

Original Studies

Middle-of-the-Night PCI Does Not Affect Subsequent Day PCI Success and Complication Rates by the Same Operator

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Objective: To determine the impact of percutaneous coronary interventions (PCI) performed during late-night hours on next day PCI performance by the same interventional cardiologist. **Background:** There is little data regarding the effects of sleep deprivation on interventional cardiologists performing PCIs. **Methods:** All primary PCIs from January 1, 2005 to December 31, 2009 between 11 PM and 7 AM were identified. All PCIs performed during the subsequent work day by the same interventionists were included in the sleep-deprived group. All other PCIs were included in the non-sleep-deprived group. Data were entered prospectively into the American College of Cardiology National Cardiovascular Data Registry (NCDR). The two groups were compared with respect to efficacy and safety endpoints. **Results:** During the 5-year period, 3,944 PCIs were performed by four operators, including 3,644 non-sleep-deprived cases and 167 sleep-deprived cases. The two groups were similar with respect to demographics, comorbidities, and procedural characteristics. There were more intraprocedural deaths in the sleep-deprived group (1.2% vs. 0.2%, $P = 0.04$); however, the adjusted odds ratio (OR) was nonsignificant (OR = 6.83, 95% confidence interval [CI] = 0.66–39.63, $P = 0.11$). Excessive bleeding at the arterial access site in the non-sleep-deprived group was more frequent (2.7% vs. 0%, $P = 0.02$). There were no differences in the combined safety or efficacy endpoints between the two groups. **Conclusion:** In this single-center study, we found no evidence that middle-of-the night procedures adversely affect safety or efficacy of procedures done the next day by the same operator. © 2012 Wiley Periodicals, Inc.

Key words: PCI; performance; STEMI; operator; fatigue

BACKGROUND

Sleep deprivation increases the risk of serious medical errors [1], percutaneous injuries [2], and motor vehicle crashes [3] in medical personnel. Increases in adverse outcomes in after-hours procedures have been reported in other medical specialties [4]. Errors in performance of procedures are higher during the day after a night of sleep deprivation [2,5] and may be associated with adverse effects on patient care [6] although this finding has not been replicated by all investigators [7–9].

Complication and failure rates of primary percutaneous coronary intervention (PCI) have been reported to be higher in procedures performed after regular working hours compared to the procedures performed

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Conflict of interest: Nothing to report.

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during regular working hours [10–12]. Proposed explanations include diurnal biologic variations in patients and their coronary lesions, diurnal differences in systems of care, and operator fatigue. To date, no study has attempted to isolate the contribution of operator fatigue to complications and success rates of PCI procedures.

The majority of primary PCIs are done after regular working hours and about one-fourth of primary PCIs are done during hours normally devoted to sleep [13]. PCI operators often work at their usual daytime assignments even after performing middle-of-the night PCI. In these situations, PCI operators may have worse outcomes and it has been suggested that this information should be disclosed to patients as part of the informed consent process [14]. The purpose of this study was to test the hypothesis that primary PCI during hours normally devoted to sleep was associated with worse outcomes of PCIs performed the next day by the same operator.

METHODS

PCI Center

The PCI center in this study is a 437-bed tertiary care hospital in rural central Pennsylvania serving 37 counties with a population of 2.4 million.

Coronary intervention at the PCI center during the study period was performed by four staff interventionists employed by the healthcare system. All operators performed >200 PCIs per year. Interventional cardiologists took call for interventions one night in four. The center performs about 240 primary PCIs per year, with about one-fourth of them occurring between 11 PM and 6 AM. Thus, each interventionist during the study period had sleep interrupted by a night-time primary PCI approximately one of every six call nights. It was very rare for two procedures to be done during one overnight period. All interventionists lived within 10 minutes of the hospital and took call from home. For an after-hours primary PCI, the typical time out-of-bed to back-in-bed was about 3 hours although some operators routinely had trouble falling asleep after a procedure.

