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The Responsibilities of Propofol-Induced Sedation during Endoscopes in relation to BIS Monitored Anesthesia Depth

Douglas David Wellons
University of Tennessee - Knoxville

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In coordination with UT Medical Center and Dr. Steve K. Patteson

Abstract

Gastroenterologists and anesthesiologists have a rigorous and ongoing debate about the use of propofol during endoscopies. The question is who should be in charge of giving the dosing for procedures. A BIS® monitor calculates the depth of anesthesia reached during sedation, and it is used in this study to compare propofol's strength to that of general anesthesia. It was shown that propofol does induce similar levels of consciousness during sedation: 82% of the time patients were recorded to be at levels coinciding or exceeding general anesthesia with a minimum level of 5 in one patient. This study supports the theory that a person trained in general anesthesia should be responsible to closely monitor the drug.

The Responsibilities of Propofol-Induced Sedation during Endoscopies in relation to BIS® Monitored Anesthesia Depth

Medicine is a dynamic field that is meant to change, or progress, towards an ultimate goal of extending life through advances in medical prevention, medical treatment, patient safety, and patient comfort. Unfortunately, these categories come under fire when the cost of care is involved, and compromises must be routinely made. Recently, there has been a widespread debate over a topic that encompasses each of these categories. The debate argues which medical personnel, anesthesia or gastrointestinal, should be in control of administering propofol during endoscopy procedures, and whether or not insurance will cover expenses. Propofol is a relatively new drug, approved by the FDA in 1989, for sedation purposes, but it is gaining quickly in popularity as the drug of choice for gastrointestinal (GI) endoscopy procedures (Aisenberg, 2006). The current problem is the FDA has a statement on the label that reads, "Propofol injectable emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure (FDA, 2003, Fig. 1)." Propofol was assigned this label because of its specific drug characteristics. Propofol is an isopropylphenol thought to interact with the inhibitory neurotransmitters of the brain, gamma-aminobutyric acid receptors (Bhandari, 2006). "The use of propofol for procedural sedation raises safety concerns because of its rapid action, pharmacokinetic and pharmacodynamic variability, and lack of a pharmacologic antagonist. Because propofol has no analgesic properties, relatively large doses are required when it is administered alone, and most patients are deeply sedated at some point during the endoscopic procedure (Aisenberg, 2006)." There is no reversal agent to

propofol, and, therefore, errors have to be treated by ventilatory and sometimes cardiovascular support (Flowers, 2006). Nurse administered propofol sedation (NAPS) is the administration of propofol by nurses with no formal anesthesia training in an attempt to cut costs, and it has full backing by gastroenterologists (Weaver, 2006). In contrast, anesthesiologists disagree with NAPS because of their lack of training (Aisenberg, 2006). The successes of propofol and the FDA's label have created three sides to the argument: anesthesiologists, endoscopists, and insurance companies.

Anesthesiologists are in support of the label, and they want their services involved whenever propofol is used. Anesthesiologists are most concerned with patient safety, and this concern has caused them to take this stance (Flowers, 2006). The American Society for Anesthesiology (ASA) has explained that propofol should be restricted only to those experienced in the skills that are required during general anesthesia; for example, endotracheal intubation (Aisenberg, 2006). Propofol is a potent drug that is able to depress cardiovascular and respiratory systems, and it needs to be monitored by those aware of its capabilities (Flowers, 2006). As of today, the errors involving propofol have been few, but their occurrences still appear. For example:

- According to the Pennsylvania Patient Safety Reporting System, over 100 error reports in which the use of propofol was cited have been reported, and sixteen percent of these were serious events including four deaths (Patient Safety Advisory, 2006).
- In a study of 33,854 patients, there were 153 deaths. Three of these deaths (0.65%) were attributable to sedation (Leslie, 2005).

- A study of 2574 cases showed that 43 patients attained hypoxemia, and another six needed mask ventilation (Weaver, 2006).
- Out of 9152 patients, there were seven people that needed additional help. Three were laryngospasms, three were prolonged apnea, and one aspiration required hospitalization.
- "There is a risk of bradycardia-related death during propofol administration which has been reported to be 1.4 in 100,000 patients. Propofol also produces dose-dependent depression of ventilation and causes apnea in approximately 25% to 35% of patients (Bhandari, 2006)."
- In a separate study of 27,500 patients, 6.7% developed hypoxemia with severe hypoxemia in 141 people, 6.2% required oxygen administration, and there was a decline in blood pressure with 3.5% of colonoscopies and 1.2% of upper endoscopies (Tohda et al., 2006).
- During 5,928 EGDs and 11,683 coloscopies, there was an 11.7 / 1,000 ratio among cases for cardiopulmonary events (Vargo et al., 2006).

