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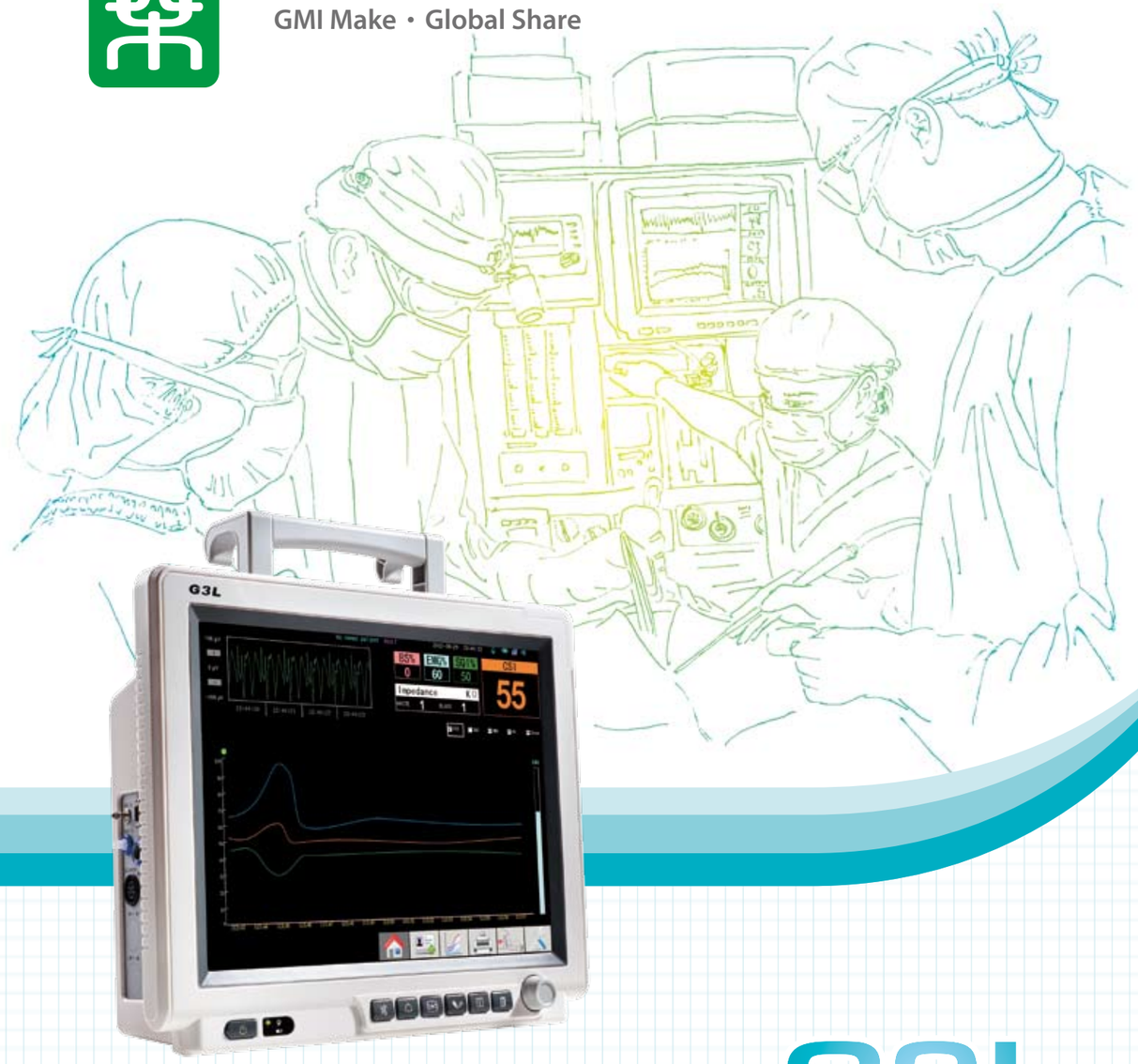

G9L

Depth of Anesthesia Monitor

General Meditech, Inc.

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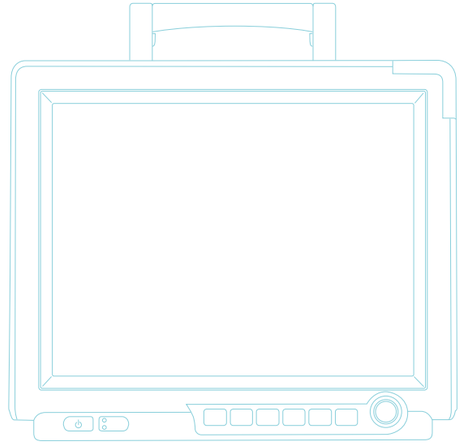


Thank you for your concern to General Meditech, Inc. and our G9L anesthesia depth monitor.

The anesthesiologist's good helper
Patient's patron saint
Monitoring depth of anesthesia in department of anesthesiology
Reflecting awareness degree in ICU

The sedation depth of anesthesia surgery have changed from “easy to be exceeded “to “easy to be insufficient” since the muscle relaxants was widely used to the anesthesia; The awareness during the surgery and the memories after the surgery have attracted more and more attention due to the lack of the monitoring method of the anesthesia depth; Sebel investigated 7 medical center of USA in 2004 and found that 25 patients of 19575 persons had awareness during the surgery(probability 0.13%),there are about 20 million patients doing general anesthesia every year, so that means about 26000 patients may have the awareness during the surgery.

