

A N I

by



Highlights



“Finding an objective pain monitoring is an increasing need during the perioperative time. Measuring the parasympathetic tone can help clinicians deal with it.”

Analgesia Nociception Index (ANI)

INTRODUCTION

A major aim of modern medicine is to alleviate pain, which has always been difficult to qualify, quantify and treat adequately.

As pain results from the conscious integration of its pathophysiological substrate called nociception, self-assessment methods are subject to high inter- and intra-patient variability.

Recent developments in anaesthesia have improved our knowledge of the pathophysiology of nociception and pain.

Opioids are among the most effective treatments of acute pain but are plagued with numerous side effects.

Overdosing opioids has been related to:

- Respiratory depression
- Homeostasis and electrolytic imbalance
- Natural killer cells immunosuppression
- Intestinal mobility problems
- Post-operative hyperalgesia.

While underdosing has been related to:

- Hemodynamic instability
- Homeostasis imbalance
- Increased catabolic activity
- Delayed wound healing

Both overdosing and underdosing of opioids have therefore direct consequences on the well being and the healing capabilities of patients.

Opioids are the most related drugs to side effects in the hospital area

- Opioids are the drugs with the higher interaction level with the other ones.
- 1 per 200 patients is suffering from respiratory depression due to an over administration of opioids.
- The Joint Commission stated (out of recordings done since 2004) that from the adverse effects including death:
 1. 47% are due to overdosing
 2. 29% are due to a lack of monitoring
 3. 11% are due by other factors

More than 2000 publications known since 1960 made evidence that Signals related to the Autonomous Nervous System should be analysed to get monitors that give the objective information about nociception.

The ANI monitor has been launched after 23 years of academic research by the Cic-It 1403 INSERM "Biosensors and E-Health", University Hospital of Lille, France, an INSERM laboratory for innovations.

The ANI technology is based on Heart Rate Variability (HRV) analysis, which allows measuring the parasympathetic (paraS) tone of the patient.

This technology allows clinicians to personalize analgesics drugs administration in order to avoid underdosing as well as overdosing, hence limiting the risk of a prolonged healing process.

1. FUNDAMENTALS

ANI is based on Heart Rate Variability (HRV) analysis, which is a way to measure the effect of Respiratory Sinus Arrhythmia (RSA) on Heart Rate through the paraS reflex loop (figure 1).

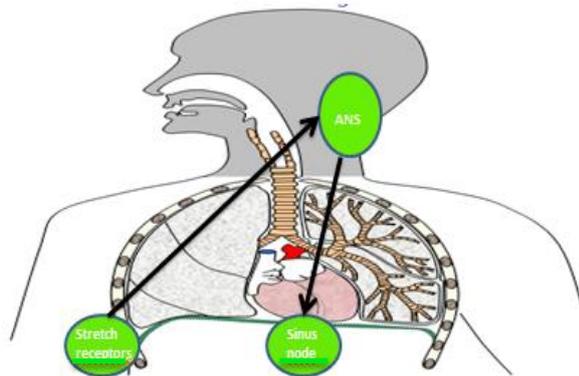


Figure 1 : schematic representation of the paraS reflex loop : from bronchiolar stretch to the vagus node (brain stem) and to the sinus node in the heart

RSA is present in all mammals and in humans in particular. Bronchiolar stretch is communicated to the vagus node in the brain stem and leads to a short upheaval of paraS tone, which is transmitted to the sinus node in the heart and induces a shortening of the RR interval, i.e. an increase of heart rate. The reason of the existence of this loop is due to its ability to optimize the blood flow through the inflated lungs during each inspiratory cycle.

RSA has been long shown to be a means to measuring paraS tone variations in animals as well as humans.

The ANI technology measures RSA, displays it as a normalized measure and quantifies it.

