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The Skin Conductance Algesimeter validated with the Numerical Rating Scale Postoperatively in Patients treated with Classical Music

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Abstract

Background: An inadequate estimation and management of perioperative pain may delay patient recovery and discharge from hospital. The aim of this study was to evaluate the efficacy of the skin conductance algesimeter index - number of skin conductance fluctuations (NSCF) per second , as compared to the Numerical Rating Scale (NRS), in perioperative pain monitoring of thyroidectomy patients for patients listening to classical music.

Methods: Forty patients scheduled for surgical thyroidectomy were randomized into two groups with partially different postoperative managements: Group C (Control) received the traditional treatment, while Group S (Study) had classical music in addition to the traditional treatment. In both groups, the postoperative pain levels were assessed using NSCF per second, NRS and self-administrated analgesic drug consumption.

Results: The C and S groups were characterized by similar levels of pain as measured by NRS and NSCF per second. The S group used less morphine than the C group (0.3 mg vs 1.1 mg; P<0.01). We also observed a significant correlation between NRS and NSCF per second when 30 minute time intervals between measurements were used (R=0.69, P<0.01). On the other hand no correlation was observed when moment-by-moment measurements were used. Both the NRS and NSCF per second decreased significantly during the postoperative period.

Conclusion: The NRS and NSCF per second performed similarly for pain assessment in the postoperative period. Classical music listening in addition to traditional treatment reduced the morphine consumption without clearly influencing the pain level as measured by NRS and NSCF per second.

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Abbreviations: NRS: Numerical Rating Scale; NSCF: Number of Skin Conductance Fluctuations per second; PCA: Patient Controlled Analgesics; JCAHO: Joint Commission on Accreditation of Healthcare Organizations; PONV: Post-Operative Nausea and Vomiting; STAI Test: State Trait Anxiety Inventory Test

Introduction

In 2001 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the US introduced standards for pain assessment and treatment in hospitalized patients[1]. In particular, "pain" was defined as the fifth vital sign[1]. This directive led to increased attention of the clinicians to pain management, but also to an increased incidence of opioid-related adverse drug reactions that have the potential for fatal outcomes[1]. Similar new guidelines for the importance of monitoring and treating pain were established by the national governments in France, Italy, and Russia, from 2010. Prof. Kehlet et al[2] showed that acute postoperative pain may develop into chronic pain - persistent pain after 3 months - in 30-40% of the patients after thoracotomy (open lung surgery). About 10% of these patients may eventually develop chronic, severe and disabling pain[2]. The important predictors of postsurgical chronic pain are preoperative predisposing factors, the intensity of early postoperative pain, and the development of neuropathic pain[2]. Given these premises, in recent years, great attention has been directed towards the evaluation of postoperative pain and the identification of new strategies to improve pain assessment. In patients evaluated for pain perception, the Numerical Rating Scale (NRS), or changes in the number of skin conductance fluctuations (NSCF) per second as measured by the SC algesimeter, were shown to be significantly correlate with the level of postoperative pain[3-6]. The sensitivity of this latter method for identifying moderate to severe postoperative pain was found to be about 90% and the specificity was found to be about 70%, using the NRS as the reference gold-standard[3-6]. Furthermore, the NSCF per second was able to correctly identify the absence of pain with an accuracy of 97%[5]. During anesthesia induction, with progressively increasing sedation, the specificity of the NSCF per second reached about 90% using the clinical stress score as the reference gold-standard[7]. It has been known for a long time that music and relaxation can be useful in pain control, especially after non-cardiac surgery[8-10]. In this respect, the evaluation of the effects of music exposure (as compared to more classical treatment approaches), could provide an important opportunity to assess the accuracy of the NSCF per second in monitoring postoperative pain in comparison to the gold standard represented by the NRS. Therefore, aim of this study was to investigate how NSCF per sec and NRS correlated in the postoperative period after thyroidectomy in patients exposed, as compared to patients not exposed, to classical music. The analgesics drug consumption was also analyzed as an objective indicator of pain perception in our samples.

Methods

Ethics: Protocol n. 321 approved by Ethical Commitee: Professor Danesi Romano, Azienda Ospedaliero Universitaria Pisana, Via Roma, 67 – 56126 PISA.

Subjects: Exclusion criteria were age < 18 years old, pregnancy, breast-feeding or known psychiatric condition. A total of 40 patients who underwent surgical thyroidectomy were included in the study.

