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Patient Safety Incidents During Overnight Polysomnography: A Five-Year Observational Cohort Study

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SCIENTIFIC INVESTIGATIONS

Introduction: Attended polysomnography (PSG) is a common procedure and is regarded as relatively safe. There have been few systematic evaluations of adverse events occurring during PSG. An understanding of the frequency and type of the adverse events during PSG should inform risk mitigation plans and the development of guidelines for sleep center accreditation. We aimed to identify, tabulate, and classify all adverse events that occurred during overnight PSG conducted at an accredited sleep center over a five-year period.

Methods: All adverse events occurring from Jan 1, 2005, to Dec 31, 2010, at the Center for Sleep Medicine, Mayo Clinic, were identified. Information was collated from calls made to emergency responders, to the adverse event reporting system, and events forwarded to the medical director.

Results: A total of 36,141 PSGs were performed over the study duration. Fifty-eight adverse events occurred during the study period (1 event/623 PSGs). Most adverse events were cardiac in nature (17/58; 29.3%), a majority involving acute chest pain. Falls were the next most common (20.6%), followed by neurologic (8.6%), pulmonary (3.4%), and psychiatric (3.4%) events. The rest were classified as miscellaneous.

There were no patient deaths during PSGs. The majority of patients experiencing an adverse event were transported to the emergency room (37/58; 63.79%). Of these, 15/37 (40.54%) were admitted to the hospital, and 3 required an ICU bed.

Conclusion: Adverse events during a PSG were relatively uncommon. Previous emphasis on cardiac arrhythmias may be overstated, as chest pain and patient falls were commonest and resulted in hospitalization more often.

Keywords: Polysomnography, adverse events

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An influential report issued by the Institute of Medicine in 1999, "To Err is Human," launched an era of unprecedented activity to improve safety in the American hospital.[1] Only more recently has attention been turned to a more keen understanding of outpatient safety.[2] Given that there are more than 300 outpatients for every one inpatient encounter, the almost exclusive focus on the inpatient environment for improving patient safety may be likened to looking for keys lost in the dark part of the parking lot under the streetlamp on account of the improved lighting conditions.[2]

Polysomnography (PSG) is a method of recording and analyzing physiologic measures associated with sleep and breathing in patients with sleep diseases. In clinical practice, it entails attended monitoring of sleeping patients, often with purely diagnostic intent, but since approximately 85% of tested patients are suspected of having sleep-related breathing disorders, PSG oftentimes is performed during the introduction of positive airway pressure (PAP) or other treatment modalities. In many ways, this monitoring, measuring, and interpreting physiologic signals is an activity that resembles those performed in "observation" areas used by some emergency centers or inpatient settings, with a few seminal differences intended. First, sleep centers generally intend to evaluate patients who are considered medically stable other than their sleep diseases, rather than those who have presented with chiefly acute medical illnesses. Secondly, sleep studies are attended by sleep technologists or respiratory therapists, not registered nurses or physicians, as one finds in the acute care setting. Finally, and importantly, PSG is not uniformly provided in settings equipped for ill or infirm patients. Instead, polysomnography may be performed in facilities inside a hospital, those that are adjacent to an acute care facility, or those operated as independent testing facilities, not attached to any other medical care facility. Less than half of such facilities (2,415 centers as of 2011) are accredited by the American Academy of Sleep Medicine (AASM), and only a few hundred are accredited by The Joint Commission (TJC). The rest are without known accreditation, and are therefore without any known safety standard requisites.

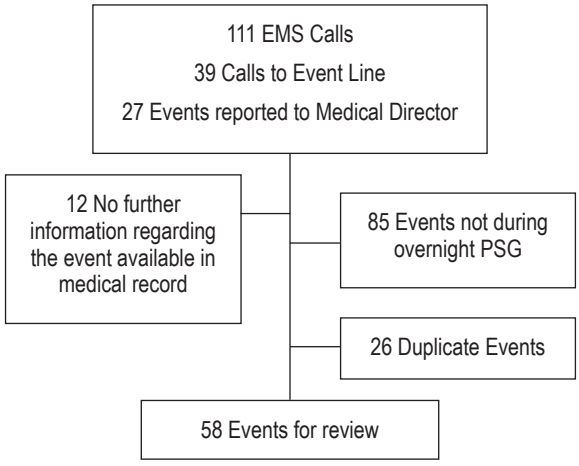
The number of PSGs performed in the United States was estimated to be around 1.17 million in 2001, and more recent

BRIEF SUMMARY

Current Knowledge/Study Rationale: Although polysomnography is a common medical procedure performed in various settings across the United States, there is very little known about the breadth of patient safety issues encountered during polysomnography. This study sought to catalogue the variety of patient safety incidents encountered during over 36,000 consecutive attended polysomnography tests at a single integrated academic medical center.