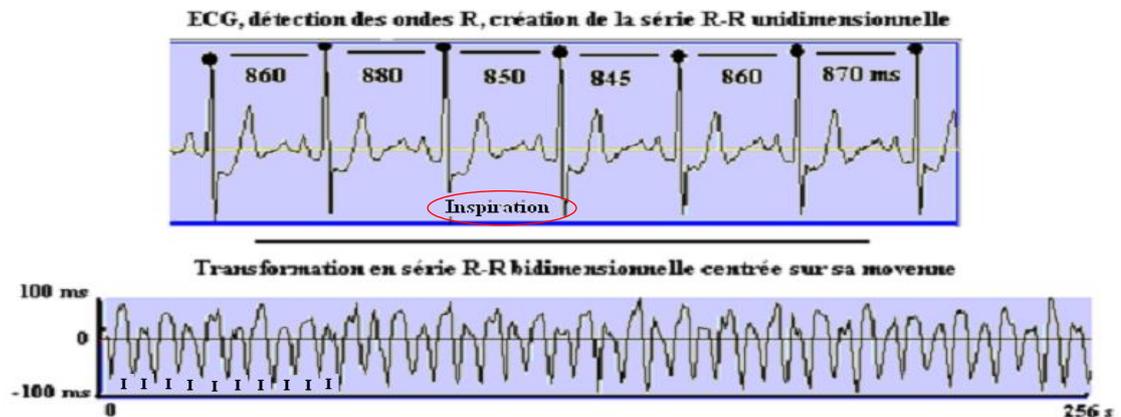


Figure 2 : upper panel : ECG with R wave detection ; lower panel : RR series with Inspiratory cycles marks as I

The ECG signal:

R waves are detected, ectopic beats are automatically corrected, the mean RR is subtracted after band pass filtering and the result is normalized, thus leading to a normalized RR series centred on 0. The RR shortenings related to inspiratory cycles are clearly visible (fig. 2, 3 and 4).

This spectral analysis leads to:

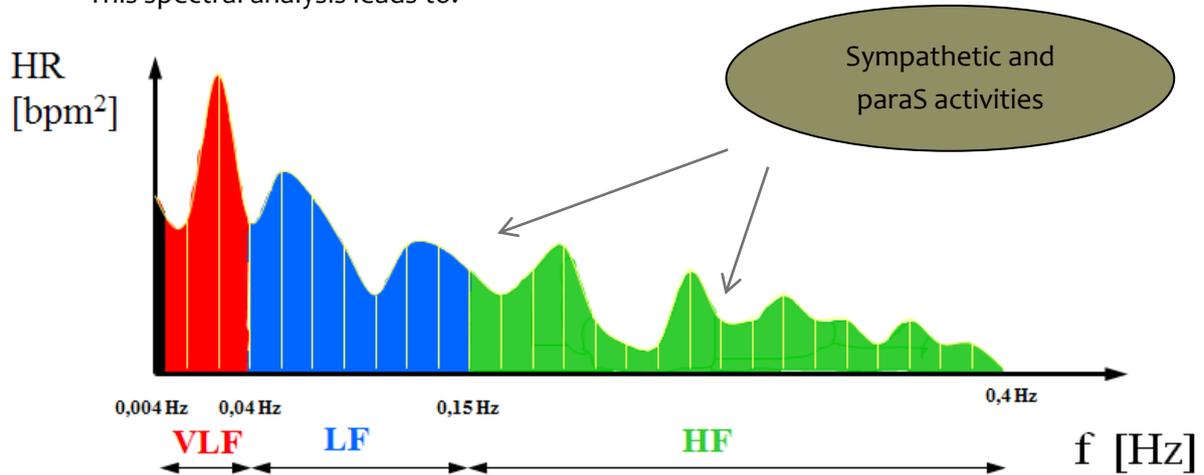


Figure 3 : spectral content of RR series <MJ : supprimer HR sur l'axe des ordonnées>

The VLF range from 0.004 to 0.04 Hz and corresponds to the thermoregulatory system and neuroendocrine activity.

The LF ranges from 0.04 to 0.15 Hz is influenced by sympathetic and parasympathetic activities

The HF ranges from 0.15 to 0.40 Hz and is only influenced by the paraS tone.

Using our innovating computing process are able to collect the frequencies from 0.15 to 0.4 hz to have a pure signal related to the parasympathetic activity while the other ranges have frequencies with information from different factors and activities.

