Pain management during the Covid-19 shorter the duration of ICU stay and decreases the mortality rate. Real time pain management should replace time consuming observational pain scores when the health care givers need to save time due to increased workload and sick leave. The PainMonitor device from Med-Storm Innovation AS meets the demand of improved pain management.

By Professor Hanne Storm MD.PhD and CEO Med-Storm Innovation AS.

Content:

A. Importance of pain assessment during critical care

Procedural pain is a frequent problem in intensive care units (ICUs). Pain, the 5th vital sign, is mandatory to assess and treat. Intensive care is a health specialty dedicated to multidisciplinary management of patients with acute organ dysfunction (1). The main objective of intensive care is to prevent further physiologic deterioration by the treatment and solution of acute and/or severe diseases and to save life during a life-threatening condition (1). ICUs are organized to meet the needs of these critically ill and mechanically ventilated patients, once their care involves a specific physical space, with support, monitoring technology, and specialized human resources (2). In ICUs, three important concepts are commonly in focus: pain, agitation and delirium (3) Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (3,4). Agitation and anxiety commonly occur in ICUs and are associated with adverse clinical outcomes, such as hypoxemia, hypotension, and/or withdrawal from alcohol and other substances (3). Lastly, delirium is known as “an acute onset of brain dysfunction, characterized by level of consciousness disturbance and cognition changes (memory deficit, disorientation, language disturbance) (3). Despite pain, delirium and agitation are interconnected, pain is the most neglected sign in ICUs. Analgesics and sedatives are medicines commonly used in ICUs with the objective to maintain comfort, relieve anxiety, facilitate care and adapt patients to ventilatory support (5). Some sedation protocols emphasize lighter use of sedatives for mechanically ventilated patients, daily sedation interruption and analgesia based on sedation protocols, which means that

analgesic administration occurs and then adding sedation if required (6–12). Currently, clinicians observed that the primary goal in ICUs should be pain and discomfort control, and then, if necessary, sedation should be performed. To achieve this goal, analgo-sedation protocols have been developed and applied in ICU patients (12). Analgo-sedation protocols that have been introduced into practice decrease duration of invasive mechanical ventilation (IMV), ventilator-associated pneumonia incidence and improve the probability of successful extubation (13–15). Pain in critically ill and mechanically ventilated patients have been studied over the last 20 years, even though pain is still present in about 50% of these patients (3). It has been reported that 29% of patients remembered pain in ICU, especially after invasive procedures (16). Another study reported an occurrence of severe pain in 63% of the surgical patients (17). All ICU patients require optimal pain medication.

One of the main causes of pain in the ICU is the medical procedures, unavoidable and necessary actions that are responsible for changes in pain intensity compared to rest (18). A study performed in Europe (The Europain® Study) observed the increase on pain intensity during (12) procedures, such as chest tube removal, peripheral intravenous insertion, wound care, mobilization, positioning, respiratory exercises and others (18). Among these routine activities, tracheal suctioning was considered the most painful, responsible for certain behaviors (grimace, facial responses and clenched fists) and changes on physiological parameters (18,19). Inadequate procedural pain treatment is a problem in the ICU, and inadequate treatment of this sign remains as a lack in the clinical setting (3). Barriers on pain management are associated to difficulties on assessment, since pain has a subjective nature and it is understood as a variable that can be measured only when reported by the person experiencing it (3). The majority of patients undergoing intensive care are unable to self-report their pain because of low consciousness levels, sedatives or neuromuscular blocking agents use and IMV (3,20) From the observation of these subjects unable to self-report, the International Association for the Study of Pain (IASP) registered that “the inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment” (4). For that, pain assessment has been increasingly introduced to the ICU professional’s routine and studies have been developed to show the relevance of measuring this sign in critically ill patients. A large number of instruments can be used for pain assessment of unconscious and mechanically ventilated patients. It is based on behaviors, observation, physiological parameters, and other body signs that can indicate nociception (21,22). However, it is agreed that these physiological indicators lack specificity in the ICU and can be influenced by many medications (vasopressors, adrenergic blockers, anti-arrhythmics, and sedative drugs) and pathological conditions (sepsis, shock, hypoxia, and fear) (23).

The high doses of analgesics and sedatives for the treatment of pain and anxiety have been associated to delirium, a predictor for death and prolonged need for ventilation. Some patients who recover from critical illness may suffer from long-term psychological disturbance such as posttraumatic stress disorder, anxiety, or depression. Various assessment tools have been used for assessment of pain and sedation in ICU. Acute pain assessment scores based on behavioral state and physiological responses in critically ill ICU patients are influenced by sedatives and neuromuscular blockade.

Med-Storm Innovation AS, www.med-storm.com including reference list, hereby wants to address how the PainMonitor device, the Skin Conductance Algesimeter, meets the required pain assessment for adult intensive care unit patients. During the Covid-19 crisis, reduced time in the ICUs due to improved pain management is of high importance.

