

Electroencephalography Leads Placed by Nontechnologists Using a Template System Produce Signals Equal in Quality to Technologist-Applied, Collodion Disk Leads

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Summary: The purpose of this study was to compare the quality of the electroencephalographic (EEG) data obtained with a BraiNet template in a practical use setting, to that obtained with standard 10/20 spaced, technologist-applied, collodion-based disk leads. Pairs of 8-hour blocks of EEG data were prospectively collected from 32 patients with a Glasgow coma score of ≤ 9 and clinical concern for underlying nonconvulsive status epilepticus over a 6-month period in the Neurocritical Care Unit at the Duke University Medical Center. The studies were initiated with the BraiNet template system applied by critical care nurse practitioners or physicians, followed by standard, collodion leads applied by registered technologists using the 10/20 system of placement. Impedances were measured at the beginning and end of each block recorded and variance in impedance, mean impedance, and the largest differences in impedances found within a given lead set were compared. Physicians experienced in reading EEG performed a masked review of the EEG segments obtained to assess the subjective quality of the recordings obtained with the templates. We found no clinically significant differences in the impedance measures. There was a 3-hour reduction in the time required to initiate EEG recording using the templates ($P < 0.001$). There was no difference in the overall subjective quality distributions for template-applied versus technologist-applied EEG leads. The templates were also found to be well accepted by the primary users in the intensive care unit. The findings suggest that the EEG data obtained with this approach are comparable with that obtained by registered technologist-applied leads and represents a possible solution to the growing clinical need for continuous EEG recording availability in the critical care setting.

Key Words: EEG signal quality, Electroencephalography leads, Templates, Rapid screening, Nonconvulsive status epilepticus assessment, EEG monitoring.

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Over the past two decades, investigations into the prevalence of nonconvulsive status epilepticus in hospitalized and critically ill patients have led to the startling discovery that up to 10% to 20% of hospitalized patients with alterations in mental status can be in nonconvulsive status epilepticus (Alroughani et al., 2009; Claassen et al., 2004; Jordan, 1993,1999; Towne et al., 2000; Young et al., 1996). Moreover, there is evidence indicating that patients with prolonged

status epilepticus are more refractory to treatment, and have significantly higher morbidity and mortality (Young et al., 1996). These facts have resulted in the development of several commercial systems designed to monitor patients continuously for 24 hours to assess for seizures in high-risk patients. This increasing availability, combined with the clinical demand for early seizure detection, has led to enormous pressure on clinical neurophysiology services to be available to initiate these studies. Further compounding this increase in demand is the growing body of evidence that in addition to seizure detection, continuous EEG monitoring may be useful in a variety of brain injured patients, including patients with subarachnoid hemorrhage (Vespa et al., 1997, 2006), ischemic stroke (Diedler et al., 2009; Hirsch and Kull, 2004; Jordan, 2004), and after cardiac arrest (Rundgren et al., 2006). Review of use at our institution confirms these trends and demonstrated a 590% increase in the volume of studies performed annually between 2005 and 2009. Although we have been able to adapt to these increasing demands for service, providing a 24-hour EEG service is not practical or financially feasible for many facilities.

As an alternative to keeping registered technologists in the hospital overnight, several screening approaches have been suggested. The use of adhesive EEG leads at the hairline could allow rapid application of leads by providers not trained in the placement of EEG leads and provide a screening assessment of brain activity (Kolls and Husain, 2007). However, in a direct assessment of the sensitivity and specificity of hairline EEG using a retrospective EEG segment database, hairline EEG was found to miss 30% of the seizures tested, many of which were generalized events (Kolls and Husain, 2007). These findings have subsequently been validated by a separate group investigating the sensitivity of a commercial product based on hairline EEG lead placement (Young et al., 2009). These data suggest that a hairline-based EEG approach is inadequate, because the high false-negative rate creates a false sense of security that one has ruled out seizures and the associated need for immediate treatment. Although it has been argued that detecting 70% of patients with nonconvulsive status epilepticus is better than not looking at all (Bubrick et al., 2007, 2010; Young et al., 2009), we argue that a viable screening tool should have a sensitivity and specificity that is comparable with the standard 10/20 lead placement. In a recent report, the addition of a central lead as previously suggested (Kolls and Husain, 2007) has resulted in significantly improved sensitivities (Karakis et al., 2010), providing proof of concept that an abbreviated set of leads, rapidly applied, can provide the basis for an effective screening tool.