Anesthesiologists believe that, because of the incidents and the risk associated with propofol sedation, their presence is required. Anesthesiologists are trained to react to any medication error or adverse effects during medical procedures. A transition towards NAPS may tarnish the record of propofol by increasing these medical errors, which would be a preventable risk. "Jo Harbaugh, an RN, was concerned about NAPS because rescuing patients from deep sedation using advanced airway management techniques has not always been the customary practice of nurses in freestanding GI centers and office settings (Flowers, 2006)." Anesthesiologists stand firm in their opinion over propofol

administration, and they will continue to fight to keep the FDA's warning label intact on the propofol bottle.

This label has gained considerable opposition from gastrointestinal groups, who support NAPS, and they are seeking its removal. "Gastrointestinal endoscopy is one of the most common interventional medical procedures performed throughout the world (Leslie, 2005)." Surveys show that propofol sedation is now present in 26% of the United States endoscopies (Aisenberg, 2006). A major reason this number has not grown even higher is due to the requirement for anesthesiologists during endoscopic procedures. "The American College of Gastroenterology petitioned the Food and Drug Administration to remove the warning from the product label for propofol, arguing that substantial clinical evidence establishes that propofol can be administered safely, effectively, and cost-effectively by gastroenterologists and by nurses working under their supervision (Aisenberg, 2006)." Much of their stance is based on the belief that NAPS has, so far, been relatively safe, and they can go along without specialized anesthesia help. In two of the studies mentioned above (9,152 cases and 2,574 cases), there were no intubations and no deaths (Weaver, 2006). There were variations, but the supporters of NAPS argue that nothing was severe enough to warrant the necessity of an anesthesiologist. Including an anesthesiologist causes heightened costs of endoscopy procedures, and economists are scrutinizing this (Aisenberg, 2006). They say that the money per life-year saved versus anesthesiologist cost will only be cost effective if the anesthesiologist saves one patient life for every 5000 cases (Aisenberg, 2006). This high a rate of involvement has not been seen, and it probably never will. Gastroenterologists are worried they are missing out on the wonderful benefits of propofol, and this requirement is causing many to stick to

traditional drugs during endoscopies. Gastroenterologists will continue to support NAPS by finding safe methods to administer propofol without an anesthesiologist present.

Insurance providers are the final factor in the administration of propofol dispute, and they develop their position largely on the views of the preceding arguments. Anesthesiologists are increasing the cost of a typical GI procedure with their presence associated with the use of propofol. Since many gastroenterologists have argued and shown they can get by without an anesthesiologist, insurers are ceasing their reimbursement of these doctors. "During the past decade, a number of insurance carriers also enacted policies restricting reimbursement to anesthesiologists during endoscopy to circumstances in which the patient is hard to sedate or clinically unstable (Aisenberg, 2006)." As fewer insurers are willing to pay anesthesiologists, patients are less able to see doctors who administer propofol unless they are willing to pay out of their own pocket. Propofol is the preferred drug for many patients, GI physicians, and nurses (Flowers, 2006). "Once you go propofol, you don't go back (Flowers, 2006)." Insurers add fuel to the fire between anesthesiologists and gastroenterologists because losing their support means losing patients, and although propofol may be preferred, many people must adhere to the health options that fit their finances. Insurers hold to the position that saves them money, and this debate is no different.

What is the correct side of this argument, and where should we stand? All sides present valid facts toward a correct way to handle propofol and use it for the benefit of all, but there is only one way to answer the propofol question; either there is an anesthesiologist involved or there is not. The purpose of the label on propofol is to restrict its use to those specialized in general anesthetics. General anesthetics affect many

parts of the body simultaneously, and the anesthesiologist is present to monitor the various body parameters while other doctors can perform the specific procedure. The purpose of this study was to show that propofol is as potent a drug as general anesthetics in regards to levels of consciousness as measured by a Bispectral Index® (BIS®) system. The null hypothesis states that propofol infusion will not create the same BIS® levels as general anesthesia. This study will gather data to determine if trained anesthesia personnel are required for treatment with propofol.