Experimental Procedure: All patients were tested with the STAI (State-Trait Anxiety Inventory) test before surgery. They received the same pre-operative and intra-operative anesthesia treatment: premedication with intramuscular (im) atropine (0.5 mg) and oral diazepam (0.1 mg/kg) 30 minutes before entering the operating theatre, induction with propofol 2% (2 mg/kg), remifentanil (0.8 mcg/kg), and rocuronium (0.6 mg/kg), and maintenance of sedation with propofol continuous infusion (4-8 mg/kg/h) and remifentanil continuous infusion (0.25 γ/kg) titrated to maintain hemodynamic parameters within basal level ± 15%. All patients were tracheal intubated and mechanically ventilated with a mixture of oxygen in air at 50%. About 20 minutes before the end of surgery, patients received intravenous (iv) ketorolac (30 mg) and iv morphine (0.05 mg/kg). After surgery, the patients were randomly assigned to one of two study groups. Patients included in the "Control Group" (C), were admitted to the Recovery Room and received the traditional treatment used to manage this kind of post-surgical patient, particularly focusing on pain control, postoperative nausea and vomiting (PONV) and other discomfort syndromes. Patient Controlled Analgesics (PCA) with morphine bolus infusion 1 mg/bolus was used for pain control. Patients included in the "Study Group" (S) were admitted in a special Recovery Room, where they remained isolated from the external environment using classical music (administered via earphones). The same post-surgical pharmacological treatment was given to both patient groups. Postoperatively, pain was assessed by using NSCF per second, the NRS and self-administrated analgesic drug consumption. Data provided by the Skin Conductance Algesimeter and the NRS were recorded at the admission to the Recovery Room (T_0), after 15 minutes (T_1) and after 30 minutes (T_2), when the patients left the Recovery Room and were discharged to the ward. Also blood pressure, heart rate, SpO_2 and temperature were measured postoperatively at T_0, T_1 and T_2.

Statistics: The number of patients included was defined based on previous studies that measured changes in perceived pain using subjective scores and NSCF per second[11,12]. Correlation between independent data was evaluated calculating the Pearson's coefficient (R). For the same parameters, the two different groups were compared using the one-tailed Mann-Whitney test for independent data, while in the same group the same parameters were studied at different times using the one-tailed Wilcoxon test for paired data.

Results

The two groups of patients were exposed to similar procedures before they entered the Recovery Room and showed no significant differences regarding preoperative STAI test score (mean ± standard deviation; Control group: = 49±13 vs. Study group: 48±14, p=n.s.). Blood pressure, heart rate and SpO_2 showed no significant differences between the two groups when measured during the Recovery Room stay (Table 1).

Table 1: Parameters registered during Recovery Room stay – mean (sd)

PARAMETERS	CONTROL GROUP	STUDY GROUP	SIGNIFICANCE
Systolic blood pressure (mmHg)	153 (18)	141 (10)	NS
Dyastolic blood pressure (mmHg)	80 (11)	84 (6)	NS
Mean blood pressure (mmHg)	101 (12)	102 (7)	NS
Heart rate(bpm)	75 (13)	77 (14)	NS
SpO_2 (%)	99 (1)	100 (1)	NS

In both groups perceived pain levels decreased during the Recovery Room stay, either measured with NRS, or using the SC algesimeter index NSCF per second. The "Study Group" showed pain levels which decreased from 4.1 to 3.45 (p<0.005) as measured by the NRS, and from 0.13 to 0.09 ($p<0.05$) as measured by the NSCF per second. The “Control Group” showed pain levels which decreased from 4.65 to 4.1 ($p<0.015$) as measured by the NRS, and from 0.14 to 0.09 ($p<0.025$) as measured by the NSCF per sec (Table 3).

