**Title**

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# Major and minor complications in extraoperative electrocorticography: A review of a national database

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## Abstract

The risk profile of extraoperative electrocorticography (ECoG) is documented almost exclusively by case series from a limited number of academic medical centers. These studies tend to underreport minor complications, like urinary tract infections (UTIs) and deep venous thromboses (DVTs), that nevertheless affect hospital cost, length of stay, and the patient's quality of life. Herein, we used data from the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) to estimate the rate of adverse events in extraoperative ECoG surgeries. NSQIP is a validated dataset containing nearly 3 million procedures from over 600 North American hospitals, and uses strict criteria for the documentation of complications. Major complications occurred in 3.4% of 177 extraoperative ECoG cases, while minor complications occurred in 9.6%. The most common minor complication was bleeding requiring a transfusion in 3.4% of cases, followed by sepsis, DVT, and UTI each in 2.3% of cases. No mortality was reported. Overall, in a national database containing a heterogeneous population of hospitals, major complications of extraoperative ECoG were rare (3.4%). Complications such as UTI and DVT tend to be underreported in retrospective case series, yet make up a majority of minor complications for ECoG patients in this dataset.

### Keywords

ECoG; Complications; Adverse events; Patient safety; Epilepsy; Seizures

## Introduction

Extraoperative electrocorticography (ECoG) is a means of obtaining high quality electroencephalographic data that can then be used to localize otherwise occult seizure foci (Lee et al., 2000; Rolston et al., 2015; Vale et al., 2013; Van Gompel et al., 2008). Without the critical information ECoG provides, many patients would not be candidates for surgery, since no definitive seizure onset zone would be recognized. Yet all surgeries carry risk. Reported case series of ECoG procedures are typically from high-volume academic centers, and often fail to report minor complications like urinary tract infections (UTIs), deep venous thromboses (DVTs), and pneumonias. Though such complications are minor, they

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nevertheless contribute to increased costs, longer inpatient stays, and worsened quality of life.

In 2005, the American College of Surgeons (ACS) created the National Surgical Quality Improvement Program (NSQIP) in an effort to identify and prevent perioperative complications (Ingraham et al., 2010; Khuri, 2005; Rowell et al., 2007). NSQIP contains a database of nearly 3 million surgical procedures from over 600 hospitals primarily in the United States, but also Mexico and Canada. The group of hospitals contains a heterogeneous collection of academic and private centers, as well as low- and high-volume hospitals. Data are entered prospectively by trained and frequently audited personnel. Strict criteria are used for complications, which are tracked for the 30 days following surgery. For instance, to qualify as a deep venous thrombosis (DVT), the diagnosis must be confirmed by imaging (duplex ultrasound, venogram, CT scan, or other definitive modality) and the patient must be treated for the DVT (or document their informed decision to refuse treatment). Asymptomatic events would not be included, nor would clinically presumed but not confirmed cases. These strict criteria will likely lead to a conservative underestimation of many complications.

Another advantage of NSQIP is the use of Current Procedural Terminology (CPT) codes for identifying surgical procedures. This compares to other databases, like the Nationwide Inpatient Sample (NIS), which only use International Classification of Diseases (ICD-9) billing codes. The ICD-9 code for ECoG (02.93), for example, is non-specific: “Implantation, insertion, placement, or replacement of intracranial: brain pacemaker [neuropacemaker], depth electrodes, epidural pegs, electroencephalographic receiver, foramen ovale electrodes, intracranial electrostimulator, subdural grids, subdural strips” (Rolston et al., 2015) This is the same ICD-9 code used for deep brain stimulation (DBS) and many other indications. Therefore, the documentation of concurrent ICD-9 codes (like refractory epilepsy) is required to ensure that only ECoG cases are extracted. This is an imperfect method, and excludes cases where additional diagnoses are not explicitly entered by billing personnel. CPT codes help in this regard due to their specificity. For example, there are four specific codes for ECoG surgery (see Table 1).

Using NSQIP, we investigated the rate and type of perioperative complications for extraoperative ECoG. This allowed us to compare the observed rate from this heterogeneous hospital sample, compared to historical reports from academic high-volume centers.

