

2521

Use of forced air warming devices to induce fever-range hyperthermia in critically ill septic patients

Anne M. Drewry, Enyo A. Ablordepey¹, Marin H. Kollef² and Richard S. Hotchkiss³

¹ Department of Emergency Medicine, Washington University in St. Louis; ² Department of Medicine, Washington University in St. Louis; ³ Department of Anesthesiology, Washington University in St. Louis

OBJECTIVES/SPECIFIC AIMS: Afebrile septic patients are twice as likely to die and develop nosocomial infections as compared with those with fever; the reason for these differences is unknown. One hypothesis is that elevated temperatures directly boost immunity and inhibit microorganism growth. However, there is little data examining the clinical effects of warming septic patients. The goal of this study was to determine whether warming afebrile septic patients to fever-range hyperthermia with noninvasive forced air warmers is feasible and safe. **METHODS/STUDY POPULATION:** This is an ongoing randomized trial on afebrile mechanically ventilated patients with severe sepsis. The intervention consisted of 48 hours of external warming with a forced air warming device to a goal core temperature of 1.5°C higher than the lowest recorded temperature within the 24 hours preceding enrollment. Efficacy of the intervention and adverse event data (i.e., increases in heart rate and vasopressor doses) were collected. Clinical outcomes included 28-day mortality and acquisition of secondary infections. **RESULTS/ANTICIPATED RESULTS:** In total, 18 patients were randomized to the control and warming groups, respectively. Baseline characteristics (including demographics, comorbidities, and illness severity scores) were similar among the 2 groups, except the control group had more males (61% vs. 28%, $p=0.04$). Median (IQR) body temperature averaged over the 48-hour intervention period was higher in the warming group [38.2 (37.6, 38.6) vs. 37.1 (36.4, 37.4) °C, $p<0.001$]. Patients in the warming group achieved core temperatures above their goal for a median of 37 (IQR 11, 45) hours during the 48-hour intervention period. There were no differences in heart rate or vasopressor dose changes or acquisition of secondary infections between the groups. Eight (44.4%) control patients and 3 (16.7%) warmed patients died by day 28 ($p=0.07$). **DISCUSSION/SIGNIFICANCE OF IMPACT:** Externally warming severe septic patients with forced air warming devices effectively raises core body temperature and is safe. Additional research will focus on cellular and immunological changes seen in warmed Versus control patients.

2022

Using father-mediated intervention to increase responsive parental behaviors and child communication in children with autism spectrum disorder: A pilot study

Michelle Flippin

University of Rhode Island

OBJECTIVES/SPECIFIC AIMS: Although parent involvement is recognized as an integral autism intervention component, and two-thirds of children are currently raised in 2-parent families, the majority of ASD parent research to date has focused on mother-implemented interventions, and fathers have been largely overlooked. However, fathers use interaction styles and language models that are different from mothers and may benefit children with ASD in unique ways. Thus there is a critical need in the field to expand our understanding of the potential contributions of various caregivers to communication outcomes. This investigation aimed to address this void in the research literature and contribute to clinical practice by including fathers in parent-implemented intervention, and adapting parent-implemented autism intervention to fit paternal interaction and communication styles. Specifically, this pilot study investigated the effects of a father-mediated intervention on parent use of responsive verbal and play strategies. Distal effects on child communication and pre-post changes in parental stress levels were also investigated. **METHODS/STUDY POPULATION:** A single subject, multiple baselines across strategies experiment was conducted with one dyad (i.e., father, child with ASD). In-home father coaching sessions were delivered weekly, targeting 4 responsive strategies (i.e., follow-in comments, follow-in directives, symbolic object play, rough-tumble play). Single subject designs are particularly suitable for autism interventions, as they allow for experimental control with participants who are from heterogeneous populations (McReynolds and Kern, 1983). Child participant was 3 years, 1 month at the start of intervention and had previously received a received community diagnosis of ASD by a psychologist. Throughout the duration of the study, the child participant attended part-day community-based day care and received

