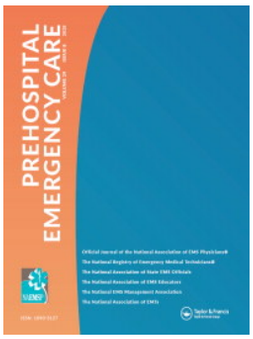

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Sittichok Leela-amornsin, Yayha Mankong, Apisada Jiso, Thitiworada Ittisan, Krittaya Chunnguleum & Pongsakorn Atiksawedparit

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The effects of tropical climate on the stability of emergency drugs used in ambulances under real EMS situations

Sittichok Leela-amornsin[1] 0000-0002-8984-7915, Yayha Mankong[1], Apisada Jiso[2] 0000-0002-4297-7819, Thitiworada Ittisan[1], Krittaya Chunnguleum[1], Pongsakorn Atiksawedparit[1,*] 0000-0003-0336-3715

[1]Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Samut Prakan, Thailand

[2]Department of Pharmaceutical Sciences, Faculty of Pharmacy, Chiang Mai University, Chiang Mai, Thailand

***Corresponding author**: Pongsakorn, Atiksawedparit, Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Samut Prakan, Thailand, pongsakorn.ati@mahidol.ac.th.

ABSTRACT

OBJECTIVES: Adrenaline (epinephrine), amiodarone, and atropine are included in the 2020 Advanced Cardiac Life Support guideline and are commonly used during cardiopulmonary resuscitation in both prehospital and in-hospital situations. The emergency drug boxes are often exposed to high ambient temperatures and very humid climates in the tropical regions. These accelerated conditions can significantly impact the drug stability. It is crucial to ensure that these medications maintain their potency to provide optimal patient care.

METHODS: Three medications, including adrenaline, amiodarone, and atropine, were packed into the emergency medical service (EMS) drug box in the resuscitation backpack. It was stored in a controlled storage environment during the non-operation periods. The resuscitation backpack was taken to the EMS operations, which were exposed to ambient temperature during the missions. All medications were divided into five batches, each of which was sent for analysis of the active ingredient every three months over a 12-month period using the High-Performance Liquid Chromatography method. The predicted concentrations of these three medications were analyzed using regression analysis.

RESULTS: During a 12-month period, there were a total of 450 prehospital missions. The average ambient temperature was 30.1°C (SD 2.09°C), and the average relative humidity was 72.18% (SD 14.96%). The temperature of the EMS drug box was 25.2°C (SD 1.65°C), while the relative humidity was 65.22% (SD 4.35%). The mean kinetic temperature, assessed at three-month intervals, ranged from 25.0°C to 25.8°C. All medications contained active ingredient levels above the regulated standards, while maintaining the drug degradation below 10% over a 12-month period.

CONCLUSIONS: In a hot and highly humid EMS climate with careful adherence to EMS medication storage protocol, adrenaline, amiodarone, and atropine maintained sufficient stability over a 12-month period when stored in a controlled environment during non-operating hours. Only atropine was predicted to degrade faster than the manufacturer's recommended expiration period.

Keywords: Prehospital Emergency Care, Drug stability, Adrenaline, Amiodarone, Atropine

INTRODUCTION

Out-of-hospital cardiac arrest is the most life-threatening condition in the emergency medical service system. The incidence of out-of-hospital cardiac arrest is approximately 30 to 100 individuals worldwide, and survival to hospital discharge is 8.8% (1, 2). Currently, the 2020 American Heart Association Guideline for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care confirmed electrical therapy and medications as an important part of the chain of survival (3). Therefore, emergency medications, e.g., adrenaline (epinephrine), amiodarone, and atropine, must be ready to use in both in-hospital and prehospital situations. Consequently, many emergency medical service (EMS) systems keep an emergency drug box stocked with resuscitation medications readily available near the point of care, ensuring immediate access during CPR.