To summarize: Med-Storm Innovation AS has the only Algesimeter device based on the principles of skin conductance changes. The Skin Conductance Algesimeter (SCA) measures painful stimuli more specific and sensitive than heart rate, heart rate variability and blood pressure because it measures directly skin sympathetic nerve activity (acetyl choline acting on muscarinic receptors) mirrored by changes in conductance palmary and plantar. The SCA is not influenced from changes in blood circulation or respiration. SCA yields reliable results unaffected by temperature, heart disease (e.g. heart arrythmia, hypertension, lung disease and blood circulatory changes (e.g. during sepsis and ECMO treatment), as well as medications that influence the blood circulation like epinephrines, beta-blockers and the hypotensive effect of alfa 2-agonists. Muscle relaxantia (acting on nicotine receptors) does not influence the SCA. SCA is assessed in real time, reacts immediately (1-2 sec delay) and has very low variation between individuals when they are at the same pain level. Physiological communication of pain by SCA is targets for patients during sedation, patients post-operative, and patients at the intensive care unit. 350 studies regarding acute pain and skin conductance changes have been performed in US, Australia and Europe. On the Skin Conductance Algesimeter device more than 70 supportive validation studies have been performed and three supportive theses showing how the technology can be used to assess pain and nociceptive stimuli. The SCA is influenced from the size of the painful stimulus because it acts through a nociceptive spinal reflex, and therefore not influenced from anxiety, different from the reported pain which is strongly influenced by anxiety. The real time data can be stored with comments and easily transported to excel for research purposes.

It is evidenced that the establishment of pain assessment protocols is responsible for better pain management, more efficient use of analgesics and/or sedatives, decrease in IMV duration, increased odds for weaning from IMV, lower risk of ventilator-associated pneumonia, central catheter-related infections, urinary tract infections, and bacteremia development, shorter duration of ICU stay and decrease in agitation events and mortality rate (24–26). Based on those positive outcomes, pain assessment is considered a strategy for a better ICU care, both for patients and to save costs for the hospitals (27).

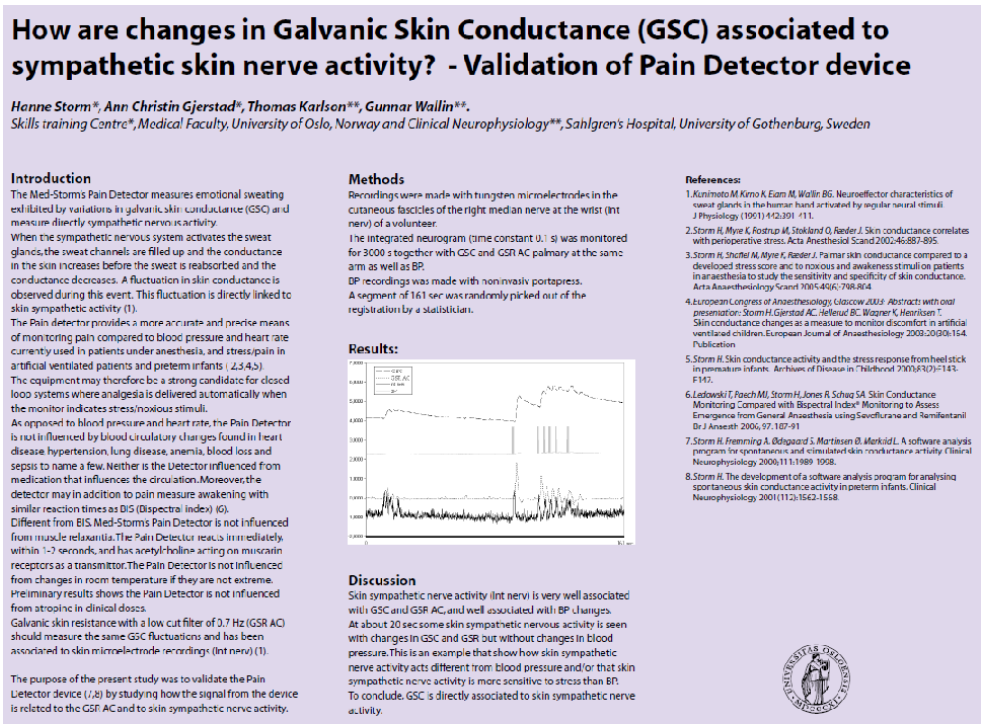
References

1. Marshall JC, Bosco L, Adhikari NK, et al. What is an intensive care unit? A report of the task force of the World Federation of Societies of Intensive and Critical Care Medicine. *J Crit Care*. 2017;37:270–276.
2. Ferri M, Zygun DA, Harrison A, Stelfox HT. Evidence-based design in an intensive care unit: End-user perceptions. *BMC Anesthesiol*. 2015;15(1):57.
3. Barr J, Fraser GL, Puntillo K, et al. Clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the intensive care unit. *Crit Care Med*. 2013;41(1):263–306.
Merskey H, Bogduk N. Part III pain terms, a current list with definitions and notes on usage. *Classification of chronic pain-descriptions of chronic pain syndromes and definitions of pain terms*. Seattle: International Association for the Study of Pain: IASP Press; 1994:207–214.
5. Mehta S, Burry L, Martinez-Motta JC, et al. A randomized trial of daily awakening in critically ill patients managed with a sedation protocol: A pilot trial. *Crit Care Med*. 2008;36(7):2092–2099.
6. Burchardi H. Aims of sedation/analgesia. *Minerva Anestesiol*. 2004;70(4):137–143.
7. Egerod I. Cultural changes in ICU sedation management. *Qual Health Res*. 2009;19(5):687–696.
8. Egerod I, Christensen BV, Johansen L. Trends in sedation practices in Danish intensive care units in 2003: a national survey. *Intensive Care Med*. 2006;32(1):60–66.
9. Mattia C, Savoia G, Paoletti F, et al. SIAARTI recommendations for analgo-sedation in intensive care unit. *Minerva Anestesiol*. 2006;72(10):769.
10. Sessler CN, Varney K. Patient-focused sedation and analgesia in the ICU. *Chest*. 2008;133(2):552–565.