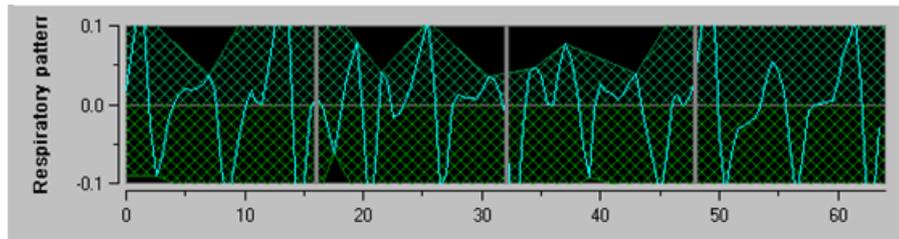


Figure 4 : normalized RR series as displayed continuously by the PhysioDoloris and the ANI monitors

The green gridded surface in figure 4 measures continuously the importance of RSA in a patient. It is automatically measured by detecting the upper and lower envelopes of the RR series. The more paraS tone there is, the greater the surface, because RSA is directly related to the amount of paraS tone present.

Because of the normalization process, the maximum possible surface of RSA is $0.2 \times 64 = 12.8$ sec. This enables to obtain an index comprised between 0 and 100 by simply dividing the measured surface by 12.8 (fig. 5).



Figure 5: maximum possible RSA surface, leading to an index comprised between 0 and 100: $ANI = 100 * AUC_{tot,nu} / 12.8^1$

There are no hidden details in the ANI computing process.

The values are updated every second. The yellow index (ANII), is directly influenced by the surgeon's induced nociception and is directly related to the patient's reactions.

¹ Ref Publication IEEE 2006, R. Logier, M. Jeanne ... « Pain/Analgesia Evaluation using heart rate variability »

2. SENSOR

POSITION

The ANI monitor collects the signal with specific ECG electrodes for the monitor. Its position must be appropriate to collect a correct ECG channel. It can be placed on the chest or in the back as follows:

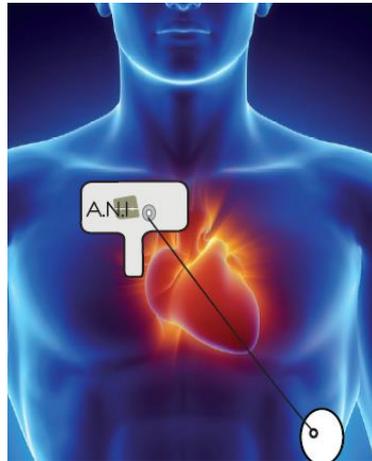


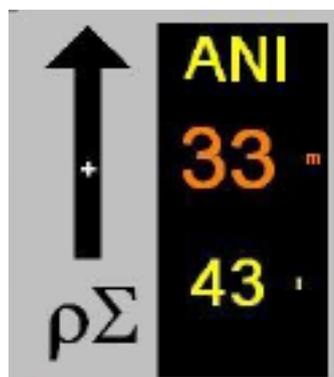
Figure 6 : placement of ANI electrodes on the chest or on the back of the patient

A waterproof adhesive covering the electrodes can help avoid losing the signal in case excessive moisture reaches the electrodes.

After two minutes of calibration, the ANI number appears in yellow on the monitor and will vary in case of reaction. As the monitor is extremely precise and sensitive, even small changes in ANI can be observed after mild stimulations are applied to the patient, such as the cold of iodine or the electric stimulation of a myorelaxation monitor.

In addition to the yellow ANIi value, the monitor displays also an orange value for ANIm, which results from a 2 min averaging of the ANIi signal and is the value that has been shown to be of interest for the titration of analgesia.

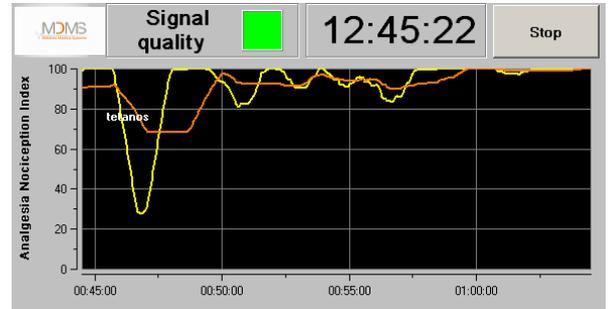
In conclusion, orange ANIm shows analgesia's effects on a patient, while yellow ANIi shows the patient's reactions to the nociception induced by the surgeon's activity.



