS 2.35 versus 1.17 P= 0.0004) where no difference between these groups were found in the IG (2.39 versus 1.55 p= 0.105).

6.1.3. OUTCOME MEASURES, PROCEDURE TIME

No statistically significant difference was found between the CG and the IG in procedure time, which is the time the patient occupied the procedure room. In addition no difference was observed in the application time, which was the lesion delivered time. Table 6.

Table 6 Measured procedure- and application time in the CG and the IG (114)

	Control group n=71	**Intervention group n= 76**	**P Value**
Procedure time min. mean± SD	195.1±33.2	194.7±34.9	0.953
RF application time mean sec. ± SD	2284.5± 1019.1	2197.3±1184.5	0.636

6.1.4. OUTCOME MEASURES, ADVERSE EVENTS

No difference was found between the groups with regards to the number of specifically defined adverse events (CG: 104 adverse events and IG: 82 adverse events, p= 0.241. In 18.3 % CI 95% [10.1;29.3] of the patients in the CG compared to 18.8 % CI 95% [11.2;29.7] in the IG, no adverse events were reported (NS).

6.2. RESULTS FROM THE QUALITATIVE STUDY (PAPER II)

Fourteen qualitative interviews were conducted between December 2010 and June 2011 with participants from the IG in the quasi-experimental study (114). Seventy nine percentages of the interviewed participants were males and the average age was 55.79 years (39-77). Seventy nine percentages of the participants suffered from paroxysmal AF, seven percentages from persistent AF and fourteen percentages of the participants suffered from long standing persistent AF. Sixty four percentages of the interviewed participants had participated in an information session prior to the ablation treatment and all patients listened to music during the procedure.

From the fourteen interviews, four categories were inductively derived: "Approach to visualization"; "Strategies of managing pain"; "Strategies of managing anxiety" and "Benefits of visualization". Two explanatory themes were subsequently identified from the comparative analysis (131, 146, 147) of the described categories: "stimulation the patients' own resources" and "being satisfied without complete analgesia". Table 7. The themes formed the theoretical explanation in relation to the purpose of the current study which was to examine patients' experiences with pain and anxiety during an intervention consisting of visualization when going through ablation of AF.

Table 7. The operationalized theory (127)

Patient quotations	Main category	Theme
- *"*I am convinced, that you have some mental resources, that we can use in contexts where it is most important to use them"(p14). - "If it is like without using too many drugs or something like that, then it's better, every-thing you can do. I think it is a great and organic way to do it in these organic times"(p13). - "I imagined it was pleasant, because it was something else than the mechanical or the medical or whatever it was"(p8).	Approach to visualization	Being satisfied without complete analgesia. Stimulating the patient's own resources.
- "When I had so much pain, I could not use it"(p11). - "I found just the right place". - "I managed to create another space, a different reality than the unpleasant reality"(p1).	Strategies of managing pain	
- "Well I felt incredibly comfortable all the way in, so you could say, that when she asked if I was nervous or anxious, I almost think, I continually said no, because I felt really comfortable"(p1). - "And that I just knew that she was there all the time - and commented on everything, and nothing was too small for her to comment on"(p11). - "I'm used to in my job that I always have control.	Strategies of managing anxiety	

This gave me the opportunity to let go of the control, it was liberating" (p2)…	
- "I think of it as a good experience, so when I came back to the ward, I came back with a good experience and it is positive" (p2)…. - "The sense of time has disappeared. A temporal shrinkage of time" (p14). - "And they help you to find something positive in your life to be happy about"(p12).	Benefits of visualization

p=participant

6.2.1. MAIN THEME: "BEING SATISFIED WITHOUT COMPLETE ANALGESIA"

"Being satisfied without complete analgesia" emerged from analyzing and interpreting across categories and signaled a high level of satisfaction even among patients who did not experience full pain relief and even though they did not find visualization useful when undergoing severe pain. First of all most interviewed patients expressed satisfaction with the use of an alternative to the medical treatment, which was different from what has normally been used in the traditional health care system. Their satisfaction also consisted in the fact that the traditional pain medication was supplemented or replaced by something else. No patients found the use of visualization mysterious and all interviewed patients would use visualization again in a possible future procedure, including a participant who did not express a positive effect from the intervention.

The positive experiences the patients had from visualization, such as an altered sense of procedure time; that they were able to exclude stressful noise from the procedure room; that they returned to the department with the impression that they had had a positive experience and were asked to think of a pleasant and secure place probably gave them an experience of satisfaction, even though they only experienced a partial pain reduction during the procedure. When using visualization, the patients also had a sense of using their own resources and a sense of being involved in their own care and treatment, which was a positive experience for them and possibly gave them strength to manage the pain so that the pain for them became tolerable.

6.2.2. MAIN THEME: STIMULATING THE PATIENT'S OWN RESOURCES

"Stimulating the patient's own resources", was the second theme that emerged from analyzing and interpreting across categories. When the nurse with a positive approach guided the patient in visualization she properly encouraged the patient to use their own recourses and at the same time facilitated the patient's sense of being efficient and resourceful, hence the participants indicated how they, by using

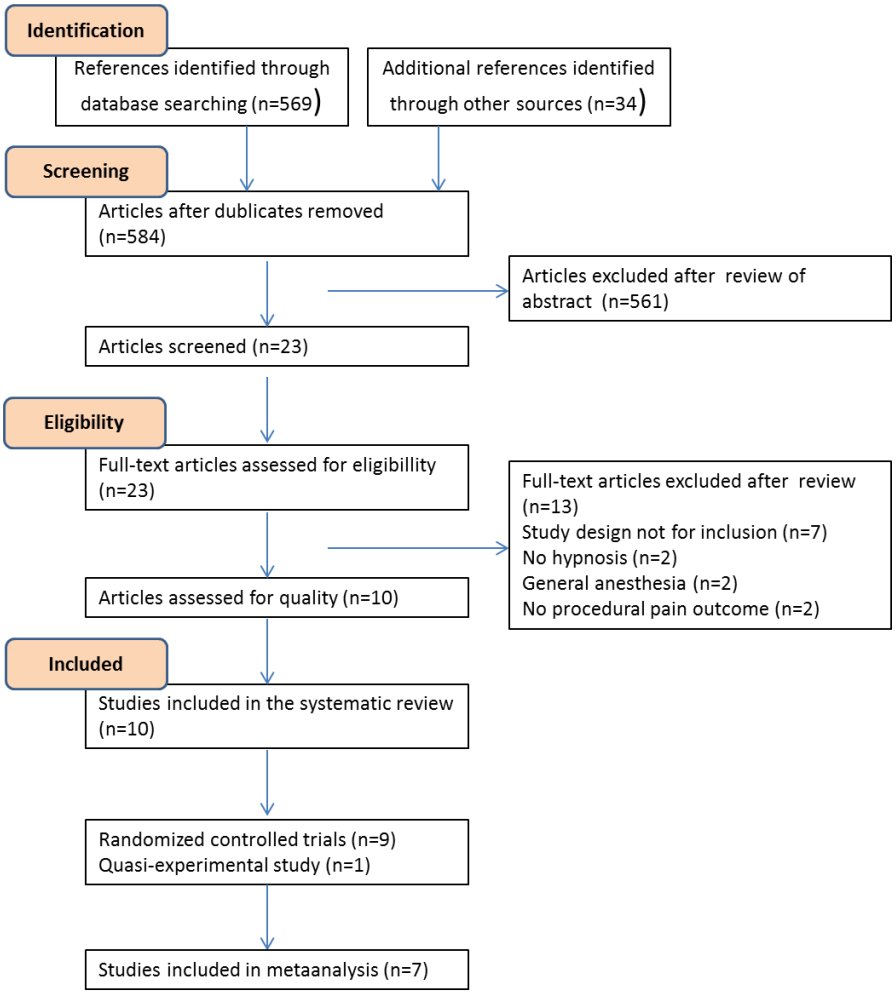
visualization, had different and individual ways of handling or coping with pain and anxiety during the ablation of AF. Some participants used strategies creating a kind of "other reality" with the focus away from the pain and other participants described how they experienced the pain but did not have to deal with the pain or go into the pain because they were occupied with something else. These patients had experienced a feeling of mobilizing their internal resources so that they were able themselves to cope with pain and anxiety and were able to control the pain helped by the nurse. They might have felt involved and active in their own care and treatment and handled pain and anxiety just the way that was most appropriate for them.

In addition some patients reported that the staff helped them to let go of control while in the procedure room, which was liberating for them. The patients felt that by focusing on a pleasant and safe place the nurse helped them to obtain the strength to create conditions to use their own resources enabling them to find their individual strategies to cope with pain and anxiety and that this gave them feeling of not needing this control. Patients were stimulated to themselves cope with this specific situation with pain and anxiety in the procedure room.