## Materials and methods

CPT codes were used to extract all ECoG procedures performed between 2005 and 2013 from the NSQIP database (Table 1). Some of the complications documented in NSQIP might reflect preexisting conditions. For instance, one tracked complication is ventilator dependence for longer than 48 h postoperatively. If a patient was ventilator-dependent preoperatively, however, this postoperative event is likely a reflection of a preexisting condition, rather than a new postoperative complication. Therefore, we excluded complications when associated preexisting conditions were present. However, if it took more than 48 h for the condition to develop and be documented, it was unlikely present at the time immediately before surgery, and therefore included as a complication. Note that this restriction was only for potential preexisting complications—all complications without evidence of preexisting conditions were included, regardless of timing (0 to 30 days postoperatively). This correction for potential preexisting conditions was done for the following complications: superficial surgical site infection (SSI), deep incisional SSI, organ space SSI, pneumonia, ventilator-dependence >48 h postoperatively, progressive renal insufficiency, acute renal failure, coma lasting >24 h, sepsis, and septic shock. Additional complications were identified by examining the postoperative diagnosis; this identified 3 cases of subdural hematoma and one of spinal fluid leak.

Complications were classified as major or minor, following prior studies of epilepsy surgery (Bjellvi et al., 2015; Hader et al., 2013). In short, major complications were defined as those likely to produce effects persisting >3 months, while minor complications were those expected to resolve in <3 months.

Statistical analysis was performed with version 23 of SPSS (IBM; Armonk, NY, USA). Averages were presented with standard deviation (SD) unless otherwise specified. Multivariate regression was done using the backward Wald method, an exclusion cut-off of 0.05 and a maximum of 200 iterations.

## Results

Using the CPT codes for ECoG surgery (Table 1), 177 cases of extraoperative ECoG were extracted from the NSQIP database between the years 2005 and 2013. Most of these procedures were for craniotomies and placement of subdural electrodes (67.8%), with burr holes and stereotactic placement (SEEG) less frequent (Table 2).

Each procedure in the NSQIP database reports a single postoperative ICD-9 diagnosis. For ECoG, the most common diagnosis was localization-related complex partial seizures (48.6%). These postoperative diagnoses also identified 3 removals of ECoG arrays for subdural hematomas, and one spinal fluid leak requiring repair (Table 3).

Complications were documented in 21 of 177 patients (11.9%; Table 4). Major complications were rare (3.4%), while minor complications occurred in 9.6% of cases. The most common minor complication was bleeding requiring a transfusion (3.4%), followed by sepsis, DVT and UTI, each in 2.3% of cases (Table 4).

Univariate analysis was used to identify potential predictors of complications. Short stature and Asian race were significantly associated with complications by this method (Table 5). Multivariate analysis was then used to account for possible cofounders. This identified only Asian race as a significant predictor of complications: odds ratio (OR) of 19.00 (95% confidence interval: 1.62, 223.03). However, given the small number of Asian patients ($n$ = 3), this is possibly spurious.

## Discussion

ECoG is a critical means of identifying potentially resectable epileptic tissue. Without ECoG, many patients with refractory epilepsy would be ineligible for potentially curative resective surgery. Like all surgery, ECoG placement and removal is associated with complications. Yet the frequency of complications is typically determined from studies by academic programs in large-volume epilepsy centers. These studies tend to underreport or fail to report minor complications such as UTIs and DVTs.

Using the NSQIP database we were able to identify 177 cases of extraoperative ECoG. The overall complication rate was 11.9%, with bleeding requiring a transfusion the most common minor adverse event (Table 4). This overall rate is slightly higher than most previous reports from academic case series. For example, Vale et al. recently reported complications in 11% of their 91 cases (Vale et al., 2013). Most other studies report lower rates. Placantonakis et al. (2010), for example, saw only two complications in their cohort of 26 patients (7.7%), with one retained electrode and one pulmonary embolus. Van Gompel et al. (2008) had a large cohort of 189 patients, and saw a still lower 6.6% rate of major complications (minor complications were not reported). Fountas and Smith (2007) report a similar 5.9% rate from 185 patients. Older studies report even lower rates of complications: for example, Wyler et al. (2009) report 0.85%; Blom et al. (1989) report no complications; and Spencer (1989) reviewed the literature and reported a 2% rate for subdural grids and 1% for depth electrodes.

Of note, we were unable to find any studies that reported UTIs as complications of ECoG, and only one study documented any DVTs (Van Gompel et al., 2008, 1.5% rate). Other studies either had no such complications or did not monitor for them.

One explanation for the increased frequency of minor complications observed in the NSQIP database is the stringency by which complications are documented. NSQIP uses well-trained and frequently audited personnel with strict criteria for the documentation of complications. In most case series, criteria are implicitly rather than explicitly defined. Moreover, NSQIP monitors for complications that could be overlooked by many surgical groups, such as pneumonia and UTIs. The more inclusive lens through which NSQIP views complications could therefore be responsible for the increased minor complication rate documented.

