



# Premedication and preoperative information reduces pain intensity and increases satisfaction in patients undergoing ablation for atrial fibrillation. A randomised controlled study



Mawahib Al-Azawy, RN, MSc<sup>a,b,\*</sup>, Kjersti Oterhals, RN, MSc<sup>a,b,e,1</sup>, Bengt Fridlund, RNT, PhD<sup>b,c,2</sup>, Jörg Aßmus, PhD<sup>d,3</sup>, Peter Schuster, MD, PhD<sup>a,e,4</sup>

<sup>a</sup> Department of Heart Disease, Haukeland University Hospital, Bergen, Norway

<sup>b</sup> Institute of Nursing, Bergen University College, Bergen, Norway

<sup>c</sup> School of Health Sciences, Jönköping University, Jönköping, Sweden

<sup>d</sup> Centre for Clinical Research, Haukeland University Hospital, Bergen, Norway

<sup>e</sup> Department of Clinical Science, Institute of Medicine and Dentistry, University of Bergen, Bergen, Norway

## ARTICLE INFO

### Article history:

Received 14 April 2014

Revised 9 January 2015

Accepted 12 January 2015

### Keywords:

Atrial fibrillation  
Catheter ablation  
Anxiety  
Nursing intervention  
Pain management  
Patient satisfaction

## ABSTRACT

**Background:** Pain and discomfort are common during radiofrequency ablation (RFA) for atrial fibrillation.

**Aims:** To compare and evaluate the effect of premedication, standardised preoperative information and preoperative anxiety on pain intensity, drug consumption and patients' satisfaction.

**Methods:** Preoperative anxiety at baseline, pain intensity during RFA, and patient satisfaction after the procedure were measured in 3 random groups. Group A (n = 20) received standard pain management, group B (n = 20) received premedication and group C (n = 20) received premedication and standardised preoperative information.

**Results:** Patients in groups B and C experienced less pain intensity ( $p < 0.001$ ) and needed fewer anxiolytics ( $p = 0.023$ ) and analgesics ( $p = 0.031$ ) compared to group A. Patient satisfaction was higher in group C ( $p = 0.005$ ) compared to group A. Increased preoperative anxiety is related to elevated drug demand ( $p < 0.05$ ).

**Conclusion:** Premedication alone or combined with preoperative information reduces and higher preoperative anxiety increases pain intensity and drug consumption during RFA. Preoperative information improves patient satisfaction.

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## 1. Introduction

Catheter-based radiofrequency ablation (RFA) is an established treatment option for patients with atrial fibrillation (AF) (January et al., 2014). A large percentage of patients treated for AF with RFA are cured and have an enhanced quality of life compared to those treated with antiarrhythmic drugs (Pappone et al., 2011). The RFA procedure can be several hours long and typically causes varying degrees of pain and discomfort for patients (Alaeddini et al., 2007). Nevertheless, the degree of pain relief for patients with AF undergoing RFA depends on the practices of each hospital's electrophysiology centre. Both general

anaesthesia and conscious sedation are used (Carnlof, Insulander, & Jensen-Urstad, 2014; Norgaard et al., 2013; Wutzler et al., 2012). The European Association for Palliative Care suggested Oxycodone as one alternative to morphine in 2001, but at the time, in many countries, Oxycodone was still considered as a step II opioid, or as a constituent of compound preparations with a non-opioid analgesic. Since that time, use of Oxycodone has increased significantly in many countries and it has become one of the most prescribed opioids in the United States (King, Reid, Forbes, & Hanks, 2011). Oxycodone is a semisynthetic opioid analgesic drug classed as a strong opioid. It has been used alone and in combination for over 80 years in the treatment of a variety of pain syndromes (Coluzzi & Mattia, 2005). Paracetamol (acetaminophen) is an analgesic useful for treating acute mild to moderate pain and can be combined with other analgesic drugs, thereby justifying its use in clinical practice (Gatti, Sabato, Di Paolo, Mammucari, & Sabato, 2010). Combinations of oxycodone and Paracetamol have a double central analgesic mechanism of action and induce rapid pain relief (Gatti et al., 2010). No gold standard exists for conscious pain management during RFA in patients with AF, but some studies have assessed deep sedation with propofol in patients undergoing RFA for AF (Wutzler et al., 2012).

