Schmerzwahrnehmung während elektrophysiologischer Untersuchungen/Ablationen und Herzschrittmacher-/ICD-Operationen

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1 Einführung in die Thematik

1.1 Hintergrund zur Thematik

Allgemeines Kriterium jeglicher Art von Schmerzen ist, unabhängig ihrer Ursache, der subjektive Charakter der Wahrnehmung und Bewertung. Nicht therapierte Schmerzen führen neben dem psychischem Stress zur verlängerten Immobilisierung und auch negativen immunmodulierenden Effekten.[1-3] Unbehandelte Schmerzen können das Risiko eines verlängerten Krankenhausaufenthaltes erhöhen.[4,5] Untersuchungen zeigen gleichzeitig, dass eine ungenügende post–operative Schmerztherapie die Entstehung chronischer Schmerzen fördern kann.[6-8] Ein adäquates Schmerzmanagement bedeutet also nicht nur eine ethische Verantwortung dem Patienten gegenüber, sondern dient der schnelleren Genesung und erhöht vor allem die Patientenzufriedenheit.[9-11] In Zeiten regelmäßiger Klinikevaluationen von Seiten der Patienten entscheiden auch solche Merkmale über die zukünftige Wahl des Behandlungsortes für Patienten.[12,13]

1.2 Inhaltlicher Gegenstand

Elektrophysiologische Untersuchungen, Ablationsprozeduren sowie Herzschrittmacher-/ ICD-Implantationen werden aufgrund erweiterter Indikationen, neuer Techniken und der älter werdenden Bevölkerung zunehmend häufiger durchgeführt.[14]

Rhythmologische Interventionen bedingen für die Patienten sowohl während als auch im Anschluss an die Prozeduren für mehrere Stunden eine strikte Rückenlage, da fast immer ein femoraler Zugangsweg bevorzugt wird. Katheterinsertionsstellen und OP-Wunden werden zuvor mittels Lokalanästhetikum infiltriert. Anschließend können aber durch eine abnehmende Wirkung der lokalen und systemischen Schmerztherapie und durch die teilweise eingeschränkte Bewegungsfreiheit weitere postoperative Schmerzen oder eine Verstärkung vorbestehender chronischer Schmerzen den Patienten unangenehm beeinträchtigen. Akute Schmerzen nach Implantation kardialer Stimulationssysteme erhöhen das Risiko für chronische Schulterdysfunktionen und Schmerzen.[8,15,16]

Das Schmerzmanagement bei rhythmologischen Untersuchungen/ Interventionen/ Operationen ist bisher je nach Klinik unterschiedlich. Dies ist möglicherweise der Heterogenität der Eingriffe, des Patientenalters (sehr jung bis sehr betagt) und der „Zwischenstellung" von Eingriffen im EPU-Labor zwischen konventioneller Operation und „Eingriff mit Punktion" geschuldet. Während längere Eingriffe wie komplexe Ablationen meist in Analgosedierung durchgeführt werden (z.B. Pulmonalvenenisolation), lassen sich kürzere EPUs/Ablationen häufig mit einer peri-interventionellen intravenösen (i.v.) Bedarfsmedikation zur Sedierung oder Analgesie durchführen. Die meisten Untersucher verzichten jedoch hierbei auf eine routinemäßige prä-interventionelle Midazolamgabe, weil dadurch Rhythmusstörungen schwieriger induziert werden können oder das Risiko eines Pneumothorax bei Punktion der Vena subclavia durch eine midazolaminduzierte tiefe Zwerchfellbewegung beim Schlafen als erhöht gilt.
Das Schmerzmanagement bei rhythmologischen Untersuchungen/ Interventionen/ Operationen unserer Abteilung wurde in einer vorherigen abteilungsinternen Untersuchung (Bode et al. 2015) re-evaluiert.[4] Dabei zeigte sich unter anderem, das ein regelmäßiges aktives Erfragen des post-interventionellen Schmerzes durch das Behandlerteam von besonderer Bedeutung zu sein scheint und dieses auch zu einer quantitativen Erhöhung von Schmerzmedikamenten (i.v. und oral) führte.
Unklar war allerdings bisher, ob die post-interventionell erfragten Werte mit den peri-interventionellen Werten, die bislang nicht erhoben wurden, assoziiert sind.

Ergebnisse aus Studien mit post-interventioneller Schmerzerfassung im Bereich operativer Fachgebiete sowie der interventionellen Rhythmustherapie verdeutlichen die Notwendigkeit eines gezielten Schmerzmanagements, weil damit negative Entwicklungen wie z.B. das Risiko für chronische Schulterdysfunktionen gesenkt werden kann.[4,11,13] Es zeigte sich allerdings auch, dass insbesondere die Vorhersagbarkeit für das Auftreten von mittleren bis starken Schmerzen post-interventionell schwierig ist.[4] Eine pauschale prophylaktische Analgesie wird auch aus grundsätzlichen Erwägungen nicht empfohlen, da nicht-steroidale Antirheumatika (NSAID) sowie Metamizol, die häufig zum Einsatz kommen,

mit einer erhöhten Rate an kardiovaskulären Ereignissen, Niereninsuffizienz und gastrointestinalen Komplikationen assoziiert sind und Metamizol ein (wenn auch seltenes) Risiko einer Agranulozytose birgt.[17-20] Bei allen Bemühungen einer optimalen Schmerztherapie erscheint es notwendig, die peri-interventionell auftretenden Schmerzen zu analysieren.
Aktuell bleibt offen, in welchem Ausmaß peri-interventionell Schmerzen auftreten und bewertet werden. Aus dieser Position heraus ergibt sich die Notwendigkeit einer Analyse peri-interventioneller Schmerzen in der interventionellen Rhythmustherapie. Verbunden damit bestehen Fragen/Forderungen an die Umsetzbarkeit einer grundsätzlichen peri-interventionellen Schmerzerfassung.

Ein geeignetes Verfahren zur Erfassung peri-interventioneller Schmerzen sollte aus Sicht der Autoren inhaltlich suffizient und organisatorisch leistbar sein, damit die Informationen des Patienten sinnvoll genutzt und in eine optimierte Schmerztherapie implementiert werden können.

Da aktuell zu den o.g. Therapien keine hinreichenden Kenntnisse sowohl über die in Frage kommenden Erfassungsmodalitäten als auch über die peri-interventionellen Schmerzen vorliegen, soll mit vorliegender Studie folgenden Grundgedanken nachgegangen werden:

1) Es erscheint naheliegend, die Patienten unmittelbar nach einer Intervention über die während der Intervention empfundenen Schmerzen zu befragen. Der Einsatz der Numeric Rating Scale (NRS) soll hierbei als ein einfaches, valides und reliables Messinstrument eingesetzt werden, um subjektiv die aktuellen und empfundenen Schmerzen zu bewerten.[21] Die NRS wird auch von der aktuellen S3-Leitlinie zur Behandlung des postoperativen Schmerzes empfohlen, um entsprechende Schmerzkategorien zu klassifizieren: geringe Schmerzen (NRS 0-3), moderate Schmerzen (NRS 4-5) und starke Schmerzen (NRS>6).[22] → Dies erscheint aus

organisatorischer und inhaltlicher Sicht gut praktikabel, da alle Patienten in der post-interventionellen Überwachung (in einem relativ ruhigen Setting) befragt werden können. Zudem wären keine Verzerrungen bei der Schmerzbewertung aufgrund eines Methodenwechsels zu erwarten.

2) Es bestehen aber Unklarheiten darüber, inwiefern allein die Zeit zwischen Intervention und Überwachung einen möglicherweise nicht unerheblichen Einfluss auf die Bewertung der während der Intervention empfundenen Schmerzen nimmt. → Dies wirft die Frage nach der Validität der post-interventionellen Angabe zur peri-interventionellen Schmerzwahrnehmung auf.

3) Ein weiterer möglicher Störfaktor im Sinne der Validität wäre eine iatrogene Beeinflussung. Allein die Mitteilung durch den behandelnden Arzt während und unmittelbar nach Abschluss der Intervention prägt möglicherweise die retrospektive Bewertung der wahrgenommenen Schmerzen. → Es ergibt sich die Frage, ob die post-interventionelle Angabe zur peri-interventionellen Schmerzwahrnehmung durch die Art der Mitteilungen im Rahmen der durch den behandelnden Arzt vorgenommenen Intervention beeinflusst wird (z.B. „ärztliches" Nachfragen nach möglichen Schmerzen, positive Kommentierung des Verlaufes der Behandlung bzw. positive Ermunterung des Patienten).