Study Impact: We found that patient safety incident occurred in 1 of every 623 polysomnograms, and that chest pain, falls, and acute neurological events were the most common. These findings suggest that future emphasis on improving patient safety be oriented towards fall reduction, ensuring access to timely evaluation of acute medical problems, and thorough medical evaluation prior to PSG.

Figure 1—Flow of patient related safety events January 1, 2005-December 31, 2010



estimates indicate the number may have quadrupled concurrently with an increase in annual Medicare payments for PSG from $62 million to $235 million from 2001 to 2009.[3,4] Thus, it is surprising that with almost certainly more than 4 million PSGs performed in varied settings annually, we have scant information about the safety of sleep studies and sleep centers. Thus far, a single multicenter study sought to quantify the frequency of predominantly cardiac events during polysomnography,[5] but to our knowledge, there are no published studies tabulating the wide range of patient safety incidents that may occur. We sought to examine and classify all identifiable patient safety incidents occurring during overnight stays at our accredited sleep center over a five-year period.

METHODS

We identified all reported safety incidents occurring at the Center for Sleep Medicine, Mayo Clinic, Rochester, MN, between Jan 1, 2005, and Dec 31, 2010. Safety incidents were defined as any patient safety concern that was reported to the medical director, the institutional safety "event line," or events that resulted in summoning emergency medical personnel or that resulted in the patient being transferred to the emergency department.

Over the study period, safety incidents were recorded in several different databases: emergency call logs, safety event database, and the medical director's concern log. First, we searched the log of all calls made to emergency responders during the study duration. During the initial portion of the study, the sleep center was located inside the hospital facility, and critical care physicians who were on call from the critical care unit provided emergency coverage. Calls for assistance to these physicians were recorded in the health record, but not in a separately indexed database. However, in 2008 the sleep center moved to an outpatient setting, and emergency coverage was provided by emergency medical technicians summoned using standard emergency medical services (EMS). All calls made to the emergency medical technicians were recorded at a central repository, and this was accessed to obtain information regarding adverse events occurring during this study period. For patients who were hospitalized, information regarding their hospital course was obtained.

At our institution, during overnight PSG, when sleep technologists encounter cardiopulmonary arrest CPR is commenced, the code team alerted and the medical director is notified. In cases where tachy/bradyarrhythmias with clinical symptoms of chest pain/pressure, dyspnea, syncope/pre-syncope are encountered, the emergency medical response team and the medical director are notified. With sinus arrest > 3 seconds or ventricular tachycardia coinciding with oxyhemoglobin desaturation, nasal CPAP is commenced and the medical director notified.

In addition, in accordance with our institutional policy, patient safety events such as medication errors or falls were reported via an "event line" phone call and stored in a central adverse event database. Finally, consistent with policy and accreditation standards, PSG technologists reported all complications to the lead technologists in the morning following the study, and adverse events were then forwarded to the Medical Director of the Center for Sleep Medicine, Mayo Clinic.

All of the databases were queried to identify safety incidents. Only incidents occurring during the overnight stay in the sleep center were included. For the study purposes, this included events occurring from the time patients presented to the sleep lab reception area at night until they were discharged the following morning. Once identified, the medical records were then reviewed to obtain further information regarding any emergency care including whether they were transferred to the emergency department (ED), care received in the ED, if patients required hospitalization, and any pertinent details from their inpatient course if admitted.

The safety incidents were classified into cardiovascular, neurological, pulmonary, psychiatric, falls, and other miscellaneous events. For patients suffering a fall, information regarding hypnotic administration during the PSG and whether fall precautions were in place was obtained. Any injuries resulting from the fall were clarified upon review of the medical record. The study was approved by the Mayo Clinic Institutional Review Board (IRB 12-000494).

RESULTS

During the study period, a total of 36,141 PSGs were performed at the Center for Sleep Medicine, Mayo Clinic, Rochester, MN. During this time period, a total of 111 calls were made to the emergency medical services. Thirty-nine adverse events were reported to the safety event line, and 27 events were reported to the medical director of the sleep lab (**Figure 1**).