The patients may have various extent of nervousness, anxiety, pain and discomfort during diagnosis surgery and therapeutic surgery when they are local anesthetized, regional anesthetized or not anesthetized; and the reflex of the patients may be more serious when there is visceral pull. In order to provide a good operation condition and make sure the patients pass through the dangerous time safely and adaptively, the American Anesthetist association (ASA) mentioned the monitored anesthesia care (MAC),the definition of MAC is that the anesthetist provide the monitoring and analgesia tech when the patients are local anesthetized, regional anesthetized or not anesthetized.

Along with the Critical Care gotten more and more attention in recent years, the suffering for patients during treatment has also been noticed. Mechanical ventilation in the treatment of patients; the daily care; invasive treatment and illness itself will all bring pain and emotional instability to patients, and cause adverse effects to the treatment and prognosis of the disease. Sedation can relieve the patient's pain and improve the patient's emotional instability; so it has been widely used.

The traditional instrument of the depth of anesthesia becomes the " ornaments” of the anesthesia department because of the high cost machine itself as long as the expensive accessories, furthermore the operation is very complicated. General Meditech Inc. and Danmeter A/S from Denmark built the G9L, the depth of anesthesia monitor. it gets the precise cerebral state index(CSI) through the fuzzy logic operations on the EEG , combining with the ECG, NIBP, SpO2, TEMP etc. basic vital signs parameters of patient, guide the anesthetic medication to reduce the risk of surgery, easily operation, economic and universal accessories, to bring you a whole new experience of depth of anesthesia monitoring.

G9L is designed to improve the efficiency of anesthesia surgery and become the conventional equipments of anesthesia surgical departments.

Looking forward to cooperate with you and wishing you happiness!

General Meditech, Inc.

Company Profile

Danmeter A/S: Danmeter A/S is a company specialized in brain and EMG signal measurement products. It has 34 years history since it's founded in 1977. The main products are: non-invasive CSM, stroke rehabilitation, Neuromuscular electrical stimulation, Incontinence treatment and Noninvasive central blood volume. The A-Line cerebral state monitor is the first generation product that was very popular in China before.

General Meditech, Inc: General Meditech, Inc is a national high-tech enterprise which specialized in development, production and marketing of monitoring series products. The senior management and R&D staffs have over 20 years experience in medical industry. GMI has its own products' intellectual property rights.

GMI has over 5000 square meters R&D and production site. Equipped with a variety of international high-end simulator, security tester, real-time detection system, which provide reliable guarantee for development and production of high quality multi-parameter patient monitors.

Our products have been exported to more than 100 countries around the world. We are not only relying on the reliable product quality, but also relying on our attentive service. Our company has a perfect pre and after-sale service system and already set up 26 offices in P. R. China. In Shenzhen headquarter, we have TOLL free hotline of **400 -6111-903** which can respond to customers immediately.

Since its establishment, GMI has been steadfastly and constantly devoted to technical work, made brilliant achievements gradually.

2003

Sep.
GMI created.

2004

Dec.
G serious patient monitor certification.

2005

Jan.
China Metrology Certification.

Feb.
ISO13485: 2003 quality system certification of medical equipment.

2006

Jun.
Shenzhen Software Enterprise Certificate issued by Shenzhen Information and Technology Bureau.

2007

Jun.
Shenzhen high-tech enterprise assertion in the expert evaluation organized by the Shenzhen Information and Technology Bureau.

Nov.
ISO9001: 2000 and YY/T0287-2003 quality system certification

2008

Aug.
CE mark for patient monitors and pulse oximeter

Oct.
FDA 510(k) Clearance for pulse oximeter

Dec.
pulse oximeter, central monitoring system and multi-parameter patient monitor were identified as "The products of independent innovation" both by shenzhen Information and Technology Bureau and Shenzhen Trade and Industry Bureau, meanwhile they were listed into 2009 government centralized procurement catalog.

2009

Sept.
National High-tech Enterprise

2010

Jan.
"Credit AAA Enterprise" by Shenzhen Credit Union Association

Feb.
FDA 510(k) Clearance for G3 Series patient monitor

Jun.
National Class Ⅲ registration certificate.

Introduction of G9L Depth of Anesthesia Monitor

As regular measurement equipment in anesthesia department, G9L has superior advantages as below:

1. The transducer has superior sensitivity and low requirement for EEG electrode which can be replaced by normal ECG Electrode. (Test cost for each patient: USD50 for BIS's special electrode, less than USD2 for G9L's common electrode)
2. With digital & classified depth of anesthesia state, direct and clear
3. Based on the data of BS% and CSI, G9L will judge patient's coma state.
4. High ability of Anti-artifact. Benchmark analysis of EEG by using fuzzy logic operation theory. the CSI will not be influenced by the disturbance on EMG from surgical electro equipments.
5. EMG reflect the state of Muscle relaxation
6. Showing vital signs parameters, therefore G9L is the unique equipment that combines multi-parameter patient monitor with depth of anesthesia monitor.
7. 15"color, high brightness, wide view angle TFT LCD screen
8. With superior advantage to be routine measurement equipment for anesthesia department
9. With Europe CE and USA FDA approval and many clinical cases, the depth of anesthesia monitor technology guarantee its performance both electrical safety and clinical use.
10. Streamlined and fashionable design, foldable hook handle, easy to carry
11. Remote control and knob operation, friendly man-machine dialogue interface, easier to operation.
12. Applicable to adults, pediatric, neonate monitoring.