3. HOW TO USE THE PARAMETER?

It is usual that the yellow ANIi will cross the orange ANIm on the trends.

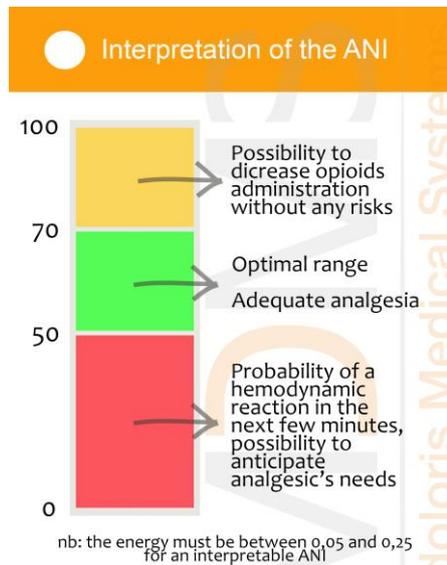
Clinical studies have so far demonstrated that keeping ANIm in the [50-70] range could benefit the patient in avoiding unwanted hemodynamic events such as hypertension and hypotension, tachycardia and bradycardia.



It is estimated that overdosing happens in average in a range of a 25% to 35% for all specialties, a correct monitoring will then avoid it.

In case the yellow ANIi decreases below 50, be aware that additional analgesia may be needed; there is time as long as the orange ANIm stays over 50, but a decreased ANIm below 50 when nociception is kept constant has been related to hemodynamic reactivity in the next 10 min.

In conscious patients, because anxiety is involved in pain feeling, studies have shown that a patient who has an ANIm over 58 is comfortable while one with an ANIm below 48 is in pain²²



²² Ref Publication BJA 2013, E. Boselli, M. Daniela-Ionescu ... «Prospective observational study of the non-invasive assessment of immediate postoperative pain using the analgesia/nociception index (ANI)»²²

4. LIMITATIONS:

Due to the fundamentals of HRV, because ANI technology is related to RSA,

- only sinus rhythm
- the absence of apnoea
- the absence of anticholinergic drugs

Can lead to a proper ANI measurement.

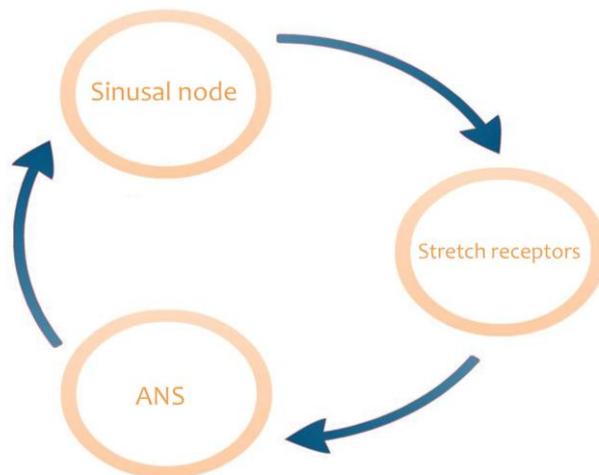
Beta-blockers don't interfere with ANI computation

Epinephrine and norepinephrine don't interfere with ANI computation most of the time, but to check the Energy of the RR series is good practice.

The Energy of the RR series is displayed in the expert mode and confirms the reliability of the indexes.

This value represents the spectral power of the entire ANS in the patient. The normal range is [0,05 to 2,5], Energy values outside this range lead to unreliable ANI values.