4) Der Schmerz ist als Empfindung emotional beeinflusst und kann nicht mit klassischen physiologischen Reizparametern ermittelt werden. Zudem gehen in diese Empfindung Aspekte wie kognitive Faktoren und psychosoziale Aspekte (z.B. Ängstlichkeit oder Depressivität) ein.[23] →Es kann vermutet werden, dass auch die Persönlichkeit (mit ihren intrapersonellen Eigenschaften) bei der Schmerzwahrnehmung und –verarbeitung sowie deren Erinnerung eine Rolle spielen könnte. Mit Hilfe des gut validierten Gesundheitsfragebogens für Patienten (PHQ-D) soll ein psychodiagnostisches Instrument, welches Screening und Fallidentifikation psychischer Belastungen und

Störungen ermittelt, im Rahmen der o.g. Studie zusätzlich zum Einsatz gebracht werden. Hierbei geht es vor allem um die Dimensionen Ängstlichkeit (GAD-7), Depressivität (PHQ-9) und somatische Störungen (PHQ-15), welche u.U. den größten Einfluss auf das Erinnerungsvermögen von Schmerzerfahrung/-wahrnehmung nehmen könnten.[24-28]

1.3 Fragestellung

Aus den unter 1.2 formulierten Hypothesen zur vorliegenden Studie resultiert der Projektansatz mit folgenden Fragestellungen:

1. In welchem Ausmaß treten peri-interventionelle Schmerzen auf?
2. Welche Faktoren (z.B. Alter, Geschlecht, Behandlungszeit oder Midazolam-Verabreichung) beeinflussen Schmerzen bzw. beeinflussen die Erinnerung an die empfundenen Schmerzen?
3. Ist ein post-interventionell eingesetzter Fragebogen geeignet, peri-interventionell empfundene Schmerzen beurteilen zu können?
4. Inwieweit nimmt die Kommunikation zwischen Personal und Patient während des Eingriffs Einflusses auf die Wahrnehmung und Erinnerung der Schmerzen?
5. Existieren intrapersonelle Eigenschaften (z.B. Angst, Depressionen und/oder somatische Störungen), die das Erinnerungsvermögen an wahrgenommene Schmerzen beeinflussen?

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Pain During "Noncomplex" Electrophysiological Studies and Cardiac Rhythm Device Surgery

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Background: There are only limited data about peri-interventional pain during cardiac electrophysiological procedures without analgosedation. In this study, peri-interventional pain and recollection of it after the intervention were evaluated. **Methods:** A total of 101 patients (43 electrophysiological/ablation procedures and 58 device surgeries) reported pain on a numerical rating scale (NRS; 0–10) before (pre), during (peri), and after (post) the intervention. Maximum pain (maxNRS) and the average of pain (meanNRS) were used for statistical analysis. Peri-interventional pain was compared with postinterventional data of the recollection of peri-interventional pain (peri-post). Patients were allocated into 2 groups (with 51 and 50 patients, respectively) to evaluate the mode of patient-staff interaction on pain recollection. Depressive, anxiety, and somatic symptom scales (Patient Health Questionnaire-15, Generalized Anxiety Disorder-7, and Patient Health Questionnaire-15) were used to analyze their influence on pain recollection. **Results:** In total, 49.6% of patients (n = 50) complained of moderate to severe pain (maxNRS) at least once during the procedure. The comparison between peri and peri-post data revealed the following (median (range)—maxNRS, peri: 3 (0–10) versus peri-post: 4 (0–9) (ns), and meanNRS, peri: 1.4 (0–7) versus peri-post: 2.0 (0–6) (ns). The mode of patient-staff interaction had no influence on pain. No effect was found for psychosocial factor concerning pain and the recollection of pain. The results of the linear regression showed no influence of low-dose midazolam on recollection of pain. **Conclusion:** Half of the patients reported moderate to severe pain at least once during cardiac electrophysiological procedures without analgosedation. However, on average, patients reported only low pain levels. Postinterventional derived data on discomfort reflect the peri-interventional situation.

KEY WORDS: pain, peri-interventional pain, catheter ablation, cardiac electrophysiology, cardiac implantable electronic device surgery, cardiac electrophysiological techniques, supraventricular tachycardia

Background

Electrophysiological procedures are performed more frequently because of an aging patient population, new techniques, and extended indications.[1] These procedures include ablation, as well as surgical interventions for implantation, explantation, replacement, or revision of cardiac implantable electronic devices (CIEDs) such as pacemakers and implantable cardiac defibrillators. According to the White Book of the European Heart

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All patients or patients' parents gave informed written consent for the procedures.

The study was approved by the local ethics committee of the University of Leipzig.

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Rhythm Association, there are a mean of 625/255 CIED procedures/catheter ablations, respectively, done per 1 million inhabitants in Europe in 2016. Data for Germany show much higher procedure numbers, with 1698/999 per million inhabitants, respectively.[1]

All of these procedures require patients to remain in a supine position for up to several hours.

Tissue damage during surgery activates nociceptors via mechanical or thermal stimuli and can cause pain, defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.[2,3] Activation of nociceptors results in release of catecholamines and, thereby, activation of the sympatho-adrenergic system.[4–6] The increased sympathetic tone increases cardiac output with a higher heart rate, increased vasoconstriction, and blood pressure. Patients who experience pain are thus more susceptible to the development of dysrythmia, myocardial ischemia, and sudden heart failure.[7] Catecholamines such as noradrenaline have negative immunomodulatory effects on the inflammatory process, which may result in increased susceptibility to infection and delayed wound healing.[5,8] In addition, pain is emotionally influenced.[9] Cognitive factors and psychosocial aspects (such as anxiety or depression) also play a relevant role.[10] Furthermore, untreated pain causes emotional distress and can increase the risk of immobilization and hence prolong hospital stay.[11–13] Finally, adequate pain management should not only be an ethical concern but also a fundamental requirement for faster recovery, better quality of life, and improved patient satisfaction. Patient satisfaction is important because it influences future decisions related to the likelihood of seeking healthcare for a specific procedure at a particular institution.[14,15] Our own study showed that postoperative pain seems to be underestimated.[11,16] The issue was addressed by the establishment of a structured pain assessment and management program that aimed to improve postoperative pain.[4,16] Our current study focused on peri-interventional pain assessment because, so far, there are only scarce peri-interventional collected data available.[17] Other studies with mostly very small cohorts asked about pain postinterventionally, reporting moderate to severe peri-interventional pain levels.[18–21] It is unclear to what extent postinterventional recollected pain reflects the peri-interventional experienced pain.

The investigation had several objectives:

1. To evaluate peri-interventional pain and determine what factors (eg, age, gender, procedure time, or midazolam administration) might influence it.
2. To determine if a postinterventional questionnaire can assess peri-interventional pain.
3. To evaluate the influence of staff-patient communication during the procedure on pain.
4. To assess if peri-interventional pain is influenced by anxiety, depression, and somatic disorders.

Materials and Methods

The pilot study was performed at the Department of Electrophysiology at the Heart Center in Leipzig, Germany, in accordance with the Declaration of Helsinki and was approved by the local ethics committee of the University of Leipzig. This is a high-volume center with about 3000 overall electrophysiological interventions per year. After informed consent was obtained, 101 consecutive patients in the inpatient electrophysiological unit were enrolled within a 4-week period in March 2016. To evaluate not only the pain of the whole cohort but also a possible influence of different communication approaches, patients were allocated on a weekly alternating basis into 2 groups. Patients were blinded to their treatment arm. All teams (physicians and nurses) were instructed on what was and was not allowed to be said to the patients. In group 1 ("informed"; G1), patients were fully informed throughout the treatment. In particular, supportive comments, such as "everything is going very well," were allowed. In addition, the patients were fully informed of the intervention's outcome before the interview about pain recollection. In contrast, in group 2 ("noninformed"; G2), only basic information was given, for example, "we start now," "we will finish in about 5 minutes," and "I will explain the outcome of the treatment afterward in the recovery room." Potentially supportive comments were never made. Finally, the pain recollection survey was conducted before the treatment results were reported. The staff was monitored by the first author to ensure that they behaved according to protocol. He remained in the laboratory throughout the procedure and collected patient data. He instructed the staff before every procedure and would have given advice in case staff did not behave according to protocol. Study design is shown in Figure 1.