Methods

Participants

After IRB approval, any adult undergoing routine upper or lower endoscopic procedures will be included in this study. These patients will be consented in the order they arrive at the hospital, and they will not be randomized. The only factor used to exclude patients is age (<18) because of problems involving informed consent and minors. Informed consent is a vital part of this study, and it must be obtained before any person is admitted to the study. Informed consent is meant to protect human patient rights and to maintain ethical values in research. Informed consent is obtained by explaining certain parameters of the study to the patient: research study goal, patient involvement, risks involved, future benefits, any changes in health care, and assure confidentiality. In this study, the goal is to decide whether persons trained in anesthetics should be in charge of propofol delivery. Patients participate by having a BIS® monitor sticker placed on their forehead during the endoscopy. The only risk may involve a slight rash from the adhesive of the sticker, and no changes to the regular healthcare occur by participating in this research. The only motivation for participants in the study would be the hope to help

future individuals through improved health care. All records are confidential, and patients' names will not be used in any publication. A goal of two hundred patients is to be obtained to finalize the project with statistical support.

Apparatus

The items used to complete this study will be described in order of their use during a typical session. The Bispectral Index® (BIS®) system is the principal tool used to conduct the research study (Fig. 5). The BIS® system is comprised of five separate pieces: BIS® sensor, patient interface cable, digital signal converter, BIS® engine, and the display monitor. These are all connected to send the measured data to the display.

> "The BIS® sensor is a sophisticated electrode system specifically designed to work with BIS® systems. The raw EEG is transmitted from the sensor through the patient interface cable to the digital signal converter. The digital signal converter receives, amplifies and digitizes the raw EEG signal for subsequent processing and analysis. The BIS® engine, the heart of the BIS® system, contains the microprocessor responsible for rapid signal processing and computation of the BIS® Index. All BIS® systems are linked to display monitors [...] with the ability to display a BIS® value, BIS® trends and important additional data (Kelley, 2003)."

USB drives were used to transfer data from BIS® to office computers. Excel was used to store data and perform statistical operations.

Procedure

When a patient would arrive in the endoscopy suite of the hospital, their consent would be obtained. After consent, patients would be rolled into the procedure room, and

the BIS® sensor would be positioned on the forehead (Fig. 5). The sensor would be connected to the display monitor which had the BIS® number blocked from the anesthesiologist to blind the study. The machine would be switched on with the start of the procedure. Patients would be enrolled and collected all day. At the end of the day, data from the BIS® system would be downloaded onto USB flash drives. This data would be transferred to office computers where it was uploaded and saved with Excel. Data had to be screened to prevent overlapping cases, and it was purged of any data recorded on patients before the start of propofol injection. Statistical evidence was finally calculated with the data.

Results

The results are derived from a patient group of 202 participants. There was an average BIS® of 49.33 for the procedures. Of the participants, 182 (90.10%) had averages below 65, and 40 (21.98%) of these had averages below 40 (Fig. 3). During the full amount of time for every procedure, 82.26% of the time patients were below a BIS® of 65, and 78 of the cases remained below 65 for the entire duration of the procedure (Fig. 4). The lowest BIS® reached was a level of five for one patient.

Discussion

The BIS® index was the main tool for this study, and it is being used to determine the depth of anesthesia for propofol administration during endoscopies. The BIS® index is a scale from 0 to 100, and this correlates to flat lining and awake, respectively (Kelley, 2003). The values collected were compared to values associated with general anesthesia in order to gauge propofol's strength. Standards developed from clinical trials range general anesthesia from 40 to 60 on the BIS® scale (Kelley, 2003, Fig. 2). If propofol can

be shown to fall within this range, it will create additional support to suggest that an anesthesiologist's presence may be preferred with propofol-induced sedation during endoscopies.

The number 65 was chosen to depict when patients were just beginning to enter a general anesthesia state. During an overwhelming majority of time (82%), patients were in the general anesthesia range, and there were many more that exceeded this level (Fig. 3). The overall average for every procedure came out to be just 49.33. It is becoming apparent that propofol is able to induce states comparable to drugs used in general anesthesia. Once, a patient's BIS® level got close to flat lining, a zero level. BIS® monitored propofol administration can be strongly associated with general anesthesia levels.

Propofol is shown to be a potent anesthetic that greatly benefits endoscopic procedures, but gastroenterologists and anesthesiologists disagree on its control during use. The null hypothesis of this study was greatly overturned, and propofol created deep levels of unconsciousness that either compared or exceeded general anesthesia's range. It is responsible to use an anesthesiologist during propofol infusion because of its strength. The FDA's label is an appropriate warning on the bottle, and propofol needs to be monitored to insure no medical errors accumulate with the drug's use in medicine. "There is no substitute for general anesthesia training and experience whenever deep sedation is administered (Weaver, 2006)."