6.3. RESULTS FROM THE SYSTEMATIC REVIEW (PAPER III & IV)

To assess the effectiveness of clinical hypnotic analgesia in the management of procedural pain; anxiety; analgesic consumption during the procedure; procedure length and adverse events in adults undergoing minimally invasive procedures a comprehensive literature search was conducted. Six hundred and three citations were identified whereas 591 where excluded after titles and abstracts were reviewed against the inclusion criteria. Ten full text papers were then retrieved for further review and assessed for methodological quality using the Joanna Briggs institutes' MAStARI checklist (133).The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) flow diagram summarizing the study selection is shown in Figure 4. Nine randomized controlled trials(2-4, 43, 44, 100, 101, 148, 149) and one quasi-experimental study(114) were included in the systematic review. The ten studies included were conducted in four different countries: USA, Canada, Turkey and Denmark and published between 1996 and 2015. A total number of 1365 participants were included in these studies with a majority being females (71%), aged between eighteen and ninety-four and the majority of participants were Caucasians (74-95%). All studies included were conducted in clinics and hospitals and participants were mostly outpatients with only two studies including examined in-patients (44, 114). All patients were awake during procedures. The minimally invasive procedures in which the intervention was examined were: ablations, tumor treatments, first trimester pregnancy termination, needle myography, biopsies, angiographies and skin lesion excisions.

Figure 4, PRISMA,(150) flow diagram summarizing study selection (Nørgaard et al. 2018, submitted)



6.3.1. METHODOLOGICAL QUALITY OF THE INCLUDED STUDIES

Even though all studies included were well designed and carried out, none of the included studies fulfilled the entire critical appraisal checklist' criteria, JBI, MAStARI (133) because e.g. the nature of the intervention prevents blinding of the treatment to the participants. The quasi-experimental study did off course not meet the criteria about randomization and concealing allocation to treatment groups to the allocator due to its design. Thus the included studies met from six to nine criteria from the assessment tool. Table 8

Table 8: Results of critical appraisal of included studies – (randomized control trials quasi-experimental trial) (Nørgaard et al. 2018, submitted)

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10
Lang EV et al.(4)	Y	U	Y	Y	N	Y	Y	Y	Y	Y
Marc I et al. (148)	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Slack D et al.(3)	U	Y	Y	Y	Y	Y	Y	Y	Y	Y
Hizli F et al.(149)	U	N	N	Y	N	Y	Y	Y	Y	Y
Marc I et al.(100)	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Lang EV et al.(2)	Y	N	Y	Y	N	Y	Y	Y	Y	Y
Lang EV et al.(43)	Y	N	Y	Y	U	Y	Y	Y	Y	Y
Lang EV et al.(44)	Y	N	Y	Y	N	Y	Y	Y	Y	Y
Shenefelt P.D.(101)	Y	U	Y	N	U	Y	Y	Y	Y	Y
Nørgaard MW et al.(114)	N/A	N	N/A	Y	N	Y	Y	Y	Y	Y

Y=yes; U=unclear; N/A= not applicable; N=no

Q1: Was the assignment to treatment groups truly random?
Q2: Were participants blinded to treatment allocation?
Q3: Was allocation to treatment groups concealed to the allocator?
Q4: Were the outcomes of people who withdrew described and included in the analysis?
Q5: Were those assessing outcomes blind to treatment allocation?
Q6: Were the control and treatment groups comparable at entry?
Q7: Were groups treated identically other than for the named interventions?
Q8: Were outcomes measured in the same way for all groups?
Q9: Were outcomes measured in a reliable way?
Q10: Was appropriate statistical analysis used?

Both the inclusion and exclusion criteria, the interventions and the outcomes were well described in all studies. The treatment and the control group were comparable in all studies and except from the intervention, treated identically. All outcomes were reliably measured and proper statistical analysis was used but many different validated measuring instruments were used to measure the outcomes and were reported differently without SD and CI.

6.3.2. THE INTERVENTION

In the 10 studies included (2-4, 43, 44, 100, 101, 114, 148, 149) the intervention "hypnotic analgesia" was compared to usual care in the institution. However, in five studies (2-4, 43, 149) there was an extra arm with either" structured or emphatic attentive behavior", "recorded hypnotic analgesia" or "hypnosis without pain suggestion". These arms were not included in this systematic review.
The intervention was either provided before the procedure, before and during the procedure or only during the procedure but it seemed that the content of the intervention was comparable in all studies with the elements: induction, progressive muscle relaxation and guided imagery with suggestions of analgesia.
In eight studies (2, 4, 43, 44, 100, 101, 148, 149), the intervention was performed face to face by an additional person in addition to the staff in the procedure room whereas in one study it was performed face to face by one of the procedure nurses (114) and in one study the intervention was a recorded version which the patient listened to before the procedure(3). All providers of the intervention were specifically trained in the intervention and how to provide it.

6.3.3. OUTCOMES

The primary outcome, "patient reported pain intensity" was reported in all studies included, the amount of pain medication used during procedure was reported in five studies (2, 4, 44, 100, 114), anxiety was reported in all studies, the procedure length in nine studies (2-4, 43, 44, 100, 101, 114, 148) and finally, observer reported adverse events were reported in eight studies (2, 4, 43, 44, 100, 101, 114, 148).

6.3.4. OUTCOME PAIN INTENSITY

Because the pain intensity was measured, calculated and reported differently in the studies, summarizing results were not possible. Nine studies used a validated VAS scale 0-10 or 0-100 and one study used a SUD scale (101).

Eight studies could not show statistically significant overall difference between the CG and the IG according pain intensity (3, 4, 43, 44, 100, 101, 114, 148). One study showed significantly lower pain intensity scores between 15 and 45 minutes into the procedure (2) and in another study it was found that pain increased more slowly over time in the group where hypnosis was used compared to the CG (43).In one study pain intensity increased over time in the CG but the curve remained flat in the IG(4). In a study pain intensity was significantly lower in the IG compared to the GC after the intervention was provided but before the procedure was started (149).

In one study patients expressed pain spontaneously significantly fewer times outside the fixed measurements point in the IG compared to CG but no statistically

significant difference was found in pain intensity when the patients expressed pain (114).

6.3.5. OUTCOME THE AMOUNT OF PAIN MEDICATION

The consumption of pain medication (Fentanyl and Midazolam) used was measured in five of ten studies (2, 4, 44, 100, 114) included in the review and in all studies there was found a statistically significant difference between the CG and the IG, thus the amount of pain medication used was significantly lower in the IG compared to the CG, reduced between 21-86%. Table 9.
Standard deviations were not reported in all but one study (114).
In one study Nitrous Oxide (N_2O) was used as a choice to control pain for the patients. A significant difference was also found between the CG and IG in this study, where 36 % (CI 95% 16-61) of the patients in the IG asked for N_2O sedation compared to 87 % (CI 95% 61-97) of the patients in the CG $p<0.01$(148).

Table 9: Results, outcome Pain medication (Nørgaard et al., 2018, submitted)

Study	**Intervention group** Fentanyl µg / Midazolam mg	**Control group** Fentanyl µg / Midazolam mg	**P Value**	**Relative reduction of average amount of medication used**
Lang 2008(2)	Mean 50(25-100) / 1(0.5-2)	75 (37.5-125) / 1.5(0.75-2.5)	0.0147	33%/33%
Lang 2000(4)	Mean 22.5 / 0.45	Mean 47.5 / 0.95	<0.0001	53%/53%
Lang 1996(44)	Mean 7(0-75) / 0.14 (0-1.5)	Mean 50.39 (0-1.25) / 1.05(0-2.5)	<0.01	86%/86%
Norgaard 2013(114)	Mean 220.7±93 (SD) / 0	Mean 292±107(SD) / 0	<0.0001	24%/24%
Marc 2008(100)	Mean 39.39 / 1.08	Mean 49.71 / 1.62	<0.0001	21% /33%

SD=Standard deviation

6.3.6. OUTCOME ANXIETY

Patient-reported anxiety during the procedure was measured in the included studies with VAS 0-10 or 0-100 in 8 studies (2-4, 43, 44, 100, 114, 148), with SUD in one study(101) and with Beck Anxiety Inventory (BAI) and Hamilton Anxiety Scale (HAS) in another study (149). As with pain intensity, anxiety was measured at different times before and during the procedure and reported differently, so summarizing was not possible.
In one study the anxiety level decreased statistically significantly in the IG in the

first 15-30 minutes of the procedure and from 30 to 45 minutes into the procedure compared to the CG (2). Another study showed a significantly lower anxiety level after 20 minutes into the procedure in the IG compared to the CG (101). In six studies no overall statistically significant differences between groups were found (3, 4, 43, 44, 114, 148). Finally in one study anxiety was significantly lower in the IG from the start of the procedure after the intervention was provided 20 minutes earlier (100) and in another study a significant difference was found between groups before the procedure, thus anxiety measured was lower in the IG (149). No anxiety measurements were carried during the procedure in this study.

6.3.7. META-ANALYSES

Two meta-analyses were performed for the outcome procedure length and adverse events where data from the studies were pooled in order to establish an exact estimate of the effect of visualization on the outcomes. As interventions were based on the same principles we regarded them as comparable, even if they were provided differently e.g. at different times, face- to- face or recorded.
The effect size estimate of the meta-analysis was Standard Mean Difference for procedure length and Risk Ratio (RR) for adverse events. Results showed no statistical heterogeneity on the procedure length outcome but a statistical heterogeneity on the adverse events outcome. The results are presented in the forest plots (Figures 5 and 6).
To perform the meta-analysis the Review Manager Version 5.3 software (Copenhagen: The Nordic Cochrane Centre, Cochrane) was used.
To test for heterogeneity, Tau^2 and Chi squared test were used. Figure 5 shows result from statistical tests for heterogeneity for procedure length presented in the forest plot and Figure 6 the forest plot for adverse events. A random effect model was used in the meta-analysis. The justification for choosing the random effect model was an assumption that the true effect was different in the included studies (151).The inverse variance method was used for the meta-analysis for procedure length while a Mantel Haenszel method was used for meta-analysis for the adverse events.