Procedures

We included only consecutive procedures without the need for deep sedation. Therefore, included were diagnostic EP studies, ablation of AV-reentry tachycardia (AVRT), AV-nodal reentry tachycardia (AVNRT), right atrial flutter (AFL), and CIED therapy. Especially during procedures to diagnose and treat supraventricular tachycardia, like AVNRT, AVRT, and AFL, there is a need to balance dysrythmia inducibility, risk of sedation-related adverse events, and patients' comfort. Noninducibility and sedation-related complications can mitigate the success of the whole procedure.[22–24] Nonetheless, patients always received local anesthesia and additional intravenous analgesia (fentanyl) on demand in a titrating manner. Intravenous midazolam as a sedative was also titrated in balance with the requirements of the procedure and patients' needs. Medications were given per discretion of the physician. Patients scheduled for procedures requiring deep sedation were excluded from this study.

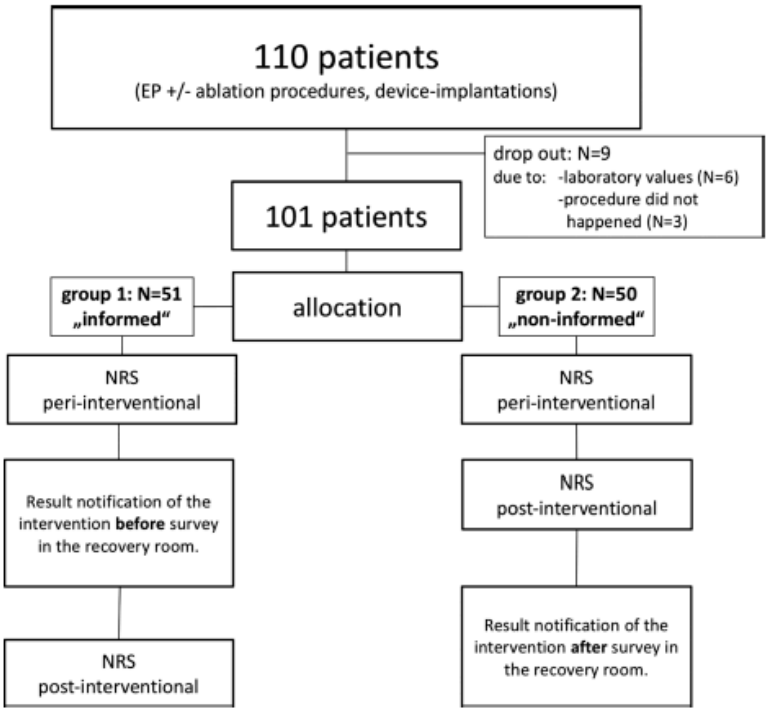

FIGURE 1. *Study design. NRS indicates numeric rating scale; EP, electrophysiological.*

Diagnostic electrophysiological and ablation procedures were performed under local anesthesia (20 mL mepivacaine; 1%). Depending on the procedure, 3 to 4 electrophysiological catheters were used via venous sheaths (5F, 6F, 8F) that were inserted into femoral veins. The corresponding procedure duration was defined as the time from femoral puncture to the removal of the sheaths. Cardiac implantable electronic device implantation, replacement, and revision procedures were performed under local anesthesia (40 mL mepivacaine; 1%). An infraclavicular incision was made, and preparation of the cephalic vein or subclavian puncture was used as access for the leads. Wound closure was performed with subcutaneous and intracutaneous absorbable sutures. All devices were implanted subcutaneously. The duration of CIED implant or explant procedure was defined as the time between first incision and last suture.

Data Collection

The numeric rating scale (NRS; 0–10) was used to evaluate the pain experienced during the intervention. The NRS is considered the most sensitive and responsive scale available. In addition, it is easy to apply for both patients and clinicians and provides data for parametric analyses.[25] Questions were asked following a standardized protocol. Numeric rating scale scores were determined using the following questions: "Do you have pain at the moment? How severe is the pain on a scale of 0 to 10? Where is the pain located?" Patients were instructed in the use of the NRS during study inclusion. Data were collected (1) 30 minutes before the procedure (pre), (2) as self-reported pain at each 5-minute interval during the procedure (peri), (3) in the recovery room within 10 minutes after the procedure (post), and (4) as a recollection of peri-interventional maximum and average pain (peri-post). The maximum pain was expressed as "maxNRS." "MeanNRS" was used to denote the average of all pain during the procedure and the value of the recollection.

Cognitive and Psychosocial Factors

Emotions, cognitive factors, and other psychosocial aspects influence pain and its perception.[9,10] To evaluate the influence of psychosocial factors, we used patient health questionnaires (Patient Health Questionnaire-9 [PHQ-9], Generalized Anxiety Disorder-7 [GAD-7], and Patient Health Questionnaire-9 [PHQ-15]; German versions). The PHQ-9, GAD-7, and PHQ-15 are brief, well-validated measures used for detecting and monitoring depression, anxiety, and somatization, respectively.[26] A score of 10 or higher (moderate to severe) suggests the presence of depression (PHQ-9), anxiety (GAD-7), and somatoform disorders and somatic symptoms (PHQ-15).[26] Subgroups, divided on the basis of scores of lower than 10 and 10

or higher in at least 1 scoring system, were analyzed separately. Data for the patient health questionnaires were collected on the day before the procedure.

Patient Health Questionnaires

Patient Health Questionnaire-9 Depression Severity

The PHQ-9 score is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all," "several days," "more than half the days," and "nearly every day," respectively. The PHQ-9 total score for the 9 items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cutpoints for mild, moderate, moderately severe, and severe depression, respectively.[27] Patients are asked whether they have been bothered by any of the following during the previous 2 weeks: (1) little interest or pleasure in doing things; (2) feeling down, depressed, or hopeless; (3) having trouble falling asleep or staying asleep, or sleeping too much; (4) feeling tired or having little energy; (5) having a poor appetite or overeating; (6) feeling bad about yourself, or that you are a failure, or that you have let yourself or your family down; (7) having trouble concentrating on things, for example, a newspaper or the television; (8) moving or speaking so slowly so that other people have noticed or alternatively being fidgety and restless; and (9) having thoughts that you would be better off dead or considering hurting yourself in some way.

Generalized Anxiety Disorder-7 Anxiety Severity

Scores on the GAD-7 are calculated by assigning scores of 0, 1, 2, and 3 to the response categories of "not at all," "several days," "more than half the days," and "nearly every day," respectively. The GAD-7 total score for the 7 items ranges from 0 to 21. Scores of 5, 10, and 15 represent cutpoints for mild, moderate, and severe anxiety, respectively.[28] Patients are asked the following: Over the last 2 weeks, how often have you been bothered by the following problems: (1) feeling nervous, anxious, or on edge; (2) not being able to stop or control worrying; (3) worrying too much about different things; (4) trouble relaxing; (5) being so restless that it is hard to sit still; (6) becoming easily annoyed or irritated; and (7) feeling afraid as if something awful might happen?

Patient Health Questionnaire-15 Somatic Symptom Severity

Scores on the PHQ-15 are calculated by assigning scores of 0, 1, and 2 to the response categories of "not at all," "bothered a little," and "bothered a lot," respectively, for the 13 somatic symptoms. Also, 2 items from the depression module (sleep and tired) are scored 0 ("not at all"), 1 ("several days"), or 2 ("more than half the days" or "nearly every day"). Scores of 5, 10, and 15 on the PHQ-15 represent cutpoints for low, medium, and high somatic symptom severity, respectively.[29] Patients are asked the following: During the past 4 weeks, how much have you been bothered by any of the following problems: (1) stomach pain; (2) back pain; (3) pain in your arms, legs, or joints (knees, hips, etc); (4) menstrual cramps or other problems with your periods (women only); (5) headaches; (6) chest pain; (7) dizziness; (8) fainting spells; (9) feeling your heart pound or race; (10) shortness of breath; (11) pain or problems during sexual intercourse; (12) constipation, loose bowels, or diarrhea; (13) nausea, gas, or indigestion; (14) feeling tired or having low energy; and (15) trouble sleeping?

Statistical Analysis

Categorical variables are reported as median and range. Continuous data are reported as mean ± standard deviation. Comparisons between interventions and temporal occurrence of pain were performed using nonparametric rank-order procedures based on the general linear model analysis of variance (ANOVA). The data were ranked from low to high NRS values and then the distributions of the ranks were analyzed; χ^2 ratios were computed using the sum of squares in the same way as for the Puri and Sen L statistics.[30,31] For this 2-factor ANOVA, main factors were group (G1 and G2), with 1 degree of freedom (df); time, with 4 time points (pre, peri, peri-post, and post; 3 df); and the interaction of group × time (3 df). All data were Bonferroni adjusted for repeated measurements.

