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## Endovascular rewarming in the emergency department for moderate to severe accidental hypothermia☆

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## ABSTRACT

**Background:** Endovascular temperature control catheters can be utilized for emergent rewarming in accidental hypothermia. The purpose of this study was to compare patients with moderate to severe hypothermia rewarmed with an endovascular temperature control catheter versus usual care at our institution.

**Methods:** We conducted a retrospective, observational cohort study of patients with moderate to severe accidental hypothermia (core body temperature less than 32°C) in the Emergency Department of an urban, tertiary care medical center. We identified the rewarming techniques utilized for each patient, including those who had an endovascular temperature control catheter placed (Quattro® or Icy® catheter, CoolGuard® 3000 regulation system, Zoll Medical). Rewarming rates and outcomes were compared for patients with and without the endovascular temperature control catheter. We systematically screened for procedural complications.

**Results:** There were 106 patients identified with an initial core temperature less than or equal to 32°C; 52 (49%) patients rewarmed with an endovascular temperature control catheter. Other methods of rewarming included external forced-air rewarming (85, 80%), bladder lavage (17, 16%), gastric lavage (10, 9%), closed pleural lavage (6, 6%), and peritoneal lavage (3, 3%). Rate of rewarming did not differ between the groups with and without catheter-based rewarming (1.3°C/h versus 1.0°C/h, difference 0.3°C, 95% confidence interval [CI] of the difference 0–0.6°C) and neither did survival (70% versus 71%, difference 1%, 95% CI -17 to 20%). We did not identify any significant vascular injuries resulting from endovascular catheter use.

**Conclusion:** The endovascular temperature control system was not associated with an increased rate of rewarming in this cohort with moderate to severe hypothermia; however, this technique appears to be safe and feasible.

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## 1. Introduction

Moderate to severe accidental hypothermia is defined as a core body temperature of <32 °C and can result in significant physiologic and metabolic changes [1,2]. Due to the risk of cardiac instability, especially at core temperatures <28 °C (severe hypothermia), active rewarming measures are generally recommended [2–4].

Active internal rewarming encompasses a spectrum of interventions, ranging in invasiveness from warmed intravenous fluids to emergency thoracotomy with mediastinal irrigation [5–9]. Additionally, there is growing evidence that peripheral extracorporeal membrane oxygenation (ECMO) is an efficient and successful means to perfuse and

rewarm a severely hypothermic patient, particularly in the setting of hypothermic cardiac arrest [10–12]. But, with the exception of ECMO and its limitation to specialized centers, there has been little advancement in active internal rewarming therapies over the past twenty years [5,8,13].

Endovascular temperature control systems have recently gained popularity to induce mild hypothermia (33–36 °C) in survivors of cardiac arrest [14]. As a corollary, these systems can also increase core temperature, using a heat-exchange catheter and console that circulates temperature-controlled saline through endovascular balloons resulting in conductive warming of central venous blood. Initial case reports support its feasibility; rewarming rates of approximately 1.5 °C/h have been described [15–21], but no large published series exist at this time. Beginning in 2007, our hospital adopted an endovascular temperature control system as an adjunct to traditional means of active internal rewarming for patients with accidental hypothermia. This has resulted in substantial institutional experience regarding the scope of utility of this technique.

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In this study, we sought to evaluate our experience with actively rewarming emergency department (ED) patients with moderate and severe accidental hypothermia using various modalities. We hypothesized that use of the endovascular temperature control catheter would be independently associated with a more rapid rate of rewarming as compared to non-catheter based active internal rewarming.

## 2. Materials and methods

### 2.1. Study design and setting

This is a retrospective, single-center, observational study of patients who presented to the ED with moderate to severe accidental hypothermia from September 2007 through March 2015. The institutional review board approved this study with a waiver of informed consent.

The study hospital is an urban, Level-1 trauma center located in (city, state, county) with >100,000 annual ED visits. The rewarming methods used were at the discretion of the treating ED physician; no protocol to dictate or sequence rewarming methods exists at our institution. In general, extracorporeal rewarming is preferred in cases of hypothermic cardiac arrest when available, but it is important to note that this study period predated our institutional ECMO program. Traditional active rewarming modalities available in our ED included forced-air rewarming blankets, warm intravenous saline infusion, body cavity lavage with warmed fluids (any combination of bladder, gastric, peritoneal, closed pleural, or open mediastinal irrigation), as well as cardiopulmonary bypass (CPB).

The endovascular temperature control system was incorporated into active internal rewarming in select ED patients in the first full year of the study period (2008). We use the Quattro® (4 balloon) and Icy® (3 balloon) intravascular heat exchange catheter placed in the common femoral vein, along with the CoolGuard® 3000 thermal regulation system (Zoll Medical, Chelmsford, MA [formerly Alsius®]).