Outcome procedure length

The procedure time differed with an average time from 16 to 195 minutes in the included studies (2-4, 43, 44, 100, 101, 114, 148).

The meta-analysis performed for procedure length included seven studies (2-4, 43, 100, 114, 148).The objective of the meta-analysis was to provide a summary effect size estimate of the effect on reduction in procedure length when using visualization or hypnosis as pain relief during the invasive procedures.

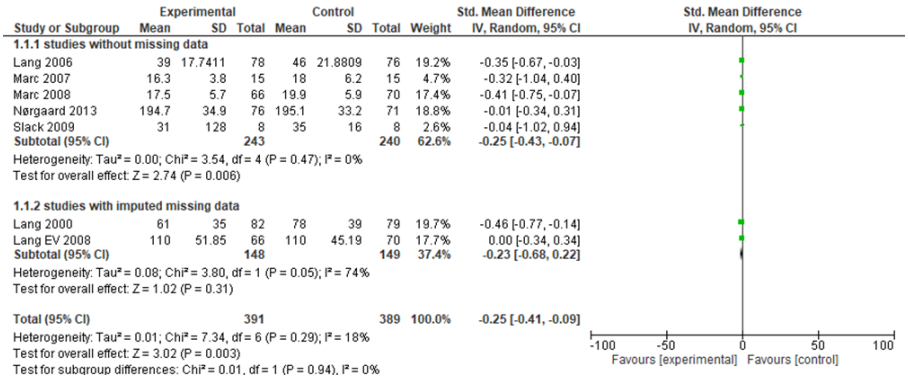
In one study (2) data was reported as medians and IQR and nevertheless was included in the meta-analysis using the following approach: Median = mean. IQR/1.35 = SD. If the distribution of the data is symmetrical, median is very similar

to the mean so it occasionally can be used directly in meta-analyses (137). However, if the data are skewed medians and means can be very different from each other and medians are usually preferred over mean if the data are skewed. In large sample sizes where the distribution of the outcome is similar to the normal distribution, the SD can be calculated as an approximation as follows: inter quartile range /1.35 (137).

Because another study (4) did not report SD, the average of the other studies has been used to impute the missing SD in this study. Furukawa et al.(152) found that imputing standard deviations either from other studies in the same meta-analysis, or from studies in another meta-analysis, yielded approximately correct results (152).

The absolute magnitude of the summary effect size was standard mean difference of -0.25 (CI 95%: -0.41, -0.09), a statistical significant result showing a small effect in reduction of procedure length. However the CI was relatively narrow which was considered a relative precise estimate.

Figur 5 Forest plot of summary estimate of the effect of reduction in procedure length (IV: Inverse variance, CI: Confidence Interval) (Nørgaard et al. 2018, submitted).



Adverse Events Outcome

Adverse events were defined in the studies as an event during the procedure which attracted extra attention from the staff in order to restore hemodynamic or cardiovascular stability.

In five out of the ten studies (2, 4, 43, 44, 114) included in this current review, adverse events were reported as an outcome, however three studies reported the number of adverse events observed in their results section even though they did not define adverse events as an outcome in their studies (100, 101, 148). In some studies, adverse events were calculated as the number per patient and in other studies as the total number for all patients.

The forest plot performed for the adverse events outcome included seven studies (2, 4, 43, 100, 101, 114, 148). A statistical heterogeneity among the studies included was found.Tau^2= 0.66, Chi^2=60.88, df =6, p<0.00001, I^2=90%. However it seemed that by using visualization adverse events did not increase.

Event rate (ER) in CG and IG, relative risk reduction (RRR), absolute risk reduction (ARR), the number needed to treat (NNT) and relative risk (RR) with 95 % CI for adverse events where possible are shown in Table 10.

Figure 6. Forest plot of adverse events (M-H: Mantel-Haenszel, CI: Confidence Interval) (Nørgaard et al. 2018, submitted).

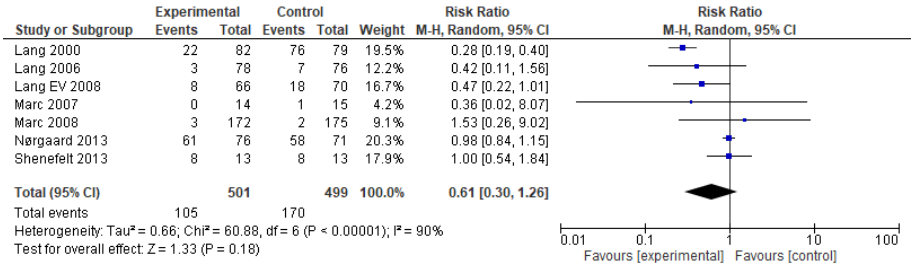


Table 10. Event rate, relative risk reduction, absolute risk reduction, number needed to treat and relative risk for the outcome Adverse Events (Nørgaard et al. 2018, submitted).

Study	**Event rate** N (%) IG/CG	**Relative risk reduction**	**Absolute risk reduction**	**Number needed to treat**	**Relative risk** (CI 95%)
Lang 2008	8/66 (12%) 18/70 (26%)	0.53	0.14	7	0.47 (0.22-1.01)
Lang 2000	22/82 (27%) 76/79 (96%)	0.72	0.69	1	0.28 (0.19-0.40)
Lang 2006	3/78 (4%) 7/76 (9%)	0.58	0.05	19	0.42 (0.11-1.50)
Marc 2008	3/172 (2%) 2/175 (1%)	-0.53	-0.01	171 (harm)	1.51 (0.26-8.97)
Marc 2007	0/14 (0%) 1/15 (7%)	0.64	0.07	17	0.36 (0.016-8.07)
Shenefelt	8/13 (62%)	0.0	0.0	infinity	1.0

2013	8/13 (62%)				(0.55-1.84)
Nørgaard 2013	61/76 (80%) 58/71 (82%)	0.02	0.02	50	1.08 (0.55-2.1)

6.4. RESULTS FROM THE MIXED METHOD STUDY (PAPER V)

The mixed methods study aimed to examine the patients' experiences with the effect of visualization during ablation of AF and its association with pain, anxiety, pain medication and procedure length.

Three main themes were identified from the analysis (153) of the integrated results from the quasi-experimental trial (114) and the qualitative interview study (127) and created the theoretical explanation in relation to the purpose of the study. The three themes identified were: "Zero pain is not always the goal"; "Not a real procedure time reduction but a sense of time shrinkage" and "Importance of nurse's presence, visualization or not". Table 11 shows the integration where how the results in the qualitative study were used to explain the results in the quantitative study in joint displays.

Table 11 Visual illustrations of the joint displays (138)

Quantitative results/outcome *Intervention group patients (IG) vs. control group patients (CG)*	**Patients experiences** *Themes (T) and categories (C) from the analysis of the interviews. Patient (p)*	**Merging/integrating results** *How Qualitative findings help to explain quantitative results*
No significant difference in the perception of pain intensity when patients scored at 15 minute intervals. IG patients spontaneously expressed pain significantly fewer times outside the 15 minute intervals 1.4±1.2 in the IG vs. 2.8±1.8 in	Being satisfied without complete analgesia (T) Stimulating the patient's own resources (T) Strategies of managing pain (C) Benefits of visualization (C) *"I managed to create another space, a different reality than the*	Patients use their very own strategies to deal with the pain and patients experienced pain, but they did not feel that they have to go into pain. They focused away from the pain by creating a space for themselves, that is, it may not be on the experience of pain intensity, one can measure the effect of intervention visualization, because the effect of visualization is that it helps

the CG. No difference in the level of perceived pain intensity when the patients spontaneously expressed pain. IG patients received significantly less analgesics than CG patients (Fentanyl) 220,7µg ± 93 (Mean ± SD) vs. 292.3µg ± 107 (Mean ± SD) p<0.0001.	*unpleasant reality" (p1)* *"I felt pain in the chest, but somehow I did not have to go into the pain"(p14)* *"Well, I think that apart from those times when it really hurt it seemed ok, and it was quite clear that between those applications I was almost asleep" (p10)* *"So, it could help to divert your thoughts that you like focus on something nice and…."(p1)* *.... "But I was far away at some point -, I could not feel when they were going to give me an injection, just lying and dreaming and such things"(p3)* .. "*You have some mental resources that we can use"(p14)* *"And at the same time if it's like being without using too many medications or so, that's better, all you can do, it's a mental way to do it, - and I think it's a good and organic way to do it"(p13)*	patients to deal with pain. The lack of significant difference in pain intensity is supported very well in the interviews, where patients express an experience of pain but not having to "enter" into the pain. The quantitative study could not provide evidence that visualization could be used to reduce pain during the ablation of AF since primary outcome pain intensity was not significantly reduced in the IG. Findings from qualitative studies however showed that patients experienced pain and used visualization as a strategy to manage the pain and expressed their positive experiences. At the same time, the quantitative results showed that patients requested less pain medication. Based on that, visualization might have an effect. Furthermore the patients felt good about that they did not need so much pain medication, and instead had the possibility to have non-pharmacological help.
No significant difference in the RF application time	Being satisfied without complete analgesia (T)	Although no statistical difference was found in procedural time between the