20 hours per week of Applied Behavioral Analysis intervention both in-home and community daycare, as well as occupational therapy and speech-language therapy for 1 hour per week. The participating father was a biological parent who resided with the child continuously since birth. In addition, the father had no other formal parent training in communication intervention before participating. **RESULTS/ANTICIPATED RESULTS:** The results of the father-implemented intervention program yielded positive results for both father and child participant. The father quickly achieved a high level of competency using 3 of the 4 targeted strategies (i.e., follow-in comments, follow-in directives, and rough-and-tumble/physical play). Follow-in comments were used more frequently than follow-in directives and rough-and-tumble play strategies were used more frequently than symbolic play. Child use of single words increased over baseline and beginning use of multiword utterances was documented. Pre-post changes in parental stress for participating father and his spouse were not significant, however patterns of change across Parental Stress Index subscales scores were noted. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This pilot investigation provided information regarding the treatment efficacy of a clinically relevant instructional program designed to enhance fathers' ability to use responsive strategies to increase communicative acts or children with ASD. The results of this investigation advance clinical practice in the ASD field by providing intervention data relating to the efficacy of father-implemented instructional programs on child communication goals.

2317

Uterine serous carcinoma is associated with a high risk of venous thromboembolism regardless of latency from surgical staging

Gregory M. Gressel, Lauren Turker¹, Shayan Dioun¹ and Nicole S. Nevadunsky¹

¹ Albert Einstein College of Medicine

OBJECTIVES/SPECIFIC AIMS: Patients with gynecologic cancer are known to have an increased risk of venous thromboembolism (VTE) in the post-operative period secondary to hypercoagulability from both malignancy and pelvic surgery. Recent literature suggests that chemotherapy itself may be thrombogenic and prophylaxis may be beneficial in ambulatory patients receiving chemotherapy. Although extended VTE prophylaxis is commonly given after surgical staging, administration of prophylactic anticoagulation during chemotherapy or radiation treatment is not routinely performed. This study seeks to characterize risk factors and timing of VTE in a cohort of women diagnosed with uterine serous carcinoma (USC). **METHODS/STUDY POPULATION:** After institutional review board approval, a cross-sectional study was performed of all women diagnosed with USC between January 1999 and January 2016 at Albert Einstein College of Medicine. Data analysis was performed using Stata version 14.2 (Stata Statistical Software: Release 14, 2015. College Station, TX: StataCorp LP). Baseline clinical data was analyzed to calculate descriptive statistics. Normality of continuous variables was visually assessed and if no substantial violations were noted, data was reported as means \pm standard deviations. Otherwise, they were reported as medians with interquartile ranges. Categorical data was presented as number of patients with percentages. Bivariate analysis was performed to assess the association between clinical variables and diagnosis of VTE. Continuous variables (age, body mass index, number of risk factors for VTE) were visually assessed for normality. Levene's test was used to assess for equal variance among groups. If no substantial violations were noted, means and standard deviations were calculated using 2 sample *t*-test for equal variance. Variables violating normality assumptions were analyzed using the Mann-Whitney *U*-test, calculating medians and interquartile ranges. Categorical and dichotomous variables (VTE risk factors, race, stage) were examined using the χ^2 test or Fisher's exact test (if expected values for more than 20% of cells were less than 5). Odds ratios were reported with 95% confidence intervals. Using a backwards stepwise elimination approach, a multivariable logistic regression model was fit to accurately examine association of risk factors with VTE, adjusting for other covariates. The resulting model was assessed for calibration and discrimination using Hosmer-Lemeshow test for goodness of fit, classification table, and ROC curve. Regression diagnostics were run in order to identify potentially influential covariate patterns in the model. First-order interactions were assessed for using product interaction terms (interaction defined as *p*-value for the likelihood ratio test <0.05). The resulting model was assessed for calibration and discrimination using Hosmer-Lemeshow test for goodness of fit, classification table, and ROC curve. A Cox proportional hazards model was also fit in order to examine the association between individual covariates and time to clot development. Log-rank testing was performed to compare survivorship experience by groups and survivorship curves were generated using the Kaplan-Meier method. Assumptions of