Diagram of the parasympathetic reflex loop



Mains limits :

- Atropine (20min) / Ephedrine (7min)
- A-Fib
- Patients with pacemaker
- Apnea
- Amines (check the energy : $0,05 < E < 2,5$)

5. PARAMETER VALIDATION

5.1 STUDIES HAVE SHOWN THAT ANI IS ABLE TO DETECT THE NOCICEPTION STIMULUS WITH A DOSE RESPONSE EFFECT, EVEN IN SITUATIONS WHERE HEMODYNAMIC IS KNOWN AS NEITHER SPECIFIC NOR SENSITIVE.

Abstract SFAR Congress, France, 2010

SFAR 2010 - Soumission de résumés

Anesthésie-douleur - Evaluation

ABS-1339

Evaluation de la balance analgésie nociception par la réactivité du diamètre pupillaire et la mesure de l'« analgesia nociception index » sous anesthésie générale

A. Lafanechère^{1*}, M. Jeanne^{1,2}, H. Lenci¹, A.-M. Debailleul¹, R. Logier², B. Tavernier¹

¹Anesthésie réanimation, ²Cic-It 807, CHRU LILLE, LILLE, France

	NoStim	TET 1	TET 2	TAP
FC (bpm)	57 (47-65)	56 (47-64)	51 (48-58) **	50 (48-53)
PAS (mmHg)	103 (95-112)	97 (89-110)	100 (87-108)	100 (88-105)
PAD (mmHg)	66 (60-71)	67 (60-72)	65 (59-70)	63 (58-65)
BIS	31 (27-36)	32 (28-35)	30 (26-35)	34 (30-40)
ANI (%)	99 (96-100)	65 (51-73) *	72 (65-87) **	63 (48-71) *
RDP (% de variation)		9 (2-16)	2 (1-6)	

TET1: remifentanyl Ce = 3 ng/ml (tetanic stimulus)

TET2: remifentanyl Ce = 6 ng/ml (Same tetanic stimulus)

Conclusion: The ANI parameter and the pupillometric analysis have correlated variations of the analgesia/nociception balance in response to standardized nociceptive stimuli non-detected by the hemodynamic common monitoring tools. Despite the pupillometric monitoring, ANI is simple, continuous and convenient to use.

5.2 STUDIES HAVE SHOWN THAT ANI IS AN EARLY DETECTOR OF HEMODYNAMIC RESPONSE DUE TO A LACK OF ANALGESIA:

Autonomic Neuroscience: Basic and Clinical 147 (2009) 91–96



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Autonomic Neuroscience: Basic and Clinical

journal homepage: www.elsevier.com/locate/autneu



Heart rate variability during total intravenous anesthesia: Effects of nociception and analgesia

Mathieu Jeanne^{a,b,c}, Régis Logier^b, Julien De Jonckheere^b, Benoît Tavernier^{a,c,*}

^a Pôle d'Anesthésie Réanimation, hôpital Roger Salengro, CHU de Lille, France

^b CIT 807 « Biocapteurs et eSanté », Institut de Technologie Médicale, CHU de Lille, France

^c Laboratoire de pharmacologie, EA 1046 – Faculté de Médecine, Université Lille II, IMPRT-IFR 114, France

Conclusions: The analgesia / nociception balance is a direct determinant of HRV during surgical anaesthesia. HFnu may behave like an early indicator of inadequate analgesia. These results have potential implication for monitoring adequacy of analgesia in healthy patients undergoing intravenous anaesthesia. Additional work is needed for application across patient populations.

5.3 STUDIES HAVE SHOWN THAT ANI IS ABLE TO DISCRIMINATE BETWEEN HEMODYNAMIC REACTIONS DUE TO NOCICEPTION WITH HEMODYNAMIC REACTIONS DUE TO ANOTHER CAUSE.

33rd Annual International Conference of the IEEE EMBS
Boston, Massachusetts USA, August 30 - September 3, 2011

Heart Rate Variability analysis for arterial hypertension etiological diagnosis during surgical procedures under tourniquet.

R. Logier, J. De jonckheere, M. Delecroix, A. Keribedj, M. Jeanne, R. Jounwaz, B. Tavernier

Conclusions: This study shows the ability of the ANI for the etiological diagnosis of hypertension during surgical procedures under tourniquet. The use of ANI during such surgical procedures could help the anaesthesiologist, reduce his decision time and avoid opioid overdose.