Given the limitations of hairline lead montages and the increasing demand for prolonged EEG monitoring, we began looking for alternative ways of allowing healthcare providers, not

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specifically trained in conventional electrode placement, to apply EEG leads accurately and quickly in a manner that meets the sensitivity and specificity standards of the 10/20 montage; the international gold standard (American Electroencephalographic Society guidelines for standard electrode position nomenclature, 1991; Guideline 5, 2006a, 2006b; Guideline thirteen, 1994; Klem et al., 1999). A template system such as the BraiNet template offers one solution (Jordan and Schneider, 2009). The template is a nonlatex containing elastic cap that can be easily applied to patients in a variety of clinical settings and requires minimal training to be able to begin using correctly (Fig. 1). The template has color-coded holes that indicate the proper EEG lead placement site and assist the user in the proper connection of the patient to the EEG recording equipment. The template can be used with disc or needle electrodes and is entirely disposable. Although this template is based on the standard 10/20 montage, it lacks 4 of the paramedian leads, F3, F4, P3, and P4 but includes the central FZ, CZ, and PZ placements in addition to the C3 and C4 leads. Given that this montage includes central leads and is based on the gold standard montage, we hypothesize that the sensitivity of this approach will approximate the 10/20 system. However, the ability of any number and configuration of leads to detect and differentiate various EEG patterns is heavily dependent on the quality of the EEG signal, which in turn is dependent on the quality of the connection and spacing of the leads on the patient's head. As a result, before sensitivity and specificity can be considered, the ability of the template and the leads to provide high-quality EEG signal data when applied by someone who is unfamiliar with traditional EEG lead placement methods must be assessed. The purpose of this study was to compare the quality of the EEG data obtained with the BraiNet template in a practical use setting, to that obtained with the standard 10/20 spaced, technologist-applied, collodion-based disk leads.

METHODS

All the aspects of this project were reviewed and approved by the local Duke Institutional Review Board and the U.S. Army Medical Research and Materiel Command Office of Research Protection, Human Research Protection Office before study initiation.

Training

Before initiating the data collection phase, representatives from Jordan Neuroscience Inc., the manufacturer of the BraiNet templates, provided several training periods over a 3-day period for our clinical service providers to attend and learn how to properly use the template system for the application of both needled and disk electrodes. Training was done 6 weeks before the initiation of data collection and consisted of the proper use of the templates and lead sets. Trainees were then provided with models and allowed to place the template and both types of electrodes onto the models under direct supervision and guidance. Only physicians and nurse practitioners applied the templates during the trial period.

Application of the BraiNet Templates

Two forms of the template kits were used during this study. The template system has been widely used and is described elsewhere (Jordan and Schneider, 2005). Both kits contained the same template (Fig. 1); however, one kit contained EEG cup electrodes (referred to as disk electrodes for the remainder of this report), and the other contained standard subdermal needle electrodes. All the electrodes were color coded to match the template and headbox amplifier labels. Application of needle leads involved application of the template followed by needle insertion. Needles were inserted in a systematic parallel fashion with tips generally oriented to the patients' feet (Fig. 1). The needles were then secured to the template using short strips of tape with EC2 cream (Grass Technologies an Astro-med, Inc., West Warwick, RI) applied to the center of the tape. Disk electrodes were secured in the usual fashion (Jordan and Schneider, 2005). The scalp was prepped with NeuPrep (Grass Technologies an Astro-med, Inc.), followed by the application of conductive paste, Elefix (Nihon Kohden America, Foothill Ranch, CA) then secured by tape with EC2 as was done for the needles. Template removal was performed 6 to 8 hours after the application by moistening the EC2 cream with water and then gently removing the electrode and excess tape and cream from the patient's hair. Once all leads were removed, the template was removed. All the templates were only used once and were discarded after recording was completed.

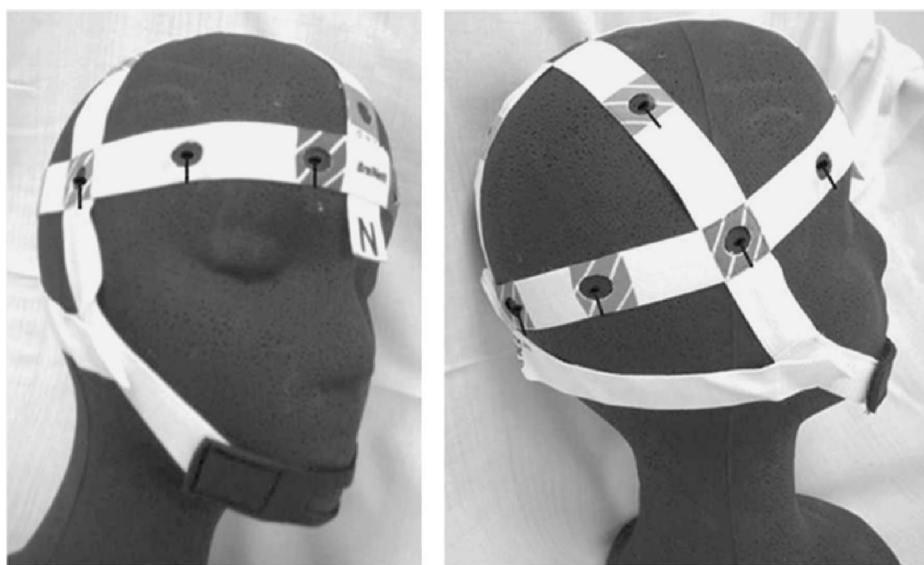


FIG. 1. Photograph of the BraiNet template in place on a model head. Disk electrodes were placed in the center of the color-coded holes using matching color-coded leads (black circles). Subdermal needle electrodes were placed as shown by the black lines. The needles were inserted near the center of the hole and oriented toward the feet to make all the leads parallel and evenly spaced. Electrodes were secured in place by applying EC2 cream and adhesive gauze over the electrode and affixing to the template straps.

