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BXCL501 is an investigational orally dissolving thin film of the highly selective α2-3 adrenergic receptor agonist, dexmedetomidine, for sublingual or buccal administration. This secondary analysis of 2 Phase 3 studies of acute agitation in patients with schizophrenia or bipolar disorder evaluated efficacy by baseline agitation severity on both the PANS-Xcited Component (PEC) total and the 5 items making up the PEC (excitation, tension, hostility, uncooperativeness, poor impulse control).

Methods: Data were from 2 Phase 3, randomized, placebo-controlled studies of adults with bipolar disorder or schizophrenia, with a total score of ≥7 on the PEC and ≥4 on at least 1 of the 5 PEC items. Participants were randomized to either BXCL501 180 mg, 120 mg, or placebo. The primary endpoint was change from baseline PEC total score at 2 hours. Moderate and severe agitation were defined as a PEC total score of 14 to 19 or ≥19, respectively. Calmness was rated on the Agitation and Calmness Evaluation Scale (ACES).

Results: Mean change in PEC total score from baseline to 2 hours postdose was significantly (P < .0001) greater for 180 mg (-10.4 & -10.4) and 120 mg (-8.4 & -9.0) doses of BXCL501 vs placebo (-4.7 & -4.9) for the schizophrenia & bipolar groups, respectively. Significant (P < .01) improvements from baseline to 2 hours in PEC total score were observed with BXCL501 vs placebo among subgroups with moderate or severe agitation. Significant (P < .0001) improvements from baseline in each of the 5 components of the PEC were observed with both doses of BXCL501 compared to placebo. These findings were consistent in both the schizophrenia and bipolar disorder groups. There were no severe or serious drug-related adverse events. Safety and tolerability results were comparable in both trials. In the schizophrenia study, the most common treatment emergent adverse events (TEAEs) were somnolence (22%; 86% mild, 14% moderate), dizziness (4.3%), oral hypotension (4.3%), and orthostatic hypotension (4.0%). In the bipolar disorder study, the most common TEAEs were somnolence (21%; 59% mild, 41% moderate), dry mouth (5.6%), dizziness (5.6%), hypotension (5.6%), and orthostatic hypotension (4.4%). No participant was unaurable as measured by the ACES. All participants were able to self-administer the film.

Conclusions: BXCL501, an investigational orally dissolving thin film formulation of dexmedetomidine, demonstrated consistent statistically significant improvement in PEC total score compared to placebo, regardless of baseline agitation severity in both schizophrenia and bipolar disorder groups. Statistically significant improvement in PEC total and all individual items (excitation, tension, hostility, uncooperativeness, poor impulse control) was observed with both doses in both groups. The most common TEAEs in both groups were somnolence, dizziness, and orthostatic hypotension. BXCL501 represents a potential approach for treating acute agitation in adults with schizophrenia and bipolar disorder.

Results: A total of 827 responses were obtained over two months. Three quarters of respondents believed care received was similar to that in a traditional emergency department. Overall positive impression of the drive-thru was 86.6% and 95% believed that it was more convenient.

Conclusion: Overall the drive-thru medical system was perceived as more convenient than the emergency department, and is viewed as a positive experience. While a dramatic change in the delivery model of medical care, if such systems are able to provide comparable levels of care, they may represent a viable option for sustained and surge health care delivery.

Impact of Lighting Conditions of Procedural Competence With Emergency Cricothyotomy

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Study Objectives: Surgical cricothyrotomy (SC) is a difficult procedure in the best of conditions with high failure rates in the battlefield environment. The difficulty of this procedure is particularly great in a low-light tactical environment where white light cannot be utilized. Traditionally, red light has been the preferred light source in such environments, but is less than ideal for medical procedures. This study examines use of Red+Green (RG) light versus Red (R) light alone.