Table 2: Parameters registered at Recovery Room admission (t_0) - mean (sd)

	CONTROL GROUP	STUDY GROUP	SIGNIFI-CANCE
NRS	4,65 (1,98)	4,10 (0,91)	NS
NFSC	0,14 (0,11)	0,13 (0,07)	NS

Table 3: Parameters trend during Recovery Room (RR) stay

	RR ADMISSION	RR DISCHARGE	STATISTICAL DIFFERENCE
CONTROL GROUP NRS	4,65 (1,98)	4,10 (0,91)	p < 0.015
STUDY GROUP NRS	4,10 (1,55)	3.45 (0,6)	p < 0.005
CONTROL GROUP NFSC/sec	0.14 (0.11)	0.09 (0,06)	P < 0.025
STUDY GROUP NFSC/sec	0,13 (0,007)	0,09 (0,08)	P < 0.05

At T_0 pain levels showed no differences between the two groups, either measured with the NRS, or using the NSCF (Table 2). The mean NRS score during the whole Recovery Room stay (30 minutes) correlated significantly with the mean NSCF per second measured for the same time period ($R=0.67$, $p<0.01$). Nevertheless, we observed no significant correlation between these two parameters when compared at T_0, T_1 or T_2.

No significant differences in pain levels were observed between the two groups at the time of discharge from the Recovery Room (T_2) (Table 4). However, the “Study Group” used less morphine (mean 0.3 mg *vs.* mean 1.1 mg, $p<0.01$) than the “Control Group”, to obtain the same pain levels (either measured with the NRS, or using the SC algesimeter index NSCF per second) at the time of discharge from Recovery Room. Suppl Table 1

Table 4: Parameters registered at Recovery Room discharge (t_2) - mean (sd)

	CONTROL GROUP	STUDY GROUP	SIGNIFI-CANCE
NRS	4,65 (1,98)	3,45 (0,6)	NS
NSCF	0,14 (0,11)	0,09 (0,08)	NS

Suppl Table 1: This table refers to the modifications of BP HR, SBP, DBP….during all time spent in recovery room (RR)
The following table refers to parameters at t_1:

	CONTROL GROUP	STUDY GROUP	SIGNIFI-CANCE
NRS	4,63 (1,96)	3,64 (0,8)	NS
NSCF	0,12 (0,10)	0,11 (0,1)	NS

Discussion

In the present study we compared postsurgical pain monitoring strategies, based on subjective and objective indicators of pain levels, in a group of patients exposed to classical music and in a group of patients who received only the pharmacological treatment. Specifically, we evaluated the efficacy of the skin conductance algesimeter index, number of NSCF per second, as compared to the NRS, in perioperative pain monitoring of thyroidectomy patients. In line with previous research, our results showed that both NRS and NSCF per second allow the detection of changes in the level of pain during the postoperative period. Moreover, in the same patients we investigated the effect of classical music listening on postoperative pain as compared to the classical pharmacological treatment alone, and we demonstrated that this approach can help to reduce the amount of administered opioid, with similar levels of perceived pain, as measured by both the NSCF per second and the NRS. Previous investigations showed that NSCF per second is correlated with perioperative stress[11] and with NRS[3-6], which is considered one of the most accurate methods for evaluating postoperative pain[12]. Indeed, our results confirmed that both NSCF per second and NRS can reliably detect changes in pain level throughout the postoperative period. In addition, we identified a significant correlation between the two methods when obtained measures were averaged across the whole Recovery Room stay. On the other hand, we did not observe a significant correlation between the NSCF and the NRS approaches at each evaluated time-point (T_0, T_1, T_2), in line with previous work[13].

Importantly, the NSCF per second has been already used successfully to monitor painful stimuli during anesthesia, intensive care, and for neonates[11,12,14-16]. When the level of analgesia increases in patients who reported moderate and severe pain, the NSCF per second and the reported pain are reduced[3-5]. As a matter of fact, changes in NSCF reflect alterations in the emotional portion of the sympathetic nervous system, which is distinct from the part influencing the micro circulation, and are therefore not associated with relevant temperature modifications[17]. Indeed, the NSCF per second correlates with changes in skin sympathetic nerve activity[17-21]. Skin sympathetic nerve activation results in the filling of the palmar and plantar sweat glands, which is followed by a transient increase in skin conductance, before the sweat is reabsorbed and the skin conductance decreases: in this condition a skin conductance fluctuation is observed. Therefore, an increase in the NSCF per second can be interpreted as the sign of activity bursts in the skin sympathetic system, and directly depends on the interaction of the neurotransmitter acetylcholine with muscarinic receptors[17-21]. This parameter is not influenced by hypovolemia, adrenergic receptor active agents, small room temperature changes or muscle relaxing agents[17-21] Moreover, the NSCF per second reacts very rapidly, within 1-2 sec, to nociceptive or painful stimuli[17-21]. The combined use of functional magnetic resonance (fMRI) and the visual analogue scale (VAS) for pain estimation during acute pain in awake volunteers demonstrated that the NSCF per second increases in parallel with pain-evoked brain responses, consistent with a correlation of the NSCF per second with pain-related autonomic processes[22,23]. Moreover, the NSCF per second has been shown to represent a reliable measure of patients’ clinical stress during tetanic stimulation and is inversely related to the dose of administered opioids[24].