A Mann-Whitney test was used to compare ordinal data or a Student t test for numeric data. To compare observed and expected numbers of subjects in different categories, we used Fisher exact test. Conventionally, NRS levels are used to classify 3 pain categories: 0 to 3, low; 4 to 5, moderate; and 6 or higher, severe.[32] Because pain therapy is recommended for NRS values lower than 3, two pain categories were used in our analyses (NRS ≤ 3 and NRS >3) for the univariate analysis.[32,33] Linear regression analysis was used to evaluate the influence of midazolam on pain recollection.

Results

A total of 101 consecutive patients (62 men, age 66.4 ± 16.4 years) undergoing 43 diagnostic electrophysiological/ablation procedures (42.5%) and 58 CIED surgeries (57%) were included. Electrophysiological procedures included ablations for AVNRT and AVRT (n = 6), AFL (n = 13), and diagnostic studies (n = 24). Cardiac implantable electronic device procedures included 37 new implantations of CIEDs, 18 generator replacements due to battery depletion, and 3 lead revisions.

Of 101 patients, 13 (13%) reported preexisting chronic low to moderate pain before their intervention, with an average NRS value of 3 (range, 1–5). This pain was in areas typical of old age, for example, low back pain,

joint pain, and headache. There was no difference for peri-interventional maxNRS between diagnostic electrophysiological studies and ablation procedures: 4 (0–9) versus 3 (0–8) ($P = .67$), and between diagnostic electrophysiological/ablation procedures and CIED surgeries: 4 (0–10) versus 3 (0–9) ($P = .17$).

Patient and procedure characteristics are summarized in Table 1.

Comparison Between Maximum and Mean Pain Peri and Peri-Post

Table 2 presents pain for the entire cohort. Approximately half complained of moderate to severe pain (maxNRS) at least once during the procedure. However, when asked for their average pain level during the procedure, most patients reported (peri vs peri-post) only low levels. The postinterventional assessment of peri-interventional pain was comparable with the peri-interventional data (Figure 2). There were no statistical differences.

A comparison between patients with NRS values higher than 3 and those with NRS values of 3 or lower (indicating pain levels) is shown in Table 3 with regard to different factors and their impact on the maximum pain (maxNRS) during the intervention.

Influence of Patient-Staff Communication

For patient-staff communication, there was no difference in the distribution of the ranks of NRS data between G1 and G2, both peri-interventional and in recollection peri-post (Figure 3). There was a significant effect for the factor "time" ($\chi^2_{3,\,N=404} = 171.7$, $P < .001$). This means that the NRS changed significantly over the 4 time points. Low ranks mean low NRS values. No effect was measured for the main factor group ($\chi^2_{1,\,N=404} = 0.004$, P = ns) and no effect for the interaction of time × group ($\chi^2_{1,\,N=404} = 1.017$, P = ns). There was also no difference for maxNRS between the peri and peri-post time points (mean ranks [95% confidence interval], 262.3 [241.9–282.8] vs 277.6 [257.9–297.3]; P = ns).

TABLE 1 Patient and Procedure Characteristics

Parameter		Total (N = 101)	Group 1: Informed (n = 50)	Group 2: Noninformed (n = 51)	*P* G1 vs G2
Sociodemographic data					
Age, y		66.4 ± 16.4	70.6 ± 10.7	62.1 ± 19.9	.009
BMI, kg/m^2		28 ± 5.7	28 ± 5.3	28 ± 6.2	.959
Male/female, N/N		62/39	30/20	32/19	.776
Chronic diseases					
Arterial hypertension		78 (77)	42 (84)	36 (70)	.227
Diabetes mellitus T2		40 (40)	21 (42)	19 (37)	.687
Gastrointestinal diseases		18 (18)	8 (16)	10 (20)	.796
Chronic pain		7 (7)	5 (10)	2 (4)	.269
Psychosocial screening					
PHQ-9 (≥10: suggestive of the presence of depression)		9 (9)	5 (10)	4 (8)	.741
GAD-7 (≥10: moderate to severe anxiety)		8 (8)	4 (8)	4 (8)	1.000
PHQ-15 (≥10: moderate to severe somatic symptoms)		20 (20)	6 (12)	14 (27)	.079
Intervention					
AVNRT/AVRT/AFL/diagnostic EP study		43 (43)	19 (38)	24 (47)	.423
CIED		58 (57)	31 (62)	27 (53)	
Time of day					
07:00–14:00		48 (48)	23 (46)	25 (49)	.843
14:00–19:00		53 (53)	27 (54)	26 (51)	
Duration of treatment, min		62 ± 35	57 ± 30	66 ± 39	.196
Pain (NRS)					
Preinterventional	NRS	0 (0–5)	0 (0–5)	0 (0–5)	.338
Peri-interventional	MaxNRS	3 (0–10)	4 (0–10)	3 (0–10)	.253
	MeanNRS	1.4 (0–7)	1.8 (0–5.3)	1.1 (0–7)	.312
Recollection of pain	MaxNRS peri-interventional	4 (0–9)	5 (0–9)	4 (0–9)	.625
	MeanNRS peri-interventional	2 (0–6)	2 (0–5)	2 (0–6)	.953
Postinterventional	MaxNRS postinterventional	0 (0–5)	0 (0–5)	0 (0–5)	.905
Pain treatment	Peri-interventional application				
	Fentanyl, µg	53.7 ± 29.6	57.9 ± 28.4	51.1 ± 30.6	.500
	Midazolam, mg/kg	0.04 ± 0.04	0.04 ± 0.04	0.05 ± 0.04	.710

Data are presnted as mean ± SD, n (%), or median (range), unless otherwise indicated.
Abbreviations: BMI, body mass index; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder 7; PHQ-15, Patient Health Questionnaire-15; AVNRT, AV-nodal reentry tachycardia; AVRT, AV-reentry tachycardia; AFL, atrial flutter; EP, electrophysiological; CIED, cardiac implantable electronic device; NRS, numerical rating scale.

TABLE 2 Distribution of Pain During the Intervention (Peri) and Its Recollection (Peri-Post)

	MaxNRS		MeanNRS	
NRS	Peri	Peri-Post	Peri	Peri-Post
0–3 (low)	n = 51; 50.5%	n = 46; 45.5%	n = 85; 84.1%	n = 83; 82.2%
4–5 (moderate)	n = 25; 24.8%	n = 22; 21.8%	n = 13; 12.9%	n = 17; 16.8%
>5 (severe)	n = 25; 24.8%	n = 33; 32.7%	n = 3; 2.9%	n = 1; 1.0%

Maximum pain levels (maxNRS) as well as average pain levels (meanNRS) are shown.
Abbreviation: NRS, numeric rating scale.

Table 4 presents the different localizations of patient's self-reported pain during the procedures. No differences between the groups (G1 and G2) were found.

A few patients denied any pain (NRS = 0) throughout the procedure. Therefore, the sum of patients reporting pain at different locations is below the overall treated cohort size.

Cognitive and Psychosocial Factors

Table 5 summarizes the differences in pain and the recollection of pain between the 2 subgroups (PHQ-9, GD-7, and PHQ-15: score <10 or ≤10). Patients with a score of 10 or higher complained significantly more often about preinterventional pain.

Midazolam

In total of 35 patients (34.7%) received midazolam during the procedures. Of these 35 patients, 24 (68.6%) received midazolam directly with the beginning of the treatment. There was no difference between the patients with or without midazolam concerning pain: maxNRS (peri), 4 (0–10) versus 3 (0–9) (P = .43), and meanNRS (peri), 1.5 (0–7) versus 1.3 (0–6.4) (P = .62). Table 6 summarizes the difference of recollection of pain in relation to time point of application of midazolam.

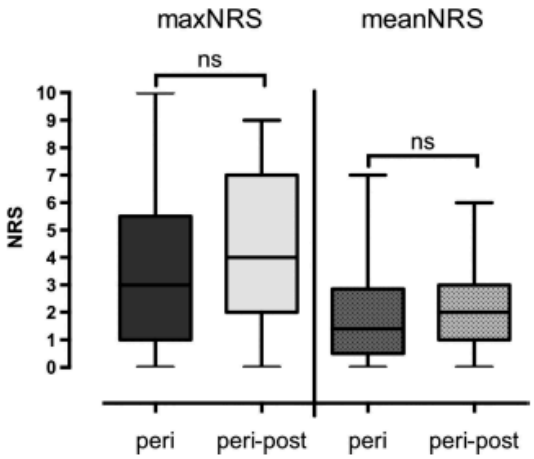

FIGURE 2. *Comparison of peri-interventional (peri) and post-interventional (peri-post) maximum pain (maxNRS) and average pain (meanNRS). NRS indicates numeric rating scale.*

A linear regression model was developed to evaluate the influence of midazolam on the recollection of pain (maxNRS and meanNRS) (Figure 4). The application rate (mg/kg) was tested against the difference between peri and peri-post recorded data (Δ NRS). The results of the linear regression showed no influence of midazolam on recollection of pain.