11. Strom T, Martinussen T, Toft P. A protocol of no sedation for critically ill patients receiving mechanical ventilation: a randomised trial. *Lancet*. 2010;375(9713):475–480.
12. Egerod I, Jensen MB, Herling SF, Welling K-L. Effect of an analgosedation protocol for neurointensive patients: a two-phase interventional non-randomized pilot study. *Crit Care*. 2010;14(2):R71.
13. Arias-Rivera S, del Mar Sanchez-Sanchez M, Santos-Diaz R, et al. Effect of a nursing-implemented sedation protocol on weaning outcome. *Crit Care Med*. 2008;36(7):2054–2060.
14. Marshall J, Finn CA, Theodore AC. Impact of a clinical pharmacist-enforced intensive care unit sedation protocol on duration of mechanical ventilation and hospital stay. *Crit Care Med*. 2008;36(2): 427–433.
15. Quenot J-P, Ladoire S, Devoucoux F, et al. Effect of a nurse-implemented sedation protocol on the incidence of ventilator-associated pneumonia. *Crit Care Med*. 2007;35(9):2031–2036.
16.Playfor S, Thomas D, Choonara I. Recollection of children following intensive care. Arch Dis Child 2000;83:445-8.
17. Puntillo KA, Stannard D, Miaskowski C, Kehrle K, Gleeson S. Use of a pain assessment and intervention notation (P.A.I.N.) tool in critical care nursing practice: Nurses' evaluations. Heart Lung 2002;31:303-14.
18. Puntillo KA, Max A, Timsit J-F, et al. Determinants of procedural pain intensity in the intensive care unit. The EuropainR study. *Am J Respir Crit Care Med*. 2014;189(1):39–47.
19. Arroyo-Novoa CM, Figueroa-Ramos MI, Puntillo KA, et al. Pain related to tracheal suctioning in awake acutely and critically ill adults: a descriptive study. *Intensive Crit Care Nurs*. 2008;24(1):20–27.
20. Shannon K, Bucknall T. Pain assessment in critical care: what have we learnt from research. *Intensive Crit Care Nurs*. 2003;19(3):154–162.
21. Joffe AM, Hallman M, Gelinas C, Herr DL, Puntillo K. Evaluation and treatment of pain in critically ill adults. *Semin Respir Crit Care Med.* 2013;34(2):189–200.
22. Morone NE, Weiner DK. Pain as the fifth vital sign: exposing the vital need for pain education. *Clin Ther*. 2013;35(11):1728–1732.
23. Hamill-Ruth RJ, Marohn ML. Evaluation of pain in the critically ill patient. Crit Care Clin 1999;15:35-54, v-vi.
24. Georgiou E, Hadjibalassi M, Lambrinou E, Andreou P, Papathanassoglou EDE. The impact of pain assessment on critically ill patients' outcomes: a systematic review. *Biomed Res Int*. 2015;2015(2):1–18.
25. Olsen BF, Rustoen T, Sandvik L, Jacobsen M, Valeberg BT. Results of implementing a pain management algorithm in intensive care unit patients: The impact on pain assessment, length of stay, and duration of ventilation. *J Crit Care*. 2016;36:207–211.
25. Payen J-F, Bosson J-L, Chanques G, Mantz J, Labarere J. Pain assessment is associated with decreased duration of mechanical ventilation in the intensive care unit: a post hoc analysis of the DOLOREA study. *Anesthesiol*. 2009;111(6):1308–1316.
27. Azevedo IF, Josimari S, DeSantana M. Pain measurement techniques: spotlight on mechanically ventilated patients. Journal of Pain Research. Journal of Pain Research 2018:11 2969–2980:

B. Validation how the Number of Skin Conductance responses, the Skin Conductance Algesimeter index, assess skin sympathetic nerve activity and pain:

B1. Gjerstad AC, Storm H, Wallin G. Evaluation of the skin conductance method by using microneurographi, abstract, ISAP, Chicago 06. Presentation sympathetic nervous system (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED):



How are changes in Galvanic Skin Conductance (GSC) associated to sympathetic skin nerve activity? - Validation of Pain Detector device

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Introduction

The Med-Storms Pain Detector measures emotional sweating exhibited by variations in galvanic skin conductance (GSC) and measure directly sympathetic nervous activity.
When the sympathetic nervous system activates the sweat glands, the sweat channels are filled up and the conductance in the skin increases before the sweat is reabsorbed and the conductance decreases. A fluctuation in skin conductance is observed during this event. This fluctuation is directly linked to skin sympathetic activity (1).
The Pain detector provides a more accurate and precise means of monitoring pain compared to blood pressure and heart rate currently used in patients under anesthesia, and stress/pain in artificial ventilated patients and preterm infants (2,3,4,5).
The equipment may therefore be a strong candidate for closed loop systems where analgesia is delivered automatically when the monitor indicates stress/noxious stimuli.
As opposed to blood pressure and heart rate, the Pain Detector is not influenced by blood circulatory changes found in heart disease, hypertension, lung disease, anemia, blood loss and sepsis to name a few. Neither is the Detector influenced from medication that influences the circulation. Moreover, the detector may in addition to pain measure awakening with similar reaction times as BIS (Bispectral Index) (6).
Different from BIS, Med-Storms Pain Detector is not influenced from muscle relaxantia. The Pain Detector reacts immediately, within 1-2 seconds, and has acetylcholine acting on muscarin receptors as a transmitter. The Pain Detector is not influenced from changes in room temperature if they are not extreme.
Preliminary results shows the Pain Detector is not influenced from atropine in clinical doses.
Galvanic skin resistance with a low cut filter of 0.7 Hz (GSR AC) should measure the same GSC fluctuations and has been associated to skin microelectrode recordings (Int nervi) (1).