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Figures

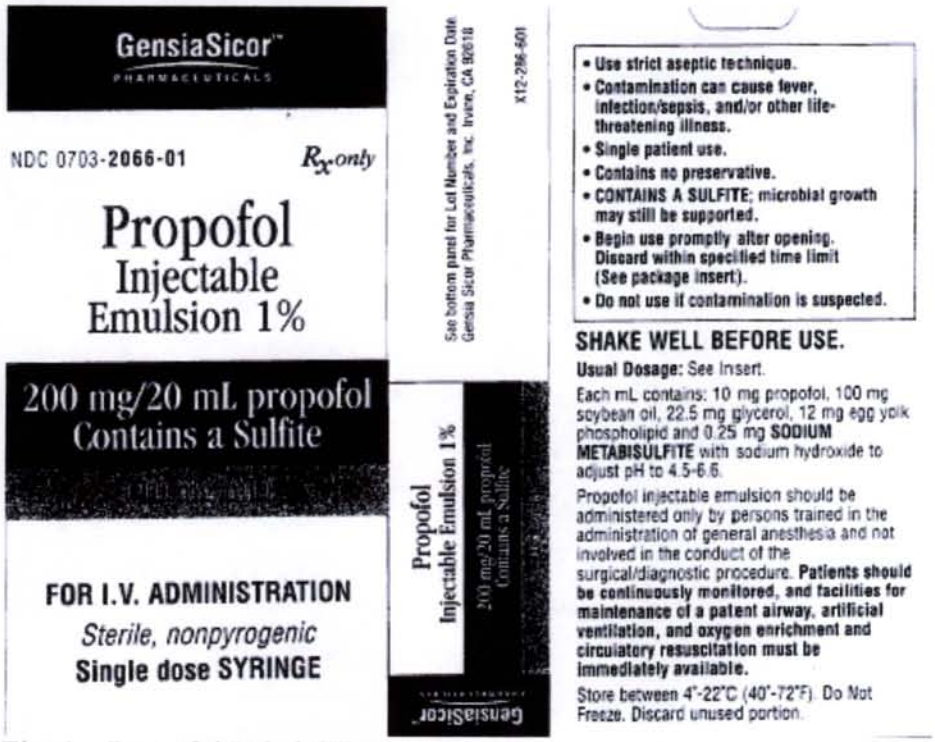

Fig. 1 – Propofol Label (FDA, 2003)

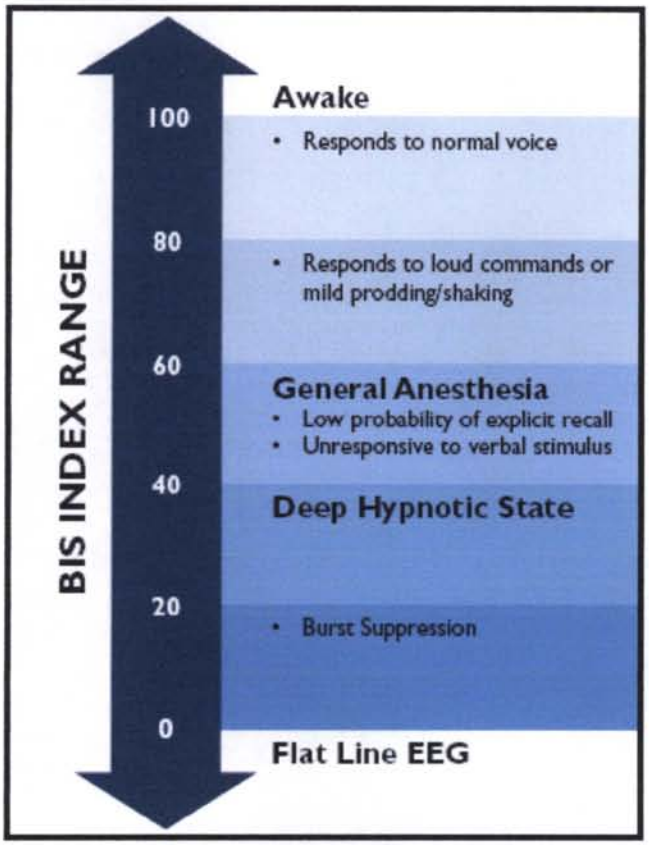

Fig. 2 – BIS Index Range (Kelley, 2003)