After excluding duplicates and events that did not occur during the overnight stay in the sleep center, there were a total of 58 adverse events during the study period. Eighty-five events that occurred during the day while the patients were being evaluated in the sleep clinic (not during PSG) were excluded from evaluation. The rate of adverse events was 1 event per 623 PSGs. Of the adverse events reported, the majority (17/58; 29.3%) were cardiovascular in nature. Falls were the next most frequent adverse event reported (12/58; 20.7%), followed by neurological (5/58; 8.6%), psychiatric (2/58; 3.4%), and

Table 1—All patient related safety events occurring during the study period

Event Class Subtypes (n)	Number of Events (% of total)	ER Visits (% of total ER Visits)	Number Hospitalized (% of total hospitalizations)
Cardiovascular Chest Pain (12) Arrhythmia (4) Cardiogenic Syncope (1)	17 (29.3)	15 (40.5)	7 (46.7)
Falls	12 (20.6)	2 (5.4)	0 (0)
Neurological Seizures (1) Syncope (2) Transient ischemic attack (1) Meningitis (1)	5 (8.6)	3 (8.1)	1 (6.7)
Psychiatry Spell (1) Psychogenic coma (1)	2 (3.4)	1 (2.7)	1 (6.7)
Pulmonary Cough (1) Dyspnea (1)	2 (3.4)	2 (5.4)	1 (6.7)
Miscellaneous Epistaxis (2) Child Abuse(2) Hyperglycemia (2) Others (14)	20 (34.5)	14 (37.8)	5 (33.3)
Total	58	37	15

pulmonary events (2/58; 3.4%). The rest of events were classified as miscellaneous (20/58; 31.6%; **Table 1**).

Of the cardiac events, the majority involved chest pain (12/17). Arrhythmias accounted for 4/17, and the remaining patient suffered cardiac syncope. The majority of patients who experienced a cardiac event were transferred to the ED (15/17). Seven of these patients were admitted to an inpatient service. None of the patients who developed chest pains were found have suffered a myocardial infarction. The arrhythmias noted were sinus tachycardia (1 patient), bradycardia with Mobitz II block (1 patient), and atrial fibrillation (2 patients). Atrial fibrillation was complicated by the development of rapid ventricular rate in one patient and a variable AV conduction block in another.

A substantial number of patients who sustained a fall during their overnight PSG received zolpidem, which was prescribed by the sleep provider, during the sleep study (41.6%). Seven of the patients who sustained a fall were on fall precautions (58.3%) as requested by the physician ordering the sleep study. Apart from two instances of minor skin bruising and knee discomfort that did not require further attention, the rest of the patients did not sustain serious injury following the fall. Two patients who sustained a fall were transported to the ED; neither was admitted.

The neurological events consisted of 2 instances of syncope, one of a seizure, and one patient who suffered a transient ischemic attack (TIA). There was also one instance of a patient with a severe headache who was found to have meningitis. The patient who developed a seizure during the PSG had a prior history of seizures. Four of the 5 patients with neurological events were transported to the ED; 2 of these patients were admitted. The patient with meningitis required ICU care.

Two patients experienced pulmonary adverse events during the study period. One developed dyspnea and another had hemoptysis. Both were transported to the ED and the patient with dyspnea was found to have pneumonia and was admitted to an inpatient bed.

Among patients who experienced psychiatric adverse events, one had a psychogenic seizure-like spell and another had an episode where they refused to open their eyes or respond to gentle stimulation. This was later characterized as psychogenic coma (DSM IV TR diagnosis of dissociative disorder NOS). This patient was transported to the ED and was admitted to an inpatient psychiatric service. The patient had no prior psychiatric history and was being evaluated for spells at the time of the PSG.

There were a total of 20 events we classified as miscellaneous. Fourteen of these patients required an ED evaluation, and 5 of these patients were hospitalized. Among the miscellaneous events, two patients experienced epistaxis during PSG. One patient had a prior history of nosebleeds and developed epistaxis after the application of PAP. The other patient had undergone an ENT surgery 2 weeks prior to PSG, and PAP was not applied during the sleep study. In both instances the patients required ED evaluation where nasal packing was applied; neither patient was admitted.

There were two instances of hyperglycemia occurring in patients who had a previous diagnosis of diabetes mellitus. Both these patients required an ED evaluation and an inpatient admission. One of these patients was admitted to an ICU as they developed diabetic ketoacidosis. There were also two instances of parentally delivered physical child abuse recorded during the study period. As all PSGs at our center have video monitoring, these instances were captured on video and documentary evidence was present for these episodes.