Electroencephalographic Data and Recording System

We collected pairs of sequential 8-hour blocks of EEG from 32 patients admitted to the neurocritical care unit with a Glasgow coma score ≤ 9 over a 6-month period from May 1, 2009, to October 31, 2009. The blocks were sequentially acquired from the same patient within the same 24-hour period using the same recording device. The studies were initiated with the BraiNet template system applied by critical care nurse practitioners or physicians. After 8 hours of monitoring, collodion leads were applied by registered technologists using the 10/20 system of placement. Regardless of the electrodes and leads used, all continuous video-EEG monitoring was performed using the Nihon Kohden ICU video-EEG monitoring equipment (Nihon Kohden America). All EEG data for this project were collected on this system as part of routine medical care. The standard digital recording configuration consisted of: display high-pass filtering at 1 Hz and low-pass filtering at 70 Hz in the anterior to posterior bipolar montage. As all recording was digital, alternative montages were available for review of the data initially. The notch filter was generally not required. These settings were used for all recordings and were initiated through a single click on the recording screen for the software. Because the data are digitally recorded, the settings are primarily for display purposes. The data can be reviewed at any time with any filter or gain settings and any montage desired.

Preparation of the Deidentified Electroencephalographic Database

The EEG data recorded were used to prepare an archive of EEG segments to be distributed to Board-certified clinical neurophysiologists, highly experienced in EEG interpretation for masked review and quality assessment. To reduce bias during the review process, all the identifiers for both patient identification and method of acquisition were removed. This was accomplished by first exporting the segments to an archive using the "portaview" function within the Nihon Kohden system. This application produces an archive that can be opened and reviewed on any computer without installing any specific review software. To remove all patient identifiers and acquisition information, selected files within the archive were opened and manually edited using a free-ware Hex editor (Hex Editor Neo, HHD Software Ltd., www.hhdsoftware.com). All the samples were montaged to look as though they had been collected with the template, and no other montages were available for use during masked review. This was required because the template samples were missing four leads and this would be readily apparent in other montages, thus unmasking the reviewers.

Collection of Online Survey Information

Online surveys (SurveyMonkey.com) were used to collect data on template use and EEG segment quality. After each use, the users were asked about the ease of use, their preferences and reasons for lead selection, clinical value of the templates, and the desire to continue to use the templates after project completion. Masked EEG review also used the same online survey service. Four Board-certified clinical neurophysiologists, highly experienced in EEG interpretation, and who were not involved in the study design or the collection of EEG segments, blindly reviewed the segments (coauthors W.G., S.S., M.S., and C.S.). Reviewers were asked to select how they thought each segment was collected (i.e., technologist-applied leads, template-applied needle or template-applied disks) and to rate the quality of the segment as poor, adequate, good, or excellent.

Assessment of Impedances

As part of the standard EEG data collection protocol at our institution, recordings are divided into 8-hour segments. Impedances are manually recorded at the initiation of every study. At the start of each 8-hour block during recording the impedances are automatically checked and recorded. Our clinical standard for impedance is $< 5 \text{ k}\Omega$. If a particular block was ended before the normal automated check, users were asked to check the impedances before discontinuing the study. The measured values were recorded directly to the EEG data files and were reviewed off-line after the data were deidentified and copied to the research database.

Assessment of Time to Initiate a Study

To formally assess the time required to initiate an EEG recording, we tracked the difference between the time the order for an EEG was placed in the computerized order entry system, and the earliest time recorded in the EEG data file for both template and technologist initiated studies. It is important to note that the times for the technologist-applied leads could not be obtained from the same patient as the template times because any given EEG study can only be initiated once. Therefore, we examined times from studies performed on other patients who were initiated with technologist-applied leads on the same day the template study data were obtained. If no other EEG studies were initiated that day, we used times from studies initiated 1 or 2 days before. Technologist study selection was random and masked to the measured time because it required study selection before crossreferencing between two different electronic databases to derive the time measure presented here.

Analysis

Comparisons of impedance measures and mean time to the first page of EEG were performed within Excel (Microsoft Office) using one-tailed unpaired *t*-tests. Lead failure rates were calculated by counting the total number of failures in each group and then dividing by the total number of recordings made with that lead application approach. The resulting average number of failures for each approach was compared using an unpaired *t*-test.

For the subjective quality data, we first asked if the rate of success in identifying the method for recording the data exceeded the expected rate. To address this question, reviewer estimates of the data collection method were tabulated as correct or incorrect for each of the three categories (template-applied disk, template-applied needle, and technologist-applied disk). There are three options for data collection. Therefore, we estimate a correct rate for random guessing to be approximately 33%. Chi-squared analysis was applied to this 2×3 table to determine if the number of correct reviewer estimates on collection approach exceeded the expected rate of 33%.