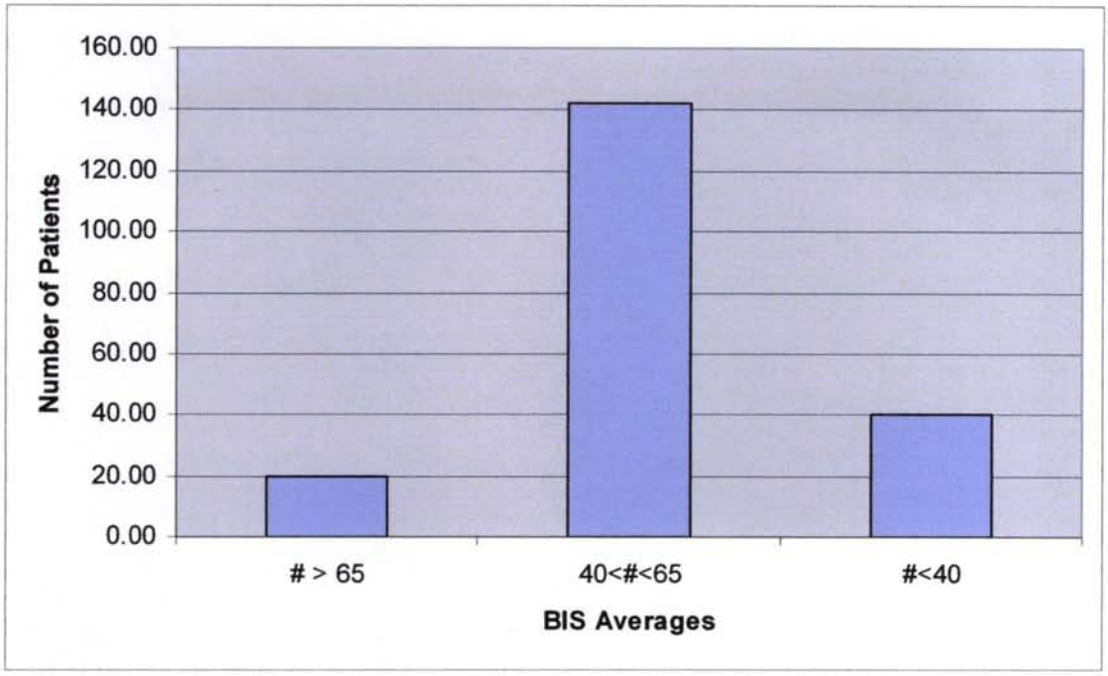
160.00
140.00
120.00
100.00
80.00
60.00
40.00
20.00
0.00
Number of Patients
> 65
40<#<65
#<40
BIS Averages

Fig. 3

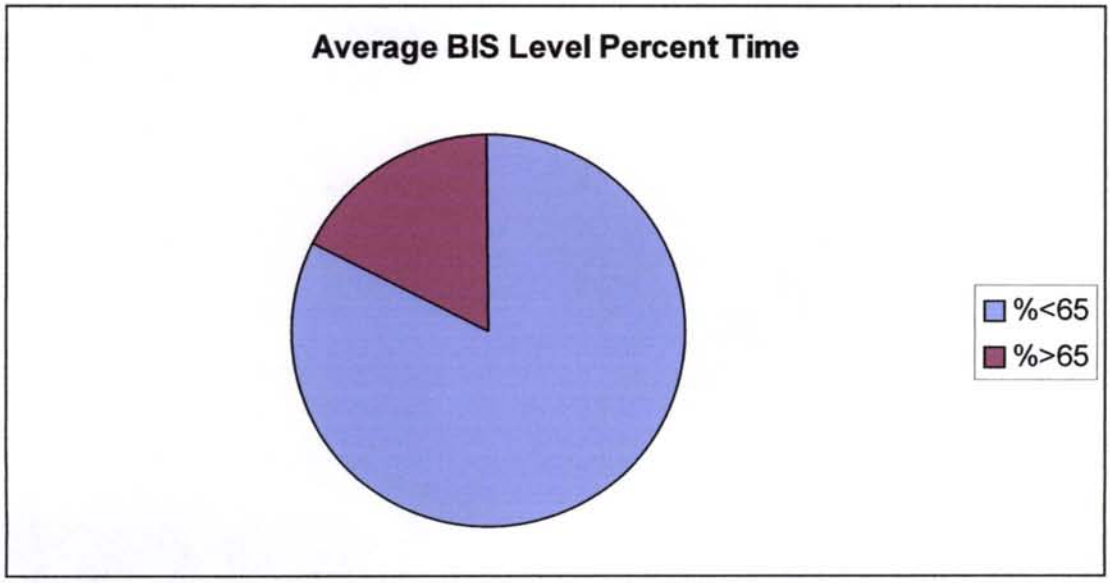
Average BIS Level Percent Time
%<65
%>65