Among the other adverse events, one patient developed sepsis. This patient had undergone a PSG that revealed complex

sleep apnea and was asked to return for a repeat overnight PAP titration. The patient in the interim underwent a bone marrow biopsy on the day of the titration study. The patient was found to have tachycardia and altered mental status at the sleep center and was transferred to the ED and required an admission to an ICU bed. Another patient who had a recent urethral stent placement developed significant hematuria requiring an inpatient admission and blood transfusion.

A patient developed significant dehydration resulting from a medication error; the patient's son administered the wrong dosage of medication resulting in aggressive diuresis. This patient required inpatient admission to correct an electrolyte imbalance. Other miscellaneous adverse events included a foot laceration following an injury sustained by a patient who cut himself on a piece of broken glass in the shower after his PSG was completed. The other adverse events included an instance of a broken Hickman catheter, severe nausea, vaginal bleeding and one instance where the PSG had to be canceled in a pediatric patient as no guardian was willing to stay overnight with the patient.

DISCUSSION

In our five-year retrospective review of sleep center overnight stays, adverse events were infrequent, occurring at a rate of at one event for every 623 PSGs. The majority of adverse events were cardiac in nature, followed by falls. The majority of the patients experiencing an adverse event were transported to the ED, and 41% of the patients transported to the ED were admitted to an inpatient setting. There were no deaths at the sleep center during overnight PSG.

Prior research into the adverse effects associated with undergoing a PSG is extremely limited. The only previous study examined reports from multiple sleep centers in 4 states, and defined adverse events as "those requiring immediate medical attention (physician call or emergency room evaluation)" or arrhythmias found by re-scoring teams.[5] In that study of 16,084 PSGs, there was one fatality from sudden cardiac death that was preceded by polymorphic ventricular tachycardia and subsequently ventricular fibrillation, 1 case of dyspnea with chest pain, 27 cases of arrhythmias prompting the PSG technologist to request immediate medical attention, and 28 cases of complex ventricular arrhythmias discerned on subsequent review of the PSG, apparently without symptoms. In their study, the event rate was 0.35% and there was 1 death. In our study, we found an overall event rate of 0.16% and no deaths. We also found comparatively fewer arrhythmias. There are several reasons we may have differing rates of adverse events. The definition of a serious adverse event in the Mehra study differs slightly from that of "safety incidents" in ours. The nature of their definition might make low harm level events or near-miss events less likely to have been reported in their study in comparison to ours. In Mehra et al., the technologists were sensitized by the sudden death that occurred early in the study period, and were instructed to be particularly vigilant in arrhythmia reporting. In addition, because the enrolled patients were part of a multicenter study, all PSGs were later reviewed independently, likely resulting in complete ascertainment of all cardiac rhythm abnormalities. Their results may therefore exhibit some degree of observer-expectancy effect. In contrast, at our center more stable arrhythmias such as the development of atrial fibrillation or non-sustained ventricular tachycardia would have been noted by the sleep specialist, but not necessarily reported as patient safety incidents. Therefore, our data underreport the frequency of cardiac arrhythmias during PSG. However, the main focus of our study was to learn about the range of patient safety incidents incurred during an overnight stay in the sleep center; stable arrhythmias, many of which are occurring most nights of the patient's life, may not be of primary interest.

In our retrospective review, falls were the second most common adverse events. Twenty-five percent of patients who sustained a fall required an ED evaluation, fortunately not leading to serious injury, but resulting in increased healthcare expenditure. This represents an opportunity for improvement. The literature reports that 60% of falls happen in homes, 30% in the community, and only 10% in institutions. Nonetheless, in hospitals, patient falls are a leading cause of death for those over 65 years of age, and are among the commonest adverse events reported. Total fall injury costs for those over 65 years old have been estimated at $27.3 billion, and some estimate that by 2020 cost of fall injuries may exceed $43.8 billion.[6] National efforts are focusing on the reduction of injurious patient falls to reduce morbidity, mortality, and healthcare costs.[7] Our sleep center long ago instituted on the PSG order sheet an opportunity for the sleep specialists to request "fall precautions." Though the majority of patients who fell were placed on fall precautions by the ordering physicians these precautions did not appear to prevent these patients from falling. Patients on fall precautions are routinely assisted with ambulation down the hall and to the toilet, and are often provided with bedside urinals. However, our sleep technologists have not received the same fall mitigation education that our inpatient nurses receive, nor are patients and their families routinely educated in the sleep center regarding potential fall risks. In addition, 5 of the 12 patients who fell received zolpidem, which was prescribed by their sleep provider to ensure adequate amount of sleep was obtained on the night of the PSG. As most patients were instructed to continue on their home medication regimen, other patients might have self-administered hypnotic agents, but information regarding this was not available. Zolpidem has been shown to be associated with an increased fall risk in hospitalized patients, and as patients undergoing PSG might have significant medical comorbidity this prescription practice might need further evaluation to ascertain whether it might result in an increased number of falls in sleep centers as well.[8]