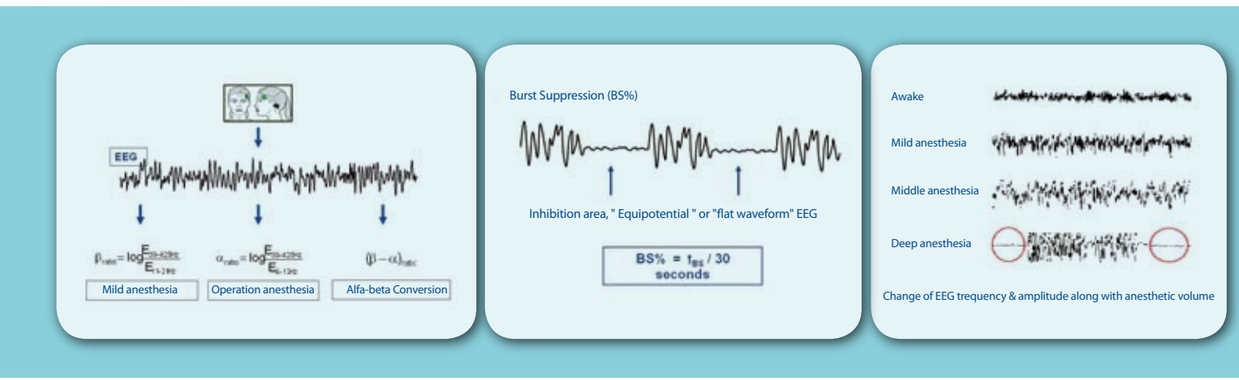
Configuration

Standard Configuration: CSI + Stand 6 parameters (SUNTECH NIBP, NELLCOR SpO2, YSI-400 Body Temperature Probe)

Optional Configuration: ETCO2, Thermal Array Printer, Wall Mount, Trolley, Touch Screen

Clinical significance

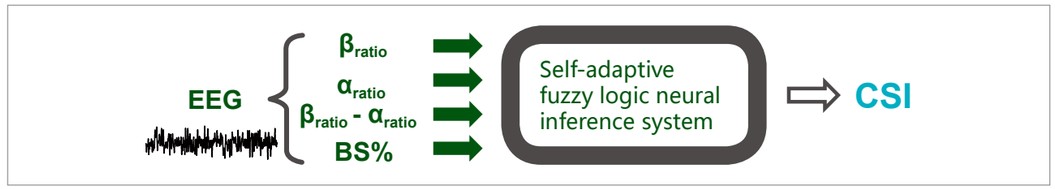
The awareness depth of anesthesia index (cerebral state index, CSI) is a new monitoring index for depth of anesthesia (Danmeter A/S); it is same as BIS to reflect the brain awareness ingredients, but it is not equivalent to BIS. The BIS monitor is using the bi-spectral analysis of EEG activity, while the CSI monitor is using adaptive neuro-fuzzy inference system, which integrated four parameters of EEG. The response time of CSI is shorter than BIS (the former response time is 10-20 seconds, the latter is 30 seconds).



Operation principle

CSI: (Cerebral State Index)

The Operating principle of CSI is using EEG, Burst suppression, EMG as a basis for data to input self-adaptive fuzzy logic inference system, its advantage is the accidental contact between the EEG and the clinical status of the patients will not be controlled by an assumed and potential mathematical function. the reaction level of consciousness in patients is with a strong following feature and more accurate, timely.



CSI significance

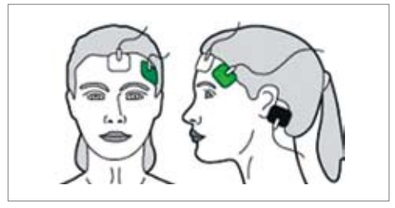
CSI	Clinical state
90 - 100	Awake
80 – 90	Drowsy
60 – 80	Light anesthesia sedation
40 – 60	Range considered as adequate for surgical anaesthesia
10 – 40	Deep anaesthesia, in most cases accompanied with BS
0 – 10	Close to coma and BS index greater than 75; When CSI less than 3, the EEG is basically isoelectric.

BS%: Burst Suppression

Indicate the burst suppression in the last 30 seconds of EEG signal when the EEG is ISO-electric or flat line. A BS%=20 means that the EEG has been ISO-electric during 20% of the last 30 seconds. Frequency, variability of burst suppression and EEG power reflect intracranial pressure's change directly.

EMG: it shows the myoelectricity energy level between the bandwidth of 75-85 Hz (0-100 logarithm), indicate the state of muscle relax.

Tips: the universal ECG electrode is applicable due to EEG transducer's superior sensitivity!