Drug stability is compromised by extreme temperatures, with previous studies showing significant degradation of drugs stored at 45°C, -20°C, or undergoing temperature cycling. For example, atropine completely degrades after eight weeks at 45°C (4, 5). This degradation primarily results from heat accelerating oxidation and hydrolysis, which adversely affect solvents, antioxidants, and pH levels in formulations, leading to a decline in both chemical and biological activity (6, 7). Additionally, the United States (U.S.) Pharmacopeia (USP) recommends that drug storage areas be maintained at a controlled room temperature of 20°C to 25°C, ensuring a mean kinetic temperature (MKT) of less than or equal to 25°C (8). The MKT represents a single isothermal value that reflects the cumulative effect of temperature fluctuations over time and is widely used to evaluate the impact of storage conditions on drug stability.

Consequently, hospital standards mandate controlled temperature, humidity, and light for the emergency drug box used in both prehospital and in-hospital settings (9-11). However, despite exposure to varied prehospital conditions, several studies of real EMS systems found less than 10% degradation of adrenaline and amiodarone in climates with mean temperatures between 10.3°C and 22.8°C (12-14). In addition, adrenaline and atropine can be stored at the highest MKT of 28.9°C for 45 days without drug degradation (15).

South East Asia is located in tropical climatic zone IVb (hot and very humid) (11), where the mean ambient temperature ranges from 27.4°C to 28.1°C (16). WHO recommends long-term stability testing conditions for active pharmaceutical ingredients and finished pharmaceutical products in Climate Zone IV at 30°C with 75% relative humidity. They recommended the labeling statement as: “Do not store above 30°C” to ensure that drug degradation remains below 10% and there is no significant change (7, 11). While real-world studies confirm stability for one year when the emergency box is maintained in a prehospital setting, several knowledge gaps have been identified. First, most studies were conducted in Europe and North America (12-14, 17), where ambient temperatures are generally lower than in tropical climates. Second, there was no evidence to determine the long-term effect of the real EMS environment on atropine, which is very sensitive when stored under inappropriate ambient conditions. Third, the appropriate expiration of EMS drugs used in tropical climates has still not been determined. Accordingly, the primary aim of this study was to evaluate the effects of EMS medication storage protocol in a tropical climate on the degradation of emergency drugs—adrenaline, amiodarone, and atropine—over a 12-month period. The secondary aim was to determine the shelf life of these medications in prehospital practice.

METHODS

Study design and setting

We conducted a prospective observational study over a 12-month period, from December 2023 to December 2024, at the EMS division of an academic center with 400 beds, annually 17,000 ED visits, and 500 EMS operations. Our EMS unit operates under a hospital-based model consistent with the Anglo-American system. Over the past five years, the average environmental temperature has been 28.8°C, with an average relative humidity of 72% (16).

The EMS medication storage protocol includes the following procedures: 1) Emergency medications are systematically arranged in an EMS drugs box which is labeled with lists of medications along with their expiration dates; 2) The EMS drugs box and rescue equipment are packed into a resuscitation backpack; 3) This resuscitation backpack is stored on a shared shelf next to the defibrillator in the medical control office for rapid accessibility; 4) The storage area is rigorously maintained under controlled environmental conditions, with a temperature range of 22°C to 25°C and a relative humidity level between 40% and 60%; and 5) The resuscitation backpack is deployed exclusively when the team responds to EMS missions, requiring mandatory post-mission restocking and immediate return to the designated storage area (Supplemental File Figure 1).

This study was approved by the Human Research Ethics Committee, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand (COA. No. MURA2023/617) and was conducted in accordance with the Declaration of Helsinki, the Belmont Report, the CIOMS Guidelines, and the International Conference on Harmonization – Good Clinical Practice (ICH-GCP).

Selection of drugs and study protocol

We selected adrenaline, amiodarone, and atropine, recognizing their critical importance as emergency medications in accordance with the 2020 Advanced Cardiac Life Support guidelines (3). Manufactures recommend adrenaline (1 mg/ml) be stored below 30°C, whereas amiodarone (150 mg/ml) and atropine (0.6 mg/ml) should be stored below 25°C (Supplemental File Table 1).