between the two groups. CG: 2284.5 ±1019.1 seconds and IG: 2197.3±1184.5 seconds, P = 0.634) No significant difference in procedure time between the two groups. (CG: 195 ± 33 minutes and IG: 195±35, P=0.953).	Stimulating the patient's own resources (T) Benefits of visualization (C) All but one of the interviewed patients had the feeling that the procedure did not last very long. *'"It went fast, so therefore when I asked to find out how long I had actually been down there, – I think it was over quickly "(p9)* *"I really thought it went.., I think it went faster because I was allowed to swim away in those fantasies"(p11)* ..." *but it (the time) is terminated in one way or another, a temporal shrink of time" (p14)* *"Well, actually, I did not really think I was thinking about it because I'm a little bad at the back of my back ..... and I had no problem at all. It went fine and when I looked up and saw that it was 12 o'clock, I thought it was .... I had no feeling that it had taken so long" (p1)*	groups, the interviewed patients from the intervention group experienced that the procedure had a short duration. The patients had a lack of sensation of time even though a procedure could last from 3 to 4 hours. The patients were activated and occupied during the procedure and used their own resources when they were guided in visualization thereby excluding the external reality.
No significant difference in anxiety between the two groups	Stimulating the patient's own resources (T)	Surprisingly low values according fear/anxiety were measured in the quantitative

at any time during the procedure. Mean anxiety in the IG 0.09 ±0.3 - 2.03 ± 2.1 and 0.10 ±0.3 to 1.84±2.4 in the CG. No significant difference between IG patients previously treated with ablation vs. ablation-naïve IG patients. 1.55 vs 2.39 p=1.05 Higher anxiety score in ablation-naïve CG patients vs. CG patients previously treated with ablation 2.35 vs. 1.17 p=0.004	Strategies of managing anxiety.(C) Approach to visualization (C) *"Well I felt incredibly comfortable all the way in, so you could say that when she asked if I was nervous or anxious I almost think I continually said no because I felt really comfortable"(p1)* *"My experience was, that the staff was very professional the whole time, and I felt that it gave me a sense of security that she constantly said: "now we stick to the plan we have in place" (p2)* *"I'm used to in my job that I always have control. This gave me the opportunity to let go of the control, it was liberating. I did not have to constantly relate to what they said, or the noise in the surroundings – what did that mean?"(p2)* *"If you could focus away from all the sounds and all the people down there (In the procedure room), so…I think that's an advantage"* (p2) "*I am convinced that you have some mental*	study. Patients' statements from the qualitative study however, support the results of the quantitative results. The patients interviewed expressed that they were very little nervous or not nervous at all - which is in line with the low values measured in the quantitative study. In the qualitative study, patients also indicated that the staff's professional behavior meant something to them and that the staff in some way allowed them (the patients) to let go of control – which might have given them a feeling of safety.

resources, that we could use in contexts where it is most important to use them" (p13).

6.4.1. "ZERO PAIN IS NOT ALWAS THE GOAL"

By integrating the results from the quasi-experimental (114) and the qualitative study (127) it became clear that what meant most to the patients was an experience in which they could handle the pain and not the intensity of the pain itself. Results from the pain assessments in the quantitative study showed significant reductions of both the amount of analgesics used and patients' spontaneous reporting of pain in the IG compared to the CG. However, a lack of significant reduction in pain intensity in the IG was integrated with the two themes from the qualitative study: "*Being satisfied without complete analgesia*" and *"stimulating the patient's own resources"*.

The patients interviewed in the qualitative study reported that they did indeed experience pain, but with help from visualization, they had a feeling of "not having to deal with the pain". They were stimulated to find and use different strategies to cope with pain, including "creating their own universe", away from the pain. A patient said*:"I felt the pain, but somehow I did not have to go into the pain"* and another patient stated: *"I managed to create another space, a different reality than the unpleasant one"* implying that it was not so important if pain was experienced during the procedure. Instead the importance of being able to deal with the pain so that it was tolerated was meaningful and gave the patients a sense of satisfaction. Also the fact that the patients were able to handle pain without too much pain medication gave them a sense of satisfaction. Some patients expressed the view that if the pain was too strong they could not use visualization.

The qualitative results thus supported and explained the quantitative results with reduction in pain medication and reduction in the spontaneously expressed pain, despite the fact that pain intensity was not significantly reduced. It could also explain why pain intensity was not significantly reduced in the IG compared to the CG when reported by the patients spontaneously outside the fixed measurements in the quantitative study. In addition, it might explain how visualization had an effect on handling of pain although the patients did not necessarily become pain free during ablation of AF. Based on this, measurement of pain intensity does not appear to be an optimal strategy for assessing the effect of an intervention such as visualization.

6.4.2. "IMPORTANCE OF THE NURSE'S PRESENCE, VISUALIZATION OR NOT"

"Importance of the nurse's presence, visualization or not", was another issue that arose from the integration of the two studies and which could contain or explain elements of both uncertainty and security. The anxiety values measured in the quantitative study were surprisingly low and statistically significant differences in anxiety levels were not found between CG and IG (NRS mean 0.1 - 1.86 in CG and mean NRS 0.09-2.03 in IG) (114). However, the interviewed patients indicated that the nurses' close presence during the procedure was of great value to them and gave them a sense of security, which could indicate that they somehow felt unsafe or insecure during the procedure. One patient said, *"And that I just knew that she was there all the time - and commented on everything, and nothing was too small for her to comment on"* (patient 11). Another patient stated, *"My experience was that the staff was very professional the whole time and I felt that it gave me a sense of security that she constantly said; now we stick to the plan we have in place"*(p2).
On the other hand several of the patients interviewed also stated that they were not nervous or anxious during the procedure: One patient said: *"I felt incredibly comfortable all the way, so you could say that when she asked if I was nervous, I almost think that I constantly said no because I felt really comfortable* "(p1) and another patient said," *I'm convinced that you have some mental resources that we could use in those contexts, where it's important to use*"(p14).
These statements indicate that patients did not feel unsafe or insecure and explain very well the surprisingly low anxiety values which were observed in the IG in the quantitative study. They do not, however, explain the low anxiety values which were also observed in CG. The importance of the nurse's presence could be associated with the patients being guided in visualization. Several patients stated that it was important that someone guided them because it was not possible to do it themselves. By the nurse's help the patients were stimulated to find their own strategy to manage anxiety. However, the close proximity of the staff was similar in both patient groups which could explain lack of significant reduction in anxiety levels in the IG compared to the CG as well as the low values observed in both groups. Furthermore, music was provided in both groups which could also have decreased anxiety(154).

6.4.3. "NOT A REAL REDUCTION IN PROCEDURE TIME BUT A SENSE OF TIME SHRINKAGE"

The third theme "Not a real reduction in procedure time but a sense of time shrinkage" describes the contrast between the lengthy ablation procedure, that visualization could not reduce in the quantitative study (114) and the patients' experiences of a short procedure time and their confidence that visualization was responsible for this experience (127). RF Ablation of AF can be a lengthy procedure and the measurements in the quantitative study indeed showed long procedure times

(CG min., mean ± SD 195.1 ± 33.2; IG min. mean± SD 194.7 ± 34.9)(114). Nevertheless, 13 out of 14 interviewed patients expressed the opinion that they perceived procedure time as short, "*but it (the time) is terminated in one way or another, a temporal shrink of time"* (p14), one patient said. Another patient said, *"I really think it went..., I think it went faster because I was allowed to swim away in those fantasies* "(p11) (127).
By integrating the results from the two studies, it turns out that while the procedural time cannot be reduced significantly by using visualization, patients are probably helped with this intervention towards an experience of an altered sense of procedure time, a kind of "timelessness" or "diffuse sense of time" hence visualization helped the participants to generate their own inner world with something to focus on and excluded the reality in the procedure room, "the external world". One patient expressed it as a feeling of being free from *"the roaring emptiness"*.

In summary, by integrating relevant results from the quasi-experimental trial (114) and the qualitative interview study (127) it was found that visualization helped patients to manage procedural pain when going through ablation of AF but did not reduce the experience of pain intensity. Furthermore, it was shown that it is not advisable to measure the effect on pain intensity with a one dimensional instrument such as NRS as done in the quasi-experimental study because visualization did not affect pain intensity much but rather the affective part of pain and was found to be a tool to help patients handling pain. In addition this study showed that the patients felt that they had experienced a short procedure time, although it was not reduced statistically significantly by using visualization even though the procedures lasted up to three to four hours. Another result of this mixed methods study was that patients experienced low levels of anxiety or no anxiety during the procedure in the qualitative study which was in line with and supported and explained the surprisingly low values of anxiety measured in the quasi- experimental trial. Despite an experience of no or a low level of anxiety and low measured values, the presence of the staff was of great importance to them in providing a feeling of security. Finally, a reduction in pain medication is important in the patient's perception and this shows that it is not only a matter of safety.

CHAPTER 7. DISCUSSION

The current practice of alleviating patients' pain and anxiety during RF ablation of AF did not seem optimal. Inadequate pain management could have serious consequences for patients' health and cause discomfort, delayed healing, chronic pain and depression postoperatively leading to longer hospital stays (5, 14). Thus the overall purpose of this present dissertation was to examine the effectiveness, meaningfulness and the feasibility of an intervention; visualization used as an adjunct to usual analgesics to manage pain and anxiety during RF ablation of AF and other minimally invasive procedures.
Due to the complexity of the problem, several research methods were used for the investigation. The goal was to achieve a deeper understanding of the effect and meningfulness of visualization which could help guide clinical practice to an optimal pain management for this group of patients.