Color	Position	Type
	Middle of forehead	Positive pole
	Left side of forehead	Reference
	Mastoid left side	Negative pole

- General Meditech Inc. and Denmark Danmeter built the G9L, the depth of anesthesia monitor.
- Danmeter released CSM after A-Line, open a new era of the depth of anesthesia monitoring, getting the precise cerebral state index(CSI) through the self-adaptive fuzzy logic neural inference operation on the EEG , combining with the ECG, NIBP, SpO2, TEMP etc. basic vital signs parameters of patient, guide the anesthetic medication to reduce the risk of surgery, easily operation, economic accessories, to bring you a whole new experience of depth of anesthesia monitoring.

Analysis of social and economic benefits

At present, there are three similar products in market: BIS of Aspect Company from USA, Narcotrend of Hannover Medical University and Anesthesia depth monitor of Danmeter from Denmark. The significant advantages are as below list for GMI G9L anesthesia depth monitor:

1 Price: BIS USA is priced at around $56,000.0 in the market (It has been purchased by Convidien in 2009); And Narcotrend is around $60,000(It was branded as Shiller Depth of Anesthesia Monitor in the former market). The price of G9L is the most favorable and reasonable one in the market.

2 Operation cost: The price of BIS's disposable electrode is $50 - $80 per patient per time (Although many doctors will reuse it in clinical application, the electrode with electronic conductive which attached to patient's skin will probably cause cross infection, if there is any accident, BIS will not be responsible for it). Narcotrend use normal nerve electrode, but you should input the patient information during application; it'll increase the burden for the medical stuff's daily work. However, CSM can use the normal ECG electrode or nerve electrode, the general electrode isn't limited by the manufacturer. It almost has no adverse reaction, and the cost is less than $2.0 per patient per time.

3 Revenue analysis: depth of anesthesia monitoring has become increasingly open and conventional nowadays. There has well-built medical charge standard and anesthetic quality control standard. In the anesthetic quality control standard, there is listing the ratio requirements of the depth of anesthesia monitoring in detail for third degree hospital and second degree hospital.

4 Expenditure analysis: G9L (depth of anesthesia) exactly reflect the situation of anesthesia depth through CSI which monitor consciousness of patient, with BS% which predict the extent of patient brain coma, supply guidance of medication for anesthesiologist, cut back the anesthetic dose, shorten recovery time, cost savings and reduce cost, increase efficiency.

5 Social benefit analysis: It exactly reflect real-time depth of anesthesia for patient, avoid medical dispute due to deep or shallow anesthesia, improve medical level of department, improve social influence of hospital, meantime, increase security of patient.

6 According to statistics, there is 30% shortage of anesthesia specialists in China. Now they are facing daily increasing clinical workload. Improving their quality and technical level is one of the effective way to easy this contradiction. G9L depth of anesthesia monitor provides a direct CSI index value which is conducive to the cultivation of young anesthesiologist. It takes 5-6 years for a common anesthesiologist to work independently in real clinical anesthesia practice . With this monitor, it will signally shorten the mature period of an anesthesiologist.

Poster Presentations (AP)

AP30 Monitoring-1

Date & Time: Thu. June 3, 2010 13:00-14:00

Site: Marinemesse, Area AACA17

AP30-1

Comparison of depth of anaesthesia using CSM and BIS at 1.0, 1.5 and 0.2 (on awakening) MAC of sevoflurane

Mazlila Meor Ahmad1/ Kamal Bashar Abu Bakar2/ Azmil Farid Zabir2/ Norsidah Abdul Manap1 Universiti Kebangsaan Malaysia Medical Centre, Malaysia1, Kuala Lumpur Hospital, Malaysia2

Purpose of the study: This was a prospective, randomized, single blinded clinical study to compare the cerebral state monitor (CSM) index values with bispectral index (BIS) values at 1.0, 1.5 and 0.2 (on awakening) MAC during sevoflurane anaesthesia in day care patients. Method: Forty-four patients undergoing elective day surgery under general anaesthesia were randomized into either CSM or BIS groups, with each group having 22 patients. Baseline CSM or BIS values were recorded before anaesthesia was induced with fentanyl 1.5 mcg per kg and propofol 2.5 mg per kg. An appropriate laryngeal mask airway (LMA) or proseal LMA (PLMA) was inserted. Inspired sevoflurane was increased to attain a MAC of 1.0 for a duration of 10 mins, following which the CSM or BIS index was recorded. Sevoflurane concentration was further increased to attain a MAC of 1.5 and maintained for 10 mins before another CSM or BIS reading was taken. At the end of the surgery as the sevoflurane concentration was reduced, a MAC value of 0.2 was maintained for 10 mins before the CSM or BIS index was again recorded. Results: The measured CSM and BIS indices at sevoflurane MAC values of 1.0, 1.5 and 0.2 (on awakening) were comparable and not statistically different (p value 0.076, 0.072, 0.088 respectively). The mean value for CSM at MAC 1.0 was 41.2 ± 2.2SD (95% CI 41.1 - 43.5) and BIS was 40.1 ± 1.7 SD (95% CI 40.0 – 42.4). At MAC 1.5 the measured CSM was 34.4 ± 1.5 SD (95% CI 24.2 – 35.9) while BIS was 33.6 ± 1.3 SD (95% CI 33.4 – 35). At MAC 0.2 the measured CSM was 80.9 ± 3.3 SD (95% CI 80.7 – 84.2) whereas for BIS was 79.4 ± 2.2 SD (95% CI 79.2 – 82.7). Conclusion: This study showed that during the monitoring of depth of anaesthesia, CSM index values were comparable with that of BIS values at 1.0, 1.5 and 0.2 (on awakening) MAC during sevoflurane anaesthesia.