the proportional hazards model was confirmed visually using log-log plots and goodness of fit assessment. RESULTS/ANTICIPATED RESULTS: A total of 413 patients were identified for inclusion in the study. The majority of patients (83%) were of non-White race. Bivariate analysis revealed no significant associations between age, BMI, or race with diagnosis of VTE ($p=0.75$, 0.49 , and 0.28 , respectively). Patients who had more than 2 risk factors for VTE had a significantly increased likelihood of VTE diagnosis ($p=0.02$). There was a highly significant association between stage of USC and diagnosis of VTE ($p=0.005$). Patients with stage III and stage IV cancer were 2.4 and 3.5 times more likely to develop VTE than patients with stage I cancer (95% CI: 1.09–5.30, 1.74–6.83, respectively). Of the 70 patients who were diagnosed with VTE, most were not postoperative (64.3%) and a large proportion developed clots while receiving chemotherapy (35.7%). Patients who developed VTE while on chemotherapy had a median Khorana score of 1 (IQR: 1, 2). In logistic regression modeling examining association of VTE with potential risk factors, covariates selected as significant for inclusion at the $p < 0.25$ level included cancer stage, composite number of risk factors, diabetes, hypertension, cardiovascular disease (CVD), and COPD. Composite risk score was identified to be a potential confounder of the relationship between individual risk factors and development of clot and was therefore left in the model for adjustment. After adjusting for other covariates, only stage 4 disease (OR: 2.66, 95% CI: 1.53, 4.64) and hypertension (OR: 2.90, 95% CI: 1.14–7.36) were associated with development of VTE and were included in the final model. No concerning violation of assumptions of logistic regression or interaction was identified. The Hosmer-Lemeshow goodness of fit test identified that the model was well-fit using 10 groupings ($p=0.35$) and receiver operator characteristic testing showed that the model had acceptable discrimination with a ROC value of 0.7. The final model was found to classify 83.1% of participants correctly. Regression diagnostics identified 4 potentially influential covariate patterns. These patterns were eliminated from the model and no meaningful differences were noted. Patients contributed a total of 16,414 person months of analysis time in study follow-up. A negative, linear association was noted between stage of cancer and time to clot development. Long-rank testing revealed a significant difference in failure by stage of disease ($p < 0.001$) and presence of hypertension ($p=0.03$). Cox proportional hazard modeling revealed that after adjustment for other covariates, only cancer stage and the presence of cardiovascular disease were significantly associated with time to failure. Patients with cardiovascular disease had a 2.02-fold increased risk of CVD compared to those without CVD (95% CI: 1.16–3.47). Those with stage 3 and 4 cancer were 3.19 (95% CI: 1.53–6.64) and 8.05 (95% CI: 4.11–15.78) fold more likely to develop VTE compared to those with stage I disease, respectively. DISCUSSION/SIGNIFICANCE OF IMPACT: Our study demonstrated that patients with USC are at high risk of developing VTE at all time points after their disease diagnosis, not just those who have undergone recent surgery. This risk is highest for women with hypertension, CVD, and stages III and IV disease. The fact that patients who developed clots on chemotherapy had an average Khorana score of 1, suggesting that they would not have been successfully risk stratified using previously published tools. To the best of our knowledge, this is the first study to report a high hazard for VTE in patients with serious endometrial cancer even several months after surgical staging. Although this is a retrospective study and cannot make inferences about VTE incidence, it generates the hypothesis that extended VTE prophylaxis may be beneficial in this cohort of patients regardless of their latency from surgical staging. Large randomized studies are needed to test this hypothesis.