Next, general linear modeling was used to compare the distribution of quality estimates and explore the impact of reviewer expectations on data interpretation using SAS v9.2 for Windows (Cary, NC). All 4 reviewers reviewed all 69 segments collected, resulting in 276 independent assessments. The 276 quality assessments obtained from these reviews were initially placed into one large database in which the lead application method was dichotomized to technologist or template applied. The quality assessments were scored poor = 1, adequate = 2, good = 3, excellent = 4; these data were then treated as ordinal. Standard univariate analysis was performed on this one large database to look for any unexpected relationships between the reviewer, segment quality and method for lead application. The database was then divided into two datasets.

One set (set A) consisted of the reviewer estimated lead type for collection, dichotomized to technologist or template, and the assigned quality rating for each reviewed segment. The second set (set B) used the reviewer quality ratings assigned to the actual lead placement approach used for collection of the data segment. The mean quality scores were calculated for each application approach within each dataset and then compared using an unpaired, one-tailed *t*-test. The general linear modeling was applied to each set to determine if the quality of a segment could be used to predict how it was recorded. The general estimating equation was then applied to each set to control for clustering of reviewer quality ratings when exploring the relationship between the quality of the segment and the method for data collection. Finally, using the general estimating equation to control for reviewer clustering, recording quality was explored using a derived dichotomous variable where quality was 'poor' (score = 1) versus 'adequate' (score = 2, 3, or 4). The mean quality scores were also calculated for these newly dichotomized data sets and compared using a one-tailed *t*-test.

RESULTS

During the 6-month trial period, we successfully initiated prolonged EEG monitoring studies with the BraiNet templates in 32 of 36 attempts. Of the failed attempts, one attempt failed as a result of significant oozing from multiple scalp wounds. Notably, the technologist-applied leads were also delayed for a day in this patient for the same reasons. Two failures clearly resulted from the extended period (6 weeks) between the training for template application and the initiation of data collection. One failure resulted from the improper use of adhesive instead of conductive agent on disk electrodes, and another failure occurred as the result of improper use of conductive agent instead of fixative agent to needle electrodes. These procedural problems did not recur after additional review of the application procedures with ICU staff and the addition of educational materials detailing the application procedures to the supplies for the template system. The fourth failed attempt was because of aged EEG lead kits. In two lead sets that were more than a year old, abnormal capacitances on needle leads resulted in extremely poor recordings that had to be terminated early, per protocol, on review by the neurophysiology service. All unsuccessful attempts occurred in the first 2 months of the study period and did not recur once newer lead sets were obtained and the educational changes mentioned above were implemented.

Objective Measures of Performance

We compared the impedances of the leads applied using the template measured at the beginning and end of the recording block with the impedances obtained with the technologist-applied collodion leads applied to the same patient for the subsequent recording periods. Our clinical standard is to keep impedances under 5 k Ω at the start of a study. On average, the template-applied leads had slightly higher impedances than those obtained with the collodion-based leads ($P < 0.001$, Fig. 2). Although higher, the average impedance for the template leads (5 k Ω) throughout the recording period was generally within our clinical standards suggesting that performance should be adequate for recording. It is also important to note that no significant differences were found between template impedances at the start and end of the recording period ($P = 0.1993$). However, the increase in technologist-applied lead impedances at the end of an 8-hour recording was statistically significant,

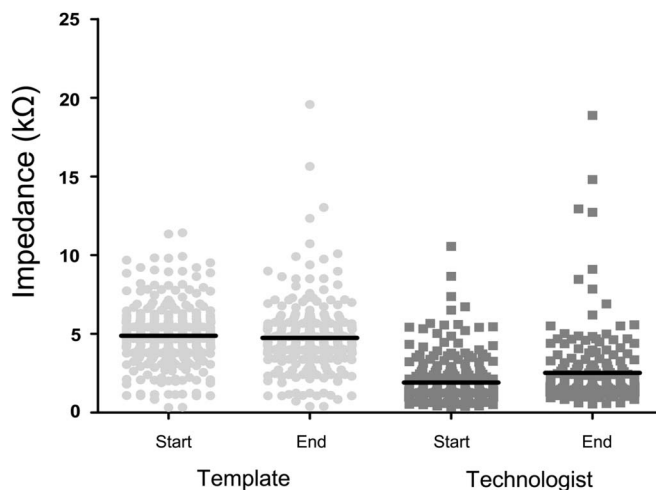


FIG. 2. Comparison of mean impedance measures. We compared impedance measures from 22 electroencephalographic (EEG) segments obtained with registered technologist-applied collodion-based leads and 28 segments obtained with BraiNet (BN) template-applied needle ($n = 23$) or disk leads ($n = 5$). Impedances were measured at the beginning (Start) and end (End) of 8-hour recording blocks to assess the impact of typical nursing care on the quality of lead connections over time. Each symbol is a single electrode impedance measure (Template Start $n = 355$, End $n = 282$; Technologist Start $n = 257$, End $n = 205$). Template-applied leads had significantly higher impedances on average ($P < 0.001$) compared with collodion leads. Both application approaches changed little over the 8-hour recording period, though the increase in mean impedance for Technologist leads was statistically significant ($P = 0.0002$).

though still within our clinical standard and unlikely to be functionally significant ($P = 0.0002$, Fig. 2).