Validation of the Cerebral State Monitor for assessing anaesthetic depth

Presentation Time: Tuesday, 9:15 a.m. - 10:45 a.m.

AUTHORS: E. W. Jensen1, H. Litvan2;

AFFILIATION: 1CREB, Sant Pol de Mar, Spain, 2Hospital Santa Creu y Sant Pablo, Barcelona, Spain.

Presentation Number: S-229

Introduction: The objective of this study was the validation of a new index, called Cerebral State Index (CSI) during cardiac anaesthesia. The CSI was defined using sub-parameters from the EEG as inputs of an adaptive neuro-fuzzy inference system (ANFIS). The advantage of ANFIS is that it does not assume an underlying mathematical function governing the causal relationship between the EEG values and the clinical state of the patient.

Methods: The study was approved by the local ethics committee. Fifteen patients, (12 male, 3 female, age 60-79 years) scheduled elective cardiac surgery were included in the study. Propofol was the only anaesthetic, administered using a TCI- pump (target 5 ug/ml plasma concentration during 5 min). CSI and BIS was monitored simultaneously and LOC defined as loss of response to a verbal command was assessed. After LOC, surgery was carried out according to the protocol of the department.

Results: Both CSI and BIS showed significant differences between awake and anaesthetised values asshown in the table (mean(SD)). During surgery, both BIS and CSI remained below 60 and in an interview24 h after surgery none of the patients reported intra operative awareness

	CSI	BIS
Awake	92(5)	94(6)
LOC	55(4)	56(4)

Discussion: The results show that in this population depth of anaesthesia can be measured reliably byusing a combination of parameters calculated from the frequency content of the EEG.

Cerebral State Index to Predict Patient Responsiveness During Sevoflurane Anesthesia. A Comparison With Bispectral Index

Presentation Time: Saturday, 11:30 a.m. - 1:00 p.m.

AUTHORS: S. S. HO, M. T. Chan, T. Gin;

AFFILIATION: The Chinese University of Hong Kong, Shatin, NT, Hong Kong Special Administrative Region of China.

Presentation Number: S-184

Introduction: The cerebral state index (CSI) is a novel indicator of anesthetic drug effect. It combines several electroencephalographic (EEG) parameters using the adaptive neuro-fuzzy inference system.1 The purpose of this study is to compare the accuracy of CSI with bispectral index (BIS) to predict patient response during sevoflurane anesthesia.

Methods: This study was approved by ethics committee. Twenty patients (12 F: 8 M), ASA 1-2, aged 20-47 years, scheduled for general surgery gave written informed consents. Patients received increasing concentrations of sevoflurane via a tight fitting face mask, until they lost response to verbal command. CSI was measured by a cerebral state monitor (Danmeter, Odense A/S, Denmark), using Fpz-A1 montage. BIS (version 3.4) was recorded

by a right frontal BIS-XP sensor, and was computed online by an A-2000 monitor (Aspect Medical, Newtown, MA). Ten minutes was allowed for equilibration before each step change (0.1%) in sevoflurane concentration. End-tidal CO2 concentration was maintained at 3.5-4.0 vol%. Patient response was assessed by an blinded observer using the modified Observer's Assessment of Alertness/Sedation (OAA/S) scale.2 Loss of response was defined as OAA/S score ≤ 2. Patient responses vs CSI or BIS were analyzed by logistic regression and sevoflurane concentration vs CSI or BIS was tested by nonlinear regression. The ability of CSI or BIS to detect OAA/S level was evaluated by prediction probability (PK, ranging from 0-1), PK of 1 indicates perfect prediction. Differences between indices were tested by Mann-Whitney test.

Results: Both CSI and BIS decreased with increasing concentration of sevoflurane (Figure A). The correlation coefficients were -0.83 and -0.79 for CSI and BIS, respectively. The values at which 50% (95% CI) of patients failed to respond to verbal command were 72 (69-75) for CSI and 69 (66-73) for BIS (Figure B). The PK (±SE) values indicates similar accuracy of CSI (0.89 ± 0.04) and BIS (0.87 ± 0.03) to predict OAA/S scale.

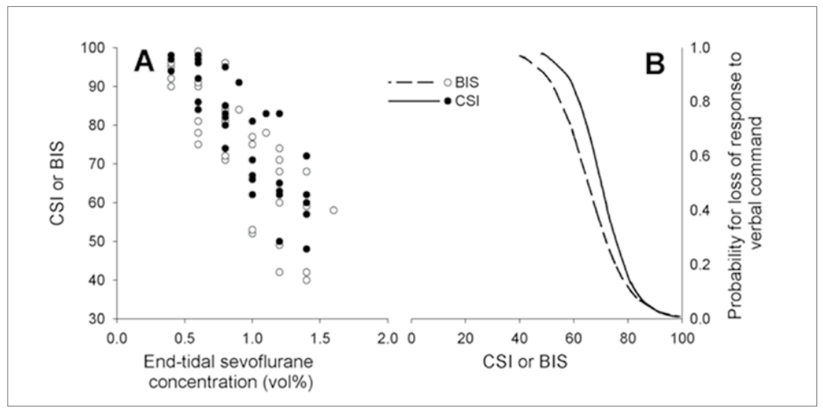
Discussion: During steady state conditions, we found that both CSI and BIS accurately detect the level of consciousness after sevoflurane anesthesia.