Interventionists did not take general cardiology call, and hence if they were not doing a catheterization laboratory procedure they were able to sleep for the full night. Interventionists A, B, C, and D estimated that during the study period, when not on call, they averaged 8, 6, 7, and 7 hours of sleep per night, respectively, and they slept <6 hours on 0%, 40%, 10%, and 15% of nights, respectively.

During the study period, call nights and catheterization laboratory daytime assignments of individual interventionists were not coordinated. About half of the call nights were followed by daytime catheterization labo-

ratory assignments. On such days, the interventionist would generally work a full day in the catheterization laboratory, regardless of sleep patterns during the previous night. In extreme cases of fatigue, the interventionist would arrange for assistance and leave early, but this was rare. Sleep-deprived technicians worked the next day, but usually not on the same team as the sleep-deprived interventionist.

Interventional Treatment

PCI was typically performed with six French guide catheters via a femoral approach, bivalirudin anticoagulation, and vascular closure with intra-arterial collagen plug or suture device. Details of diagnostic catheterization and PCI (e.g., postdilatation, IIb/IIIa inhibitor treatment) varied among the interventionists. Care of the acute myocardial infarction patient after the procedure was assumed by cardiology fellows, internal medicine residents, and general cardiologists.

Patients

We identified all primary PCI procedures at the medical center from January 1, 2005 to December 31, 2009 with start times between 11 PM and 7 AM. We next identified the interventionist who performed each procedure. These index primary PCI procedures were excluded from all further analyses. All PCIs performed during the *subsequent* work day (7 AM–11 PM) by the *same* interventionist were included in the sleep-deprived group. All other work-day PCIs were included in the non-sleep-deprived group.

Data Collection

The study was approved by the institutional investigational review board. Data on all patients were entered prospectively into the ACC NCDR. Data were collected during and immediately after PCI by the catheterization laboratory technical staff and operator, and information about the remainder of the hospitalization was obtained at the time of discharge by cardiology advanced practitioners.

Data Analysis

Demographic and procedural data are reported as percentages or means (\pm standard deviation). Categorical data were compared using Pearson's χ^2 statistic or Fisher's exact test (in case of small expected numbers). The two-sample *T*-test was used for continuous variables (displayed means). Sleep-deprived procedures were compared to non-sleep-deprived procedures with respect to baseline and procedural characteristics, complications (safety endpoints), and success rates

TABLE I. Baseline Patient Characteristics

	Non-sleep-deprived group (N = 3,644)	Sleep-deprived group (N = 167)	P
Age (mean ± SD)	64 ± 11.9	63±12.5	0.28
Female gender	1,209 (33.2%)	59 (35.3%)	0.62
Body mass index (mean ± SD) ^a	30.7 ± 11	30.9±8.6	0.81
Prior myocardial infarction	884 (24.3%)	35 (21%)	0.38
Congestive heart failure	298 (8.2%)	13 (7.8%)	0.97
Diabetes mellitus	1,190 (32.7%)	56 (33.5%)	0.88
Peripheral vascular disease	441 (12.1%)	17 (10.2%)	0.53
Hypertension	2,560 (70.3%)	118 (70.7%)	0.98
Smoking (current)	920 (25.3%)	52 (31.1%)	0.1
Previous bypass surgery	555 (15.2%)	21 (12.6%)	0.41
Previous coronary intervention	996 (27.3%)	33 (19.8%)	0.04

^aBMI was unavailable for 59 patients.

(efficacy endpoints) at the individual operator level and overall for the institution.

Categories of complications were prospectively categorized as “operator-dependent” or “operator-independent,” recognizing that these categories were artificial and might be invalid in individual cases. Prospectively planned analyses compared sleep-deprived and non-sleep-deprived groups with respect to safety endpoints (individual types of complications, operator-dependent complications, complications per physician, and any complication), and efficacy endpoints (PCI success rates).