The purpose of the present study was to validate the Pain Detector device (7,8) by studying how the signal from the device is related to the GSR AC and to skin sympathetic nerve activity.

Methods

Recordings were made with tungsten microelectrodes in the cutaneous fascicles of the right median nerve at the wrist (Int nerv) of a volunteer.
The integrated neurogram (time constant 0.1 s) was monitored for 3000 s together with GSC and GSR AC palmary at the same arm as well as BP.
BP recordings was made with non invasiv portapress.
A segment of 161 sec was randomly picked out of the registration by a statistician.

Results:

Discussion

Skin sympathetic nerve activity (Int nervi) is very well associated with GSC and GSR AC, and well associated with BP changes.
At about 20 sec some skin sympathetic nervous activity is seen with changes in GSC and GSR but without changes in blood pressure. This is an example that show how skin sympathetic nerve activity acts different from blood pressure and/or that skin sympathetic nerve activity is more sensitive to stress than BP.
To conclude, GSC is directly associated to skin sympathetic nerve activity.

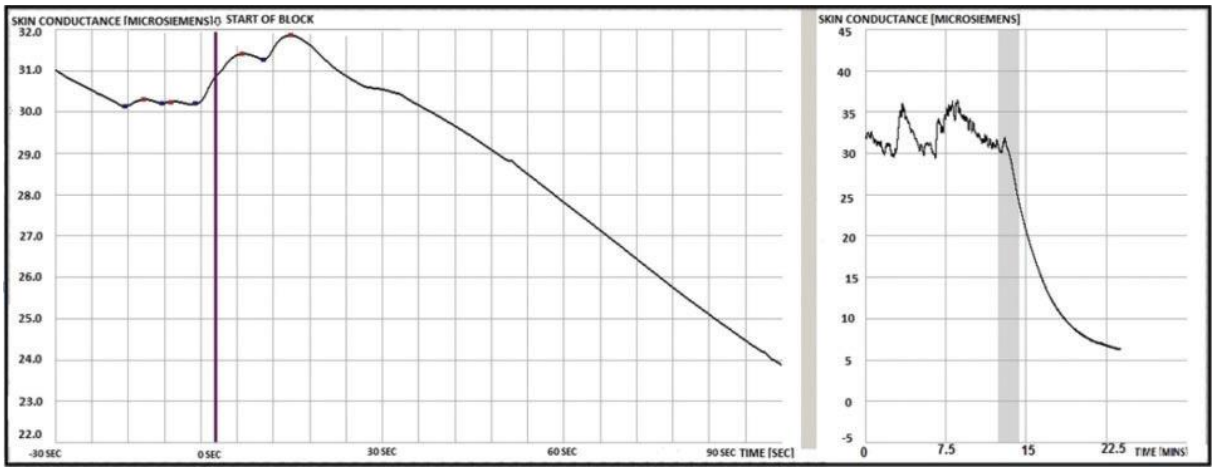
References:

1. *Kunimoto M, Kimo K, Eam M, Wallin BG.* Neuroeffector characteristics of sweat glands in the human hand activated by regular neural stimuli. J Physiology (1961) 442:101-111.
2. *Storm H, Myre K, Rostrup M, Stokland O, Raeder J.* Skin conductance correlates with perioperative stress. Acta Anesthesiol Scand 2002;46:887-895.
3. *Storm H, Shoftel M, Myre K, Raeder J.* Palmar skin conductance compared to a developed stress score and to noxious and awakeness stimuli on patients in anaesthesia to study the sensitivity and specificity of skin conductance. Acta Anaesthesiolog Scand 2005;49(6):798-804.
4. *European Congress of Anaesthesiology, Glascow 2005: Abstracts with oral presentation: Storm H, Gjerstad AC, Hellerud BC, Wagner K, Henriksen T.* Skin conductance changes as a measure to monitor discomfort in artificial ventilated children. European Journal of Anaesthesiology 2005;20(30):154. Publication
5. *Storm H.* Skin conductance activity and the stress response from heel stick in premature infants. Archives of Disease in Childhood 2001;83(2):F143-F147.
6. *Ledowski T, Paech MJ, Storm H, Jones R, Schug SA.* Skin Conductance Monitoring Compared with Bispectral Index® Monitoring to Assess Emergence from General Anaesthesia using Sevoflurane and Remifentanil. Br J Anaesth 2006; 97:107-91
7. *Storm H, Fremming A, Ødegaard S, Martinsen Ø, Markid L.* A software analysis program for spontaneous and stimulated skin conductance activity. Clinical Neurophysiology 2000;111:1989-1998.
8. *Storm H.* The development of a software analysis program for analysing spontaneous skin conductance activity in preterm infants. Clinical Neurophysiology 2001(112):1562-1568.