At the beginning of the study, 125 ampules of Adrenaline, 125 ampules of amiodarone, and 250 ampules of atropine were packed in a separate bag and kept in a resuscitation backpack along with a portable temperature and humidity data logger (Medicool, MDC-PP165). Temperature and humidity were continuously recorded every 30 minutes over the study period. Stability testing was divided into five batches, which were at the start date (time zero) and at 3, 6, 9, and 12 months, respectively. For each test, 25 ampules of adrenaline, 25 ampules of amiodarone, and 50 ampules of atropine were picked up for stability testing every three months.

Drug stability, including sediment, color, pH, and active pharmaceutical ingredient (specification by high-performance liquid chromatography method), was determined at the Center of Analysis for Product Quality, Faculty of Pharmacy, Mahidol University, in accordance with the U.S. Pharmacopeia 2023 (18-20).

In addition, the data regarding environmental temperature and humidity during the study period were obtained from the records of a meteorological station located one kilometer from the EMS unit.

Statistical analysis

Continuous data were described as mean (standard deviation: SD) or median (interquartile range: IQR) when they were normal or non-normal distribution, respectively. Categorical data were described as a number and its percentage. The temperature and relative humidity of the environment and the resuscitation backpack were revealed by plotting their medians (IQR) over a 12-month study period. For each batch of drug stability testing, the characteristics were reported as visual color and sedimentation, mean pH, and mean drug concentration. The percentage of the target temperature (less than 25°C) and humidity (less than 60%) of the resuscitation backpack was also plotted over the study period. The MKT for each quarter during the 12-month period was calculated using the monthly average temperatures, obtained by averaging the minimum and maximum recorded values for each month, see Supplemental File Table 2. The Linear regression lines were constructed to assess the associations of MKT and drug concentrations (8, 15, 21).

In addition, measured drug concentration and time periods were fitted in a linear regression model to predict drug concentration over a 36-month period. All statistical analyses were performed using Stata software, version 18.0.

RESULTS

Over the 12-month period, we executed 450 EMS missions, resulting in an overall operational duration of 33,882 minutes. The median operation time for each EMS mission was 77 minutes (IQR 43 – 98 minutes). For each EMS mission, the minimum operation time was 10 minutes, whereas the maximum time was 153 minutes.

Inside the resuscitation backpack containing the EMS drug box, the mean temperature was 25.2°C (SD 1.65°C). The recorded temperatures ranged from a minimum of 21.3°C to a maximum of 30.4°C. The mean relative humidity was 65.22% (SD 4.35%). The relative humidity varied between a minimum of 55.7% to a maximum of 82.4%. In the storage area, the mean temperature was 23.5°C (SD 1.16°C) and the mean relative humidity was 56.42% (SD 4.46%). In the storage area, the temperature ranged from 21°C to 26°C, while the relative humidity ranged from 47% to 69%. In the outdoor environment, the mean ambient temperature was 30.1°C (SD 2.09°C), which ranged from a minimum of 22.4°C to a maximum of 35.5°C. The mean ambient relative humidity was 72.18% (SD 14.96%), and it varied between 30.7% and 98.8%. The mean temperatures and relative humidity for both the environment and the resuscitation backpack over the 12-month study period are illustrated in Figures 1 and 2.

Of the total 450 EMS missions, 250 EMS missions (55.56%) had a mean temperature exceeding 25°C. January recorded the lowest percentage of missions with a mean temperature above 25°C, at only 18.75%. In contrast, June experienced the highest percentage of recorded temperatures exceeding 25°C, reaching 85.11%. Regarding relative humidity, May recorded the lowest percentage of relative humidity over 60%, at 73.81%. Meanwhile, both June and November maintained relative humidity levels above 60% throughout every operation.