5.4 STUDIES HAVE SHOWN THAT ANI'S ACCURACY IS FAR MORE SENSITIVE AND SPECIFIC THAN OTHER AVAILABLE TECHNOLOGIES:

Pediatric Anesthesia

Pediatric Anesthesia ISSN 1155-5645

ORIGINAL ARTICLE

Pain monitoring in anesthetized children: first assessment of skin conductance and analgesia-nociception index at different infusion rates of remifentanyl

Nada Sabourdin, Michel Arnaout, Nicolas Louvet, Marie-Laurence Guye, Federica Piana & Isabelle Constant

Department of Anesthesiology, Armand Trousseau Hospital, AP-HP, UPMC, Paris, France

Conclusion: After the stimulation, ANI was significantly decreased compared with pre stimulation values for all remifentanyl infusion rates. This decrease was greater at $0.04 \mu\text{g}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$ than at the other infusion rates. Skin conductance, heart rate and blood pressure were not modified by the stimulations, whatever the dose of remifentanyl. ANI might provide a more sensitive assessment of nociception in anesthetized children than hemodynamic parameters or skin conductance.

5.5 STUDIES HAVE SHOWN THAT ANI STAYS RELIABLE EVEN IN SITUATIONS OF HIGH ANXIETY AND HIGH PAIN,:

International Journal of Obstetric Anesthesia (2012) 21, 146–151
0959-289X/\$ - see front matter © 2012 Elsevier Ltd. All rights reserved.
doi:10.1016/j.ijoa.2012.01.001



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www.obstetanaesthesia.com

ORIGINAL ARTICLE

The Analgesia Nociception Index: a pilot study to evaluation of a new pain parameter during labor

M. Le Guen,^a M. Jeanne,^b K. Sievert,^a M. Al Moubarik,^a T. Chazot,^a P.A. Laloë,^a J.F. Dreyfus,^c M. Fischler^a

^a Department of Anesthesiology, Hôpital Foch, Université of Versailles, Suresnes, France

^b Department of Anesthesiology, Intensive Care and Clinical Investigation Centre for Innovative Technology, CHRU Lille, France

^c Clinical Research Unit, Hôpital Foch, Université of Versailles, Suresnes, France

Conclusion: The Analgesia Nociception Index has an inverse linear relationship with visual analogical pain scores. Further studies are necessary to confirm the results of this pilot study and to look at the influence of epidural analgesia on the Analgesia Nociception Index.

5.6 STUDIES HAVE SHOWN THAT ANI CAN BE USED TO PREDICT THE LEVEL OF PAIN AFTER AWAKENING: AN ANI VALUE BELOW 50 BEFORE THE PATIENT WAKES UP PREDICTS A VAS OVER 3 IN PACU.

BJA Advance Access published December 8, 2013

British Journal of Anaesthesia Page 1 of 7
doi:10.1093/bja/aet407

BJA

Prediction of immediate postoperative pain using the analgesia/nociception index: a prospective observational study

E. Boselli^{1,2*}, L. Bouvet¹, G. Bégou¹, R. Dabouz¹, J. Davidson¹, J. -Y. Deloste¹, N. Rahali¹, A. Zadam¹ and B. Allaouchiche^{1,2}

¹ Department of Anaesthesiology and Intensive Care, Édouard Herriot Hospital, HCL, Lyon, France

² Claude Bernard Lyon I University, University of Lyon, Lyon, France

* Corresponding author: Hôpital Édouard Herriot, Service d'anesthésie-réanimation, 5 place d'Arsonval, 69003 Lyon, France.
E-mail: emmanuel.boselli@chu-lyon.fr

Conclusions: The measurement of ANI immediately before extubation after inhalation-remifentanyl anaesthesia was significantly associated with pain intensity on arrival in PACU. The performance of ANI for the prediction of immediate postoperative pain is good and may assist physicians in optimizing acute pain management.

5.7 STUDIES HAVE SHOWN THAT ANI IN CONSCIOUS PATIENTS IN PACU, IS CORRELATED WITH THE COMMON PAIN SCALES. THIS OBJECTIVE AND CONTINUOUS PARAMETER WILL HELP PHYSICIANS MANAGE OPIOID TITRATION IN PATIENTS UNABLE TO COMMUNICATE.