Comparison of the quality of the connections over time in more detail was approached in two ways: first, by comparing the numbers of lead failures; second, by comparing variations in the impedances over time. Over an 8-hour period of routine nursing care, the mean number of lead failures was similar for both lead application methods, 0.93 failures for the template-, and 0.83 failures for the technician-applied leads ($P = 0.4392$). The variance for a given lead set was calculated at the start and the end of recording for 28 template sets and 18 technologist sets. Comparison of the variance in impedance initially and over time demonstrated no significant differences between the two application approaches (Fig. 3). Given that it is inequality between the lead impedances, which produces significant signal artifact, we calculated the largest difference between any two leads in a set, (regardless of the likelihood of them being used as a lead pair), and compared the differences in template- with technologist-applied leads. As shown in Figure 3, impedance differences were similar for both methods even using the more conservative approach of 'largest' difference. There was a larger difference between the application approaches at the beginning of the recording compared with the end, suggesting relatively greater stability in the impedances for template leads over time ($P = 0.005$ at start, $P = 0.281$ at end). Although these small differences (<2 K Ω) are statistically significant in some cases, the differences measured for both lead applications are too small to produce any clinically significant artifact in the recordings.

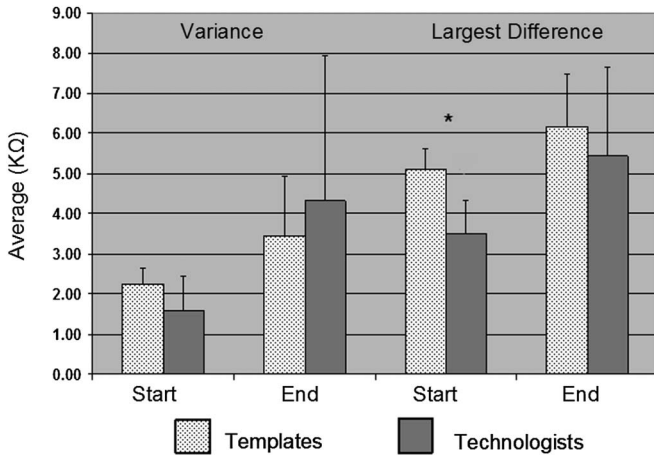


FIG. 3. Comparison of the average variance and maximum differences in impedance measures from technologist ($n = 22$ lead sets) and template-applied leads ($n = 28$ lead sets). The variance and largest difference in impedance was determined for each electrode set at the beginning (Start) and end (End) of each 8-hour recoding block. These measures were then averaged for each application approach, and the standard error (error bars) was calculated. Comparison of the means using an unpaired, one-tailed t -test did not demonstrate any significant differences for most comparisons. Only the largest differences at the start of recording (*) were significantly different, and no difference was seen at the end of the 8-hour block ($P = 0.005$).

Our final objective measure was the time required to initiate a study. As shown in Figure 4, the use of the templates reduced the average time to obtain EEG data by 3 hours ($P = 0.0006$). The longest delay for the template group (6 hours, 43 minutes) occurred

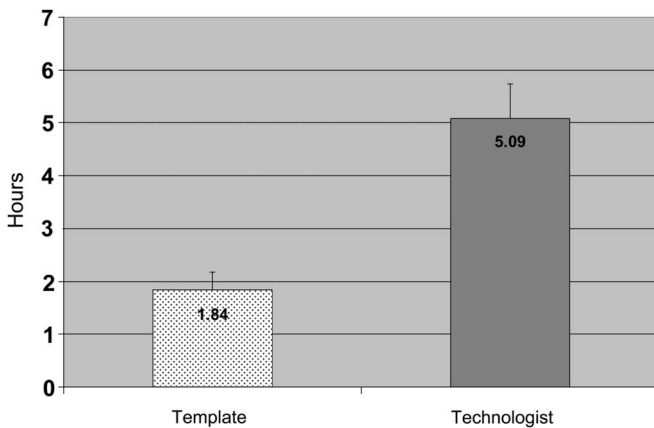


FIG. 4. Using templates, bedside care providers were able to begin recording electroencephalographic (EEG) data over 3 hours faster compared with the standard approach to initiating studies. Times were derived from taking the difference between the timestamp on the order in the computerized order entry system and the first time recorded in the EEG data. Comparison of the mean time (provided in bold in hours) required to begin recording shows a significant reduction in study initiation time ($n = 19$ for templates, $n = 35$ for technologist-applied leads, unpaired t -test, $P < 0.0001$).

as a result of patient care emergencies that interrupted and delayed the completion of the template study. However, given this is a practical issue and is likely to be a common problem in real practice, that time is reported here and included in the analysis. The outlier for the technologist group (18 hours, 34 minutes) occurred as a result of high clinical volume on the day of initial request and a gap in overnight technologist coverage, which resulted in the delay of the study until the following day. If this outlier for the technologist group is excluded, the mean time for application is 4 hours and 37 minutes, which is still significantly longer than the mean time (1 hour and 50 minutes) to record using the templates ($P < 0.0001$).