### 2.2. Study protocol

We queried the electronic medical record (EMR) to identify ED patients of any age treated in the critical care resuscitation rooms with either (1) an ED diagnosis of accidental hypothermia (ICD-9-CM 991.6), or (2) an initial recorded temperature  $\leq 32$  °C. All temperature measurements were core temperatures (obtained through either rectal or esophageal probes). Next, study investigators reviewed each record and excluded patients who met any of the following criteria: patients with mild hypothermia (initial core temperature  $> 32$  °C), those with non-survivable injuries who were pronounced dead without attempts at rewarming, and those patients who suffered cardiac arrest and were not rewarmed higher than 33.5 °C for the purposes of therapeutic hypothermia. This last group merited exclusion to ensure the most accurate results regarding rates of rewarming.

After the final study cohort was identified, medical record data was collected in duplicate by two investigators (JH, UA) using standardized data collection methods for chart-review research [22–24]. Variables collected included age, gender, prehospital vital signs and interventions (if the EMS record was available), ED vital signs, cardiac rhythms, electrocardiogram results, intubation, presence of trauma, initial Glasgow coma scale (GCS) score, computed tomography (CT) results, alcohol level, hypothermia circumstances (indoor versus outdoor/environmental), rewarming techniques utilized, disposition, and survival.

All temperature measurements for the hospital encounter were captured directly from the EMR to generate rewarming rates. Rewarming rates could not be calculated for the 4 patients who had CPB because the operating room did not record detailed temperature data in the EMR during the study period. For the rest of the patients ( $n = 102$ ), the temperature data was processed such that the difference between the initial temperature and the temperature value at approximately the 2-hour, 4-hour, and 6-hour mark were identified. This delta

temperature was then divided by the precise number of minutes (not the rounded value) elapsed between the two temperature readings to calculate the rate of rewarming per hour averaged over approximately 2, 4, and 6 h. We chose to focus on the rewarming rate over the first 4 h for the study outcome, as it is clinically relevant and had the least missing data, as compared to the 2- or 6-hour rewarming rates.

### 2.3. Data analysis

Inter-rater agreement was calculated on a random sample of 20 charts from the initial duplicate data collection. Inter-rater agreement for this data collection was 88%, indicating a kappa of 0.82. If there were discrepancies identified between the duplicate chart abstractions, they were resolved by consensus review by two other investigators (MP, LK). Based on pre-existing case reports and previous publications, we hypothesized that the mean rate of rewarming for the temperature control catheter group would be 1.5 °C/h and 1.0 °C/h for the group without catheter based rewarming. With a standard deviation of 1.0, and an alpha of 0.05, we would need 41 patients per group to detect such difference with 80% power.

We used descriptive statistics to summarize continuous variables (using means and standard deviations [SD]) and categorical variables (using counts and proportions), pertaining to key study characteristics. We performed additional comparisons of survivors versus nonsurvivors, and of exposure hypothermia (primarily found outdoors) versus other hypothermia (found indoors). These comparisons were made by calculating differences in means or differences in proportions with associated 95% confidence intervals (CIs).

To assess our primary study question of whether rewarming strategy was associated with differences in rewarming rate, we calculated the mean change in temperature (with associated 95% CIs) for numerous rewarming technique subgroups. The primary analysis compared the group who had a temperature control catheter placed versus those who did not.

In addition to the calculation of unadjusted rates of rewarming as previously described, we created multiple linear regression models to identify whether the temperature control catheter was independently associated with rate of rewarming. This was performed based on the understanding that there was nonrandom selection of patients who received catheter-based rewarming. We did not perform stepwise or univariate analyses to select model variables; the variables included in the model other than receipt of an endovascular temperature control catheter were all selected a priori and included initial core temperature, occurrence of cardiac arrest, presence of traumatic injuries, use of other body cavity rewarming techniques (as a dichotomous yes/no variable), and circumstances of hypothermia (found indoor versus outdoor). This indoor versus outdoor term was used instead of a variable for each individual admission diagnoses (i.e. sepsis, liver disease) due to the heterogeneity of the population and given that the count frequency would be low for each diagnosis, resulting in an unstable over-fit model. A sensitivity analysis was performed by creating a second model using the same variables previously described, but adjusting with a propensity score to control for the likelihood of being treated with a temperature control catheter.

Model fit diagnostics were performed by analyses of the residuals versus each of the predictor variables in the regression model. We also evaluated the normality of the residuals with quantile plots and the Shapiro-Wilk test for normality. We tested for heteroscedasticity with a residual versus fitted value plot, and assessed for multicollinearity with the variance inflation factor statistic for each independent variable in the linear model. All statistical analyses were performed using Stata (Version 12.0, StataCorp, College Station, TX) and SAS (Version 9.4, SAS Institute Inc., Cary, NC).

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