In order to answer the questions asked about the intervention's effectiveness, meaningfulness and feasibility when used during ablation of AF, a quasi-experimental study was used to test its effectiveness; a qualitative study was used to investigate the meaningfulness of the intervention, a mixed methods study proposed to gain a deeper understanding of the association between the effect of the intervention and the patients' experiences with the intervention thereby supporting the effectiveness and the meaningfulness of the intervention, and finally a systematic review was performed to support the results in the effectiveness study.
Based on the included studies, visualization used as an adjunct to usual analgesics is recommended as an intervention to relieve pain during the ablation of AF and other invasive procedures. But there are still questions remaining for future research.

7.1. DISCUSSION OF THE MAIN RESULTS

7.1.1. THE EFFECTIVENESS OF VISUALIZATION? (PAPER I, III AND IV)

The results from Study I (114), where a quasi-experimental design was used to test the effectiveness of visualization showed a significant (24%) reduction in the amount of analgesics used during the RF ablation of AF in the IG compared to the CG although no difference was found in the perception of pain intensity and anxiety. The patients expressed spontaneously pain a significantly fewer number of times outside the scheduled measurements in the IG. There was no reduction in procedure length and numbers of adverse events.
The results found in the quasi-experimental study are in line with previous research in the field, as the systematic review in this dissertation investigating the effect of hypnosis on procedural pain during minimally invasive procedure (Paper IV, Nørgaard et al 2018 submitted) showed that using visualization or hypnosis together with usual pain medication reduced the amount of analgesics required without reducing the overall pain intensity. In the review it was found that the amount of

pain medication used during procedures was reduced between 21 and 86 % although pain intensity and anxiety in general were not reduced significantly which supported our findings. However, a significant reduction of pain or anxiety at times during the procedure was found in some studies (2, 4, 43). We have chosen not to perform meta-analysis of the outcomes, pain intensity, anxiety and the amount of pain medication because we have found too much variation of the data from the included studies and because there are several studies with reporting data lacking which required us to manipulate or estimate in too many studies, which might have led to bias in the results. The measurements were performed before and during the procedure as time points and were carried out with very different time intervals with respect to the type and duration of procedure.
By contrast a meta-analysis was performed of the outcome procedure length on the basis of data from the studies included in the systematic review (Nørgaard et al., 2018, submitted) A statistically significant though slight reduction of the procedure length was found. The result should be taken with precaution as in two of seven included studies mean and SD were estimated and based on imputed values although it has been found safe to borrow SD's from other studies included in a meta-analysis and a sensitivity analysis was provided (152). However the most important aspect of this result is both from the perspective of the patient and also from a resource perspective visualization or hypnosis does not prolong the procedure time. Furthermore, no increased risks in relation to adverse events were found in the included studies.
Effectiveness has been described as the extent to which an intervention, when used appropriately, achieves the intended effect (113). Based on this it can be concluded that visualization was found effective by reducing the amount of pain medication required when used during ablation of AF, not, however, by reducing pain intensity in general.

It was surprising that both the amount of pain medication and numbers for self-reported spontaneous pain could be significantly reduced in the studies when pain intensity could not. Both the quasi-experimental study and the studies included in the systematic review (2-4, 43, 44, 100, 148, 149), measured pain as pain intensity using the same one-dimensional instrument, VAS or NRS. Also, a recent critical review investigating the effect of hypnosis on procedural pain in children and adults with 29 randomized controlled trials included (38), concluded that hypnosis may affect subjective pain intensity and pain unpleasantness differentially.
That raises the question of whether pain intensity is the correct outcome for effects measurements of an intervention such as visualization or whether the instruments used are generating misleading results. This could ultimately result in rejection of an otherwise useful intervention.

7.1.2. THE MEANINGFULNESS OF VISUALIZATION? (PAPER II AND V)

Results from the qualitative interviews enabled us to explore the patients' experiences with visualization (127), thus gaining an understanding of the mechanisms for the use of visualization and an insight into what participation in this kind of pain treatment meant to the patients. The results in this study were based on useful and valid data that were sufficient to answer the research questions asked.

Based on that, we concluded that visualization was a useful and meaningful method for patients to relieve pain without reducing pain intensity as initially anticipated. Despite complete analgesia not being achieved the patients expressed the view that visualization provided some pain relief and stimulated their individual strategies in managing pain and anxiety, in the sense that some patients created their own internal reality where they could exclude the pain or "not go into the pain" even though they experienced it. Patients furthermore reported high levels of treatment satisfaction and other non-pain-related benefits such as an experience of short procedure time, even though this was not the case in chronological terms, excluding stressful noise and a permission to let go of control.

Two previous studies have examined patients' satisfaction with hypnotic analgesia both using structured questions for either questionnaires or telephone interviews (108, 109). One study found a high level of treatment satisfaction among 30 participants with chronic pain despite the patients not achieving complete pain relief (109). These patients reported both pain related and non-pain related benefits from hypnosis. The other study of women undergoing pregnancy termination found a higher degree of satisfaction with the treatment or procedure among women who were guided in hypnosis compared to patients in the CG and 97% of these women would recommend hypnosis to a friend undergoing similar procedures (108).

When patients, as shown in the qualitative study in this dissertation (127), were stimulated to use their own resources to find the individual strategies needed to deal with pain and anxiety, they experienced an involvement in pain management. A major factor in strategies to improve the quality of pain management is patients' participation in the pain assessment and the pain management (9). Patients' participation in pain management in hospitals resulted in improved outcomes on pain relief, satisfaction with care and less time in severe pain (155, 156). Moreover, it was found that if patients participated in their own pain management, even if limited to pain assessment, they wanted to take responsibility and to control the pain. However, the majority of patients wanted to share responsibility for pain management with the healthcare professionals (157).

By using a mixed methods study with an explanatory sequential design (139, 140, 142) merging results from the qualitative study to explain the findings of the quantitative study, we were able to generate a more complete knowledge and

understanding in terms of the effectiveness and meaningfulness of the intervention. With the results of this mixed methods study (138), it became clearer why there was no reduction in pain intensity. Visualization affected the patients' management of pain so that they still experienced the pain but were stimulated to find strategies to cope with it.

The question as to whether the positive effect of visualization on the patients perception of pain as opposed to the level of pain intensity, had an impact on the possible physically deleterious effects of pain, such as prolonged wound healing, development of chronic pain and depression could not be addressed in the studies performed within this dissertation and should be the subjects of future research projects.

Furthermore by using this mixed methods design the surprisingly low anxiety values found in the quasi-experimental study (114) were well supported by the patients' experiences, as expressed in the interviews. Surprisingly, in the quantitative study the patients did not experience severe anxiety as found in other studies investigating patients' anxiety during elective surgery or invasive procedures (72, 74) and there was no difference in anxiety between the two groups. That raised the possibilities that either there was no effect of visualization on anxiety or the instrument used for measuring (NRS) failed to detect an effect. However, results from the systematic review (Nørgard et al. 2018, submitted) showed similar results with no overall reduction in anxiety score, except for a tendency to a reduction in a few individual studies (2, 101). The qualitative results on anxiety thus supported the findings in the quantitative study. Because of the low anxiety scores in both the CG and the IG, much larger patient numbers would have been required in order to provide a sufficient weight for a meaningful comparison among the CG and the IG.

From the mixed methods study visualization appeared to be an effective and meaningful intervention to manage pain but did not seem to affect the intensity of pain. This provided supportive evidence that pain intensity measurement seemed not to be a useful means of measuring the effect of the intervention and the affective component of the pain thus remained un-assessed.

7.1.3. THE FEASIBILITY OF VISUALIZATION IN CLINICAL PRACTICE?

Feasibility has been described as the extent to which an activity is practical and practicable and whether or not an activity or intervention is physically, culturally or financially possible within a given context (113).

The intervention in the quasi-experimental study was tested for more than half a year in a busy daily clinical practice, where procedure nurses provided the intervention based on a manual that had been altered for patients undergoing ablation of AF. With the quasi-experimental design, it was possible to complete this very practical study without adding more resources to the procedure room hence the procedure length was not extended and no additional staff was needed in the procedure room (114). In addition the intervention did not lead to interruption of any

procedures as also found in other previous studies (2, 4, 43). The production level in the cardiac cath. lab. was maintained without cancellations due to the study. It was possible to train all nurses from the team in the intervention and all staff was able to learn structured attentive behavior and provide it in daily practice. In contrast previous similar studies have used an extra research assistant or person to provide the intervention (2, 4, 43, 44, 100, 101, 148) which could complicate an evaluation of feasibility in daily practice with the existing resources. Results from a meta-analysis of five studies from the systematic review (Nørgaard et al. 2018 submitted) of this dissertation including the quasi-experimental study (114) showed that the procedure length was not increased by visualization or hypnosis. On the contrary, a significant reduction with an absolute magnitude of summary effect had a Standard mean Diff -0.25 (CI 95 %: -0.41-0.009), showing visualization' positive effect on reduction on procedure length which also supports the feasibility of visualization.
Patients were positively motivated to use this intervention regardless of age, gender, education or type of AF (114). Seventy six patients used visualization without discomfort or complications and only 13 patients did not wish to participate in the study, respectively in the CG and IG, for reasons not reported. Therefore we do not know if that was because they did not want to use visualization.
Based on the above, we conclude that visualization is a safe and feasible intervention which is easy to implement when used as adjunct to usual analgesics for relieving pain during ablation of AF in a cardiac cath. lab.