Discussion

To the best of our knowledge, this is the first study that systematically and prospectively validated pain recollection after noncomplex electrophysiological procedures for supraventricular tachycardia and CIED surgery in conscious patients. The study evaluated peri-interventional pain in a larger cohort than previously reported, as well as the influence of patient-staff communication on recollection of pain.[17–19]

Untreated pain, regardless of its cause, represents substantial emotional distress for patients. Postinterventional pain assessment and management programs have been introduced and evaluated in several fields (electrophysiological interventions, orthopedic, visceral, urological, and other surgical specialties), but peri-interventional pain lacks sufficient data.[34–36]

In our cohort, about half of the patients complained of moderate to severe pain (maxNRS) at least at 1 time point during the intervention. On the other hand, 51% reported low pain levels (NRS, 0–3) on average during the intervention. Only a few studies about ablation of supraventricular tachycardia dealt with perioperative pain: Timmermans et al reported only maximum pain levels after radiofrequency-energy application in 7 patients undergoing ablation of right AFL. Patients experienced pain with values of 38.2 ± 25.3 on a visual analog scale, which is comparable to NRS 3.8 and in line with our repetitive data acquisition and results.[17] Postinterventional reporting of peri-interventional pain in small studies for radiofrequency ablations by Lowe et al and Chan et al described higher pain levels with NRS values of 6.1 ± 3.5 (32 patients) and 5.4 ± 3.4 (9 patients), respectively, in patients without any systemic analgesia and sedation.[18,19] These results are supported by data from Selvaraj and colleagues[21]; however, it is not clear if these are maximum or average pain values. Data from other more or less similar procedures (eg, carotid artery stenting and

TABLE 3 Impact of Different Factors on Maximum Pain During the Procedures

Factor	Kind of Data		MaxNRS Peri-intervention <3 n = 35	MaxNRS Peri-intervention ≥3 n = 66	P
Age, y	Numeric	Mean ± SD	68.1 ± 14.9	65.4 ± 17.4	.436
Procedure time, min	Numeric	Mean ± SD	46.4 ± 30.9	70.2 ± 34.3	.009
Procedure, n	Nominal	EP/CIED	11/24	32/34	.139
Duration AVNRT/AVRT/AFL/diagnostic EP study, min	Numeric	Mean ± SD	62.7 ± 43.1	83.6 ± 32.9	.026
Duration CIED surgery, min	Numeric	Mean ± SD	39.0 ± 20.4	57.5 ± 30.9	.013
PHQ-9	Ordinal	Median (range)	3 (0–17)	3 (0–13)	.732
GAD-7	Ordinal	Median (range)	3 (0–17)	2.5 (0–14)	.509
PHQ-15	Ordinal	Median (range)	6 (0–17)	7 (0–18)	.324
Gender, n	Nominal	Female (male)	14 (21)	25 (41)	.834
Midazolam, n	Nominal	Yes (no)	10 (25)	25 (41)	.387

Abbreviations: NRS, numeric rating scale; AVNRT, AV-nodal reentry tachycardia; AVRT, AV-reentry tachycardia; AFL, atrial flutter; EP, electrophysiological; CIED, cardiac implantable electronic device; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder 7; PHQ-15, Patient Health Questionnaire-15.

peripheral angiography) reported comparable pain levels. Peri-interventional pain evaluations in CIED implants are rare.[24,37–39] Data exist only for defibrillation testing during implantation of implantable cardioverter defibrillators and routine conscious sedation with midazolam, propofol or midazolam, morphine, and promethazine for implantation of implantable cardioverter defibrillators, which was not comparable to our cohort. Data for pacemaker implantation under local anesthesia are lacking.[39,40]

In our study, all patients experiencing any pain (NRS 1–10) indicated the location of pain. Our results concerning frequency and localization are in line with results with a previous study.[14] Patients with CIED interventions were mostly confronted with pain directly at the implantation site, whereas ablation and diagnostic electrophysiological procedures caused pain at the inguinal puncture site and intrathoracic during radiofrequency ablation, also described by Timmermans et al.[17] Overall, pain is subjective and interindividually different, but on average, patients experience low pain levels with short pain peaks during puncture and energy delivery. As deeper sedation/general anesthesia can be associated with adverse hemodynamic effects, more organizational efforts, and costs but also can challenge the inducibility of supraventricular tachycardia. Its use should be reserved for selected patients.[24,39,41]

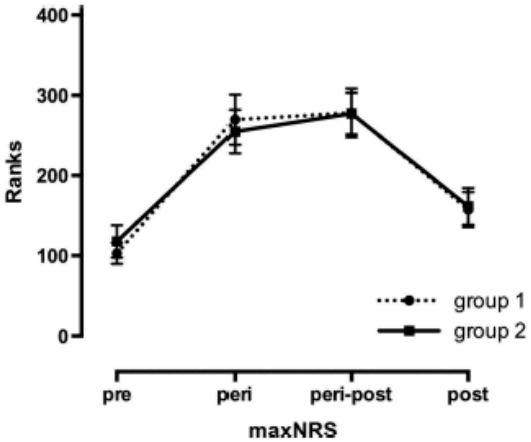

FIGURE 3. *Distribution of mean ranks (95% confidence interval) of maxNRS on different time points. Pre, before the procedure; peri, during the procedure; peri-post, remembrance of max NRS collected in the recovery room; post, maxNRS after the procedure. G1, informed; G2, noninformed. NRS indicates numeric rating scale.*

We analyzed different factors and their impact on pain. A higher level of pain was observed in procedures (for both CIED and electrophysiological ± ablation) with a longer duration. Patients with NRS scores lower than 3 had a significantly shorter procedure duration. Bollmann et al found that postinterventional pain correlates with longer procedural times and larger intraoperative narcotic requirements.[42–45] There is a lack of evidence whether maximum or average pain values are more important for patient satisfaction.

There were no differences for the peri and peri-post measurements. We found that all of our patients could remember the peri-interventional pain. In the literature, there are only few studies available that focus on procedural pain recollection. Most of these studies were conducted in the context of obstetrics and labor pain. In such cases, the pain is much more intensive and emotionally connected with the total experience of birth.[46,47] Therefore, our data are not comparable to these findings. The potential of our study is to show that postoperative questionnaires as done by other researchers[18–21] on pain during an intervention could reliably reflect the perioperative status, as so far, there have been no validation data available. Therefore, postinterventional questionnaires on peri-interventional pain can be assumed to be reliable and the derived NRS values can be included as a validated

TABLE 4 Localizations of Patients' Self-reported Pain

Procedure	Pain Localization	Total	Group 1: Informed	Group 2: Noninformed	*P* (Fisher Exact Test)
AVNRT/AVRT/AFL/diagnostic EP study		n = 43	n = 19	n = 24	
	Back	2 (4.7)	2 (10.5)	0 (0)	.104
	Inguinal region	7 (16.3)	2 (10.5)	5 (20.8)	.437
	Chest/inspiration	17 (39.5)	7 (36.8)	10 (41.7)	.765
	Shoulder	5 (11.6)	1 (5.3)	4 (16.7)	.247
	Others	5 (11.6)	4 (21.1)	1 (4.2)	.086
CIED		n = 58	n = 31	n = 27	
	Wound	45 (77.6)	23 (74.2)	21 (77.8)	1.000
	Others	4 (6.9)	2 (6.4)	2 (7.4)	.886

Data are presented as n (%). A few patients denied any pain (NRS = 0) throughout the procedure. Therefore, the sum of patients reporting pain at different locations is below the overall treated cohort size.
Abbreviations: AVNRT, AV-nodal reentry tachycardia; AVRT, AV-reentry tachycardia; AFL, atrial flutter; EP, electrophysiological; CIED, cardiac implantable electronic device; NRS, numeric rating scale.

hospital performance marker. At least in our hospital, these patient-oriented performance measures are done to highlight areas for improvement. We have noticed during our previous research that some patients hide their pain if not asked explicitly. Therefore, postinterventional surveys are a way to reveal problems in pain management. We believe that structured peri-interventional pain management should be established if a therapy on demand is wished, but we are unaware if this is available for every clinic so far. Such a pain management approach requires regular pain assessments and structured treatment paths.