The detailed findings from the drug stability testing were summarized in Supplemental File Table 3. After 12 months, the degradation of adrenaline, amiodarone, and atropine was less than 10% compared to their initial active ingredient levels, which were above the stability standards established by the U.S. Pharmacopeia – National Formulary (USP-NF) (22). The concentration levels of medications were observed to decline as follows: Adrenaline concentration decreased by 4.2%, diminishing from 100.1% to 95.9%. Amiodarone concentration exhibited a decrease of 6%, reducing from 107.7% to 101.7%. And atropine demonstrated the most significant decrease, with a reduction

of 7%, declining from 105% to 98%. Notably, despite these reductions, all medications can maintain concentrations above the recommended thresholds for pharmaceutical manufacturing, with adrenaline and amiodarone remaining above 90%, and atropine exceeding 93%. The pH levels of the three emergency medications showed no clinically significant differences over the 12-month period. Specifically, the pH of adrenaline decreased from 3.28 to 3.26, amiodarone's pH decreased from 3.78 to 3.64, and atropine's pH decreased slightly from 4.41 to 4.40. Additionally, there were no changes in overall color or sediment in any of the medications throughout the year.

The associations between calculated MKT and the remaining drug concentrations are illustrated as regression lines in Figure 3. Increasing MKT was associated with a decline in the concentrations of all three medications. Notably, atropine exhibited a more rapid reduction compared with adrenaline and amiodarone.

The predicted concentrations of adrenaline, amiodarone, and atropine were plotted by fitting observed concentrations with time periods, using a linear regression model (Figure 4). The results showed that the concentration of adrenaline was expected to decline below 90% after 30 months. Amiodarone's concentration was predicted to fall below 90% after 36 months, while atropine was anticipated to decrease below 93% after 18 months.

DISCUSSION

We conducted a 12-month prospective cross-sectional study to determine the effects of EMS medication storage protocol in a tropical climate on the stability of adrenaline, amiodarone, and atropine. All drugs degraded by less than 10% and showed no significant changes in sediment, discoloration, or pH. Our linear regression models predicted that adrenaline and amiodarone concentrations would decline below 90% of their initial values after approximately 30 and 36 months, respectively. The increasing MKT was associated with a concentration reduction of all three medications. In addition, the concentration of atropine was estimated to decrease to less than 93% after 18 months. Crucially, all medications maintained stability above USP-NF limits (18-20) by the study's end. Consequently, our storage protocol supports a one-year expiration date, which is acceptable for EMS operations in tropical climates.

After 12 months, the concentration of adrenaline decreased by only 4.2%, indicating stability remained above 90%. Our results are consistent with existing EMS studies conducted in Europe and North America (4, 12-14), but differ from the study conducted in South Africa (23). Although the mean tropical ambient during the study period was 30.1°C, our practice strictly controlled the temperature of the drug storage area between 22°C to 25°C during non-operation hours. This led to the temperature inside the resuscitation backpack being approximately 23.5°C, which aligns with the various storage conditions reported in several European and North American studies (4, 12-14). While the drug packages are exposed to ambient environmental conditions during EMS missions, they are returned to the storage area afterward. Additionally, the median operation time was only 77 minutes, and half of the drug packages experienced temperatures below 25°C. In contrast, the setting of the study in South Africa was different. Adrenaline potency decreased significantly by up to 22.73% after only eight weeks of storage in ambulances parked outdoors, where environmental temperatures varied from 16.5°C to 46.7°C (23). Continuous exposure to heat might lead to higher degradation than observed in our study. This highlights the importance of storing adrenaline at or below room temperature, which can significantly reduce its degradation rate. Consequently, the drug stability in this condition remained comparable to that achieved the standard storage conditions.

Our results indicate that the active pharmaceutical ingredient in amiodarone can be preserved for a longer period than adrenaline. The findings are consistent with prehospital studies in Luxembourg and Switzerland, where amiodarone and adrenaline were stored for over a year in ambulances parked indoors or helicopters housed in hangars during non-operational hours (12, 14). This may be

attributed to the small difference in drug storage bag temperatures between our study (25.2°C) and those in European studies (17.1–22.9°C). As a result, the active ingredients of both amiodarone and adrenaline persisted over 90% (based on their standards) (18, 20) after 12 months.