BJA Advance Access published April 16, 2013

British Journal of Anaesthesia Page 1 of 7
doi:10.1093/bja/aet110

BJA

Prospective observational study of the non-invasive assessment of immediate postoperative pain using the analgesia/nociception index (ANI)

E. Boselli^{1,2*}, M. Daniela-Ionescu¹, G. Bégou¹, L. Bouvet¹, R. Dabouz¹, C Magnin¹ and B. Allaouchiche^{1,2}

¹ Department of Anaesthesiology and Intensive Care, Édouard Herriot Hospital, Hospices Civils de Lyon, Lyon, France

² Claude Bernard Lyon I University, University of Lyon, Lyon, France

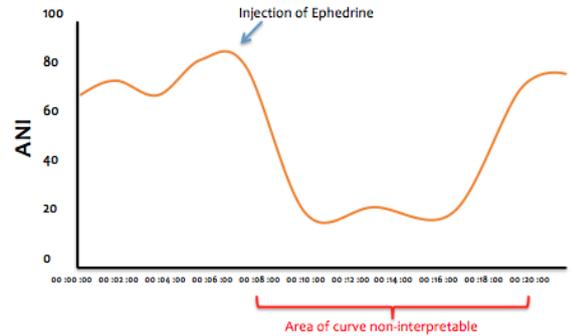
* Corresponding author: Service d'anesthésie-réanimation, Hôpital Édouard Herriot, 5 place d'Arsonval, 69003 Lyon, France.
E-mail: emmanuel.boselli@chu-lyon.fr

Conclusions: A measurement of ANI during the immediate postoperative period is significantly correlated with pain intensity. The measurement of ANI appears to be a simple and non- Examples how different drugs affect ANI values:

6. INTERACTION EXAMPLES

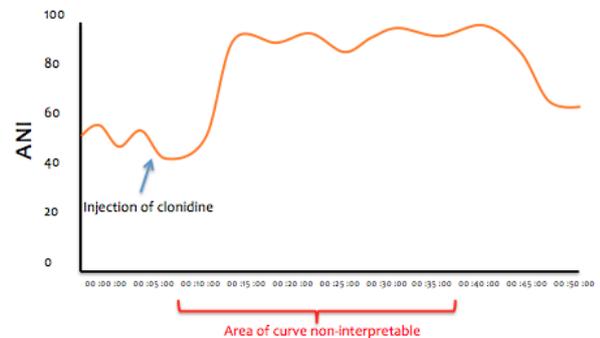
Ephedrine administration:

As a consequence of the Parasympatholytic effect of Ephedrine, ANI values drops and stays low as long as this drug is active (around 10 min). Energy decreases below 0,05, which means that ANI is not relevant during that period.



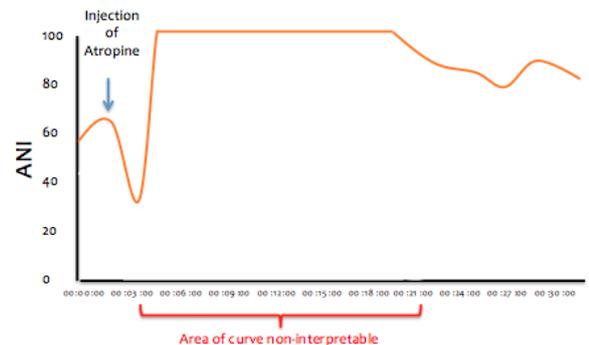
Alpha-2-agonists (Clonidine) administration:

Alpha 2 agonists are parasympathomimetic drugs that may increase ANI values (in case of clonidine during approx. 40 min).