Patel and colleagues[48] found that hospital rating was significantly influenced by patients' communication with nurses, response time of hospital staff, and communication with physicians. Therefore, we hypothesized that communication with nurses and physicians may influence the recollection of pain. With the 2-factor ANOVA, we could show that there are no major effects by communication group and no interaction effect (time × group). This means that there were no differences between groups in terms of changes in NRS over the time points (pre, peri, peri-post, and post). However, the factor time revealed a significant effect during the time course, with low pain levels before and directly after the procedure and higher levels during the procedure. The different modes of patient-staff communication in this investigation did not influence the perception and recollection of pain.

It is questionable if cognitive factors and psychosocial aspects (such as anxiety or depression) influence pain. Therefore, we compared persons with higher score values (≥10) in 1 or more of the PHQ screening tests with persons with lower score values. We could not find any difference during and after the interventions. An increased anxiety score and/or depression score may not affect pain or the recollection of pain. However, patients with scores of 10 or higher had higher NRS values before intervention.

Anterograde amnesia is possible as an acute side effect of high-dose (>0.08 mg/kg) midazolam.[49–51] Therefore, midazolam treatment might have an influence on pain perception/recollection. Patients with and without midazolam had similar maximum pain levels during the

TABLE 5 Comparison of Pain During Intervention and the Recollection of Pain in Patients With Scores <10 and ≥10 in 1 or more Screening Tests (Patient Health Questionnaire-9, Generalized Anxiety Disorder 7, and Patient Health Questionnaire-15)

	PHQ-9/GAD-7/PHQ-15		*P* (Mann-Whitney Test)
	Score <10	Score ≥10	
Total number	83 (82.2)	28 (27.8)	–
Preinterventional	47.98 (0; 0–5)	58.88 (0; 0–5)	.005
MaxNRS (peri)	48.98 (3; 0–10)	53.98 (4; 0–10)	.538
MeanNRS (peri)	48.34 (0; 0–7)	57.93 (0; 0–6)	.141
MaxNRS (peri-post)	51.44 (0; 0–9)	49.86 (0; 0–9)	.810
MeanNRS (peri-post)	50.55 (0; 0–5)	52.16 (0; 0–6)	.804
Postinterventional	49.05 (0; 0–5)	56.09 (0; 0–5)	.244

Data are presented as n (%) or mean ranks (median; range).
Abbreviations: PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder 7; PHQ-15, Patient Health Questionnaire-15; NRS, numeric rating scale.

TABLE 6 Comparison of Pain in Relation to the Application of Midazolam Before or During the Time Course of the Intervention

Midazolam Application		Peri	Peri-Post	*P*
First dose before procedure (n = 24)	MaxNRS	3 (0–10)	4 (0–7)	.67
	MeanNRS	1.3 (0–7)	2 (0–5)	.13
First dose during procedure (n = 11)	MaxNRS	5 (0–8)	4 (0–9)	.77
	MeanNRS	2.4 (0–4)	2 (0–5)	.69

Data are presented as median (range).
Abbreviation: NRS, numeric rating scale.

What's New and Important

- The use of a postinterventional questionnaire to record peri-interventional perceived pain can be used well.
- Different modes of patient-staff communication did not influence the recollection of peri-interventional pain.
- Low dosages of midazolam therapy do not affect the recollection of peri-interventional pain.
- Scores (≥10) of psychosocial factors (PHQ-9, GD-7, and PHQ-15) do not affect the recollection of peri-interventional pain.

procedure. It should be noted that the mean dosages in our study were low (0.04 ± 0.04 mg/kg). The results showed no influence of low-dose midazolam on recollection of pain. It is questionable whether patients treated with midazolam would have complained of higher pain values if not treated. However, the pain data collected after the intervention did not deviate from peri-interventional data. At least, this suggests that there was no distortion of memory.

Limitations

This study was planned as a pilot study because of scarce data on pain during ablation/diagnostic electrophysiological procedures for supraventricular tachycardias and CIED procedures with mainly local anesthesia. Therefore, our results are based on a small number of consecutive patients in a single center, reflecting a typical mixed real-life patient cohort at our inpatient electrophysiological unit. Surprisingly, there were no differences in pain perception between patients undergoing diagnostic or ablation electrophysiological procedures for supraventricular tachycardias or CIED procedures. However, because of the small subgroups, interpretation of these data should be done with caution. The allocation scheme has its limitations and can cause bias. However, organizational requirements with staff changes between morning and late shifts and between the electrophysiological laboratories and the need for 2 different patient-staff communication schemes made a per-patient randomization not feasible. Therefore, study rules were monitored by the first author. Despite the fact that there was a difference in age in the groups (group 1: informed and group 2: noninformed), all patients were in the same age group. To generalize our results to other patients, further investigations with more patients and controlling for additional determinants of pain are required.

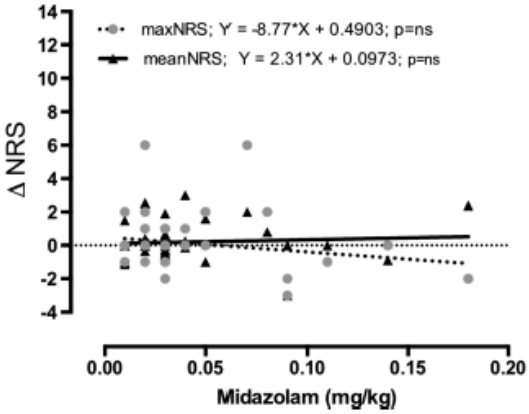

FIGURE 4. *Linear regression of midazolam (mg/kg) application and difference between peri and peri-post recorded data (Δ NRS). Dots represent Δ maxNRS and triangles represent Δ meanNRS. NRS indicates numeric rating scale.*

Conclusion

During so-called noncomplex cardiac electrophysiological procedures and cardiac rhythm device surgery, half of the patients complained of moderate to severe pain at least at 1 time point. However, 51% reported low pain levels (NRS, 0–3) on average during the intervention. These data support the policy of a demand-based sedation and analgesia instead of deep sedation/general anesthesia to avoid an overtreatment with its risk for side effects in larger patient populations.

A postinterventional evaluation of peri-interventional pain was comparable to the actual peri-interventional data. Neither an influence of the type of patient-staff communication nor a psychosocial factor on the pain recollection could be determined. Low-dose midazolam therapy had no influence on pain memory. Therefore, a postinterventional evaluation of peri-interventional patient discomfort may be a tool in hospital performance evaluations.

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3 Zusammenfassung der Arbeit

Dissertation zur Erlangung des akademischen Grades Dr. med.

Schmerzwahrnehmung während elektrophysiologischer Untersuchungen/Ablationen und Herzschrittmacher-/ICD-Operationen

eingereicht von: Dr. phil. Sven Fikenzer, M.Sc.

angefertigt in: Abteilung für Rhythmologie, Herzzentrum Leipzig

Betreuer: Prof. Dr. Dr. med. Andreas Bollmann
Dr. med. Kerstin Bode, M.Sc.

Beschluss über die Verleihung des Doktorgrads vom: 25.02.2020

Elektrophysiologische Untersuchungen, Ablationsprozeduren und Herzschrittmacher-/ ICD-Implantationen werden angesichts erweiterter Indikationen und neuer Techniken und der älter werdenden Bevölkerung immer häufiger durchgeführt. Aufgrund der verschiedenen Notwendigkeiten und Empfehlungen sind die Patienten häufig nicht analgosediert. Die in diesem Rahmen auftretenden Schmerzen sind bis dato nicht hinreichend untersucht. Angesichts einer hohen Bedeutung des Schmerzes in der Patientenversorgung stellt sich die vorliegende Arbeit der Evaluation der peri-interventionellen empfundenen Schmerzen sowie ihrer Erinnerung (post-interventionell).

Bezogen auf die gestellten Problem- und Fragestellungen der Studie kann Folgendes resümiert werden:

1) Während elektrophysiologischer Untersuchungen/Ablationen und Herzschrittmacher-/ICD-Operationen klagte die Hälfte der Patienten an mindestens einem Zeitpunkt über mittlere bis starke Schmerzen (im Sinne eines maxNRS). Allerdings war auch feststellbar, dass bei 84% der Patienten die durchschnittlich empfundenen Schmerzen während des Eingriffs niedrig waren (meanNRS: 0-3). Diese Daten unterstützen das Vorgehen einer bedarfsgerechten Sedierung und Analgesie anstelle einer tiefen Sedierung/Vollnarkose, um eine Überbehandlung mit dem Risiko von Nebenwirkungen bei größeren Patientengruppen zu vermeiden.

2) Wesentlicher Faktor für die Höhe der empfundenen Schmerzen war die Behandlungsdauer. Dies galt sowohl für die elektrophysiologischen Untersuchungen/ Ablationen als auch für die Herzschrittmacher-/ICD-Operationen. Für die anderen untersuchten Faktoren (Geschlecht, Alter, bedarfsadaptierte i.v. Midazolamgabe) konnte in der vorliegenden Studie kein Hinweis auf zusätzlichen Einfluss gefunden werden.