Fig. 4

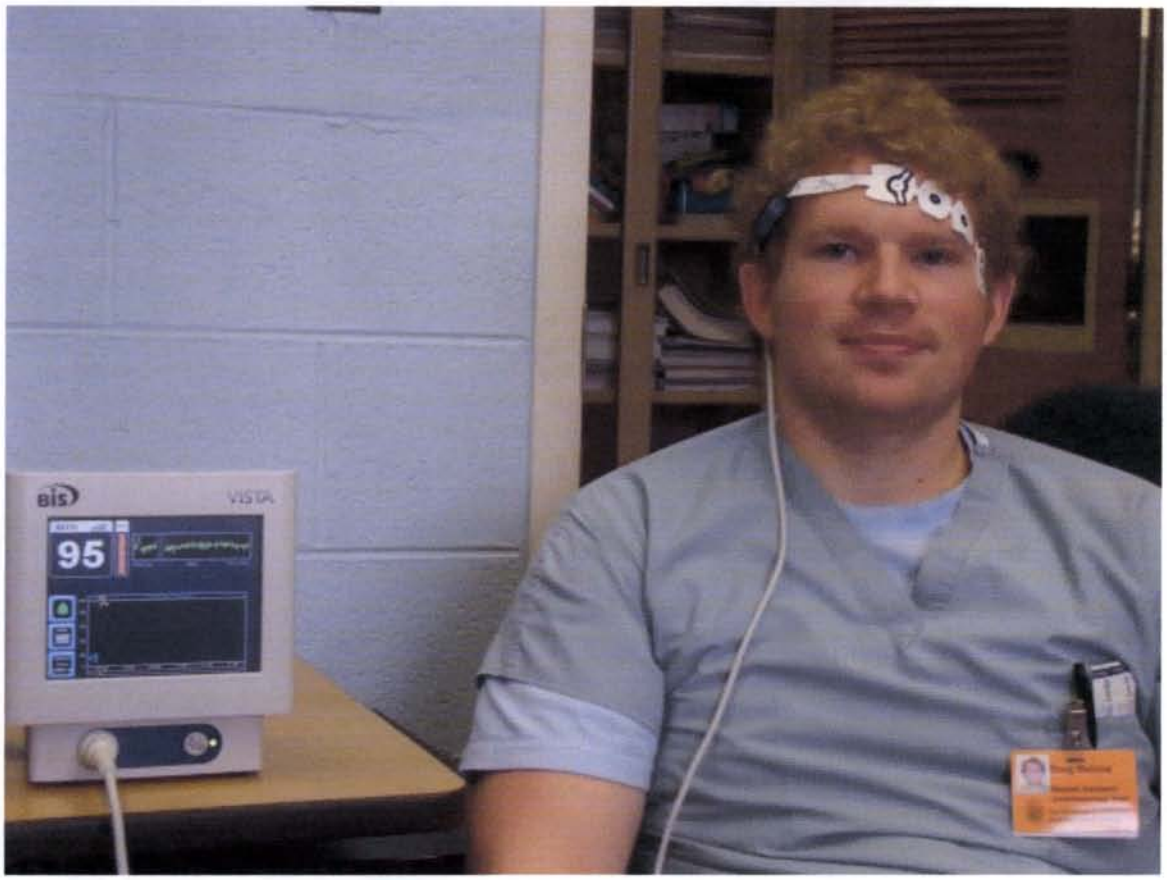

Fig. 5 – Attached BIS® System.