Separate multivariate logistic regression models were constructed to identify independent correlates of complications and death in the catheterization laboratory. The primary predictor in each model was sleep-deprived vs non-sleep-deprived status. Possible covariates included all baseline and procedural characteristics (Tables I and II) with univariate $P \geq 0.10$, and operating physician. P -values <0.05 were considered statistically significant.

Definitions

Definitions for all endpoints were those used by the NCDR. This included three possible PCI outcomes:

1. Complete success—all attempted lesions treated successfully (with either stenting or balloon angioplasty) with residual stenosis of $<50\%$.
2. Partial success—at least one attempted lesion with residual stenosis of 50% or more.
3. Complete failure—all attempted lesions with residual stenosis of 50% or more.

RESULTS

During the 5-year interval, 3,944 PCIs were performed by four operators, including 3,644 non-sleep-

TABLE II. Procedural Characteristics

	Non-sleep-deprived group (N = 3,644)	Sleep-deprived group (N = 167)	P
<i>Indication for procedure, n (%)</i>			0.4
ST-elevation myocardial infarction	831 (22.8%)	47 (28.1%)	
Non-ST elevation myocardial infarction	737 (20.2%)	29 (17.4%)	
Unstable angina	893 (24.5%)	37 (22.2%)	
Stable angina	797 (21.9%)	37 (22.2%)	
Atypical chest pain	148 (4.1%)	9 (5.4%)	
Other	238 (6.5%)	8 (4.6%)	
<i>Arterial access site, n (%)</i>			0.4
Femoral	3,295 (90.4%)	153 (91.6%)	
Radial	300 (8.2%)	10 (6%)	
Brachial	41 (1.1%)	3 (1.8%)	
Other	8 (0.2%)	1 (0.6%)	
<i>Method of hemostasis, n (%)</i>			0.19
AngioSeal	1,791 (49.2%)	95 (56.9%)	
Perclose	666 (18.3%)	30 (18.0%)	
Manual compression	525 (14.4%)	20 (12.0%)	
Other	662 (18.2%)	22 (13.2%)	
<i>Anticoagulation, n (%)</i>			
Bivalirudin	1,520 (41.7%)	68 (40.7%)	0.86
GP IIb/IIIa inhibitors	1,369 (37.6%)	63 (37.7%)	0.97
Heparin	2,554 (70.1%)	112 (67.1%)	0.46

deprived cases and 167 sleep-deprived cases. The two groups were similar with respect to demographics, comorbidities, and procedural characteristics (Tables I and II). Previous PCIs were more common in the non-sleep-deprived group (27.3% vs 19.8%, $P = 0.04$).

Intraprocedural death was more frequent in the sleep-deprived group (1.2% vs. 0.2%, $P = 0.04$), although by multivariate analysis it was not significant (adjusted OR = 6.83, 95% CI = 0.66–39.63, $P = 0.11$). Excessive bleeding at the arterial access site was more common in the non-sleep-deprived group (2.7% vs. 0%, $P = 0.02$; adjusted OR not calculated owing to 0% incidence in one group). There were no differences in other individual safety endpoints or in the combined safety endpoints (Table III). The adjusted OR for any operator-dependent complication in the sleep-deprived vs. nonsleep-deprived group was 0.61 (95% CI = 0.31–1.22, $P = 0.16$). There were no differences in efficacy endpoints between the two groups (Table IV).

There were no significant differences among individual operators in overall operator-dependent or operator-independent complication rates (Table V). The incidence of any complication before discharge for operators A, B, C, and D were 11.7%, 10.7%, 10.4%, and 12.7%, respectively ($P = 0.4$). One operator had fewer complications during sleep-deprived cases than during non-sleep-deprived cases (0% vs. 13%, $P = 0.04$;