Methods: Tactical Combat Casualty Care-certified Navy Corpsmen (N=33) were provided 15 min of standardized instruction followed by hands-on practice with the Tactical CricKey (TCK) and the H&H bougie-assisted (BA) Emergency Cricothyotomy Kit. Participants were then placed in a dark environment to allow their eyes to adjust after which they performed SC on a manikin with both devices using both R and RG light (4 total iterations per participant). Application time, success, participant preference, and participant confidence were analyzed using repeated-measure ANOVA and non-parametric statistics at α = 0.05.

Results: There were high levels of successful placement (>87.5%) in all 4 cohorts with no statistical difference between the groups. Light choice did not appear to affect placement time with either of the 2 kits (P = .88). Within each light choice, TCK was faster than BA in R light (P = .005) and RG light (P = .005). On post-event surveys, participants reported that RG decreased difficulty (P = .0001) and increased confidence (P = .0001).

Conclusion: RG light seems to increase confidence and decrease perceived difficulty when performing SC, though no difference in placement time or success was observed. Further investigation on live tissue is needed to draw conclusions regarding BA vs. TCK and to further evaluate RG vs R light.

Most Rattlesnake Envenomation Patients Receive Multiple Doses of Antivenom

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Study Objective: Antivenom is dosed to clinical effect. Previous reports from a smaller dataset showed that most patients envenomed by rattlesnakes require multiple doses of antivenom, regardless of whether they were treated with Fab or Fab’12 antivenom. This study expands previous work to incorporate 2020 data, and describes the dose and timing of both ovine Fab and equine Fab’12 antivenom administration for rattlesnake victims.

Methods: We performed a post hoc analysis of prospectively collected observational data. Rattlesnake envenomation cases in the American College of Medical Toxicology (ACMT) Toxicology Investigators’ Consortium (ToxIC) North American Snakebite Registry (NASBR) treated in 2019 and 2020 were stratified by antivenom administered. Patients receiving both antivenoms were excluded from this analysis. Descriptive statistics and graphical presentation were used to understand total antivenom dosing.

Results: Among 196 rattlesnake envenomation patients receiving antivenom, 77 patients (39.3%) received Fab antivenom, 59 (30.1%) received Fab’12 antivenom, and 60 (30.6%) received both products. Among patients receiving only Fab antivenom, the median total antivenom dose was 10 vials (IQR: 6 - 12), and 56 patients (72.7%) received over one antivenom dose. The median interval between Fab doses was 6.0 (4.5 - 8.0) hours. The Fab’12 only group received a median of 18 (10 - 24) vials of antivenom, and 41 patients (69.5%) received multiple doses. The median interval between Fab’12 doses was 5.1 (3.5 - 8.5) hours. The mean (SD) total antivenom dose

WITHDRAWN

Patient Perceptions of Drive Through Medical Treatment Facilities During the COVID-19 Pandemic

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Study Objectives: The cumulative burden of the COVID-19 virus on the US healthcare system is substantial. To help mitigate this burden, novel solutions including tele-health and dedicated screening facilities have been utilized. However, there is limited data on the efficacy of such models and none assessing patient comfort levels with these changes in health care delivery. The aim of our study was to evaluate patients’ perceptions of a drive through medical treatment system in the setting of the COVID-19 pandemic.

Methods: In response to the COVID-19 pandemic, NMCP’s emergency department established a drive-through medical evaluation facility (DMEF) in proximity to the emergency department. The DMEF was designed to allow full evaluation of patients to include: vital signs, complete medical history, clinician physical examination, limited point-of-care testing and medication distribution. All patients presenting to the emergency department with symptoms of potential COVID etiology and deemed non-critical were directed to the DMEF for initial evaluation. Patients were surveyed about their experience following their visit. An anonymous questionnaire consisting of 5 questions, utilizing a 5-point Likert scale was distributed via electronic tablet.

Conclusion: Overall the drive-thru medical system was perceived as more convenient than the emergency department, and is viewed as a positive experience. While a dramatic change in the delivery model of medical care, if such systems are able to provide comparable levels of care, they may represent a viable option for sustained and surge health care delivery.