B2. Gungor S, Rana B, Fields K, Bae JJ, Mount L, Buschiazzo V, Storm H. Changes in the Skin Conductance Monitor as an End Point for Sympathetic Nerve Blocks. Pain Medicine 2017; 18: 2187–2197 (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED):

Abstract:

Objective. There is a lack of objective methods for determining the achievement of sympathetic block. This study validates the skin conductance monitor (SCM) as an end point indicator of successful sympathetic blockade as compared with traditional monitors.
Methods. This interventional study included 13 patients undergoing 25 lumbar sympathetic blocks to compare time to indication of successful blockade between the SCM indices and traditional measures, clinically visible hyperemia, clinically visible engorgement of veins, subjective skin temperature difference, unilateral thermometry monitoring, bilateral comparative thermometry monitoring, and change in waveform amplitude in pulse oximetry plethysmography, within a 30-minute observation period. Differences in the SCM indices were studied pre- and postblock to validate the SCM.
Results. SCM showed substantially greater odds of indicating achievement of sympathetic block in the next moment (i.e., hazard rate) compared with all raditional measures (clinically visible hyperemia, clinically visible engorgement of veins, subjective temperature difference, unilateral thermometry monitoring, bilateral comparative thermometry monitoring and change in waveform amplitude in pulse oximetry plethysmography; P £ 0.011). SCM indicated successful block for all (100%) procedures, while the traditional measures failed to indicate successful blocks in 16–84% of procedures. The SCM indices were significantly higher in preblock compared with postblock measurements (P< 0.005).
Conclusions. This preliminary study suggests that SCM is a more reliable and rapid response indicator of a successful sympathetic blockade when compared with traditional monitors.



Left: Detail of recording from the skin conductance monitor (SCM) showing the time period from when the sympathetic nerve block injection was given, start of block (time period 0), until when the block worked. Right: Overview of the skin conductance recording before, at the start of block, and after the block worked. The detail is from the gray area in the overview. The skin conductance responses disappear after the nerve block.

B3.Brain activity associated with the electrodermal reactivity to acute heat pain Dubé AA, Duquette M, Roy M, Lepore F, Duncan G, Rainville P. NeuroImage 45 (2009) 169–180. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS NOT USED - Electrodermal activity is the same as skin conductance activity).

Abstract.

Pain is associated with the activation of many brain areas involved in the multiple dimensions of the experience. Several of those brain areas may also contribute to the monitoring and regulation of autonomic activity but this aspect of pain responses has been largely overlooked in human imaging studies. This functional magnetic resonance imaging (fMRI) study relied on blood-oxygen level dependent (BOLD) signal to investigate subject-related differences in brain activity associated with the individual differences in electrodermal responses evoked by 30 s noxious (pain) and innocuous (warm) thermal stimuli. Pain-related activity (pain–warm) was found in the thalamus, somatosensory cortices (leg area of SI/MI, SII, and insula), the anterior cingulate cortex (ACC), and the amygdala. Brain activation related to stimulus-evoked electrodermal activity was identified by modeling the predicted BOLD responses with the magnitude of each subject's skin conductance reactivity. Subjects showing larger skin conductance reactivity to the innocuous and/or noxious stimuli displayed larger stimulus-evoked brain responses in the somato-motor cortices (SI/MI, SII, and insula), the perigenual and supracallosal ACC, the orbitofrontal cortex and the medulla. Further analyses revealed brain activation more specifically associated with the pain-related skin conductance reactivity in the supracallosal ACC, amygdala, thalamus, and hypothalamus. These findings demonstrate that individual differences in electrodermal reactivity partly reflect differences in pain-evoked brain responses, consistent with a role of these structures in the monitoring/regulation of pain-related autonomic processes.

B4. Günther AC, Schandl AR, Berhardsson J, Bjärtå A, Wållgren M, Sundin Ö, Alvarsson J, Bottai M, Martling CR, Sackey PV. Pain rather than induced emotions and ICU sound increases skin conductance variability in healthy volunteers. Acta Anaesthesiol Scand. 2016 Sep;60(8):1111-20. doi: 10.1111/aas.12751. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED)

Abstract

BACKGROUND:

Assessing pain in critically ill patients is difficult. Skin conductance variability (SCV), induced by the sympathetic response to pain, has been suggested as a method to identify pain in poorly communicating patients. However, SCV, a derivate of conventional skin conductance, could potentially also be sensitive to emotional stress. The purpose of the study was to investigate if pain and emotional stress can be distinguished with SCV.

METHODS:

In a series of twelve 1-min sessions with SCV recording, 18 healthy volunteers were exposed to standardized electric pain stimulation during blocks of positive, negative, or neutral emotion, induced with pictures from the International Affective Picture System (IAPS). Additionally, authentic intensive care unit (ICU) sound was included in half of the sessions. All possible combinations of pain and sound occurred in each block of emotion, and blocks were presented in randomized order.

RESULTS:

Pain stimulation resulted in increases in the number of skin conductance fluctuations (NSCF) in all but one participant. During pain-free baseline sessions, the median NSCF was 0.068 (interquartile range 0.013-0.089) and during pain stimulation median NSCF increased to 0.225 (interquartile range 0.146-0.3175). Only small increases in NSCF were found during negative emotions. Pain, assessed with the numeric rating scale, during the sessions with pain stimulation was not altered significantly by other ongoing sensory input.