Subjective Performance

Analysis of the survey data obtained from template users immediately after each template use revealed some important observations. Based on responses, 62% of the templates were applied by NPs, 22% by Neurocritical Care fellows, and the balance by attending physicians. Overall, 29% were applied in under 30 minutes, 58% of the studies were recording EEG in under 40 minutes, and 87% were recording in under 60 minutes. Only 12.5% took >1 hour to apply. Eighty-one percent of the template applications used needles. Seventy-eight percent of the respondents believed that the templates were easy to use with the most difficult part involving starting and configuring the computer software to begin the digital recording. Of the 4 studies that took more than 1 hour to place the leads, 1 was a failed study because of oozing and bleeding of scalp wounds in a trauma patient, which also prevented technologist leads from being placed for a full 24 hours after the failed template attempt. Another was a disk electrode application that resulted in high impedances that were difficult to correct. No information or reasons for the prolonged time to connect the patient and record EEG were provided for the two remaining studies.

After the trial period, 63% of respondents used the templates 1 to 5 times, and 25% had used it 6 to 10 times during the trial period. These primary users of the templates reported they believed needles were superior in performance were generally faster, remained in place longer, and provided a better study quality than did disk electrodes in their relatively inexperienced hands. Most of the failed template study attempts involved the attempted use of disk electrodes. Needles were preferred for their ease of use, shorter time to apply, and generally low impedances on the first attempt. After the trial, most template users believed they could safely use the templates in patients with higher Glasgow coma score scores (≤ 10). Most respondents also believed the templates were underused, with 25% reporting significant numbers of patients that the templates could have been used on during the trial period. All the respondents believed the templates became easier to use over time, and 75% believed they had improved care. All the respondents believed the improved quality of care was worth the trouble of connecting the templates, and all wanted to continue using the templates once the trial period was over.

As a result of the high use of needle electrodes in this study, we explored the ability to acquire computed tomography (CT) scans without removing the leads. This would be a tremendous benefit because it would allow patients to be scanned faster because the CT study is not delayed waiting for EEG leads to be removed. Rather, it allows EEG monitoring to resume the moment the scan is completed or go uninterrupted in the case of portable CT technology. These advantages would be in addition to the obvious reduced work for the technologists. We tested this during the trial period and found that the templates, when used with the needle electrode sets, did not produce any significant artifacts in the images obtained by CT (Fig. 5). Angiography could also be performed without removing the leads (data not shown).

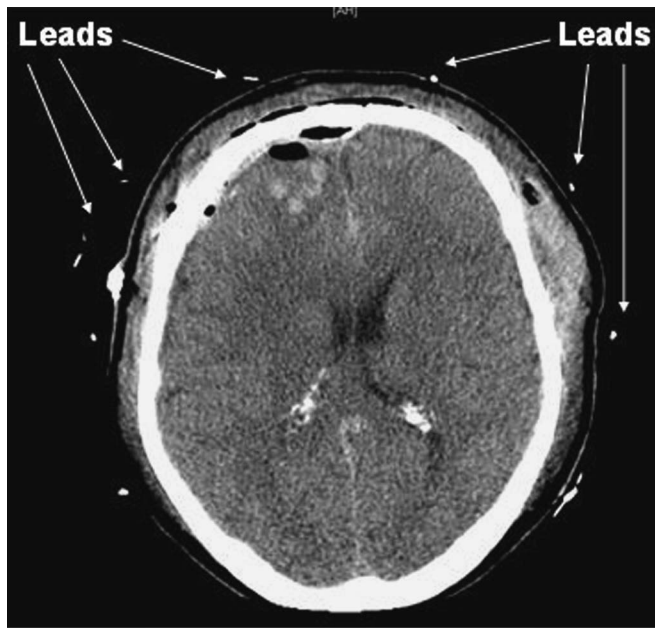


FIG. 5. Computed tomography (CT) scanning can be performed without removing the leads. The widespread acceptance of the needle leads prompted us to look at imaging quality in one of the patients with a set of needle leads applied. There was no loss of image quality or shadow artifact from the leads.

Masked Electroencephalographic Segment Review

Although the above results would suggest that the template leads should perform as well as the technologist-applied leads, the final test of the quality of the EEG data is the review of the data by Board-certified clinical neurophysiologists who are highly experienced in EEG interpretation. The reviewers were given three options for lead placement; thus, it is expected that they would correctly identify a given segment 33% of the time if they were randomly guessing how the EEG data were obtained. Analysis of the number of correct determinations for EEG lead type revealed the reviewers to be correct 33% of the time. Chi-squared analysis of these data verified that correct identification of the recording method was independent from the true recording method ($\chi^2 = 0.83$).