Reference:

1. IEEE Trans Syst Man Cybern 1993,23:665-685.

2. J Clin Psychopharmacol 1990;10:244-51.

Figure. Changes of CSI and BIS at different sevoflurane concentration (A). Probability of loss of response to verbal command as a function of CSI and BIS (B).

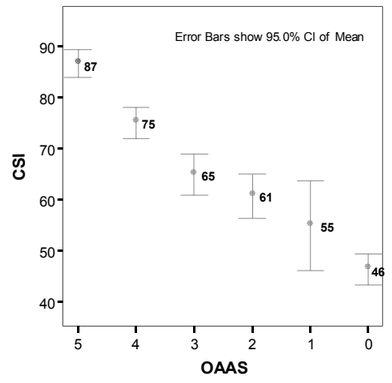


Definition of a new index for depth of anesthesia using EEG sub-parameters combined by fuzzy logic.

Authors: BE Rodriguez, MSc[1], EW Jensen, PhD[1], P Martinez, MSc[1], H Litvan, MD, PhD[1], MMRF Struys, MD, PhD[2]
[1]Cardiac Anesthesia Research Unit, Hospital Santa Creu I Sant Pau, Barcelona, Spain
[2]Gent University Hospital, Gent, Belgium

Background and Goal of Study. The objective of this study was to show that a reliable index for assessing consciousness in anaesthetised patients could be defined using sub-parameters from the EEG as inputs of an adaptive neuro-fuzzy inference system (ANFIS). The advantage of ANFIS is that it does not assume an underlying mathematical function governing the causal relationship between the EEG values and the clinical state of the patient. The performance of the new index, called Cerebral State Index (CSI), was evaluated in a retrospective study.

Materials and Methods. After Gent Hospital Ethics Committee approval, informed consent was obtained from 20 ASA I female patients (18-60 years), scheduled for ambulatory gynecologic surgery. The data has recently been published in another study1. Propofol infusion was initiated until the patient had no response to noxious stimuli (Observer's Assessment of Alertness and Sedation scale (OAAS) 0). OAAS level was estimated every 4min. and the effect-site concentration for propofol was calculated using the Schnider model. Four EEG sub-parameters (beta ratio=log(E30-42.5Hz/E11-21Hz), alpha ratio=log(E30-42.5Hz/E6-12Hz), beta – alpha ratio=log(E6-12.5Hz/E11-21Hz) and Burst Suppression) were used to define the inputs to the fuzzy system. The output of the fuzzy system is the CSI.



Results and Discussions. The prediction probability (Pk) between the CSI and OAAS was 0.92. The figure shows the box plot of the CSI versus the OAAS for the data set.

Conclusion. The results show that in this population depth of anaesthesia can be measured reliably by using a combination of parameters calculated from the frequency content of the EEG.

References. 1.Struys MMRF et al. Anesthesiology 2002; 96:803-16

Cerebral state index during anaesthetic induction: a comparative study with propofol or nitrous oxide

R. E. ANDERSON [1], G. BARR [1] and J. G. JAKOBSSON [2]

[1]Department of Cardiothoracic Anaesthetics and Intensive Care, Karolinska Hospital, and [2]Department of Anaesthesiology, Sabbatsberg Hospital, Stockholm, Sweden

Background: Confidently predicting the depth of anaesthesia for the individual patient and independently of drug(s) type using EEG-based monitors has proven difficult. This open, randomized, explorative study of day surgical patients evaluates the ability of the Cerebral State Monitor™ (Danmeter AB, Odense, Denmark) of anaesthetic depth to identify loss of response (LOR) using either propofol or N20 for induction.

Methods: In this open, randomized study, day surgical patients (n = 10 in each group) were studied using the Cerebral State Index Monitor™. After baseline measurements, induction to LOR was achieved with either repeated

30-mg boluses of propofol every second minute or with N20 (after premedication 5 min before with 30 mg propofol) increased every other minute in 15% increments (max. 75%). Sedation level was evaluated every other minute using the Observer's Assessment of Alertness/Sedation scale

Results: Baseline values were 91 (82—98) and 94 (82—100) for N20 and propofol patients, respectively. During induction CSITM decreased with increasing sedation in patients given propofol ($P < 0.001$) but not in patients given nitrous oxide. Median value at LOR was 56 (40—76) and 95 (87—100) for the propofol and nitrous oxide group of patients, respectively.

Conclusion: The Cerebral State Index™ behaves as other depth of anaesthesia monitors with a progressive decrease during propofol induction but loss of consciousness with N20 results in no change in CSI™.

Accepted for publication 7 January 2005

Key words: Ambulatory surgical procedures; electroencephalography; intraoperative monitoring; nitrous oxide; propofol.

Acta Anaesthesiologica Scandinavica (2005)
Acta Anaesthesiol Scand 2005
ACTA ANAESTHESIOLOGICA SCANDINAVICA
doi: 10.1111/j.1399-6576.2005.00737.x

Cerebral State Index: Reliable Differentiation between Consciousness and Unconsciousness?