PT #	AVEBIS	MINBIS	AVGSQ	EMG	%<65
1	64.64	40	88.11	39.82	46.43
2	56.09	45	86.18	30.73	100.00
3	52.13	34	81.40	31.40	100.00
4	55.33	44	79.67	30.17	100.00
5	57.00	45	68.13	34.25	87.50
6	43.78	31	61.44	34.22	100.00
7	56.29	28	90.65	29.88	94.12
8	67.27	57	79.73	39.00	27.27
9	56.85	36	85.25	34.15	95.00
10	51.00	34	82.00	33.37	94.74
11	38.60	28	75.80	36.80	100.00
12	50.75	26	63.88	36.13	75.00
13	60.29	42	77.14	35.86	71.43
14	61.87	41	89.47	31.93	100.00
15	63.77	45	85.85	30.31	76.92
16	46.13	22	72.30	41.65	82.61
17	66.86	58	83.71	35.71	42.86
18	35.34	22	75.74	33.89	94.29
19	51.95	29	88.21	38.54	84.62
20	36.04	16	87.83	33.13	95.83
21	49.53	35	87.79	35.26	100.00
22	61.00	34	68.33	42.33	50.00
23	50.42	27	70.11	30.68	94.74
24	43.43	32	82.57	30.14	100.00
25	70.11	46	86.19	38.44	40.74
26	44.43	24	79.14	35.62	95.24
27	41.15	24	63.65	33.25	85.00
28	35.45	21	64.42	30.87	100.00
29	54.50	35	85.07	36.71	85.71
30	60.14	34	81.41	32.36	63.64
31	54.65	35	90.09	28.09	100.00
32	50.29	33	87.54	28.97	88.57
33	55.71	33	89.10	33.26	93.55
34	48.63	32	78.13	38.94	100.00
35	19.90	6	70.60	28.30	100.00
36	34.93	24	80.00	35.43	100.00
37	61.50	47	87.40	30.55	80.00
38	56.10	34	80.00	37.70	70.00
39	55.08	26	87.00	33.40	88.00
40	58.16	7	82.65	33.03	38.71
41	49.40	25	85.67	33.03	100.00
42	52.57	32	70.43	33.43	100.00
43	38.13	26	71.63	31.38	87.50
44	28.50	21	64.17	36.17	100.00
45	38.00	26	75.50	31.25	100.00
46	44.71	32	79.06	32.71	100.00
47	44.22	28	87.44	28.61	100.00
48	69.00	40	91.13	41.75	31.25
49	49.08	32	67.67	30.50	100.00
50	52.13	26	72.74	34.10	70.97
51	39.25	34	63.00	31.25	100.00

52	28.75	11	74.06	32.88	100.00
53	41.74	23	82.79	34.82	92.31
54	67.40	43	68.40	44.80	40.00
55	44.81	22	82.38	29.13	93.75
56	59.00	24	48.00	45.75	50.00
57	68.00	40	78.36	43.18	54.55
58	45.58	33	88.63	28.71	100.00
59	48.89	33	91.70	30.89	92.59
60	47.81	31	82.05	32.00	95.24
61	54.67	31	86.83	31.33	91.67
62	82.86	65	67.00	41.14	0.00
63	42.80	21	77.80	30.00	100.00
64	30.64	20	81.50	27.29	100.00
65	32.53	20	73.35	29.94	100.00
66	47.11	34	79.89	29.95	100.00
67	62.27	49	83.45	31.36	90.91
68	32.33	27	30.67	35.00	100.00
69	28.48	22	83.92	27.68	100.00
70	51.03	28	85.03	34.50	81.25
71	71.67	65	45.00	38.00	0.00
72	43.84	21	71.00	36.37	73.68
73	53.00	33	72.87	32.07	93.33
74	42.89	22	88.00	27.89	100.00
75	57.47	39	85.53	29.89	84.21
76	51.63	24	57.88	48.00	62.50
77	40.95	28	89.19	28.76	100.00
78	45.75	27	89.70	30.60	95.00
79	45.24	25	92.89	29.83	100.00
80	54.97	33	91.37	31.23	85.71
81	31.18	23	81.82	28.36	95.45
82	25.66	13	85.48	25.86	100.00
83	30.05	21	83.89	27.95	94.74
84	28.71	21	79.29	33.41	94.12
85	44.17	32	61.83	34.50	100.00
86	35.50	16	81.75	38.25	87.50
87	50.81	25	80.50	39.50	62.50
88	48.50	38	75.13	35.25	100.00
89	56.66	36	91.88	29.78	90.63
90	51.79	32	89.68	28.96	82.14
91	38.88	28	76.50	29.25	100.00
92	47.29	25	76.24	35.53	70.59
93	39.00	24	72.35	31.76	94.12
94	53.17	30	77.50	36.75	83.33
95	30.04	21	81.04	31.26	100.00
96	26.27	17	62.54	30.95	97.30
97	32.63	22	81.25	29.50	100.00
98	34.86	25	68.86	30.10	100.00
99	45.80	27	80.72	29.08	92.00
100	55.95	39	90.19	37.95	85.71
101	76.83	65	88.94	45.94	0.00
102	56.40	42	86.80	31.95	90.00
103	56.25	45	57.00	37.00	100.00