Despite this body of evidence - including present results - clearly substantiate the use of the NSCF per second to evaluate pain levels in the postoperative period, further studies will be required to better define the reason of the discrepancies between this objective parameter and the subjective pain perception. In fact, our results indicate that while the NSCF could represent an easy to learn, and low-cost parameter for measuring postoperative pain, it may not fully reflect the actual pain perceived by the patient. Given these premises the use of the NSCF approach should be mainly limited to cases in which the patient's capability to communicate with the external world is reduced. In other conditions, the NRS should represent the preferential approach.

A second aim of the present study was to evaluate the effects of music listening on postoperative pain perception. We demonstrated that environmental isolation during the Recovery Room stay, obtained with classical music, allows reaching the same pain control as standard treatment with a significantly inferior use of morphine and other analgesic drugs. Indeed, previous studies showed that music can efficiently contribute to pain control, especially after non-cardiac surgery[8-10].

One review including 42 randomized controlled trials of the effects of music interventions in perioperative settings showed that music intervention had positive effects on reducing patients' anxiety and pain in approximately half of the papers reviewed[25]. Our results further confirmed what is well known for example for spinal anesthesia[26-28], although some authors do not agree regarding general anesthesia (29 *vs.* 30). A possible reason for these contrasting results could lie in the different kind of surgery, which influences immediate postoperative pain levels: generally lower in thyroid surgery as compared to other types of surgical interventions (as we also observed from our results on pain trend during Recovery Room and hospital stay). Indeed, previous studies indicate that music intervention can have multiple, desirable clinical effects, primarily including reduction of pain, anxiety, and stress (reviewed in[25]). Music intervention is easy to implement, and patients usually enjoy the music and can use it as a self-management technique for distraction or relaxation[25]. In previous studies, most of the music interventions were performed postoperatively and the listening period lasted from 15 to 30 minutes. As in our own investigation, most of the studies used headphones to provide music to the patients[25]. The type of music was soothing (i.e. 60 to 80 beats per min), and in most of the studies self-selected music was used[25]. The self-selected music included the patients' own favorite music chosen from a selected list of musical genres. In other studies, one specific genre of music was provided by the researchers. This included new age music, classical music, slow instrumental music, piano, and pan flute[25]. Interestingly, the genre and duration of the soothing music do not seem to influence the effectiveness of the music intervention[31]. It has been reported that the tempo of the music is the most important factor, with slow and flowing music with 60 to 80 beats per min having positive outcomes on relaxation and pain relief[25]. Based on previous observations, it has been suggested that the music used therapeutically should be non-lyrical, with low tones, minimal bass and percussion, and volume level at maximum of 60dB[25]. The possibility to reduce postoperative levels of pain with lower doses of analgesics may allow the reduction of the incidence of relevant side effects, such as nausea, vomiting, and respiratory depression. If these side effects are reduced, also a shorter hospital stay could be expected.

The limitation of this study can be discussed; the number of patients was twenty in each group which seems few especially when studied after surgical thyroidectomy which is not anticipated to be very painful. Results from other studies show that groups of 10 and more patients show differences from before to during painful stimuli according to NSCF[16]. Twenty patients in each group are therefore sufficient according NSCF, also shown by the obtained statistical significant values in this study.

Based on the results in this and other studies, we suggest that classical music can be used postoperatively to reduce the perceived pain at least in surgical procedure with anticipated low level of pain. More research is needed to find out if classical music should be included as a standard procedure to reduce acute pain.

Conclusion

In conclusion, the present study showed that the Skin Conductance Algesimeter, the NSCF per second can represent a valid approach when monitoring pain postoperatively in thyroidectomy patients, especially for those individuals that are not able to communicate with the external world, and that classical music listening may have a positive effect on pain control by reducing the need for analgesics.

Conflict of Interest: Hanne Storm MD. PhD, Associate Professor, Medical Faculty, University of Oslo, is also CEO and co-owner of Med-Storm Innovation that has developed the Skin Conductance equipment used in this study. She contributed to the preparation of the manuscript.

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