CONCLUSION:

In healthy volunteers, NSCF appears to reflect ongoing autonomous reactions mainly to pain and to a lesser extent, reactions to emotion induced with IAPS pictures or ICU sound.

B5. Study to examine how reported pain is strongly influenced by anxiety: Storm H, Günther A, Sackey JP, Bernhardsson J, Bjärtå A. Measuring pain – physiological and self-rated measurements in relation to pain stimulation and anxiety. Acta Anaesthesiol Scand. 2019;1–8. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED)

Abstract

Introduction: The aim of the present study was to investigate how emotions influence pain, measured by one subjective self-rated measure, the numeric rating scale (NRS), and one objective physiological measure, the number of skin conductance responses (NSCR).

Method: Eighteen volunteers were exposed to conditions with pictorial emotional stimuli (neutral, positive, negative), authentic ICU-sound (noise, no-noise) and electrical stimulation (pain, no-pain) individually titrated to induce moderate pain. When using all combinations of picture inducing emotions, sound, and pain, each of these conditions (12 conditions lasting for 60 seconds each) were followed by pain ratings. Ratings of arousal (low to high) and valence (pleasant to unpleasant) were used as indicators of affective state for each condition. Mean NSCR was also measured throughout the experiment for each condition.

Results: Even though NRS and NSCR increased during painful stimuli, they did not correlate during the trial. However, NSCR was positively correlated with the strength of the electrical stimulation, r = 0.48, P = 0.046, whereas NRS showed positive correlations with the anxiety level, assessed by affective ratings (arousal, r = 0.61, P < 0.001, and valence, r = 0.37, P < 0.001).

Conclusions: The NRS was strongly influenced by affective state, with higher pain ratings during more anxiety-like states, whereas NSCR correlated to the strength of electrical pain stimulation. That

reported pain is moderated by anxiety, puts forward a discussion whether reduction of the anxiety level should be considered during analgesia.

C. Validation how the Number of Skin Conductance responses, the Skin Conductance Algesimeter index, assess pain in adult patients during intensive care:

Summary:

	Intubated patients	Non-intubated patients	Variables assessed	Stimuli/ Sensitivity and Specificity	Ski conductance responses per sec - Cut-off value moderate and severe pain to none and mild pain / increase during painful stimuli	Correlation sedation score
FDA protocol: Hansen J 2018 "Prospective observational study"		100	-Reported pain -Reported anxiety	Thorax drenage removal Sensitivity (true positive): During stimuli 86% Specificity (true negative): Before 89% After 91%	Cut off value 0.20 skin conductance responses per sec, increased during pain stimuli (P=0.000)	
Gunther AC 2013 "Prospective observational study"	20	20	-MAAS (sedation score) -Skin Conductance responses per sec -Reported pain	All stimuli routine performed in ICUs	Cut off value 0.20 skin conductance responses per sec for MAAS > 2*, increased during pain stimuli (P=0.000)	Yes, correlation with MAAS
Khanna P 2018 "Prospective observational study"	60		-HR -Blood pressure -Ramsay (sedation score)	-Suction from trachea -positioning	Increased during pain stimuli (P=0.000)	Yes, correlation with Ramsay
Aslanidis P 2018 «Prospective observational study"	25		-HR -Blood pressure -BIS -Respiratory rate -CPOT (pain score) -ANPS (pain score) -Ramsay (sedation score)	Pressure on nail bed	Increased during pain stimuli (P=0.000)	
Aslanidis P 2017 «Prospective observational study"	25		-HR -Blood pressure -Respiratory rate -Ramsay (sedation score) - CPOT	Suction from trachea Sensitivity (true positive): 88%.	Increased during pain stimuli (P=0.000)	
Aslanidis P 2018	25		-HR -Blood pressure -BIS -Respiratory rate -CPOT (pain score)	Arterial blood gas pooling	Increased during pain stimuli (P=0.000)	

			-Ramsay (sedation score)			

- MAAS 2 or less, the patients are well sedated and does not need more analgesia during painful stimuli.

C1.Hansen JO, Storm H, Boglino-Hörlin A, Le Guen M, Gayat E, Fischler M. Skin conductance as a pain assessment tool during chest tube removal: An observational study. Eur J Pain. 2017 Eur J Pain. 2017 Jul;21(6):987-996.

Abstract

Background: Skin conductance variability to assess pain has shown varying results. Skin conductance responses per second (SCR) during a standardized painful stimulus in awake adults may give further understanding of the method's validity. The purpose of this study was to validate the SCR with the visual analogue scale (VAS) for pain (P-VAS) and anxiety (A-VAS) during chest tube removal (CTR).

Methods: Ninety-five patients receiving epidural or non-epidural treatment, scheduled for CTR, were studied. Pain or anxiety was considered when VAS > 30 mm; the SCR cut-off value reflecting pain was ≥0.2 SCR.

Results: SCR values could not be recorded in eight cases before CTR, six cases during CTR and seven cases after CTR. CTR induced increases in SCR, P-VAS and A-VAS ($p < 0.001$). Seventy-seven percent of all pairs of P-VAS and SCR values were well-classified; P-VAS ≤ 30 mm and SCR < 0.2 or P-VAS > 30 mm and SCR ≥ 0.2. SCR obtained before CTR differentiates between patients with and without pain during CTR in all patients ($p = 0.04$) and in the subgroup of non-anxious patients ($p = 0.02$), but not in the subgroup of anxious patients. SCR obtained during CTR had similar values in patients with and without pain in all patients and in the subgroup of anxious patients, but in the subgroup of non-anxious patients SCR during CTR differentiates patients with and without pain ($p = 0.009$).
Conclusions: SCR increases during painful procedures. Preprocedural SCR may help predict reported pain in patients exposed to painful procedures. SCR during CTR differentiates between patients with and without pain only in non-anxious patients.

