

Official Title:

The Effect of EMG Activity on Anesthetic Depth Monitoring :
Comparison Between Phase Lag Entropy and BIS

Date of the document: September 8th, 2017

NCT03230929

Study Protocol

Objectives

Phase lag entropy (PLE) is an index that quantifies the complexity of functional connections occurring between measurement areas of electroencephalogram (EEG). It records the electric activity signal of the brain via a sensor attached to the scalp, especially forehead, amplifies the measured EEG signal via the measurement module, and then processes the data. In this study, we will investigate whether the measurement method of the depth of anesthesia based on the PLE using phase lag entropy monitor (PLEM) 100 rather than the BIS algorithm reflects the anesthetic depth well without being affected by the electromyogram (EMG) activity.

Design

Prospective observational study

Inclusion criteria

Among adult males and females between the ages of 20 and 60, those who can voluntarily express their intention to participate in research, corresponding to the classification of physical status I and II of the American society of anesthesiologists (ASA).

Exclusion criteria

Patients who have lesions that can affect EEG such as cerebral hemorrhage, cerebral apoplexy and epilepsy and who have disease that can affect EMG such as muscular dystrophy, muscle stiffness, inflammatory muscular lesions, metabolic myopathy, congenital myopathy, myasthenia gravis are excluded from the subject.

Classification of physical status by ASA

Class I - healthy normal patient

Class II - patients with mild systemic disease but no functional limitation

Methods

Intravenous administration of 2% propofol and remifentanil would be done for total intravenous anesthesia. After intravenous injection of rocuronium 0.6 mg/ kg for muscle relaxation, endotracheal intubation would be performed. Then, anesthesiologist attaches the sensors of bipectral index (BIS) and PLEM 100 on the forehead of the patient, and adheres the neuromuscular monitoring device on the medial side of the wrist and the ipsilateral thumb to continuously monitor the state of consciousness and muscle relaxation before, during and after surgery. Before the end of surgery, the degree of neuromuscular relaxation should be within deep block (train-of-four count < 2) and the concentration of 2% propofol should be adjusted for maintaining BIS between 50 and 60. Reversal of muscle relaxant could be performed by intravenous injection of sugammadex 4 mg/ kg in the case of deep neuromuscular relaxation, and 2 mg / kg in the case of shallow muscle relaxation degree under neuromuscular monitoring. After then, monitor and record the values of BIS, PLEM 100, and neuromuscular monitoring in 1 minute increments for 5 minutes.