3) Eine post-interventionelle Erhebung von peri-interventionellen Schmerzen war mit den tatsächlichen peri-interventionell erhobenen Daten vergleichbar. Dies spricht dafür, dass ein post-interventionell eingesetzter Fragebogen bei nicht analgosedierten Patienten/Eingriffen eingesetzt werden kann, wenn eine Befragung aufgrund von Verfahrensumständen während der Intervention nicht möglich ist. Dies kann insbesondere für eine bedarfsgerechte Schmerzmittelgabe im Falle wiederholter Eingriffe (z.B. Re-Ablationen) relevant sein.

4) Ein initial vermuteter „iatrogener" Einflussfaktor auf die Schmerzwahrnehmung und -erinnerung konnte in dieser Untersuchung nicht ermittelt werden. Den Daten zufolge scheint die Art der Kommunikation (zugewandt/empathisch vs. rein formell) keinen Einfluss zu haben.

5) Die Daten der Untersuchung legen nahe, dass intrapersonelle Eigenschaften (z.B. Angst, Depressionen und/oder somatische Störungen) die Schmerzwahrnehmung und das Erinnerungsvermögen an wahrgenommen Schmerzen nicht beeinflussen. Da die Datenmenge allerdings in der vorliegenden Studie sehr klein ist, sollte dieses Ergebnis mit Vorsicht betrachtet werden. Hier erscheint es sinnvoll, dies in einer größeren Stichprobe zu überprüfen.

6) Zudem fanden wir, dass eine niedrig dosierte Midazolam-Therapie (0,04mg/kg i.v.) keinen Einfluss auf das Schmerzgedächtnis hatte. Da eine anterograde Amnesie als akute Nebenwirkung bei einer hohen Dosis (>0,08 mg/kg i.v.) von Midazolam beschrieben wird, sollte dies bei höheren Midazolamdosen berücksichtigt werden.

Aus der Untersuchung ergeben sich somit folgende neuen Erkenntnisse:

1. Die Verwendung eines post-interventionellen Fragebogens zur Erfassung peri-interventionell wahrgenommener Schmerzen kann gut genutzt werden.

2. Verschiedene Formen der Kommunikation zwischen Patienten und klinischem Personal hatten keinen Einfluss auf die Erinnerung an peri-interventionelle Schmerzen.

3. Bedarfsadaptiert verabreichte i.v. Midazolamdosen, welche sich meist im niedrigen Dosisbereich befanden, hatten keinen Einfluss auf die Erinnerung an peri-interventionelle Schmerzen.

4. Psychosoziale Faktoren (PHQ-9; GD-7, PHQ-15) mit hohen Scores (≥ 10) zeigten keinen Einfluss auf die Erinnerung peri-interventionell empfundener Schmerzen.

4 Literatur

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I Darstellung des eigenen Beitrages

Folgende Tätigkeiten und Inhalte wurden im Rahmen der Planung, Durchführung, Auswertung und Erstellung des Manuskripts durch meinen persönlichen Beitrag (Dr. Sven Fikenzer: SF) realisiert:

Planung und Konzeption:

- Idee und Grobkonzept (SF gemeinsam mit Dr. K. Bode)
- Erstellung des Prüfplans und Ethikantrags (SF gemeinsam mit Dr. K. Bode)
- Erstellung der Untersuchungsmaterialien (Fragebögen, Patientenaufklärung etc.) (SF, Dr. K. Fikenzer, Dr. K. Bode)
- Erstellung der Datenbank (SF)

Durchführung der Untersuchung:

- Patientenakquise und Einschluss in die Studie (SF, Dr. K. Fikenzer, Dr. K. Bode)
- Datenerhebung während der Interventionen (vor, während und nach) (SF)

Auswertung und Analyse der Daten:

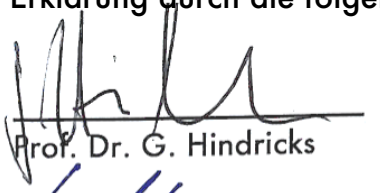
- Daten in Datenbank einpflegen (SF)
- Statistiken (SF)
- Diskussion der Ergebnisse (SF mit Dr. K. Bode, Dr. K. Fikenzer und Prof. A. Bollmann)

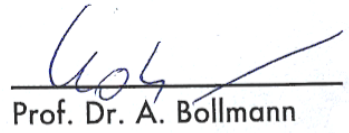
Erstellung des Manuskripts:

- Erstellung aller Stufen bei der Entwicklung des Manuskripts von Roh- bis Endversion (SF)
- Inhaltliche und sprachliche Korrekturen durch Dr. K. Bode, Dr. K. Fikenzer, Prof. A. Bollmann
- Finale kritische Korrektur durch alle Co-Autoren

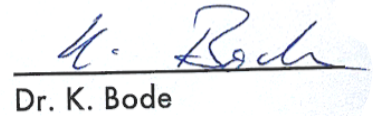
Bestätigung des persönlichen Beitrages des Doktoranden:

Im vorliegenden Verfahren ist der Doktorand gleichsam korrespondierender Autor, so dass die Erklärung durch die folgenden Co-Autoren erfolgt:

1) 
Prof. Dr. G. Hindricks

2) 
Prof. Dr. A. Bollmann

3) 
Dr. K. Fikenzer

4) 
Dr. K. Bode

II Selbstständigkeitserklärung

Hiermit erkläre ich, dass ich die vorliegende Arbeit selbstständig und ohne unzulässige Hilfe oder Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe. Ich versichere, dass Dritte von mir weder unmittelbar noch mittelbar eine Vergütung oder geldwerte Leistungen für Arbeiten erhalten haben, die im Zusammenhang mit dem Inhalt der vorgelegten Dissertation stehen, und dass die vorgelegte Arbeit weder im Inland noch im Ausland in gleicher oder ähnlicher Form einer anderen Prüfungsbehörde zum Zweck einer Promotion oder eines anderen Prüfungsverfahrens vorgelegt wurde. Alles aus anderen Quellen und von anderen Personen übernommene Material, das in der Arbeit verwendet wurde oder auf das direkt Bezug genommen wird, wurde als solches kenntlich gemacht. Insbesondere wurden alle Personen genannt, die direkt an der Entstehung der vorliegenden Arbeit beteiligt waren. Die aktuellen gesetzlichen Vorgaben in Bezug auf die Zulassung der klinischen Studien, die Bestimmungen des Tierschutzgesetzes, die Bestimmungen des Gentechnikgesetzes und die allgemeinen Datenschutzbestimmungen wurden eingehalten. Ich versichere, dass ich die Regelungen der Satzung der Universität Leipzig zur Sicherung guter wissenschaftlicher Praxis kenne und eingehalten habe.

Markkleeberg, 25.06.2019

.....	.....
Datum	Unterschrift

III Lebenslauf

Dr. phil. Sven Fikenzer, M.Sc.

Persönliche Daten

25.09.1975	geboren in Karl-Marx-Stadt (jetzt Chemnitz) verheiratet, 3 Kinder

Berufserfahrung

Seit 01/2020	Arzt in Weiterbildung Klinik und Poliklinik für Kardiologie, Universitätsklinikum Leipzig
seit 11/2018	Dozent für „Grundlagen der Medizin" im Studiengang BA Soziale Arbeit Diploma Hochschule, Studienzentrum Leipzig
2016 – 2017	Studiengangsentwicklung „B.A. Bewegungscoaching und Gesundheit" dba – Deutsche Berufsakademie für Sport und Gesundheit, Baunatal
seit 07/2016	Dozent für Trainingslehre und Sportmedizin Deutsche Fitnesslehrer Vereinigung e.V. (DFLV)
seit 2015	Presidente Honorário (Ehrenpräsident) STEP Germany Angola S.A. (Deutsch-Angolanisches Kompetenznetzwerk)
seit 01/2014	Geschäftsführender Partner STEP Angola GmbH, Leipzig/Luanda
12/2011-09/2013	Mitglied der akademischen Hochschulleitung Deutsche Hochschule für Prävention und Gesundheitsmanagement GmbH, Saarbrücken
12/2011-09/2013	Vorsitzender des Forschungsausschusses Deutsche Hochschule für Prävention und Gesundheitsmanagement GmbH, Saarbrücken
10/2010-09/2013	Professor für Trainings- und Gesundheitswissenschaften Deutsche Hochschule für Prävention und Gesundheitsmanagement GmbH, Saarbrücken
10/2009-09/2010	Wissenschaftlicher Mitarbeiter für Trainings- und Bewegungswissenschaften BSA-Akademie, Saarbrücken
seit 08/2006	Geschäftsführender Gesellschafter STEP Projects, Marketing & Sports GmbH, Markkleeberg
2005 – 2008	Wissenschaftlicher Mitarbeiter für Forschung und Lehre Universitätsklinikum Herzzentrum Leipzig (Leitung: Prof. Dr. med. G. Schuler)
2002 – 2010	Dozent für Sportmedizin und Fußball Internationaler Trainerkurs (ITK) als Teil der auswärtigen Kultur- und Bildungspolitik der Bundesrepublik Deutschland, Sportwissenschaftliche Fakultät, Universität Leipzig,
2001 – 2009	Wissenschaftlicher Mitarbeiter für Forschung und Lehre Institut für Sportmedizin und Prävention, Universität Leipzig (Leitung: Prof. Dr. med. M. Busse)
1999 – 2001	SHK und Tutorentätigkeit Institut für Sportmedizin und Prävention, Universität Leipzig (Leitung: Prof. Dr. med. M. Busse)