104	80.94	49	70.19	49.78	12.50
105	63.50	45	80.90	37.30	50.00
106	46.05	35	87.86	27.91	100.00
107	40.25	24	67.69	31.50	100.00
108	51.48	23	82.81	39.62	66.67
109	54.89	40	81.84	34.32	89.47
110	41.50	31	83.94	27.44	100.00
111	57.12	43	82.76	31.71	100.00
112	64.80	45	66.50	33.90	50.00
113	70.57	56	83.79	41.00	28.57
114	38.14	24	51.86	41.00	100.00
115	57.88	42	68.63	38.50	75.00
116	54.42	31	85.08	30.33	100.00
117	53.29	38	67.57	30.00	85.71
118	41.25	25	82.44	34.50	87.50
119	72.07	63	77.86	43.43	0.00
120	55.10	36	86.45	30.80	90.00
121	42.86	28	88.48	28.86	97.62
122	47.00	39	76.00	38.00	100.00
123	62.74	37	85.42	34.26	63.16
124	51.40	31	70.00	30.90	80.00
125	48.48	22	76.48	31.90	95.24
126	63.78	42	87.94	36.00	50.00
127	63.00	47	76.50	40.13	75.00
128	32.17	22	70.33	30.67	100.00
129	67.60	39	62.00	42.40	20.00
130	31.62	23	78.54	31.38	100.00
131	38.33	24	53.67	37.17	100.00
132	52.71	26	86.09	36.23	77.14
133	30.31	23	69.94	38.50	100.00
134	41.65	23	72.59	33.18	82.35
135	58.43	41	87.29	42.79	71.43
136	42.93	24	84.64	30.29	92.86
137	54.36	35	83.79	35.29	100.00
138	45.92	33	76.62	31.54	100.00
139	61.00	45	93.50	30.69	81.25
140	40.38	25	77.75	32.00	93.75
141	47.96	23	88.09	30.35	100.00
142	55.05	30	82.37	35.21	68.42
143	56.35	42	87.47	33.76	100.00
144	69.00	68	20.50	57.50	0.00
145	40.08	23	79.53	33.03	100.00
146	44.48	5	83.36	37.64	78.79
147	41.22	31	90.22	28.67	100.00
148	24.88	20	69.04	30.75	100.00
149	46.63	29	88.63	30.46	100.00
150	41.14	28	82.29	32.71	100.00
151	53.34	31	78.29	35.29	76.32
152	43.00	28	86.40	34.20	90.00
153	29.75	20	84.95	29.70	100.00
154	48.80	24	88.60	32.33	90.00
155	60.93	44	84.29	35.21	92.86

156	41.42	27	84.17	32.42	100.00
157	53.27	29	79.64	40.55	63.64
158	42.44	22	69.22	41.56	66.67
159	41.82	25	84.12	30.82	94.12
160	68.52	48	84.68	38.72	40.00
161	50.50	32	79.92	32.33	100.00
162	49.67	38	66.33	38.17	100.00
163	58.35	29	75.38	43.31	57.69
164	76.72	69	88.17	47.94	0.00
165	41.68	24	78.79	30.76	97.06
166	28.43	20	61.71	31.86	100.00
167	47.29	24	82.52	31.67	95.24
168	55.14	40	81.57	41.57	85.71
169	26.52	21	73.00	30.00	100.00
170	69.52	58	83.93	39.78	18.52
171	46.09	24	88.31	29.77	91.43
172	59.23	46	85.23	29.23	100.00
173	47.80	28	52.80	35.00	80.00
174	45.06	30	84.41	32.18	94.12
175	42.31	25	76.66	29.24	96.55
176	42.15	26	88.69	32.35	100.00
177	31.43	17	87.35	29.30	100.00
178	72.04	52	85.43	48.65	8.70
179	28.00	22	73.36	29.93	100.00
180	53.27	41	80.40	28.20	100.00
181	44.73	29	88.46	29.27	100.00
182	49.55	24	80.05	35.65	75.00
183	41.59	24	84.94	31.65	94.12
184	50.73	37	86.00	30.80	93.33
185	52.25	42	78.50	29.38	100.00
186	41.58	18	78.83	32.00	100.00
187	62.44	47	82.00	34.81	75.00
188	78.54	74	79.92	50.00	0.00
189	50.81	36	90.94	31.81	90.32
190	33.77	24	83.55	28.45	95.45
191	76.85	67	87.10	41.20	0.00
192	44.27	21	84.73	39.82	81.82
193	53.67	29	72.33	40.33	66.67
194	42.94	33	88.00	28.44	100.00
195	45.58	30	83.83	28.75	91.67
196	63.33	33	87.33	34.61	55.56
197	64.82	30	76.36	45.55	27.27
198	52.10	33	89.05	32.20	90.00
199	56.83	25	57.17	44.83	50.00
200	32.57	25	77.00	30.14	100.00
201	44.00	16	87.62	34.62	100.00
202	38.00	26	70.83	30.00	100.00
AVERAGE	49.33	31.98	78.73	34.22	82.26

# > 65	20.00		%<65	82.26	AbsoluteMin 5
40<#<65	142.00		%>65	17.74	
#<40	40.00		%=100	78.00	