7.2. DISCUSSION OF METHODOLOGICAL ISSUES

By using a quantitative and qualitative method as well as a mixed methods design and a systematic review, this dissertation gained both a broad and profound insight into the effectiveness, meaningfulness and feasibility of visualization used during ablation of AF. In addition, an understanding was obtained of how patients experienced being guided in visualization during ablation of AF. We would not have been able to achieve these results with a single research method alone. Previous research does not appear to have investigated this issue on this specific patient group or this specific invasive procedure to this extent and very few studies have investigated patients' experiences or satisfaction with visualization during ablation of AF or during other invasive procedures (108, 109). Nor has a mixed method design been used where patients' experiences have been used to explain results in quantitative studies about visualization's effect as pain relief during ablation of AF or other invasive procedures.

7.2.1. THE QUASI-EXPERIMENTAL DESIGN (PAPER I)

A quasi-experimental study; a design with a control group but without randomization, was used to test the effectiveness of the intervention, visualization, used to reduce pain during RF ablation of AF (Paper I). The quasi-experimental design was chosen, knowing that risk of selection bias with confounders was an

inevitable factor in this design (117, 158). Applicability and feasibility in clinical practice with an effectiveness study was important (159). Due to the clinical issue with the inadequate pain management, it was necessary to find a workable solution, which could relieve patients' pain and which could be implemented in daily clinical practice with the usual staff providing the intervention. Furthermore, it was important that all nurses from the team could perform this intervention in the future so it could be provided to patients regardless of which nurses were on duty. The intervention consisted of both visualization and structured attentive behavior, that is, if randomization was to be performed, the nurses in the team had to change behavior towards the patients depending on whether patients were in CG or IG and this might cause bias with contamination of the groups. Therefore the CG was conducted first, then the nurses were trained and finally the IG was carried out thereby minimizing contamination.

Due to the nature of the intervention blinding was not possible, hence the intervention could not be provided without staff knowing that they provided it and the patients not knowing that they received it. The lack of double blinding implied a risk that the Hawthorne effect could occur due to patients' awareness of being observed, or the staff being aware of the intervention. However, it has been questioned in recent years, whether this effect can occur in contexts other than the one where it was originally observed (160, 161). Still the possibility of a Hawthorne effect bias affecting the results should be considered.

However, in the CG nurses might also have been more attentive knowing that the patients were included in a study and hereby reducing the true effect of the intervention.

A triple blind randomized controlled trial is considered the highest level of validity (117) with regards to assessing causality and to eliminate confounding. Blinding was however not possible in this study. On the other hand it might be argued that previous studies (2, 4, 43, 100) have been able to use a randomized controlled design and were not blinded either. Those studies used an extra research assistant to provide the intervention during the procedure and did not train the staff in the intervention until after the study, thereby preventing evaluation of feasibility of the intervention in clinical practice. Blinding was not performed in all but one study in the systematic review in this dissertation (3).

Cluster randomization might have been an alternative and feasible approach to investigate the effect of visualization (162), performing the CG in one hospital and the IG in another. Using this design the study could be carried out as an effectiveness study; close to practice with the procedure nurses involved, but there are other difficulties in conducting a cluster randomized controlled trial (162, 163). Selections bias might have been reduced even though it could still be a risk. However, the risk of differences in care and treatment between two hospitals leading to other differences between the CG and IG than those related to the intervention would then have biased the results.

7.2.2. THE QUALITATIVE INTERVIEW STUDY DESIGN (PAPER II)

In order to examine and gain understanding about how the patients undergoing ablation of AF perceived an intervention such as visualization to reduce pain and anxiety, a qualitative interview study (117, 124) was carried out. To our knowledge this study is the first qualitative study exploring patients' experiences with visualization used to relieve pain and anxiety during ablation of AF. Individual face-to-face in depth semi-structured interviews were carried out with patients who had participated and finished the IG in the quantitative study (117). Participants were selected to represent both gender, age, type of AF, patients undergoing ablation of AF for the first time and patients undergoing a re-do procedure in addition to patients with both positive and negative comments on visualization seeking the best representativeness of participants in the intervention group and patients undergoing ablation of AF. It was a deliberate choice that the patients should be able to say something about the specific use of the intervention. Therefore no patients from the CG were interviewed. Interview with patients from the CG, might have provided supportive information about the impact of the intervention, e.g. experience of a short procedure length or safety and security of the staff's close presence. Based on the interviews we made, we therefore cannot ascribe these effects to the IG alone.
Fourteen interviews (18% of the IG) were conducted, thereafter data saturation was obtained: additional data no longer contributed anything new to our understanding of the topic and no new coding appeared (117, 164), however, the concept of data saturation is controversial because of how data saturation is assessed. To assess the sample size of this qualitative study (127) in this dissertation it might be considered that with the 14 participants included in it, the collected data were strong and sufficient to add a great deal of new knowledge to a field where there was not much present knowledge. Considering that the aim of the study was relatively narrow (experiences of a specific intervention), participants in the study were willing to be interviewed, no one refused to participate and although not everyone had much to say each participant contributed with their individual experiences of the use of visualization and they could all contribute with important new knowledge.

The questions from the interview guide worked well in terms of getting the participants to share their experiences of visualization and being relevant to providing answers to the research questions. However, the last question that was asked from the interview guide, "Is there anything else you want to tell about your experience when using visualization during ablation?" actually turned out to be the question which the participants had the most comments on and which possibly gave them the best opportunity to reflect on their experiences with visualization. It was often in this question that the patients talked about experiences of losing control, the importance of the presence of the nurse and the importance of -and attitude towards visualization. The quality of the interviews was judged to be good, even though the interviewer did not have much experience with the interview technique from the very start. This was remedied prior to the study interviews by conducting two pilot interviews with an additional interviewer and supervision from experienced

researchers. The interviewer, however, had a thorough knowledge and interest of invasive cardiology which enabled her to remain focused during data collection. The fact that the interviewer had long experience and detailed knowledge of invasive cardiology could on the other hand have prevented more detailed and open questioning to issues related to the invasive procedure.
Finally by performing an inductive content analysis, the ambition was not to cover everything about the phenomenon examined, but rather to present patterns relevant to the aim (131) which we believe was obtained with those 14 participants. It enabled us to sufficiently answer the research question and new knowledge was generated about the intervention.
The categories and themes derived from the analysis were based on - and covered all the 14 participants' experiences and were at the same time mutually exclusive and exhaustive in terms of adequately representing an understanding of how the participants used visualization during ablation of AF and what it meant to them in managing pain and anxiety.

Alternatively, a focus group interview could have been used as a method of getting participants' perspectives as to whether visualization could be a useful method of managing pain and anxiety during ablation of AF (124). The focus group interview is useful for a dialogue between participants from e.g. the intervention group in which the dynamics of the group are utilized to gain a variety of perspectives on the topic. In the focus group interview, knowledge is generated from discussion of a phenomenon. If this design had been used, the participants' shared experience could have been exploited to test an intervention. However, one should be aware that in a focus group interview knowledge could have been be suppressed instead of generated due to the personal bodily nature of patients experiences from this particular intervention. Moreover, participants in the IG had not met on other occasions and therefore did not know each other.

7.2.3. THE SYSTEMATIC REVIEW OF EFFECTIVENESS (PAPER III AND IV)

A systematic review of effectiveness (Nørgaard et al. 2018, submitted) was conducted as a part of this dissertation to validate the results found in the quasi-experimental study (114) and to examine the effect of visualization or hypnosis used in conjunction with usual analgesics to reduce pain, anxiety, the amount of pain medication and adverse events during other invasive procedures (Paper III and IV). To ensure both rigour and transparency this systematic review was based on a protocol (135) (Paper III) as required by JBI (113).
The systematic review included both randomized and non-randomized studies considering the best available evidence as suggested in the JBI approach (113, 134).

The quantitative results of this systematic review found a statistically significant reduction in pain medication in the five studies measuring this outcome (2, 4, 44,

100, 114) despite a statistically significant reduction of pain intensity not being found when using hypnotic analgesia during minimally invasive procedures. Unfortunately a meta-analysis could not be performed on the outcomes pain intensity and anxiety due to differences in measuring and reporting the outcomes as well as missing SD.

Thus, assessment and calculation methods for measurements used in pain clinical trials have been described as more complex and not just straightforward due to time intervals measured, the dimension of the pain and uncertain trajectories (165). However as mentioned above findings from a qualitative study (127) showed that patients did experience pain but used hypnosis as a strategy to manage it. In all studies included in this systematic review, the pain intensity was measured by using standard instruments developed to measure pain intensity in trials assessing effectiveness of an intervention which is obviously different from assessing patient's management of pain. In line with this it was previously shown that hypnotic analgesia does not work by simple reduction of pain sensation but instead induces a dissociation from the pain and a separation of pain intensity and unpleasantness (38). From a methodological point of view it is important to discuss the risk of such bias when performing a systematic review without considering this type of problems.This was discussed previously (page 64) considering the choice of instruments for measuring particular outcomes. The systematic review is considered to be the highest level of evidence and is invaluable for informing practice with the best available knowledge. There is a risk that despite rigorous research methods used in a well conducted systematic review, conclusions might be misleading and miss or not recognize the effect of an effective intervention, because the studies included have measured patient-related outcomes with instruments that do not capture the true essence of the phenomenon.
Another important methodological issue to consider is the inclusion of meta-analyses or lack of the same in systematic reviews with similar intervention studies as in this systematic review. In a previous systematic review investigating hypnosis on procedural pain direct pooling was a problem due to great differences in type, location and level of pain experienced. Therefore the results were simplified and so the indicator of effectiveness was the percentage of the number of measures in which the IG (hypnosis) had significantly lower pain scores than the CG in relation to the total number of measures (38). However meta-analyses have been conducted in previous systematic reviews in adults undergoing surgical procedures on some outcomes (pain, emotional distress medications and physiological parameters) but with limitations due to information being insufficiently reported in the studies included (115, 116). Furthermore it is unclear in how many of the included studies in the two meta-analyses, imputed values have been applied. However, earlier systematic reviews have been widely oriented when hypnosis was investigated on pain and anxiety. Children, adolescents and adults have been included in the same systematic review, likewise patients for both major and minor surgery, as well as invasive and medical procedures and patients in general and local anesthesia,

respectively. There is a need for a debate between researchers in the field so that an alignment in measurement and reporting of outcomes is strengthened. Development of a core outcome set for trials of interventions such as visualization or hypnosis might be a solution (166).