Atropine showed the highest degradation rate, with a 7% decrease at 12 months, and its predicted concentration diminished to below 93% (based on its standard) (19) after only 18 months. Laboratory study by Armenian et al. (5) reported complete degradation after continuous storage of atropine at 45°C over a four-week period, whereas it remained stable at low temperatures. This finding can be explained by the properties of the ester compound (tropine and tropic acid), in which heat accelerates the hydrolysis reaction. Therefore, exposure to high temperatures or frequent temperature fluctuations during EMS missions enhances degradation and eventual loss of efficacy.

A previous study reported no degradation of adrenaline and amiodarone in 45 days of storage under the higher MKT environment up to 28.9°C (15). However, our results showed a negative correlation between the remaining concentration of adrenaline, amiodarone, and atropine versus MKT after a 12-month study period, indicating drug concentration declined with increasing cumulative thermal stress, even within the narrow MKT range observed (25.0–25.8°C). Importantly, the variation in stability among these drugs underscores the need to monitor EMS medication storage protocol, particularly in hot and humid climates.

Humidity can influence drug degradation, depending on drug formula and packaging, through physical alterations, accelerated chemical reactions (oxidation and hydrolysis), and increased microbiological growth. Rawas-Qalaji et al. (24) showed that prefilled adrenaline in unsealed plastic syringes stored at 38°C for three months retained only 60% potency in a low relative humidity environment (15%) but 90% in a high relative humidity environment (95%). Interestingly, light exposure did not impact adrenaline stability. However, the emergency drugs included in our study were aqueous solutions for intravenous injection and stored in unopened glass ampoules, which are well-known for their protection against humidity. Consequently, we suppose that environmental humidity is not expected to affect the stability of our three emergency medications.

The strength of our study is that we represent the first study exploring the effects of EMS medication storage protocol on emergency drugs stability in an EMS environment in Asia, particularly in a hot and very humid climate. Moreover, we measured both quantitative (i.e., concentration and pH) and qualitative (i.e., sedimentation and color) stability of adrenaline, amiodarone, and atropine to ensure their accuracy. Finally, data were collected and archived over a 12-month period to capture seasonal variation, thereby facilitating the prediction of future levels of active ingredients.

For clinical implications, our findings indicate that adrenaline, amiodarone, and atropine maintained drug stability above the standard level over a 12-month period under this EMS storage protocol. Additionally, the predicted concentration of atropine suggests that drug degradation in a tropical EMS environment occurs more rapidly than the manufacturer's recommended expiration date, even when the storage area temperature was controlled. In contrast, the predicted concentrations of both adrenaline and amiodarone indicate slower degradation, exceeding the manufacturer's expiration date. These findings have some limited generalizability to other environments that have higher EMS mission rates or prolonged exposure to thermal stress under uncontrolled conditions. Nevertheless, EMS personnel should ensure compliance with drug storage protocols by maintaining controlled storage conditions. Medications should be deployed for EMS operations and promptly returned, ensuring that the duration of uncontrolled environmental exposure is minimized.

For research implications, we also found the effects of tropical ambient conditions on drug stability. This emphasizes that several research areas on EMS drug management are required, such as the development of drug storage protocols, container devices that maintain optimal conditions, and a

real-time monitoring system could enable evaluation of the impact of actual conditions on drug stability.

LIMITATIONS

Our study had some limitations. First, we did not assess the impact of light, which can be a stress factor affecting drug stability. Ultraviolet light can activate photo-oxidation, leading to accelerated drug degradation. However, in our clinical practice, we protect the medications from light by amber color ampules and pouches, kept in the EMS drug box, and are only accessed for patient use. Importantly, we did not find any color change or sediment in these three medications. Second, each medication in this study was from one manufacturer, which may have a different drug formulation, solvent, container, or storage recommendation from other manufacturers. This variability may impact the broader applicability to various manufacturers. Lastly, our study was conducted in a single ground EMS unit in a tropical region (ambient temperature of 31°C and relative humidity of 72.18%). Thus, we had a specific protocol to minimize stress factors by storing the resuscitation backpack in a controlled environment. Other EMS units may have different contexts, such as high/low frequency of EMS missions, longer mission durations, or different EMS medication storage protocols. Therefore, applying our results should be adjusted for different clinical settings.