\* Corresponding author. Tel.: +47 96876975.

E-mail addresses: [mawahib.tahir.al-azawy@helsebergen.no](mailto:mawahib.tahir.al-azawy@helsebergen.no) (M. Al-Azawy), [kjersti.oterhals@helse-bergen.no](mailto:kjersti.oterhals@helse-bergen.no) (K. Oterhals), [Bengt.Fridlund@hhj.hj.se](mailto:Bengt.Fridlund@hhj.hj.se) (B. Fridlund), [jorg.assmus@helse-bergen.no](mailto:jorg.assmus@helse-bergen.no) (J. Aßmus), [peter.moritz.schuster@helse-bergen.no](mailto:peter.moritz.schuster@helse-bergen.no) (P. Schuster).

<sup>1</sup> Tel.: +47 55975451, +47 95890403.

<sup>2</sup> Tel.: +46 361 01233, +46 767 611233.

<sup>3</sup> Tel.: +47 55975539, +47 9708890.

<sup>4</sup> Tel.: +47 55 976714; fax: +47 55 975150.

Delivering preoperative information to patients plays an important role in reducing anxiety, the need to use analgesic drugs (Johansson, Nuutila, Virtanen, Katajisto, & Salantera, 2005) and increasing patient satisfaction (Hepner, Bader, Hurwitz, Gustafson, & Tsen, 2004; Roth et al., 2005). Nurses are well suited to provide this information for patients undergoing RFA (Scott, 2004). The aim of this study was to compare and evaluate the effect of premedication and delivery of standardised preoperative information to patients on pain intensity, total consumption of analgesic and anxiolytic drugs during RFA, and patients' satisfaction with pain management during RFA. We also assessed the influence of preoperative anxiety on study outcomes.

## 2. Methods

### 2.1. Study design and setting

We used a randomised controlled trial (RCT) design. The study was conducted between February 2012 and June 2012 in the electrophysiology laboratory at a university hospital in western Norway. It was not possible to estimate the subject sample size using power analysis because of a lack of comparable data in the literature. Therefore, we arbitrarily chose to include 60 patients, randomly assigned to three groups: control group A, intervention group B, or intervention group C. The computer-generated randomisation scheme used random permuted blocks of 20 patients per group. Patients were randomly assigned during hospitalisation and before RFA. The electrophysiologist was blind to the patients' group assignment, but patients and nurses in the RFA laboratory were not blinded (single-blind design).

### 2.2. Intervention strategies

Patients in the control group (A) were given the local standard pain management, which comprised an analgesic (morphine) and an anxiolytic (diazepam) given intravenously (i.v.) as needed during RFA. An antiemetic (metoclopramide 10 mg, i.v.) was administered shortly before the first dose of morphine, according to the local standard procedure. Participants in intervention groups B and C were given premedication (a combination of oxycodone and Paracetamol) tablets 1 h before arrival at the RFA laboratory in addition to the usual pain management received by control group A. Patients weighing 50 to 80 kg were given 10 mg of oxycodone and 1500 mg of Paracetamol orally, whereas patients weighing >80 kg were given 20 mg of oxycodone and 2500 mg of Paracetamol orally. All participants in groups B and C also received 10 mg of metoclopramide orally as a premedication. The dosages and administration were recommended by an anesthesiologist and a specialist from the pain clinic. Morphine and/or diazepam were given intravenously as needed during the RFA procedure. Participants in intervention group C received standard preoperative information in addition to premedication. The nurse from the RFA laboratory spoke to each participant for 10–15 min the day before the procedure, informing about the procedure and expected pain during the RFA. The information focused on localisation and the characteristics of pain, when pain occurs, pain duration, and possible causes of pain. The patients were encouraged to verbally inform the nurse as soon as they felt pain and to accept pain treatment rather than endure pain as long as possible.