Significance: Preprocedural SCR may help predict reported pain in patients exposed to painful procedures. Procedural SCR accuracy improves in a subgroup of non-anxious patients. P-VAS is influenced by anxiety different from SCR.

Calculations of sensitivity, true positive was assessed during the painful events, and specificity, true negative was assessed before and after the painful events:

Sensitivity, true positive during the painful event: 86,9%

Specificity, true negative before the painful event: 91,0%

Specificity, true negative after the painful event: 88,1%

C2. Palmar skin conductance variability and the relation to stimulation, pain and the motor activity assessment scale in intensive care unit patients. Günther AC, Bottai M, Schandl AR, Storm H, Rossi P and Sackey PV. Critical Care 2013, 17:R51. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED)

Abstract

Introduction: Many intensive care unit (ICU) patients describe pain and other adverse feelings that may impact long-term psychological morbidity. Sympathetically mediated palmar skin conductance variability is related to emotionally induced perspiration and correlates with pain levels in the perioperative setting but has not been studied in ICU patients.

Methods: Twenty non-intubated and 20 intubated general ICU patients were included in this observational study. Patients were monitored with the MED-STORM Pain Monitoring System®. The number of skin conductance fluctuations per second (NSCF) was measured in parallel with bedside observation during one hour of intensive care, including rest, procedures and patient-staff interactions. Arousal-agitation level was monitored with the motor activity assessment scale (MAAS). Pain was monitored with the numeric rating scale (0 to 10) in patients able to communicate or by observation in patients unable to communicate.

Results: In non-intubated patients, NSCF increased with increasing stimulation/pain but also with higher MAAS (P = 0.002). An interaction effect was found, with increased NSCF response to stimulation/pain with increasing MAAS (P < 0.001).

In intubated patients, NSCF increased significantly with increasing stimulation/pain (P < 0.001). For intubated patients, increasing stimulation/pain was associated with increased NFSC for any given degree of stimulation in intubated patients.

Conclusions: In critically ill patients, NSCF may be more useful evaluating emotional distress rather than pain alone. Intubation by itself give high NFSC levels. It needs to be assessed whether NSCF monitoring is clinically useful and whether controlling emotional distress with the aid of such monitoring may impact on patient care and outcomes.

C3. Khanna P, CChandralekha[1], Ravinder Kumar Pandey RK, Sharma A. Pain assessment in the critically ill mechanically ventilated adult patients: Comparison between skin conductance algesimeter index and physiologic indicators Saudi J Anaesth. 2018; 12 (2), 204-208. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED).

Abstract

Background and Objectives: Critically ill patients are unable to communicate effectively, so it is difficult to assess their pain and analgesic requirement. Skin conductance algesimeter (SCA) index is a device that primarily measures changes in skin conductance real time to assess pain.

Methods: We planned this quantitative prospective observational study to assess pain in the critically ill mechanically ventilated patients in comparison to physiologic indicators such as blood pressure and heart rate. A repeated measures design was chosen, and a sample size of 180 was taken from 60 patients with sepsis, acute exacerbations of chronic obstructive

pulmonary disease, community-acquired pneumonia, and postsurgical patients in the Intensive Care Unit (ICU). The two painful procedures chosen were tracheal suction and patient positioning. The data were collected at rest, at tracheal suctioning, 20 min later at positioning of the patient, and final reading 20 min later. Three testing periods, each including 4 assessments for a total of 12 pain assessments with sixty patients, were completed during each patient's ICU course. A total of six assessments were done with the patient at rest and three each with pain stimulus of tracheal suctioning and patient positioning.
Results: There was a significant increase in both hemodynamic variables during painful procedures except for the heart rate during positioning. The correlation between the SCA index and Ramsay scale was negative and significant.
Conclusions: This instrument might prove useful to measure pain in uncommunicative critically ill patients and to evaluate the effectiveness of analgesic treatment and adapt it.

C4. Aslanidis T, Grosomanidis V, Karakoulas K, Chatzisotiriou A. Electrodermal Activity Monitoring during Endotracheal Suction in Sedated Adult Intensive Care Unit Patients. Folia Med (Plovdiv) 2018;60(1):92-101. doi: 10.1515/folmed-2017-0063 *(THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED).*

Abstract

Background: Endotracheal suctioning of respiratory secretions is one of the most common causes of pain and discomfort in Intensive Care Unit environment. The electrical properties of the skin, also known as electrodermal activity (EDA), are considered as an indirect measure of autonomous nervous system.
Aim: This study explores EDA changes during endotracheal suction in sedated adult critical care patients; and compares these changes to other monitoring parameters.
Materials and methods: Skin conductance variability, selected hemodynamic and respiratory parameters, bispectral index (BIS) and ambient noise level, were monitored during 4 hour routine daytime intensive care nursing and treatment in an adult Intensive Care Unit. 4h-measurements were divided into 2 groups, based upon the sedation level (group A: Ramsay sedation scale 2-4 and group B: 5-6 respectively) of the patients. Selected recordings before and after endotracheal suction (stress events) were performed. Seven stress events from Group A and 17 from Group B were included for further analysis. Patients' demographics, laboratory exams and severity scores were recorded. Pain status evaluation before every event was also performed via 2 independent observers.
Results: In both groups the rate of EDA changes was greater than in other monitoring parameters. Yet, in group A only selected parameters were significantly changed after the start of the procedure, while in group B, every parameter showed significant change ($p<0.05$). Groups were similar for other confounding factors.
Conclusion: EDA measurements are more sensitive to stress stimuli, than cardiovascular, respiratory or even BIS monitoring. Deeper sedation seems to affect more the intensity of EDA changes during suction.