There are many limitations to registry studies like NSQIP. Foremost, the complications tracked by NSQIP are not specific to neurosurgery, but are generalized across all surgical specialties, including things like stroke, myocardial infarctions, DVTs, pulmonary emboli, surgical site infections, wound dehiscences, and more. NSQIP does not include complications specific to neurosurgery like spinal fluid leaks or subdural hematomas, unless they require a return to the operating room and subsequently generate an informative postoperative diagnosis. The real rate of these complications might be therefore higher, as suggested for example by data from the NIS, where spinal fluid leaks affected 11.7% of patients (Rolston et al., 2015). Additionally, because this is a general database, a more refined grading scale for complications, like that of Mathon et al. (2015) or Wellmer et al. (2012), is unfortunately not feasible. Improved grading schemes would take into account longer follow-up (NSQIP is restricted to 30 days) and additional incidental or transient complications (like incidental imaging findings that do not require treatment) (Mathon et al., 2015; Wellmer et al., 2012). Registries specific to neurosurgery, like the National Neurosurgery Quality and Outcomes Database (N2QOD), will help with this lack of specificity in the future (Asher et al., 2015).

Lastly, multivariate analysis of patient-level predictors of complications revealed only one significant factor in the NSQIP data: Asian or Pacific Islander race. However, while technically statistically significant, this predictor was based on data from only 3 patients, and we therefore do not believe it should be extrapolated to larger population sizes. Additionally, because demographics can correlate with a hospital's geographic location (not reported in NSQIP), there is always a chance that these types of predictors reflect a particular hospital with a particular patient population, rather than a true underlying race or ethnicity factor. Ultimately, because of the low complication rate of ECoG, it will take a considerably larger database to isolate significant patient-level predictors—which is further motivation for supporting national-level databases of surgical procedures and their complications, like NSQIP.

## Conclusions

ECoG is an indispensable tool for identifying resectable seizure foci. Complications from ECoG surgery are most frequently reported by large academic centers, which often underreport minor complications like UTIs and DVTs. Using data from the American College of Surgeons NSQIP dataset, which rigorously documents surgical complications, we identified an overall rate of adverse events in ECoG surgery of 11.9%. The majority of these complications were minor and included adverse events not tracked in previous studies, like UTIs. More work must be done to confirm these rates and identify ways of reducing complications in ECoG procedures. Nevertheless, ECoG remains the only route to potentially curative epilepsy surgery for many patients. The benefits of eradicating potentially life-threatening seizures will in many cases outweigh the risk of minor adverse events form ECoG and ultimately resective epilepsy surgery.

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**Table 1**

CPT codes for ECoG surgery.

| CPT code | Description |
|---|---|
| 61531 | Subdural implantation of strip electrodes through one or more burr hole for long-term seizure monitoring |
| 61533 | Craniotomy with elevation of bone flap; for subdural implantation of an electrode array, for long-term seizure monitoring |
| 61535 | Craniotomy with elevation of bone flap; for removal of epidural or subdural electrode array, without excision of cerebral tissue (separate procedure) |
| 61760 | Stereotactic implantation of depth electrodes into the cerebrum for long-term seizure monitoring |

**Table 2**

Frequency of procedures from 2005 to 2013.

| Procedure | Number of procedures | Frequency |
|---|---|---|
| Burr hole for subdural electrodes | 30 | 16.9 |
| Craniotomy for subdural electrodes | 120 | 67.8 |
| SEEG | 9 | 5.1 |
| Removal of electrodes | 33 | 18.6 |
| Total | 177 | |

**Table 3**

Postoperative diagnoses.

| Diagnosis | Number (%) |
|---|---|
| Localization-related, complex partial seizures | 86 (48.6) |
| Unspecified epilepsy | 42 (23.7) |
| Localization-related, simple partial | 26 (14.7) |
| Generalized convulsive seizures | 7 (4.0) |
| Brain tumor | 6 (3.4) |
| Subdural hemorrhage | 3 (1.7) |
| Generalized non-convulsive epilepsy | 1 (0.6) |
| Device complication | 1 (0.6) |
| Other | 3 (1.7) |

## Table 4

Frequency of complications.

| Complication | Number of patients (%) |
|---|---|
| Major | |
| Subdural hematoma | 3 (1.7) |
| Stroke | 1 (0.6) |
| Organ space SSI | 1 (0.6) |
| Attempted suicide | 1 (0.6) |
| *Total major* | 6 (3.4) |
| Minor | |
| Bleeding requiring transfusion | 6 (3.4) |
| Sepsis | 4 (2.3) |
| DVT | 4 (2.3) |
| UTI | 4 (2.3) |
| Wound disruption | 2 (1.1) |
| Spinal fluid leak requiring repair | 1 (0.6) |
| Progressive renal insufficiency | 1 (0.6) |
| Unplanned reintubation | 1 (0.6) |
| Pneumonia | 1 (0.6) |
| Superficial SSI | 1 (0.6) |
| *Total Minor* | 17 (9.6) |
| Any complication | 21 (11.9)[a] |

SSI = surgical site infection; UTI = urinary tract infection; DVT = deep venous thrombosis.