CONCLUSIONS

In tropical climates, when EMS medication storage protocols are carefully followed, adrenaline, amiodarone, and atropine maintained stability exceeding established standards, with degradation remaining below 10% over a 12-month period. None of these emergency medications exhibited any significant changes in color, pH, or sedimentation. However, atropine was predicted to degrade faster than the manufacturer's recommended expiration period.

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DECLARATION OF INTEREST: The authors declare that they have no competing interests.

DECLARATION OF GENERATIVE AI IN SCIENTIFIC WRITING: During the preparation of this work, the authors used ChatGPT 5.0, Google Gemini 2.5, and Grammarly to refine and modify the language. After using this tool, the authors reviewed and edited the content as needed. The authors take full responsibility for the content of this publication.

DATA SHARING STATEMENT: The datasets used and/or analyzed during the study are available from the corresponding author on reasonable request.

AUTHORSHIP STATEMENT: SL, YM, and PA made a considerable contribution to the study, including the conception of the study, study design, conduct of the study, data collection, data analysis, and interpretation of the results. KC and AJ performed the conception of the study, study design, and interpretation. TI performed the study design. All authors participated in drafting, revising, or critically reviewing the manuscript. All authors gave final approval of the version to be published, agreed on the submission of the manuscript, and agreed to be accountable for all aspects of the work.

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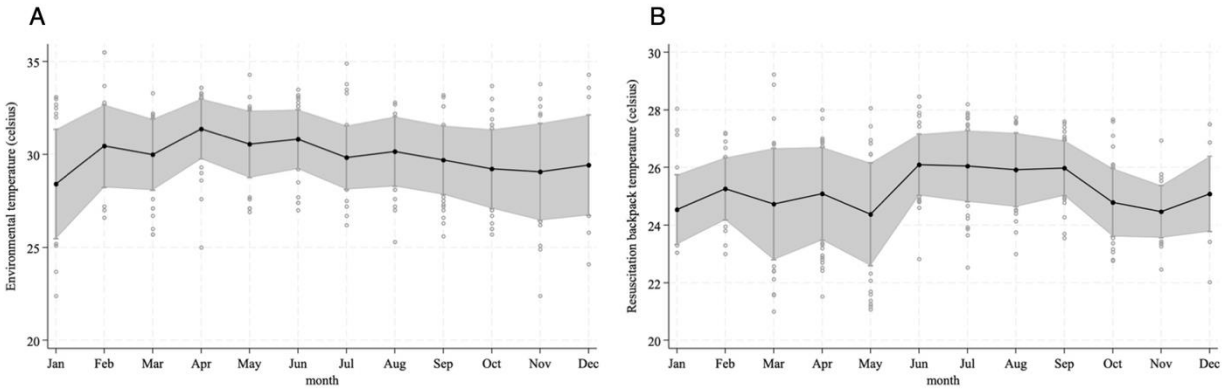

Figure 1: Mean temperatures of the environment (A) and the resuscitation backpack (B) over the 12-month period