2479

Acute care research competencies for clinical research professionals: A practitioner inquiry approach and assessment

Jacqueline Knapke, Brett Kissela, Lynn Babcock and Schuckman Stephanie
University of Cincinnati

OBJECTIVES/SPECIFIC AIMS: Acute care research is a unique area of clinical research that demands specialized skills, knowledge, and talents from empathetic professionals working in the field. Building off existing competencies for clinical research professionals, the Cincinnati Acute Care Research Council (ACRC) developed additional areas of competency for professionals working in the acute care research discipline. METHODS/STUDY POPULATION: Qualitative data obtained from job shadowing, clinical observations, and interviews were analyzed to understand the educational needs and desires of the acute care research workforce. We then utilized Bloom's Taxonomy to build acute care research competencies that are measurable for job performance and build off of foundational clinical research professionals' domains and competencies

developed by the Joint Task Force of Clinical Trial Competency. RESULTS/ANTICIPATED RESULTS: Results suggest 35 special interest competencies for acute care clinical research professionals under 8 common domains set by the Joint Task Force of Clinical Trial Competency. Additionally an approved ACRC tactic, from actionable learnings through community assessments throughout 2017, is the creation of a Task Force made up of acute care research Principal Investigators and Clinical Research Directors to focus on the identified training and professional development obstacles in the clinical research enterprise. DISCUSSION/SIGNIFICANCE OF IMPACT: The competencies developed for acute care research should serve as guidelines for training a workforce prepared for the challenges of conducting research with each acute audience, as its own vulnerable population. These competencies will guide development of a multi-pronged program of professional development that will include new hire onboarding, new hire on-job training, and ongoing on-job training.

2485

Advancing research professionals through competency assessments

Rebecca N. Brouwer, Denise Snyder, Deborah Hannah and Christine Deeter
Duke University Medical Center

OBJECTIVES/SPECIFIC AIMS: Describe the framework for tier advancement of research professionals. Describe the various forms of assessments of competencies. How competencies are used to provide transparency into professional development opportunities. Discuss the results of the first tier advancement opportunity for research staff. METHODS/STUDY POPULATION: These processes were developed at Duke, an academic medical center with over 2000 active clinical research protocols and 300 new clinical trials per year. Roughly 500 employees are categorized into tiered classifications, allowing them opportunities for advancement through competency testing. Approximately 10% opted for tier testing, and their results will be shared. RESULTS/ANTICIPATED RESULTS: Competency assessments were developed for all 42 of Duke's research professional competencies, some using 2 modalities of testing. Almost 12% of the research professionals classified in tiered positions opted to attempt the tier advancement process. Of those, 37 completed, and the vast majority reached their desired tier. Results by competency will be provided. DISCUSSION/SIGNIFICANCE OF IMPACT: The use of objectively assessed competencies is an important step in the development of a workforce. By (1) maintaining alignment with industry standards for competencies, (2) holding staff to a high bar, and (3) offering a consistent approach to career growth, Duke is working to develop and maintain a workforce that supports high quality research.

2345

An electronic roadmap to customized human research training plans

Jennifer Maas, Megan Hoffman, Janet Shanedling, Jason Kadrmaz, Trung Ngo and Jacob Johnson
CTSI, University of Minnesota

OBJECTIVES/SPECIFIC AIMS: To respond to the need for a simple tool to answer individual researchers questions: Exactly what training do I need to complete for my study and my role? Where can we go to find a comprehensive record of my research training? METHODS/STUDY POPULATION: Identify the factors that determine what training is required for each role (i.e., PI, coordinator, biostatistician) at the University, their role on the research study, type of funding, population being studied and responsibilities/duties on the research team. Develop an inventory of training required according to federal and local regulations and guidelines. Identify other related factors that ensure ongoing compliance for research professionals (i.e., medical licenses, CVs, immunizations, and credentials). Collaborate with programming professionals to explore and confirm the feasibility of such a Web site. Incorporate formal usability and pilot testing as part of the programming design process. Develop User Guide and Marketing and Launch plan for users and supervisors. Implement phased launch of the site with Google analytics, and evaluate the experience of phase I users. RESULTS/ANTICIPATED RESULTS: Three months user data and evaluation results demonstrated: 149 users created Training Roadmaps on the site. Users were from 67 different department codes, with the Department of Psychiatry the primary user. 20 users responded to a survey three months after launch. Research coordinators were the primary focus for phase I and represented almost half of the users. Survey respondents rated the site ease of use and clarity of the site as its