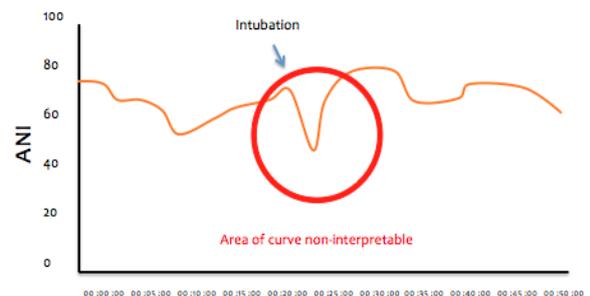
Atropine administration:

Atropine acts as a parasympaticolytic, leading to a drop in ANI. As it also interferes with the sinus node, it stops the influence of the vagus node there, which leads to a paradoxical effect, and an increased ANI (to approx. 100) until its effects weans off. The energy decreases below 0,05, meaning that ANI is not reliable during that period.



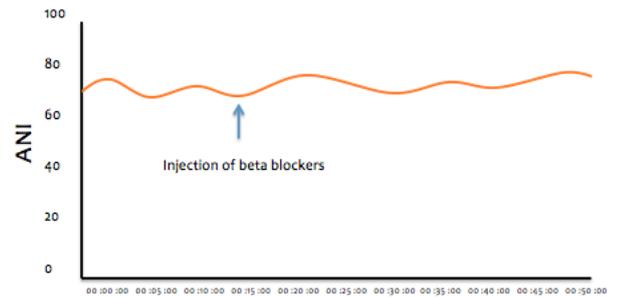
Intubation:

As intubation is made under apnoea, RSA disappears, so that ANI values are not reliable. The Energy decreases below 0,05, meaning that ANI is not reliable during that period.



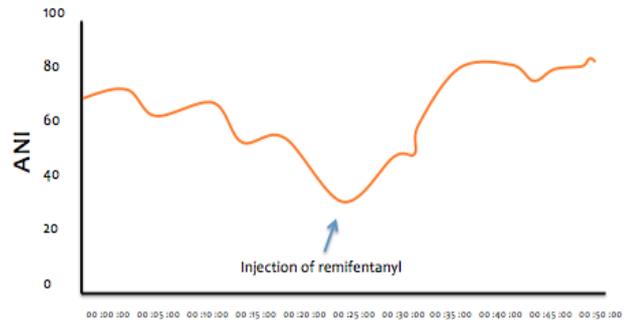
Beta-blockers administration:

Beta-blockers have no impact on ANI values as they do not interfere with the HRV but interfere with the heart rate variations (tachycardia – bradycardia).



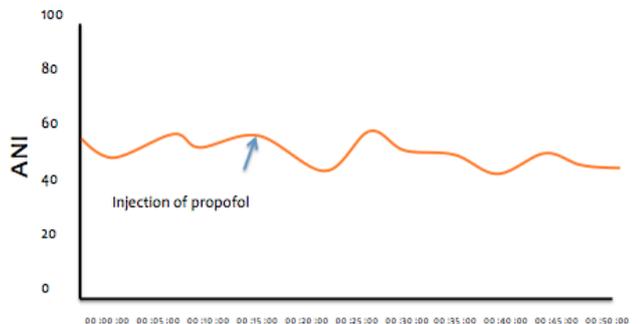
Remifentanyl, sufentanil, etc... administration:

Adding opioids leads to an increase of ANI trends. Differences in ANI behaviour depend mainly on the contextual half-life of each drug.



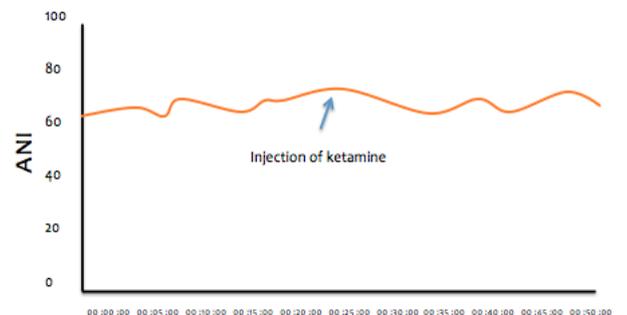
Propofol administration, sevoflurane, desflurane, isoflurane increase :

Anaesthetic agents have no impact on ANI values, but can affect the Energy of the RR signal.



Ketamine administration at anti NMDA dosage :

Ketamine titrated to prevent post-operative hyperalgesia has no impact on ANI values.



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