TABLE III. Safety Endpoints

	Non-sleep-deprived group (N = 3,644)	Sleep-deprived group (N = 167)	P
<i>Operator-dependent complication</i>			
Death in the catheterization lab	6 (0.2%)	2 (1.2%)	0.04
Emergent coronary bypass surgery	12 (0.3%)	0	0.99
Coronary artery perforation	19 (0.5%)	0	0.99
Stroke	17 (0.5%)	1 (0.6%)	0.55
Periprocedural myocardial infarction	129 (3.5%)	3 (1.8%)	0.66
Cardiac tamponade	4 (0.1%)	0	0.99
<i>Access site complications</i>			
Excessive bleeding	100 (2.7%)	0	0.02
Vessel occlusion	15 (0.4%)	1 (0.6%)	0.51
Peripheral embolization	1 (0.03%)	0	0.99
Vessel dissection	49 (1.3%)	2 (1.2%)	0.99
Pseudoaneurysm	21 (0.6%)	0	0.99
Arteriovenous fistula	4 (0.1%)	0	0.99
Retroperitoneal bleed	18 (0.5%)	0	0.99
Any of the above	169 (4.6%)	3 (1.8%)	0.087
Any operator-dependent complication	321 (8.8%)	9 (5.4%)	0.16
<i>Operator-independent complication</i>			
In-hospital death	52 (1.4%)	4 (2.4%)	0.31
Urgent or elective bypass surgery	22 (0.6%)	0	0.62
Cardiogenic shock (after procedure)	51 (1.4%)	3 (1.8%)	0.99
Congestive heart failure	51 (1.4%)	3 (1.8%)	0.99
Contrast nephropathy	22 (0.6%)	0	0.62
Any complication	418 (11.5%)	13 (7.8%)	0.17

TABLE IV. Efficacy Endpoints

	Non-sleep-deprived group (N = 3,644)	Sleep-deprived group (N = 167)	P
Complete success ^a	3,504 (96.2%)	161 (96.4%)	0.03
Partial success ^b	43 (1.2%)	5 (3.0%)	
Complete failure ^c	97 (2.7%)	1 (0.6%)	

^aComplete success—all attempted lesions treated successfully (with either stenting or balloon angioplasty) with residual stenosis of <50%.

^bPartial success—at least one attempted lesion with residual stenosis of 50% or more.

^cComplete failure—all attempted lesions with residual stenosis of 50% or more.

TABLE V. Safety and Efficacy Endpoints by Individual Interventionist

	A			B			C			D		
	non-sleep-deprived (N = 438)	Sleep deprived (N = 14)	P	non-sleep-deprived (N = 1,431)	Sleep deprived (N = 84)	P	non-sleep-deprived (N = 747)	Sleep deprived (N = 39)	P	non-sleep-deprived (N = 1,028)	Sleep deprived (N = 30)	P
All operator-dependent complications	41	1	1.0	140	5	0.3	85	3	0.6	129	0	0.04
All operator-independent complications	26	2	0.2	64	3	1.0	41	4	0.2	67	1	0.7
Complete success	427	13	0.1	1,378	80	0.2	716	38	0.3	983	30	0.7
Partial success	3	1		22	3		8	1		10	0	
Complete failure	8	0		31	1		23	0		35	0	

adjusted OR not calculated owing to 0% incidence in one group).

DISCUSSION

The most important finding of this study was lack of evidence for the hypothesis that middle-of-the-night PCI is associated with increased failure or complication rates of PCI performed on the subsequent day by the same operator. Numerical but statistically nonsignificant trends for combined complications tended to contradict that hypothesis, and failure to successfully open all lesions was more common in the non-sleep-deprived group.

In-laboratory death occurred more frequently in the sleep-deprived group. However, after adjustment for baseline factors, this difference was no longer significant. Although this trend toward higher mortality in the sleep-deprived group is of concern, it is the result of a small number of events ($n = 2$ deaths).

Although *failure* to open *all* lesions attempted was numerically higher in the sleep-deprived group, failure to open any lesions attempted was more common in the non-sleep-deprived group. It is likely that the statistically significant differences in the sleep-deprived vs non-sleep-deprived groups with respect to complete success, partial failure, and total failure were not clinically significant. It is possible, but less likely, that sleep-deprived operators were less likely to attempt (and fail) to open chronic total occlusions, which constituted the vast majority of complete failure cases.