Electrodermal activity is skin conductance activity.

C5. Aslanidis T Grosomanidis TAV, Karakoulas K, Chatzisotiriou A. Electrodermal Activity during Blood Pooling for Arterial Blood Gases Analysis in Sedated Adult. Intensive Care Unit Patients. Med. Sci. 2018, 6, 20; doi:10.3390/medsci6010020. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED).

Abstract:

Introduction-Aim: Electrodermal activity (EDA) is considered a measure of autonomous 19 nervous system activity. This study performed an exploratory analysis of the EDA changes during 20 blood pooling for arterial blood gas analysis in sedated adult critical care patients and correlated 21 the variations to other monitored parameters.
Methods: EDA, along with others parameters were 22 monitored during 4 hour routine daytime intensive care nursing and treatment in an adult ICU. 4h-23 Measurements were divided into 2 groups, based upon the sedation level. Selected recordings 24 before and after blood pooling for arterial blood gases analysis (stress event) was performed. Nine 25 stress events from Group A and 17 from Group B were included for further analysis. Patients' 26 demographics, laboratory exams and severity scores were recorded.
Results: For both sedation 27 levels, EDA changes are much greater than any other monitoring parameters used. The changes are 28 noticed in both measurement (15sec and 60sec), even though in the 60sec measurement only selected 29 EDA parameters are significantly changed after the start of the procedure.
Conclusion: EDA 30 measurements are more sensitive to given stress event, than cardiovascular or respiratory 31 parameters. However, moe studies are needed in order to identify the real stress-load and clinical 32 significance of such stimuli, which are considered otherwise painless in those patients.

Electrodermal activity (EDA) is skin conductance activity.

C6. Aslanidis T, Grosomanidis V, Karakoulas K, Chatzisotiriou A. Electrodermal Activity Monitoring During Painful Stimulation in Sedated Adult Intensive Care Unit Patients: a Pilot Study. Acta Medica (Hradec Králové) 2018; 61(2): 47–52. https://doi.org/10.14712/18059694.2018.50. (THE MED-STORM INNOVATION PAIN MONITOR DEVICE WAS USED)

ABSTRACT

Introduction-Aim: Newer methods, such as infrared digital pupillometry and electrodermal activity (EDA) measurement have been suggested as good alternatives for analgesia monitoring in critically ill patients. This study analyzed EDA changes due to pain stimulus in sedated adult critical care patients
Methods: Skin conductance variability, selected hemodynamic and respiratory parameters, Bispectral index (BIS) and ambient noise level, were monitored during 4 hour routine daytime in an adult ICU. 4h-Measurements were divided into 2 groups, based upon the sedation level of the patients: Group A – Ramsay Sedation Score 2–4 and Group B – Ramsay Sedation Score of 5–6. Selected recordings before and after pain stimulus were performed. The stimulus chosen was the pressure applied to nail bed for 10 sec, which was performed routinely during neurological examination. Patients' demographics, laboratory exams and severity scores were recorded. Pain status evaluation before every event was also performed by 2 independent observers via Critical Care Pain Observation Tool (CPOT) and Adult Non Verbal Pain Score (ANVPS) Results: In both groups the rate of EDA changes was greater than other monitoring parameters: more in Group A than in Group B. Yet, the difference between groups was not statistically significant.
Conclusion: EDA measurements are greater to pain stimuli, than cardiovascular, respiratory or even BIS monitoring. These encouraging results suggest that, further studies are needed to better define EDA role in ICU.

Electro dermal activity (EDA) is skin conductance activity.

D. Three theses focusing on the Med-Storm Innovation Pain Monitor device during intensive care:

D1. Anders Günther MD. PhD. From Department of Physiology and Pharmacology Karolinska Institutet, Stockholm, Sweden: SKIN CONDUCTANCE VARIABILITY AND STRESSFUL EXPOSURES IN CRITICAL CARE (ADULTS).

D2. Ann Christin Gjerstad MD.PhD. From the Institute of Clinical Medicine, Medical faculty, University of Oslo, Oslo, Norway. IS SKIN CONDUCTANCE A PREDICTOR OF AROUSAL, NOXIOUS STIMULI AND PAIN IN THE SEDATED AND ANESTHETIZED PATIENT (ADULTS AND CHILDREN).

D3. The full text of Aslanidis T thesis about EDA (skin conductance activity) in ICU patients (adults) can be found in the National Archive of PhD Theses in the following link https://www.didaktorika.gr/eadd/handle/10442/43587 In the full text, you can find the full data; not only from the papers published; but also more data that was included in the these but were not published. Data are presenting for pp150-232 with this order:

1. **Diagram of the whole project.**
2. **Workload of the project**
3. **Descriptive variables of the two groups in details**
4. **Sound stimul data**
5. **Suction data**
6. **Pain data**
7. **Other stimuli**