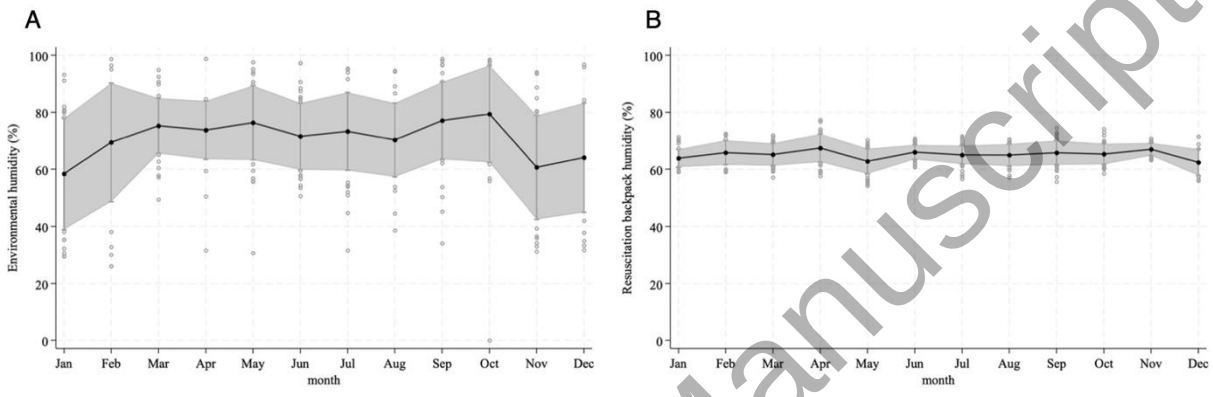

Figure 2: Mean humidity of the environment (A) and the resuscitation backpack (B) over the 12-month period

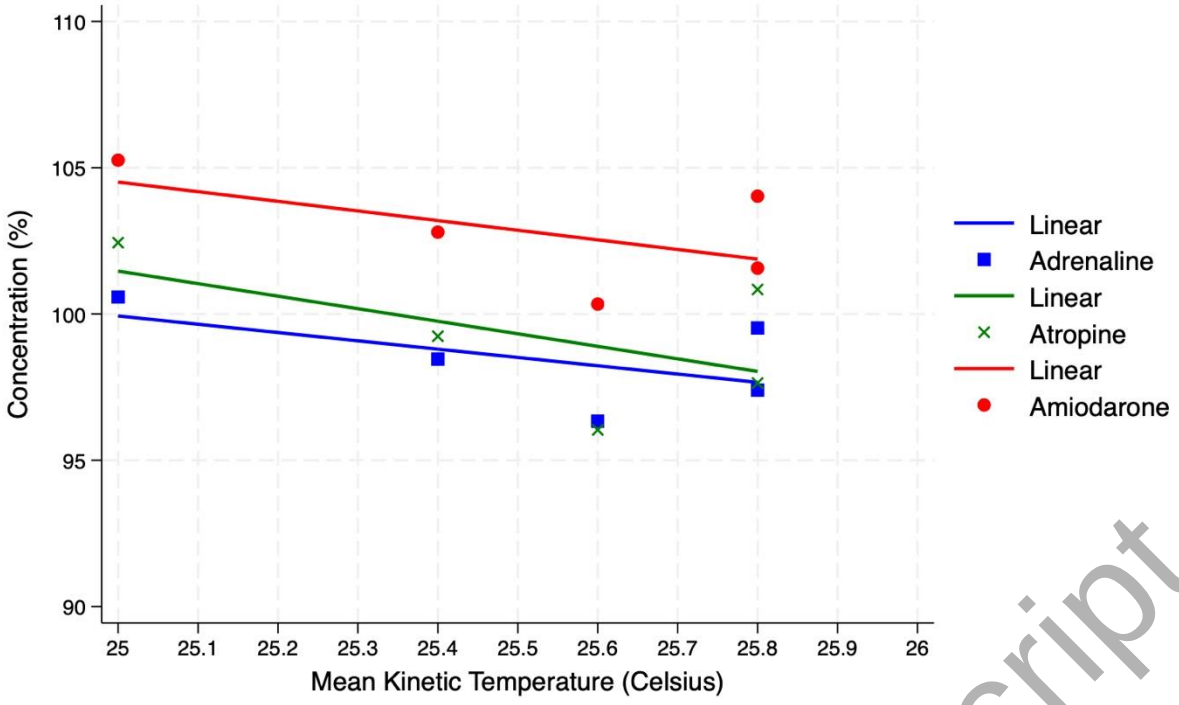

Figure 3: Associations between mean kinetic temperature and concentrations of adrenaline, atropine, and amiodarone