Three of our patients required hospitalization to an ICU setting. These included a patient who developed serious headache and had developed meningitis, a patient who developed sepsis, and another patient with a prior diagnosis of diabetes who developed ketoacidosis. While the patient who developed ketoacidosis was seen in evaluation on the day of the PSG, there was a lag of a few days between the evaluation and night of PSG in the other two patients. An evaluation by a medical provider closer to the date of the PSG might have resulted in these conditions being picked up earlier, avoiding the necessity of a transfer to the ED and an ICU admission.

Patients who were evaluated at the Center for Sleep Medicine and were thought to a have a high probability of having seizures were referred to the Epilepsy Monitoring Unit for further evaluation, likely resulting in the low number of adverse events related to seizures in our sample.

In our series, we discovered two instances of physical child abuse, which were captured on video. Sleep labs provide a unique opportunity and environment in which interactions between parents and children and also between caregivers and vulnerable adults can be assessed. Most sleep labs also use videography during the PSG, which provides objective evidence of these interactions. Sleep laboratories will need to consider policies regarding how the staff would ensure patient safety, clear guidelines for intervention during the study in case of concern about abuse, and their role in reporting these events to local protection services. The two cases in our series were reported to child protection services and video evidence was cited in the reporting.

Sleep center accreditation strives to improve quality and safety of patient care. Considering the prominence of cardiac-related events, the recognition and response to cardiac arrhythmias in real time requires adequately trained and attentive personnel and appropriate monitoring equipment. The AASM center accreditation standards specify sleep technologist training and job descriptions along with ongoing tests of signal recognition as well as some minimum patient-to-technologist ratios to enhance monitoring. Additionally, the AASM accreditation is quite specific regarding quality of monitoring equipment. The Joint Commission accreditation is somewhat less specific regarding qualifications for sleep technologists, does not specify a staffing level, and does not specify type or quality of monitoring equipment. Both sets of standards address the physical plant of the sleep center, though the AASM standards are far more prescriptive. However, neither accreditation designates fall risk mitigation standards. Other important patient safety concerns, not reported in our series (and not specifically addressed in the AASM accreditation) regards infection control efforts, medication safety (specifically medication control), and patient security. There is room for improvement in current accreditation standards.

In recent times, home sleep testing is being used increasingly, especially in patients with a high pretest probability of having sleep apnea and those without major medical comorbidities. In relation to the adverse safety events associated with PSGs, home sleep testing might result in a decrease in falls and other injuries occurring at the sleep center. However, other events such as cardiac arrhythmias and seizures might be missed.

We tried to capture all the safety incidents that occur during overnight PSG. We were able to collect information from multiple sources ensuring that all voluntarily reported safety incidents were identified. We also were able to access information regarding the outcome of the ED visit and the course of the inpatient stay. However, our study must be viewed in light of some of the limitations inherent to a retrospective review and voluntary reporting. We relied on voluntary reports, which are only one source of patient safety information. Some estimates suggest that such voluntary reporting systems account for less than 10% of all safety incidents that occur in the acute care setting.[9,10] Learning about safety incidents via patient reports, via office of patient affairs, surveys, audits using "trigger tools" or random review, and automated review of electronic medical records are all tools that have been more fully developed in the inpatient safety programs, but not yet systematically applied in outpatient venues.

CONCLUSION

Our retrospective review of 36,141 PSGs revealed that adverse events during a PSG were relatively uncommon, and a minority of these requires hospitalization. Previous emphasis on cardiac arrhythmias may be overstated, as chest pain and patient falls were commonest and resulted in ED evaluation/hospitalization more often. A small number of adverse events could have been anticipated and likely prevented if patients at risk were identified and medical personnel evaluated these patients prior to the PSG.

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DISCLOSURE STATEMENT

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