Furthermore, how to calculate and report pain and anxiety measurements when measured in many point-in-time measurements during the different procedures has been discussed. Comparison of averages measurements, and maximum measurements has been the usual way of analyzing pain and anxiety scores measured during procedures as well as with analyzing slopes but it has not yet been possible to identify a single unifying measure for acute pain when measured during procedures (165) and so further research in this area is warranted.

7.2.4. THE MIXED METHODS DESIGN (PAPER V)

In this dissertation a mixed methods study with an explanatory sequential design (140, 142) was used to provide a deeper and more comprehensive understanding of how visualization, could help patients handling pain and anxiety through the ablation of AF with new insights beyond the information gained from the individual studies included (139, 141). Neither the quasi-experimental study, which provided a more general description of visualization used during ablation of AF nor the qualitative interview study which provided a more detailed understanding, could alone expand the relevant area of knowledge about the visualization to the extent that the mixed methods approach could. Thus we considered a mixed methods design to be the most sufficient and comprehensive means of obtaining answers to the research question. We used Creswell's definition of a mixed methods design (167) as a research design (or methodology) in which the researcher collects, analyzes and mix both quantitative and qualitative data in a single study or a series of studies. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of the research problems than either approach alone. The issue in this study (138) was therefore less on a paradigmatic choice and more practical in nature. The quantitative and the qualitative methods were in that way not separated but parts of a coherent whole and quantitative and qualitative methodologies were combined with advantage. There was a need for a deeper explanation of the results of the quasi-experimental study, such as the reduction of pain medication despite no reduction in pain intensity and the low anxiety scores. Therefore the explanatory sequential design seemed ideal to use, because results from the qualitative study could then be used to explain the surprising results. Thus, based on American pragmatism, which emphasizes that the validity of research is not to be found in (philosophical) discussions on what is in the world (ontology) and the ability to obtain knowledge about it (epistemology) but by contrast, research and the knowledge generated should rather be judged on how it helps to answer questions and understand the phenomena that concern us (167, 168). However, some researchers have argued against integration of quantitative and

qualitative methods because of a possibility of incompatibility between the positivist and interpretive research paradigms although discussions about this have been declining over the years (169).
The mixed methods design has been recommended by European Society of Cardiology in recent years in order to obtain increased involvement of the patient's perspective when the effectiveness of an intervention is investigated to improve cardiovascular care (170).

7.3. GENERALIZABILITY

The study population in Paper I (116) was all adult patients referred for RF ablation of AF who were able and willing to give written informed consent. Seventy five percent of eligible patients were included in the study. The majority of the study population was male (66-71%) with a mean age of 60 years. The ethnicity of participants was Caucasians. The gender, age and ethnicity distribution in this study population were comparable to another Danish study of ablation of AF (160). However the restriction on ethnicity and culture, all patients being Caucasian and from a western country, might compromise generalizability to continents with different population compositions, thus warranting further research.
Significantly more patients with paroxysmal AF as well as fewer patients with long-standing persistent AF were included in the IG compared to the CG (116). This selection bias which might be due to the study design lacking randomization, might also compromise generalizability (110). However, we found no differences between patients with different types of AF in either baseline pain or anxiety in the effectiveness of visualization. In light of this we conclude that the results can be generalized to patients with the same characteristics undergoing ablation of AF in the same setup using conscious sedation.
The large study populations in the studies included in the systematic review (Paper IV) were predominantly women (71%), Caucasian (74-95%) from western countries and aged between 18 and 94 years which constituted a broad sample of patients undergoing a variety of minimally invasive procedures under a light conscious sedation. Caution should, however, be exercised when generalizing results in terms of gender, culture and ethnicity, warranting further research. On the other hand, visualization has been investigated in a large variety of invasive procedures on in- and out patients in hospitals, both in terms of length and degree of invasive procedure with similar results on some of the outcomes which support the recommendation of using visualization during minimally invasive procedures. Gender differences in susceptibility to hypnosis have been investigated in very few studies showing a small advantage for females compared to males in hypnotizability score (171, 172). No studies investigating gender differences in the use of visualization or hypnosis in reduction of procedural pain has been found. However, in the qualitative study in this dissertation (127) in which both men and women were interviewed about their use of hypnosis as pain reduction and how it helped them during ablation of AF, there were no differences in terms of use of and success with

hypnosis during the procedure. In conclusion, our results could be generalized to patients undergoing minimally invasive procedures, but specific precaution must be taken in relation to ethnicity and culture where more research is required with a recommendation for larger research studies to be conducted.

The extent to which the findings from the qualitative study (127) can be used or transferred as a guide for the use of visualization during ablation of AF or during other invasive procedures is determined by how thick, sufficient and relevant the findings obtained are and of the recipient of the information (117). In order to be transparent in the description of the research process, this study was described in terms of sampling, data collection and analysis and by interviewing the 14 specific participants from the IG in the quantitative trial (114) we gained relevant and sufficient information to answer the research question asked (127). But to evaluate the extent to which our results apply or can be transferred to other settings is up to the reader (173). However, qualitative knowledge is sparse in this area and more qualitative research is needed about the use of visualization or hypnosis during ablation of AF and other invasive procedures in general to support quantitative results with the intention of a wider use of visualization.

CHAPTER 8. CONCLUSION

The overall purpose of this present dissertation was to examine the effectiveness, meaningfulness and the feasibility of an intervention, visualization used as an adjunct to usual analgesics to manage pain and anxiety during RF ablation of AF and other minimally invasive procedures.

Based on the studies included in this dissertation it can be concluded:
In a quasi-experimental trial with a control group it was found that visualization and structured attentive behavior reduced the amount of pain medication used during the RF ablation of AF significantly. Pain intensity could, however, not be reduced significantly but the patients expressed pain spontaneously significantly fewer times outside the fixed measurement points. No statistically significant reduction was found in anxiety, numbers of adverse events or procedure length.

From a qualitative interview study two themes reflected the patients' experiences with the intervention, visualization used for pain relief during ablation of AF: "stimulation of the patients' own resources" and "being satisfied without complete analgesia". Patients expressed the view that by using visualization they achieved some pain relief and were supported in using their own individual strategies in handling and controlling pain and anxiety. They perceived visualization as a positive experience without inconvenience.

Results from a mixed methods study where results from the quasi-experimental study and results from the qualitative interview study were integrated identified three themes: "Zero pain is not always the goal"; "Not a real procedure time reduction but a sense of time shrinkage" and "Importance of the nurse's presence, visualization or not". Visualization helped patients to cope with the pain and did not affect the experience of pain intensity. The patients thus experienced the pain but had an experience of not having to deal with it. Based on that, a suggestion is that the effect of an intervention such as visualization should not be measured on the reduction of pain intensity with a NRS because visualization does not affect the experience of pain intensity. The patients appreciated the fact that the use of analgesics could be reduced which therefore constituted both a safety and a satisfactory aspect. It thus had not only a safety value but a satisfaction for the patients. Even though the patients did not experience severe anxiety during the procedure; the close presence of the staff provided a sense of safety to them. Finally it was found that although ablation of AF is a long lasting procedure the duration of which could not be reduced by using visualization, the patients had a perception of ablation as a short procedure when using visualization.

From a systematic review of ten studies, it was found that the available evidence suggests that hypnosis is effective in reducing the consumption of analgesic

medication used during the procedure however; it has little effect on the primary outcome pain intensity and the outcome anxiety during minimally invasive procedures. The studies included were difficult to compare with regards to measurements and reporting outcomes which precluded a meta-analysis on several outcomes. It is safe to use visualization and the procedural time is not extended but may even be reduced slightly.

In summary, visualization was, with the research methods used in this dissertation found to be effective and meaningful for patients in managing pain during the ablation of AF and might be a useful intervention during other invasive procedures. Furthermore, visualization was a feasible intervention that can be used in daily clinical practice without additional resources.

CHAPTER 9. IMPLICATIONS FOR RESEARCH

This PhD dissertation adds important results to sparse current evidence on a non-pharmacological intervention to manage pain and anxiety during ablation of AF and other minimally invasive procedures. Nevertheless further research should be considered for the future.
How to measure the effect of an intervention such as visualization when used to relieve pain during minimally invasive procedures is a challenge. In future research development of a useful multidimensional instrument for measuring the effect of such an intervention or further development of an already existing measurement tool need to be considered.
Outcome data measurements are crucial to ensuring continued improvement of intervention strategies in reducing pain. Because of inconsistently measured and reported outcomes in the clinical trials addressing visualization or hypnosis it is recommended to develop core standard outcome sets for future trials investigating visualization or hypnosis. The ability to compare findings or to pool data for meta-analysis would thereby be enhanced.