Overall complication rates for all operators were statistically similar. One operator had a statistically lower complication rate in sleep-deprived cases (0 vs. 13%, $P = 0.04$). This may have been owing to the play of chance, or this operator may have been particularly cautious or careful about performing PCI when sleep deprived to purposefully compensate for any perceived or supposed deficits.

Physician fatigue has been linked to serious medical errors [1], percutaneous injuries [2], and motor vehicle

crashes [3]. Sleep deprivation impairs hand–eye coordination in surgeons performing laparoscopy [15] and leads to more complications [6]. Lack of sleep has deleterious effects on cognitive and neurobehavioral functions of the brain [16,17]. An integrated program of measures to prevent sleep deprivation and to deal with its effects across the specialties of medicine has been proposed [18]. It has been suggested that sleep-deprived physicians should obtain informed consent from patients that includes information about possible risks associated with sleep deprivation [14].

These issues may be relevant to interventional cardiology. Primary PCI performed between 6 PM and 8 AM was associated with significantly higher rates of angioplasty failure (6.9% vs. 3.8%, $P < 0.01$) and 30-day mortality (4.2% vs. 1.9%, $P < 0.01$) compared to the procedures performed during regular work hours (8 AM–6 PM), although the authors acknowledged that the finding may be owing to the differences in ischemic times and circadian variations in platelet and blood characteristics [11]. More recently, complications were higher and major adverse cardiac events (death, myocardial infarction, and revascularization) were more frequent (adjusted OR = 2.66, $P = 0.001$) in procedures performed between 7 PM and 7 AM [10]. Conversely, in a smaller study, no differences in clinical events and hospital mortality were found between patients treated with primary PCI during the day or at night [19].

None of the studies mentioned above has clearly correlated physician fatigue as an independent predictor of adverse clinical outcomes, and several studies have failed to find such an association [7–9]. We could find only one study correlating sleep deprivation with adverse outcomes, and this was only in physicians with <6 hr of sleep, performing surgical and gynecologic procedures [6].

Although almost all interventional cardiologists work at least occasionally while sleep deprived, the cardiology community has given remarkably little attention to whether sleep-deprived cardiologists can practice safely. In this area, cardiology may lag behind much of the medical community. Larger databases should be evaluated to identify any warning signals of correlations between sleep deprivation and procedural outcomes. In the meantime, it would be prudent for sleep-deprived interventionists to minimize risk by deferring emergency cases to colleagues and avoiding ad hoc elective high risk PCIs, when possible [20].

LIMITATIONS

This is a small study with limited power to demonstrate small but potentially clinically significant increases in complication rates of fatigued operators. It was under-powered to detect significant differences in

rare events (such as death or emergency bypass surgery), and lack of statistically significant differences in rare events between groups should not be interpreted as proof that such differences do not exist. We could not include lesion complexity in our model because the NCDR changed its descriptions of lesion complexity mid-way through the study. Our database did not capture middle-of-the-night procedures other than primary PCIs although these were few in number. The categorization of categories of procedural complications as “operator dependent” vs “operator independent” was based on judgment although eliminating this distinction did not affect the results. The extent of sleep deprivation or number of hours worked in the middle of the night was not quantified for each case. The results of this study may not be generalizable to other institutions for several reasons. The experienced moderate-volume operators in this study may have functioned better when sleep-deprived than would less-experienced operators or over-stressed high-volume operators. Even when performing middle-of-the-night PCI, most operators managed to sleep at least several hours which may have been enough to prevent the deleterious effects of sleep deprivation reported by others. Interventionists at our institution functioned as part of a team and often relied on the judgment and assistance of catheterization fellows and technicians; their assistance may have prevented sleep-deprived interventionists from committing errors.

CONCLUSION

In this small single-center study, we did not find evidence that middle-of-the-night procedures adversely affected safety or efficacy of procedures done the next day by the same operator. Evaluation of larger databases should be performed to exclude such an effect.

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