Given that the reviewers could not determine how a particular segment was collected, we explored if the template data were of equal quality to the technologist data. To assess this, we first converted the quality ratings to a quality score. Univariate analysis on this dataset revealed a statistically significant association between the reviewer and the segment quality score ($P < 0.0001$). No other interactions were found. The data were then divided into two datasets based on the anticipated recording method or the actual method of segment recording. The distributions of quality ratings for these two datasets are shown in Figures 6A and 6B, respectively. It is clear from the shifted peak in Figure 6A that the reviewers were heavily biased toward the technologists. Our primary question was to determine if the lead type could be predicted by the segment quality. As a first level of analysis, we compared the mean quality score for the two methods of application. Template leads scored significantly lower on average (1.9 ± 0.72 , mean \pm SD) than technologist leads

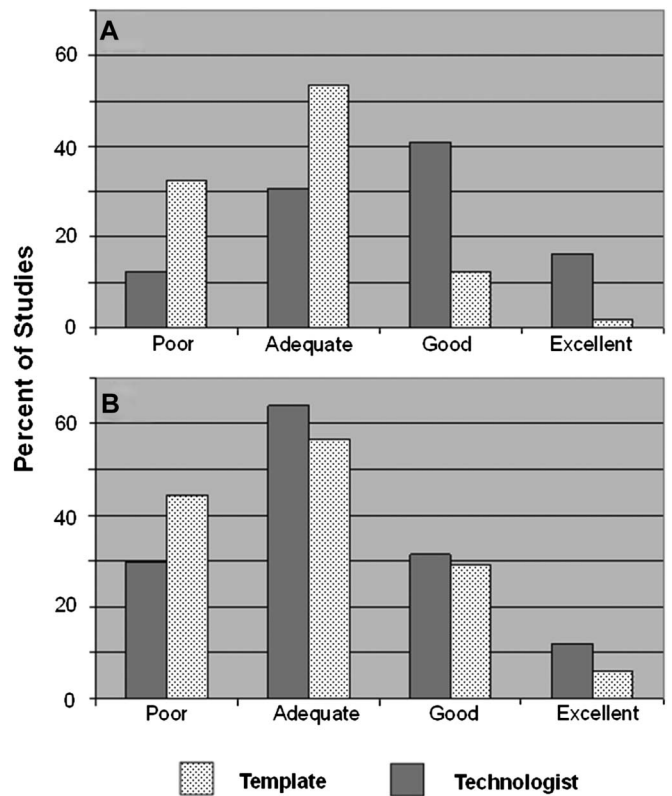


FIG. 6. Subjective quality assessment distributions are similar for both lead application approaches. The number of segments with each quality rating was determined for each reviewer, and then this was summed across reviewers and divided by the total number of segments reviewed ($n = 276$) to get the proportion of studies with a given rating. The ratings were then assigned to the template or technologist group based on either the reviewers' guess (A) or the known application approach (B) used. The skew in the distribution of the quality ratings when using the reviewer-assigned electrode types is easily seen in (A). Linear regression analysis did not show significant differences between the quality distributions when the known application approach was used (B), confirming equivalence of the quality distributions.

(2.5 ± 0.91) when using set A ($P < 0.0001$). However, no significant difference in mean scores (2.2 ± 0.85 for template and 2.1 ± 0.86 for technologist) was seen when using set B ($P = 0.3810$). We then wanted to know if there was a significant difference in the overall quality distributions between the two methods of lead application. Regression analysis using set A and controlling for reviewer effects on quality scores confirmed a significant difference between the 2 quality distributions ($P < 0.001$). However, no difference in the quality distributions was found when set B was used, and we controlled for the effects of the reviewer on quality scores ($P = 0.378$).

Despite showing no significant difference between the quality distributions for template and technologist-applied leads, there was still the possibility that the templates resulted in a greater number of poor quality studies overall. We further evaluated this by dichotomizing the quality to 'poor' vs. 'adequate.' When analysis was applied to set A, quality and method were highly correlated ($r^2 = 0.053$,

$P < 0.0001$). However, when we applied this analysis to set B (true recording method) we found that poor segments were not more likely to be recorded with the templates compared with technologist-applied leads ($r^2 = 0.010$, $P = 0.05$). To further confirm this finding, we calculated mean quality scores for the dichotomized datasets. For set A, the mean score for templates was 1.7 ± 0.47 , while the mean score for the technologist leads was 1.9 ± 0.33 ($P < 0.0001$). However, when set B was used the means were 1.7 ± 0.47 and 1.8 ± 0.41 for template and technologist leads, respectively ($P = 0.276$).

DISCUSSION

The primary objective for this project was to determine if EEG leads placed by health care providers that have not been certified as EEG technologists, using a commercially available, Food and Drug Administration approved, 10/20 system-based template (BraiNet) can produce EEG signals that are equal in quality to those obtained with collodion applied disk leads placed by certified technologists using the 10/20 placement system. Our analysis of both objective and subjective measures of signal quality indicate functional equivalence between technologist-applied and template-applied leads in a practical use setting.