[a]Note that 3 patients had both major and minor complications, therefore the total number of patients with "Any complication" is lower than the sum of *Total major* and *Total minor* to avoid double counting.

## Table 5

Predictors of complications, NSQIP 2005–2013.

| Characteristic | No complication (%) | Complication (%) | Univariate odds ratio (95% CI) or t-test *p*-value | Multivariate odds ratio (95% CI) |
|---|---|---|---|---|
| Age (years) | 35.1 ± 13.3 | 39.3 ± 16.0 | $p = 0.253$ | |
| **Height (inches)** | **67.1 ± 3.9** | **65.1 ± 4.1** | **p = 0.041** | **n/s** |
| Weight (lbs.) | 180.7 ± 46.1 | 178.5 ± 47.0 | $p = 0.841$ | |
| BMI | 28.2 ± 7.1 | 29.8 ± 8.5 | $p = 0.417$ | |
| ASA | 2.5 ± 0.6 | 2.6 ± 0.6 | $p = 0.692$ | |
| Gender | | | | |
| Female | 78 (50.0) | 14 (66.7) | 1 [Reference] | |
| Male | 78 (50.0) | 7 (33.3) | 0.50 (0.19, 1.31) | |
| Hispanic Ethnicity | | | | |
| No | 140 (89.7) | 16 (76.2) | 1 [Reference] | |
| Yes | 10 (6.4) | 3 (14.3) | 2.63 (0.65, 10.54) | |
| Unknown | 6 (3.8) | 2 (9.5) | 2.92 (0.54, 15.68) | |
| **Race** | | | | |
| White | 133 (85.3) | 14 (66.7) | 1 [Reference] | |
| Black or African American | 9 (5.8) | 1 (4.8) | 1.06 (0.12, 8.96) | |
| American Indian or Alaska Native | 2 (1.3) | 0 | n/a | |
| **Asian or Pacific Islander** | **1 (0.6)** | **2 (9.5)** | **19.00 (1.62, 223.03)** | **19.00 (1.62, 223.03)** |
| Unknown | 11 (7.1) | 4 (19.0) | 3.45 (0.97, 12.30) | |
| Diabetes | | | | |
| No | 155 (99.4) | 21 (100.0) | n/a | |
| Yes | 1 (0.6) | 0 | | |
| Tobacco use | | | | |
| No | 121 (77.6) | 13 (61.9) | 1 [Reference] | |
| Yes | 35 (22.4) | 8 (38.1) | 2.13 (0.82, 5.54) | |
| Severe COPD | | | | |
| No | 155 (99.4) | 19 (90.5) | 1 [Reference] | |
| Yes | 1 (0.6) | 2 (9.5) | | 16.32 (1.41, 188.57) |
| Preoperative systemic inflammatory response (SIRS) | | | | |
| No | 151 (96.8) | 19 (90.5) | 1 [Reference] | |
| Yes | 4 (2.6) | 2 (9.5) | 3.97 (0.68, 23.17) | |
| Dyspnea | | | | |
| No | 156 (100.0) | 20 (95.2) | n/a | |
| Yes | 0 | 1 (4.8) | | |
| Hypertension | | | | |
| No | 140 (89.7) | 17 (81.0) | 1 [Reference] | |
| Yes | 16 (10.3) | 4 (19.0) | 2.06 (0.62, 6.88) | |
| Chronic steroid use | | | | |

| **Characteristic** | **No complication (%)** | **Complication (%)** | **Univariate odds ratio (95% CI) or t-test *p*-value** | **Multivariate odds ratio (95% CI)** |
|---|---|---|---|---|
| No | 154 (98.7) | 21 (100.0) | n/a | |
| Yes | 2 (1.3) | 0 | | |
| Bleeding disorder | | | | |
| No | 155 (99.4) | 20 (95.2) | 1 [Reference] | |
| Yes | 1 (0.6) | 1 (4.8) | 7.75 (0.47, 128.82) | |
| Procedure | | | | |
| Craniotomy for electrode placement | 105 (67.3) | 15 (71.4) | 1 [Reference] | |
| Burr hole for electrode placement | 28 (17.9) | 2 (9.5) | 0.50 (0.11, 2.32) | |
| SEEG | 9 (5.8) | 0 | n/a | |
| Removal | 29 (18.6) | 4 (19.0) | 0.97 (0.30, 3.13) | |

Characteristics significant in univariate analysis are shown in bold. All variables significant in univariate analysis were used in multivariate analysis (backward Walk method). n/a = not applicable (insufficient data).