The quantitative studies investigating visualization or hypnosis used during minimally invasive procedures do not capture patients' experiences and the literature in this field is sparse. Therefore it is recommended that more qualitative research studies be done. By involving patients' experiences in the research we got a better understanding of how visualization can be used by patients during minimally invasive procedures and this could help in identifying possible adjustments in providing the intervention.

Further research is needed in the form of large, well-designed controlled trials, randomized or quasi-experimental studies to assess and validate whether hypnosis is effective for handling pain during invasive procedures. However, studies should not differ fundamentally from the daily clinical practice with regards to resources and conditions when conducted. Thus there is a need to focus more on studies in which effectiveness is the goal rather than efficacy.

Finally to fully evaluate the effectiveness of visualization or hypnosis during minimally invasive procedures, further research is needed to determine the effect of potential moderators such as dose of hypnosis (the length of the intervention and when to be provided) during a procedure, hypnotizability and participants' expectations of hypnosis, as well as visualization's effect in relation to gender ethnicity and culture.

CHAPTER 10. IMPLICATIONS FOR PRACTICE

The results of this dissertation recommend visualization and structured attentive behavior as a suitable adjunct to usual analgesics in managing pain used during RF ablation of AF as well as during other minimally invasive procedures when the Traditional methods to handle pain fail to provide sufficient pain relief for patients. On the basis of this dissertation it is not possible to recommend the length of the visualization session.

Visualization could be an alternative to general anesthesia which has potential risk for patients and which is commonly used in many countries when patients undergo ablation of AF. By using visualization for handling pain, the patients are involved in their own pain management because they are stimulated to use their own resources to manage pain and anxiety, thus using their very own individual strategies to cope in a way that is best for them. It is well known that patients' participation in pain care has a positive impact on patient reported outcomes as satisfaction.

Visualization is safe to use with no inconvenience reported by the patients and because visualization is effective in reducing consumption of strong pain medication used during the procedure it also affects the post-observation period after the procedure with increased safety and thus saves resources. The main problem for patients who had to undergo ablation of AF was that the patients had pain during the procedure because the pain treatment was inadequate. Due to the risk of overdosing there was a limit to how much pain medication could be given. Visualization not only helped the patients manage the pain but also reduced use of strong pain medication.

Visualization is easy to implement in daily clinical practice in a cardiac cath. lab, with no extra costs except for training of the staff. It is easy for the staff to learn, feasible and appropriate as a pain management strategy to use when patients undergo ablation of AF.

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APPENDICES

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Appendix A. Manual for visualization

A.1. Relaxation and visualization (114)

A.1.2. Progressive muscle relaxation, guided imaginary
1. Induction. Progressive muscle relaxation, guided imaginary to an autobiographic pleasant place according to individual preference (beach, garden, wood). Integration of perceptions of colors, sounds, smells, and kinesthetic feelings. Feelings of success, calm, peace of mind, and inner strengths were anchored.

2. Suggestions to incorporate the noise from the medical procedure environment.
Example: "As you breathe in and as you breathe out – deep, nice and easy – you may be aware of the noise surrounding you. Just let all the sounds fade away in to the background. Actually sounds can pass without listening to them in a conscious way. It happens every day. Whenever you decide to stop listening to the noise....you may just let the noise fade away and provide you with silence …. then the noise might bring you an even deeper state of silence. All the time you will clearly hear my voice and everything else you want to listen to. It may very well be possible that the noise of the medical procedure environment just remind you about that you are safe, that it is time to relax and float in to a day dream. You might experience that the noise from the moving medical procedure environment just enables you to feel even more comfortable and relaxed… and be able to enjoy all the wonderful things happening at your pleasant place."

4. Suggestions of analgesia using autobiographic experiences of Analgesia.
Example: ''Just feel how you can remain relaxed and enjoy everything you can do in your pleasant place. Begin to experience how it is possible for you slowly to change the feeling – how you can gradually change the sensation of that specific area in the chest. ..almost like a tickling experience … or a nice warm feeling spreading in the chest or maybe even a feeling of analgesia. Remember how you once had a successful experience of total anesthesia at the dentist …or at the doctor ..or at the hospital or whatever you might remember, just remember that nice good relief from pain. Maybe you remember how you were totally numb . . .like all sensations in the area is blocked .. unable to pass any sensation on. The feeling of a nice, very powerful analgesia spreading wherever you need it. Allow yourself to just let it happen in the way most suitable for you. You can still breathe easily and nice and let this feeling of analgesia grow in your chest with every breath you take…you may begin to let this feeling grow stronger and stronger in your chest.. with every breath you take… while you may become even more wonderfully relaxed with your mind totally occupied by the all things happening in our wonderful place feeling very safe."
Example during application: "What you are about to experience now, will soon be over. It will only last a minute and you will experience the time to be much shorter..

just let it pass through.. you only have seconds left ..just let it pass through.. just think of the nice long break you will have afterwards . Just think about your pleasant comfortable safe place and just let everything else slide away ..far away... just feel how you can let your body be treated … but you can be in another place… you can become so focused and so occupied with all your senses of the wonderful things that can happen in your pleasant and wonderful safe place.. in fact you may be so occupied thinking of all these nice things in your special place that you might forget all about the things happening around the body."

Appendix B. Manual for structured attentive behaviors (114)

1. Matching the patients verbal preferences	e.g. Listen carefully to the patients word choices and include the terms that reflect their preference in your own speaking
2. Adapting to the patients nonverbal communication patterns	e.g. If the patients speech pattern is breezy and quick, avoid giving long pedanting explanation
3. Listening attentively	Implies that the patient choose the topic. Repeating back what the patient has said – assures that the nurse understands correctly, and gives the patient the opportunity to make corrections
4. Providing the perception of control	e.g. "let us know at any time what we can do for you
5. Swiftly responding to the patients requests	e.g. if the patient complains of chill while on the procedure table, quickly provide a blanket
6. Avoiding negatively valued language	e.g. "you will feel a burn or a sting"
7. Using emotionally neutral descriptors	e.g. "this is the local anesthetic"
8. Encouraging the patient	e.g "You are not giving up makes it possible for us to complete the procedure much faster"

APPENDIX C. SYMPTOM CHECKLIST 92 (64)

SYMPTOMS CHECKLIST 92

Instruktion

Nedenfor er anført en række problemer og gener, som man undertiden kan have. Læs venligt hver enkelt grundigt. Når du har gjort det, bedes du sætte et kryds i den cirkel, der bedst beskriver, **i hvor høj grad det pågældende problem har voldt dig ubehag i løbet af den sidste uge inklusiv i dag.** Afkryds kun én cirkel for hvert problem. Hvis du skifter mening, bedes du slette din første markering tydeligt.
Det er af stor betydning, at du besvarer alle spørgsmålene.

I hvilken grad har du været plaget af:	**Slet ikke**	**Lidt**	**Noget**	**En hel del**	**Særdeles meget**
1. Nervøsitet eller indre uro	○	○	○	○	○
2. At du føler dig bange på åbne pladser eller på gaden	○	○	○	○	○
3. Rysten	○	○	○	○	○
4. At du pludselig bliver bange uden grund	○	○	○	○	○
5. At føle dig bange for at forlade dit hjem alene	○	○	○	○	○
6. At føle dig ængstelig	○	○	○	○	○
7. Hjertebanken	○	○	○	○	○
8. Frygt for at køre med bus eller tog	○	○	○	○	○
9. At være nødt til at undgå visse ting, steder eller aktiviteter, fordi de skræmmer dig	○	○	○	○	○
10. At du føler dig anspændt eller opkørt	○	○	○	○	○

11. At føle ubehag blandt mange mennesker, f. eks i butikker eller i biografen	○	○	○	○	○
12. Anfald af rædsel eller panik	○	○	○	○	○
13. At føle dig nervøs, når du er overladt til dig selv	○	○	○	○	○
14. At du føler dig rastløs, at du ikke kan sidde stille	○	○	○	○	○
15. En følelse af, at der vil ske dig noget slemt	○	○	○	○	○
16. At du er bange for at besvime i andres påsyn	○	○	○	○	○
17. Skræmmende tanker og forestillinger	○	○	○	○	○

APPENDIX D. INTERVIEW GUIDE

The interview guide (127)

Could you describe your experience from yesterday where you went through ablation?

Did you experience pain during the procedure?

How did you experience pain?

What do you think visualization did to you according to your experience of pain during the procedure?

Can you tell how you used visualization when you experienced pain?

Was your experience with pain different this time? How?

Did you feel anxiety or fear before and during the procedure?

How did visualization work for you according to your anxiety?

What did it means to you that the nurse guided you in visualization?

Was it yourself who decided to participate in this study?

Why did you participate?

What did it mean to you to participate in this intervention?

What was your opinion to visualization before you participated?

If you need a re do ablation would you prefer visualization? Why?

Was it possible for you to find a secure and pleasant place to focus on?

Tell how you used your secure and pleasant place?

How did you think about the time in the procedure room?

Is there anything else you want to tell about your experience when using visualization during ablation?

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