A72 October 22, 2005 9:00 AM - 5:00 PM Room Hall I2

Jasmin Blum, M.D., Stefanie Klesper, M.D., Eberhard F. Kochs, M.D., Gerhard Schneider, M.D. Department of Anesthesiology, Technische Universität München, Klinikum r. d. Isar, Munich, Germany

Introduction: The Cerebral State Monitor (CSM) is a new monitor that indicates the level of consciousness during general anesthesia. Based on spontaneous EEG processing, the CSM calculates the Cerebral State Index (CSI) which is a unitless number from 0 to 100 that inversely correlates with depth of hypnosis. We calculated the prediction probabilitiy (P_K) [1] of CSM to separate consciousness from unconsciousness in surgical patients.

Materials and Methods: EEG recordings from a previous study of 40 unpremedicated patients undergoing elective surgery were analyzed offline. Approval from the university´s ethics committee and written informed consent were obtained from all patients. Patients were randomly assigned to receive (1) sevoflurane-remifentanil (≥ 0.2 mcg kg^{-1} min^{-1}) or (2) propofol-remifentanil (≥ 0.2 mcg kg^{-1} min^{-1}). Patients were asked every 30 sec to squeeze the investigator's hand. Remifentanil and sevoflurane or propofol were given until loss of response to command (LOC1). A blood pressure cuff was inflated on the right forearm to occlude the circulation and retain the ability to squeeze the hand to command (Tunstall's isolated forearm technique) [2] during succinylcholine administration and tracheal intubation. After intubation, propofol or sevoflurane was stopped until return of consciousness (ROC1) and then restarted to induce loss of consciousness (LOC2). After surgery, drugs were discontinued (ROC2). PK was calculated from CSI values 30 sec before and immediately after LOC and ROC.

Results and Discussion: PK for the differentiation between consciousness and unconsciousness was 0.751. The present data set is very challenging, because the transition between anesthetic levels occurred very slowly. Moreover, the short intervall of 30 seconds between asking the patients to squeeze hand allows to select the analyzed clinical endpoints very close to each other. When considering this fact, a PK of 7.51 is a promising result. In previous studies with comparable study design, PK of Narcotrend (P_K 0.5) [3], BIS [3], and PSI ($P_K < 0.7$) [3] were lower.

Conclusion: Of all the analyzed EEG-based monitors, the CSM provided the most reliable differentiation between consciousness and unconsciousness.

References: [1] Smith WD et al., Anesthesiology 1996; 84:38-51; [2] Tunstall ME, BMJ 1977; 1:1321; [3] Schneider G et al., Br J Anaesth 2003; 91:329-35 [4] Schneider G et al., Anesthesiology 2004; 101:1105-11 Anesthesiology 2005; 103: A72

Monitoring the level of consciousness: BIS vs CSI

Authors: Massó E, Rodriguez M, Flo A, Ibáñez C, Jensen EW, Canet J

Hospital Universitari Germans Trias I Pujol, Barcelona, SPAIN

Introduction: The analysis of the EEG signal allows the monitoring of the level of consciousness during general anaesthesia. Recordings of the Bispectral Index (BIS, Aspect Medical Systems, MA, USA) and the Cerebral State Index (CSI) (Cerebral State Monitor, Danmeter, Odense, Denmark) have been correlated with the level of depth of anaesthesia and the auditory evoked potential records.

Objectives: To compare prospectively the monitoring of the level of depth of anaesthesia with the BIS and CSM during anaesthetic induction with sevoflurane.

Material and Methods: The study included 10 patients scheduled for cardiac surgery. Premedication consisted of diazepam 10mg the day before and the morning preceding surgery. In the operating room the invasive blood pressure, ECG, pulsioximetry and end tidal sevoflurane concentration were monitored. Basal values were registered and fentanil 1µg.kg and midazolam 10 mg.kg-1 administered intravenously. Inhalational induction was then started with sevoflurane 2% or 4% and fentanil 4-5µg.kg-1. After the loss of eyelash reflex and apnea, rocuronium 0.6mg. kg-1 were also administered. All parameters and sevoflurane concentrations were registered for the following phases of surgery: start of induction, loss of response to verbal stimuli, loss of response to tactile stimuli, loss of eyelash reflex, start of apnea, NMBA administration, intubation and every 2-10 minutes after intubation. The BIS and CSI indexes were compared using a Spearman rho correlation. The results are showed as N(%) or mean value (rank). $P<0.05$

Results: Records were obtained for seven patients: 3 scheduled for valve and 4 for coronary surgery. Anthropometric details were: age 62(51-84) years, 6 male/1 female, weight 69(55-89)kg, height 164(157-178)cm, ASA 3/4 : 2/5. Basal values were: BIS 96 (87-98) and CSI 93 (86-98), at apnea BIS 84

(70-96) and CSI 78 (67-88) and for intubation BIS 41 (30-48) and CSI 44 (37-57), after this phase both indexes kept values under 50. Correlation between BIS and CSI for all phases of the study was significant $p<0.001$, $R2=0.85$ with the equation CSI=0.8BIS+13.4

Conclusions: This preliminary results indicate that there is a good correlation between the BIS and CSI record during inhalational induction with sevoflurane. The adequate depth for surgical (40-60) or deep (10-39) anaesthesia was only obtained with both devices after apnea and muscular relaxation. Further studies are needed in order to define the performance of the Cerebral State Monitor and its correlation with the BIS on different levels of consiousness.