### 2.3. Patients and criteria

Patients (N = 60) with paroxysmal or persistent AF were enrolled in the study. The definition of paroxysmal and persistent AF followed the guidelines of American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) (ACC/AHA/ESC) (January et al., 2014). The patients had to be ≥ 18 years old, diagnosed with paroxysmal or persistent AF, admitted to the cardiology department for RFA treatment and able to read and write Norwegian.

Patients with AF previously treated with RFA and patients who used opioids as pain management for other diseases were excluded.

### 2.4. Standard RFA strategy

A standard ablation strategy was performed via venous access and a single transseptal puncture. In patients with paroxysmal AF, circumferential pulmonary vein isolation (PVI) was performed (January et al., 2014). In patients with persistent AF, ablation of complex fractionated atrial electrograms (CFAEs) (Li et al., 2011) was performed in addition to PVI using a 3D-mapping system. Inferior vena cava–tricuspid valve isthmus block (CTI block) was performed in patients who had atrial flutter in addition to AF. Patients remained in bed for a minimum of 6 h after the procedure.

### 2.5. Measurements

Pain intensity during the RFA was assessed with the Numeric Pain Rating Scale (NPRS). The NPRS is validated to assess pain using a 0-to-10-point scale, in which zero represents no pain and 10 represents the worst possible pain (Hjermstad et al., 2011). A numeric scale of 1–10 was used to measure patients' satisfaction with pain management and preoperative information. One represents very dissatisfied and 10 represents very satisfied.

We used the anxiety component of the Hospital Anxiety and Depression Scale (HADS-A) to measure patient anxiety preoperatively. A score of 0–7 is considered normal and a score of ≥ 8 abnormal. HADS is a 14-item, self-administered questionnaire composed of seven items constituting the anxiety scale (HADS-A) and seven items constituting the depression scale (HADS-D). Symptoms are graded on a 0-to-3 scale (0, no symptoms; 3, severe symptoms) (Bunevicius, Peceliuniene, Mickuviene, Valius, & Bunevicius, 2007). HADS has been validated and used in a Norwegian population (Bjelland, Dahl, Haug, & Neckelmann, 2002). Patients' age, diagnosis, gender, weight, height, body mass index (BMI), and level of education were recorded. Electrocardiogram (ECG), oxygen saturation (SaO<sub>2</sub>), and non-invasive blood pressure were monitored continuously throughout the entire procedure. RFA time (seconds) and strategy were noted at the end of the procedure.

### 2.6. Data collection

Patients who agreed to participate filled out the HADS-A form before randomising and the RFA procedure. The cardiac ward nurses collected the data before and after the RFA. The RFA nurse collected data (see Table 1) every 15 min throughout the entire RFA procedure. The patients were asked to score the pain intensity at NPRS and all the pain in-

**Table 1**

Data collection for patients before, during, and after radiofrequency ablation (RFA).

#### Baseline data

- Preoperative anxiety (HADS-A)
- Age, gender, weight, height, education level (elementary school, high school, college/university)

#### During the RFA

- ECG, SaO<sub>2</sub>, BP
- Pain intensity (NPRS)
- The degree of wakefulness (awake, tired, light sleeper, difficult to awaken, natural sleep)
- Total analgesic dose (morphine)
- Total anxiolytic dose (diazepam)
- Total RFA time (seconds)
- Total procedure time (minutes)

#### After the RFA at the cardiac ward

- Pulse, heart rhythm, BP, SaO<sub>2</sub>, nausea, vomiting, degree of wakefulness
- Patient's satisfaction with pain management during RFA and patient's satisfaction with the preoperative information

Abbreviations: HADS-A, Hospital Anxiety and Depression Scale-Anxiety; ECG, electrocardiogram; SaO<sub>2</sub>, oxygen saturation; BP, non-invasive blood pressure; NPRS, Numeric Pain Rating Scale.

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