There is a growing need for an easy to use, rapid screening tool for the assessment of seizures in patients with altered mental status. Prior attempts to limit leads and change the complexity of lead application have failed to provide a high sensitivity for seizure detection. The requirement for central leads mandates a more careful placement approach with a minimum number of leads. Our current data suggest that the BraiNet templates provide a low cost, disposable, easy-to-use solution that produces EEG signals that are equal in quality to those obtained with collodion applied leads. Although the impedances were higher on average for the templates, this is likely the result of the high proportion of needle leads used in this group, which are expected to have higher average impedances because of their significantly smaller surface area (12.8 mm^2) compared with disk leads (78.5 mm^2). Indeed, these small differences in impedance did not produce clinically significant signal differences in the EEG because quality ratings were equal for technologist and template-applied leads. Further, direct assay of the effects of increasing impedance on signal quality suggest that impedances as high as $40 \text{ k}\Omega$ can still result in acceptable signal quality (Ferree et al., 2001). Clearly, impedances this high would not produce acceptable recordings within the artifact riddled ICU environment in which 60-Hz noise is only one concern. This is the reason the clinical standard continues to be to maintain impedances $<5 \text{ k}\Omega$. However, the fact that newer digital recording methods combined with our data suggest that high-quality recordings can be made using templates.

The largest concern with template-applied leads was that their use would result in more poor quality studies. We comprehensively assessed this and could not find significant differences in the quality distributions, quality scores, or the number of poor quality recordings. Given the degree of bias in the reviewers and the limited experience of the primary users of the templates, our results would seem quite robust and convincingly show the distribution of subjective recording quality to be the same between recordings made with template-applied electrodes and those made with technologist-applied electrodes.

Clearly, the value of a lead placement approach is dependent on the ease of use and speed with which it can be used. This is particularly true if the approach is to be considered as a possible screening tool. Further, if those expected to use the equipment do not support it or believe that it does not have the potential to positively

impact care and service then it is doomed to fail. In our survey data obtained from the primary users of the templates, the overwhelming majority believed there was an important role for the templates in our service, and they supported the continued use of the templates. The primary users believed that the templates had improved care and that the time it took to apply the leads using the templates was well worth the effort in exchange for the improved level of care. The respondent perception that care was improved was likely based on the reduced latency in which EEG studies were started and interpreted. On average, the templates were providing EEG data a full 3 hours earlier than our standard approach of waiting for a technologist after placing an order in the computerized order entry system. This, combined with the fact that the vast majority of the template studies were initiated in <50 minutes makes this template based approach a viable solution to the rapid assessment tool need.

One unexpected finding was the rapid acceptance of needle EEG electrodes. Before this trial, needle EEG leads in our institution were only used for intraoperative monitoring cases and were not used for either inpatient or outpatient EEG. Indeed, during the pretrial training most of the trainees voiced concern about the use of needle leads and were decidedly committed to disk electrodes. Further, nursing had safety concerns that needles would become dislodged and “free” in the patient’s bed. As a result, special bright orange signs were requested to notify nursing and all who entered the patient’s room that needle leads were present on the patient. However, shortly after the trial began, the advantages of the needles became apparent. There was no need to prep the scalp for the needle leads making them easier and faster to apply, and the leads did not have to be removed for CT scans. As a result, there was a very rapid migration to the needle leads by the primary users. Nursing acceptance came later, when it became clear that the leads were not frequently dislodged as expected. Nursing was also noted to actively report and in some cases replace loose or poor quality leads as they now had confidence in their ability to correctly identify the problem leads and had the skills and supplies necessary to repair the lead. Further, the simplified travel to CT with reduced delays, because the leads did not have to be removed, was also a strong contributor to the acceptance of needle leads by nursing.

One major weakness of the current project was the limited number of EEG segments, which, combined with the serial data collection protocol, prevented the assessment of sensitivity and specificity of the template montage we used. We did determine that none of the masked readings differed from the original reading performed on the 10/20 acquired data; however a formal assessment of the BraiNet montage and other montage subsets is needed and will be the focus of future studies on this approach to EEG acquisition. Thus, all we can conclude from the current work is that the EEG signals obtained with electrodes placed by providers not certified as EEG technologists using a template system are equivalent in quality to technologist-applied leads. We cannot be certain that the montage of electrodes present in the template will provide the same sensitivity and specificity for the various EEG patterns seen in patients with acute mental status changes and acute brain injuries in the ICU. However, the recent report that the addition of central leads to a limited montage can result in high sensitivity and specificity is encouraging (Karakis et al., 2010).

CONCLUSIONS

The main question addressed in this project was to determine if the EEG signal quality obtained with electrodes placed by providers not certified in EEG lead placement using a template

system would be similar to that obtained by certified technologists using the 10/20 placement system. Formal, systematic assessment of the EEG data demonstrated that using leads placed with a template is faster and produces EEG signals of equal quality to those obtained with standard technician-applied collodion leads. This is an important finding, because it may allow more centers to provide 24-hour EEG service and initiate studies to screen patients for status epilepticus and determine those that are most appropriate for transfer to larger centers, and initiate medical treatments sooner. This study design prevented the assessment of sensitivity and specificity of the template montage and more formal, comprehensive assessment of this is required. Indeed, further studies will focus on the validation of the sensitivity and specificity of the montage used with the templates, and the more rapid deployment of this method, and moving it to the Emergency Department setting to determine if its performance continues to meet clinical standards of care in the hands of nonneurology-oriented, nontechnologist healthcare providers.

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