Monitoring depth of anesthesia in children: BIS monitor and Cerebral State Monitor (CSM)

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Introduction. The aim of the study was to evaluate the performance of the Cerebral State Monitor (CSM) (Danmeter A/S, Odense, Denmark) for the monitoring of depth of anesthesia during sevoflurane induction in pediatric patients. The CSM calculates an index (Cerebral State Index or CSI) in a 0-100 range. The CSI values were compared with the bispectral (BIS pediatric sensor) index values (Aspect Medical Systems, USA) for both the awake and asleep states.

Methods. The study population was formed by ten male pediatric patients aged 2-11 years old, and weight(SD) 20(8)kg scheduled for elective herniorraphy or minor urologic surgery. Sevoflurane was administered for induction of anesthesia until loss of consciousness. In all cases the patient had both monitors attached. Penile or caudal block was completed after sevoflurane induction and laryngeal mask insertion. Anesthesia was fully maintained with sevoflurane and 50% N2O/O2. After surgery the gas was discontinued and the laryngeal mask removed on intolerance. BIS and CSI values were recorded for both the awake state (on arrival at the OR) and asleep state (just before laryngeal mask insertion). Results are noted as mean (range).

Results. The monitor index values for the awake state were CSI 93 (86-100) and BIS 94 (90-98). For the asleep state the index values were CSI 45 (40-62) and BIS 42 (23-61). The prediction probability (Pk) for index prediction of the awake/asleep states was 1 for both monitors. The correlation coefficient (R2) between both indexes was 0.95.

Discussion. The CSI achieved good correlation values for monitorization of the awake and asleep states of anesthesia for this specific study population. This preliminary results are part of a broader study with a larger number of subjects and comparing more anesthetic states and drug consumption values, among other parameters.

Comparative evaluation of the cerebral state index and the bispectral index during targetcontrolled infusion of propofol

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Background. Cerebral state index (CSI) has recently been introduced as an intra-operative monitor of anaesthetic depth. We compared the performance of the CSI to the bispectral index (BIS) in measuring depth of anaesthesia during target-controlled infusion (TCI) of propofol.

Methods. Twenty Chinese patients undergoing general anaesthesia were recruited. CSI and BIS, and predicted effect-site concentration of propofol were recorded. The level of sedation was tested by Modified Observer's Assessment of Alertness/Sedation Scale (MOAAS) every 20 s during stepwise increase (TCI, 0.5 mg ml_1) of propofol. The loss of verbal contact (LVC) and loss of response (LOR) were defined by MOAAS values of 2–3 and less than 2, espectively.

Baseline variability and the prediction probability (PK) were calculated for the BIS and CSI. The values of BIS05 and CSI05, BIS50 and CSI50, BIS95 and CSI95 were calculated at each end-point (LVC and LOR).

Results. Baseline variability of CSI was more than that of BIS. Both CSI and BIS showed a high prediction probability for the steps awake vs LVC, awake vs LOR, and LVC vs LOR, and good correlations with MOAAS values.

Conclusion. Despite larger baseline variation, CSI performed as well as BIS in terms of PK values and correlations with step changes in sedation.

Br J Anaesth 2005
Keywords: anaesthesia, depth; anaesthetics i.v., propofol; monitoring, cerebral state index; monitoring, bispectral index

Accepted for publication: August 24, 2005
BJA Advance Access published October 6, 2005

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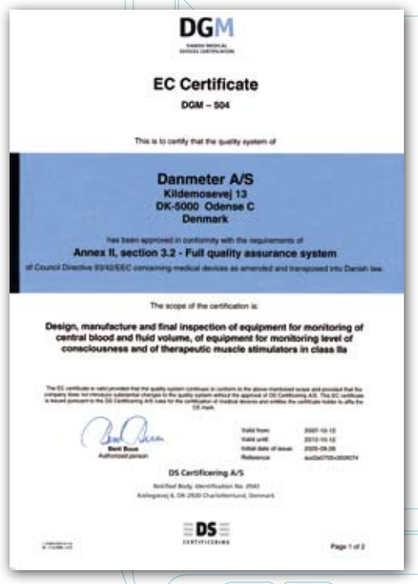

Europe CE certificate

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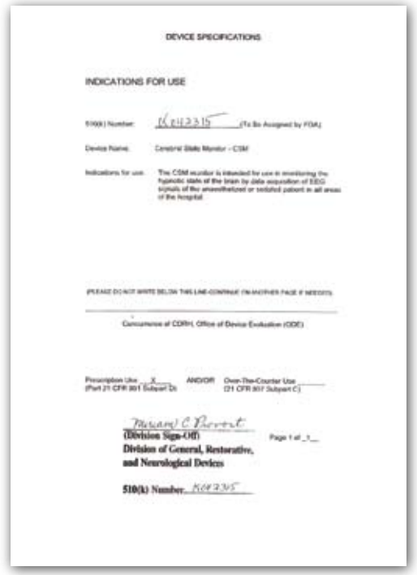

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