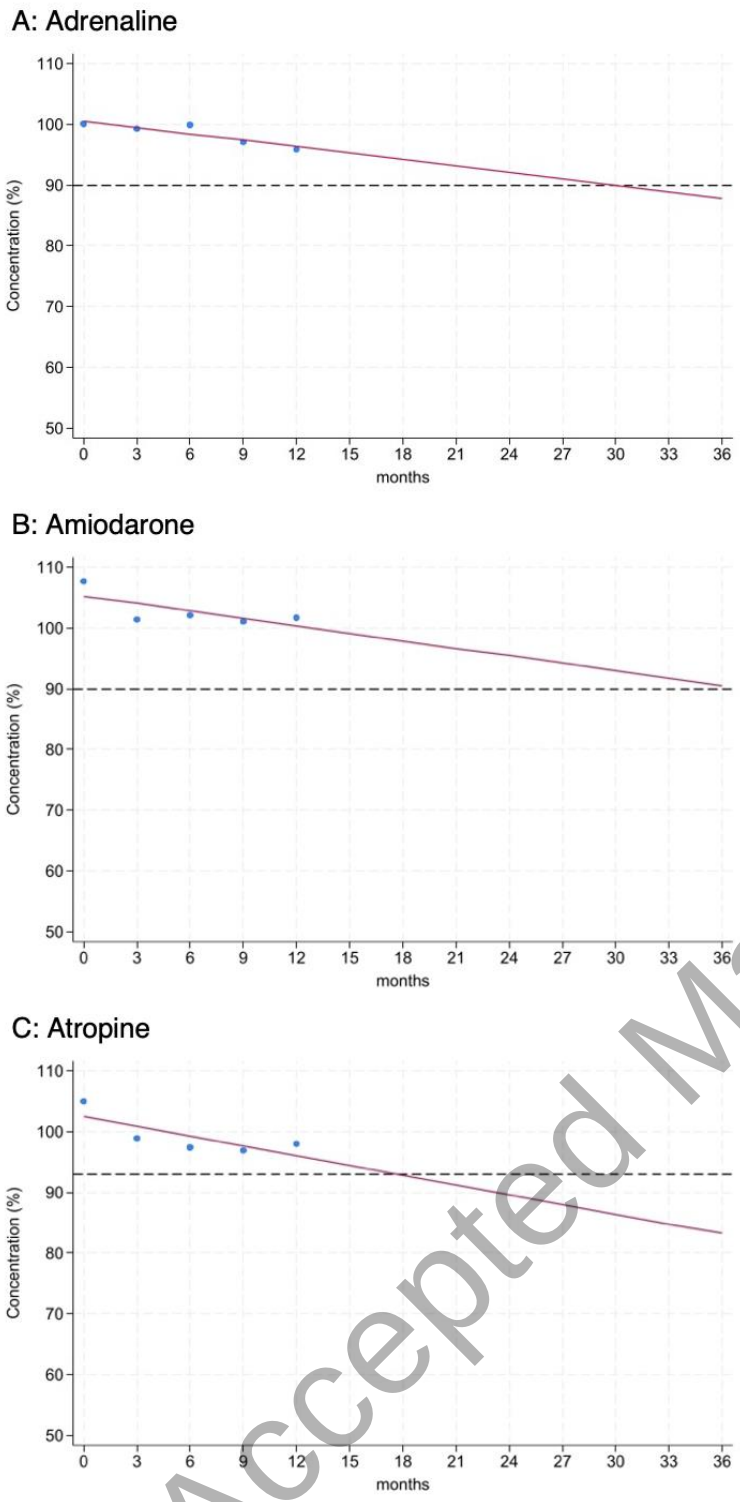

Figure 4: Predicted concentration over 36 months of adrenaline (A), Amiodarone (B), and Atropine (C)