Reviewer/Gutachter

seit 2019	Scientific Reports (Nature)
seit 2019	Sports Medicine (Springer)
seit 2018	J Sports Med Phys Fitness – The Journal of Sports Medicine and Physical Fitness
seit 2011	EJSS – European Journal of Sport Science
2012 – 2013	AHPGS – Akkreditierungsagentur für Studiengänge im Bereich Gesundheit und Soziales

Forschungsschwerpunkte/Klinische Studien

aktuell	Akute und chronische Effekte unterschiedlicher Trainingsformen und Belastungsmodalitäten auf das Herz-Kreislaufsystem
2012-2013	Effekte verschiedener Periodisierungsformen im fitnessorientierten Krafttraining
2011-2012	Gesunde Polizei Thüringen Risikostratifikation der KHK bei Polizeibeamten, Thüringen
2005-2008	Leipziger Schulstudie Einfluss einer kontrollierten Erhöhung der körperlichen Aktivität bei Schulkindern auf das kardiovask. System und das atherogene Risiko (AG Prof. G. Schuler)
2004-2008	Physiologische Ursachen für das Verhalten belastungsspezifischer EKG Charakteristika im Vergleich zu anderen Kenngrößen der Belastung (Arbeitsgruppe Prof. Dr. Dr. med. M.W. Busse)

Mitgliedschaften

seit 2018	DGK – Deutsche Gesellschaft für Kardiologie (Arbeitsgruppe Sportkardiologie)
seit 2011	dvs – Deutsche Vereinigung Sportwissenschaft
seit 2002	BDFL – Bund Deutscher Fußballlehrer (stellv. Verbandsgruppenleiter, VG Nord-Ost)

Schulbildung/Dienst/Ausbildung

12/2019	Approbation und Berufserlaubnis als Arzt
12/2019	3. Staatsexamen Humanmedizin, Universität Leipzig
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01/2009	Promotion im Fach Sportwissenschaft, Universität Leipzig, Abschluss: Dr. phil.
2008 – 2009	Masterstudiengang „Rehabilitation und Prävention", Universität Leipzig, Abschluss: M.Sc.
1996 – 2001	Diplomstudiengang Sportwissenschaft, Universität Leipzig, Abschluss: Dipl. Sportlehrer
1995 – 1996	Grundwehrdienst Bundeswehr (Ausbildung zum Stabsdienstsoldat)
1990 – 19995	Allgemeine Hochschulreife, Gymnasium Wanne, Herne
1987 – 1990	Kinder- und Jugendsportschule (KJS), Leistungssport: Sportschwimmen
1882 – 1987	POS Hans Beimler, POS Wilhelm Pieck, POS Heinrich Heine (Vorbereitung KJS)

Zusatzqualifikation

seit 10/2016	Fitnesstrainer-A-Lizenz (Deutsche Fitnesslehrer Vereinigung e.V., DFLV)
seit 06/2011	GCP (good clinical practice) für Prüfärzte und Studienteams
seit 04/2008	Medizinische Trainingstherapie (MTT)
seit 11/2002	Lizensierter Fußballtrainer (DFB-A-Lizenz, UEFA-A-Level)

Markkleeberg, 25.02.2020

IV Publikationen

Publikationsliste Dr. phil. S. Fikenzer, M.Sc.

1) Busse, M., Nißing, A., Tegtbur, U., Miltzow, S., Thomas, M. & Fikenzer, S. (2004). QT-Zeit und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2004 5 (2): 39-44

2) Busse, M., Nißing, A., Tegtbur, U., Miltzow, S., Thomas, M. & Fikenzer, S. (2004). PQ-Zeit und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2004 5 (2): 45-49

3) Busse, M., Nißing, A., Tegtbur, U., Miltzow, S., Thomas, M. & Fikenzer, S. (2004). P-Dauer und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2004 5 (3): 50-54

4) Busse, M., Nißing, A., Tegtbur, U., Miltzow, S., Thomas, M. & Fikenzer, S. (2004). PQ-Strecke und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2004 5 (3): 55-58

5) Busse, M., Nißing, A., Tegtbur, U., Miltzow, S., Thomas, M. & Fikenzer, S. (2004). QRS-Komplex und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2004 5 (3): 59-62

6) Fikenzer, S., Nißing, A., Tegtbur, U., Thomas, M. & Busse, M. (2005). ST-Strecke und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2005, 6(1):19-23.

7) Fikenzer, S., Nißing, A., Tegtbur, U., Thomas, M. & Busse, M. (2005) T-Dauer und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2005,6 (2):24-28.

8) Fikenzer, S., Nißing, A., Tegtbur, U., Thomas, M. & Busse, M. (2005) P-VM und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2005, 6 (3):46-50.

9) Fikenzer, S., Nißing, A., Tegtbur, U., Thomas, M. & Busse, M. (2005) R-VM und Herzfrequenz bei Belastung. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2005, 6 (3): 51-56.

10) Busse, M., Falz, R., Tegtbur, U, Thomas, M., Drechsler, K., Schulze, A. & Fikenzer, S. (2006). Bedeutung des Studienfachs für die arterielle Hypertonie bei Studenten der Universität Leipzig Klinische Sportmedizin/ Clinical Sports Medicine Germany (KCS) 2006; 7(3): 23-26

11) Fikenzer, S., Falz, R., Tegtbur, U., Thomas, M., Drechsler, K., Schulze, A. & Busse, M. (2006). Prävalenz der arteriellen Hypertonie bei Studenten der Universität Leipzig Klinische Sportmedizin/ Clinical Sports Medicine Germany (KCS) 2006; 7 (2): 19-22

12) Meidl, D., Busse, M. & Fikenzer, S. (2006). Ökonomisch orientierte Lösungsansätze zur Dopingproblematik im Hochleistungssport. Klinische Sportmedizin/Clinical Sports Medicine Germany (KCS) KCS 2006; 7(3): 27-32.

13) Walther, C, Fiehn, E., Fikenzer, S., Drechsler, K., Sonnabend, M., Bublitz, B., Busse, M. & Schuler, G.C. (2006). Steigerung der körperlichen Aktivität bei Schulkindern: Erste Ergebnisse des Leipziger Schulprojektes (2006). Clin Res Cardiol 95: Suppl 5 (2006) Beitrag P1336, DOI: 10.1007/s00392-006-0388-5

14) Fikenzer, S., Anke, R., Falz, R., Tegtbur, U., Thomas, M., Drechsler, K, Schulze, A., Hoppe, St. & Busse M. (2007). Einfluss einer Kreatin-Supplementierung auf Leistung, maximale Sauerstoffaufnahme, Atemminutenvolumen und Laktat im maximalen Belastungstest. Klinische Sportmedizin/Clinical Sports Medicine - Germany (KCS) 2007 8 (3) 22-27

15) Fikenzer, S., Drechsler, K., Tegtbur, U., Thomas, M., Falz, R., Schulze, A. & Busse, M. (2007). Einfluss von ß-Blockade auf die Laktatsenke. Klinische Sportmedizin/ Clinical Sports Medicine - Germany (KCS) 2007 8 (2) 13-16

16) Fikenzer, S., Drechsler, K., Falz, R., Tegtbur, U., Thomas, M., Schulze, A., Bressau, K., Hoppe, St. & Busse, M. (2007). Einfluss von Beta-Blockade auf das Herzminutenvolumen im maximalen Belastungstest. Klinische Sportmedizin/Clinical Sports Medicine - Germany (KCS) 2007 8(1) 1-7

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