Inadvertent Hypothermia After Procedural Sedation and Analgesia in a Cardiac Catheterization Laboratory: A Prospective Observational Study

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Objectives: **To identify the prevalence of and risk factors for inadvertent hypothermia after procedures performed with procedural sedation and analgesia in a cardiac catheterization laboratory.**

Design: **A single-center, prospective observational study.**

Setting: **A tertiary-care private hospital in Australia.**

Participants: **399 patients undergoing elective procedures with procedural sedation and analgesia were included. Propofol infusions were used when an anesthesiologist was present. Otherwise, bolus doses of either midazolam or fentanyl or a combination of these medications was used.**

Interventions: **None**

Measurements and Main Results: **Hypothermia was defined as a temperature <36.0°C. Multivariate logistic regression was used to identify risk factors. Hypothermia was present after 23.3% (n = 93; 95% confidence interval [CI] 19.2%-27.4%) of 399 procedures. Sedative regimens with the highest prevalence of hypothermia were any regimen that included propofol (n = 35; 40.2%; 95% CI 29.9%-50.5%) and the use of fentanyl combined with midazolam (n = 23; 20.3%; 95% CI 12.9%-27.7%). Difference in mean temperature from pre-procedure to post-procedure was –0.27°C (standard deviation 0.45). Receiving propofol (odds ratio [OR] 4.6 95% CI 2.5-8.6), percutaneous coronary intervention (OR 3.2; 95% CI 1.7-5.9), body mass index <25 (OR 2.5; 95% CI 1.4-4.4) and being hypothermic prior to the procedure (OR 4.9; 95% CI 2.3-10.8) were independent predictors of post-procedural hypothermia.**

Conclusions: **A moderate prevalence of hypothermia was observed. The small absolute change in temperature observed may not be a clinically important amount. More research is needed to increase confidence in the authors' estimates of hypothermia in sedated patients and its impact on clinical outcomes.**

KEY WORDS: conscious sedation, deep sedation, hypothermia, temperature, monitoring, risk factors, cardiac catheterization laboratory

Inadvertent postoperative hypothermia is a known adverse effect of general and regional anesthesia. It has been reported to occur in 50% to 90% of anesthetized patients[1,2] and is associated with increased risk of adverse cardiac events and infections, greater intraoperative bleeding, and prolonged hospital stay.[3] Anesthesia practice patterns in the cardiac catheterization laboratory (CCL) are different from the operating room. The majority of procedures are performed with procedural sedation and analgesia (PSA), not general or regional anaesthesia.[4,5] However, the CCL is similar to the perioperative environment in that patients can be exposed for long periods of time to a low ambient room temperature. Moreover, pharmacologic agents used for PSA in the CCL, such as benzodiazepines, opioids, and propofol, impair normal thermoregulation.[4,6,7] As such, patients undergoing procedures with PSA in the CCL may be at risk of hypothermia and, consequently, also be at risk for the adverse impact that hypothermia has on clinical outcomes.[8] Yet, to the authors' knowledge, no previous studies have investigated the prevalence of hypothermia in patients who received PSA. Furthermore, although guidelines for prevention of hypothermia are applicable for patients who receive general or regional anesthesia in the CCL, they do not provide recommendations for management of body temperature during procedures that are performed with PSA.[9,10] For these reasons, the authors sought to identify the prevalence of hypothermia after procedures that were performed with PSA in a CCL. A secondary aim of the study was to identify risk factors for hypothermia.

METHODS

A single-site prospective observational study was conducted in accordance with the principles outlined in the Declaration of Helsinki.[11] Approval for the study was obtained from the Uniting Care Health Human Research Ethics Committee (2014.18.124).

Setting and Subjects

This study was undertaken in a tertiary-care private hospital that services more than 500 inpatients in a metropolitan city in Australia. A convenience sampling design was used. Patients were included in this analysis if they had undergone an elective procedure with sedation in 1 of the 3 CCLs operating in the hospital and had their temperature measured after the procedure. Patients noted by the anesthesiologist in the anesthetic record to have received a general anesthetic were excluded because a substantial evidence base along with clinical practice guidelines already exist to guide practices related to the maintenance of normothermia for these patients.[9,10]

Sedation was administered either by an anesthesiologist or a nurse, according to direction from the cardiologist performing the procedure. Premedication with oral benzodiazepines varied according to cardiologist preferences. Propofol, typically administered by an infusion at this site, was used for sedation only when an anesthesiologist was present during cardiac arrhythmia ablation procedures, permanent pacemaker implantation, and implantable cardioverter-defibrillator implantation. Otherwise, bolus doses of either midazolam or fentanyl or a combination of these medications was used. No specific criteria

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were applied throughout the data collection period that dictated the circumstances in which an anesthesiologist was required to administer sedation for a procedure.

The decision to use either monitored anesthesia care or procedural sedation and analgesia without an anesthesiologist present was solely at the discretion of the cardiologist performing the procedure. Intravenous, intra-arterial, or irrigation fluids used during procedures were not warmed. Routine monitoring of sedated patients included level of consciousness, blood pressure, electrocardiogram and pulse oximetry, as well as end-tidal carbon dioxide when propofol was used. Temperature monitoring of sedated patients was not routine at the data collection site. Normal clinical practice involved passive warming with heated blankets during the procedure for all patients. Active warming was applied only for general anesthesia at the data collection site.

Data Collection

Nurses were asked to use a data collection form designed specifically for this study to collect demographic data (age, sex, height, and weight), procedural characteristics (duration of procedure, sedative and analgesic medications administered), body temperature (pre- and post-procedure), and thermal comfort (pre- and post-procedure) for all patients undergoing procedures with sedation. Although warming intravenous or irrigation fluids seems to attenuate perioperative hypothermia, the total amount of unwarmed fluids used has not been identified as a predictor of hypothermia.[9,10] Therefore, the authors did not measure the total amount of fluids used during procedures. Similarly, the amount of blood loss was not identified as a risk factor for perioperative hypothermia in systematic reviews performed by the American Society of PeriAnesthesia Nurses (ASPAN) or the National Institute of Health and Care Excellence (NICE).[9,10] For this reason, the authors did not measure the amount of blood loss.

Body temperature was measured using the same infrared aural canal thermometer, which was calibrated in accordance with the manufacturer's instructions (Genius™ 2, Kendall, with accuracy of ±0.2°C in the range of 33°C-42.2°C; Covidien, Dublin, Ireland). Pre-procedural temperatures were recorded as soon as possible after patients were admitted to the CCL, within 5 minutes after the end of procedures. Post-procedure temperatures were recorded as soon as possible after the end of the patient's procedure, within 10 minutes after the end of procedures. Three temperatures were recorded at each timepoint, with the highest of the measurements used for analysis. Room temperature was measured using a digital thermometer. Thermal comfort was measured using a 5-point scale (too cold, cool, just right, warm, too warm). Nurses also observed patients for physical signs of hypothermia, including shivering. Missing data that could be collected retrospectively, such as demographics and procedural characteristics, were collected from medical records.

Statistical Analysis

Data were transferred from the data collection tools into SPSS v21 for analysis (IBM Corp., Armonk, NY). Descriptive statistics (frequencies and percentages) were used to summarize categorical data, whereas means and standard deviations (SD) were calculated to describe the continuous data. Confidence intervals (CI) were calculated to provide an estimation of the prevalence of hypothermia and shivering. A cut point of <36.0°C was used to classify patients as hypothermic because evidence has shown that this level of core hypothermia in the immediate postoperative period for noncardiac surgery was associated with adverse outcomes.[12]

The authors planned to recruit at least 374 participants in order to estimate the prevalence of hypothermia within a 95% CI range of ±5%. Logistic regression was used to identify demographic and clinical characteristics that predicted hypothermia (ie, risk factors). Variables previously identified to predict inadvertent postoperative hypothermia in the surgical population, (age, gender, body mass index [BMI], preoperative temperature, premedication, types of sedation used, and the duration of procedures) were compared in order to identify potential risk factors using χ^2 and t-tests. Some variables, such as procedural duration, BMI, preoperative temperature, and ambient room temperature, were dichotomized for the analyses. This decision was made to increase the potential clinical application of the results, as it was believed these variables would better assist the targeting of warming interventions towards patients at risk for hypothermia when dichotomized (eg, procedures that lasted for longer than an hour were all interventional procedures in the authors' sample). To identify which factors independently predicted hypothermia, variables with a p value < 0.20 on univariate analysis were entered into a backward stepwise logistic regression model in order to estimate the odds ratios (ORs) and 95% CI.

RESULTS

Over the 6-month data collection period from May to November 2014, a total of 1,618 procedures were performed. The 121 procedures performed under general anesthesia were excluded. Patients' temperature was measured after 399 procedures during which PSA was administered. Included procedures were 125 (31.3%) coronary angiograms, 104 (26.1%) percutaneous coronary interventions, 3 (0.8%) right heart catheterizations, 81 (20.3%) permanent pacemakers, 35 (8.8%) implantable cardioverter-defibrillators, 9 (2.3%) diagnostic electrophysiology studies, 21 (5.3%) ablations of cardiac arrhythmias, and 21 (5.3%) peripheral endovascular procedures. Demographic characteristics (age, sex, and BMI) of the sample did not differ significantly ($p < 0.05$) from patients whose temperature was not measured after their procedure.

Hypothermia (<36.0°C) was present after 23.3% ($n = 93$; 95% CI = 19.2%-27.4%) of the procedures. Table 1 shows a breakdown of the prevalence of hypothermia according to the type of sedation regimen utilized as well as descriptive statistics for the temperature of all patients included in the authors' sample, as well as those who became hypothermic for each of the various sedation approaches. The mean temperature difference from pre-procedure to post-procedure ranged from –0.11°C (SD 0.46) for the patients who received fentanyl only, to –0.39 (SD 0.55) for the group of patients who received propofol. A larger mean temperature difference from pre-procedure to post-procedure of –0.79 (SD 0.41) was observed