Session: Immunizations/Delivery: Oral Poster Symposia

Preventing Post-Vaccination Presyncope and Syncope in Adolescents Using Simple Clinic-Based Interventions: a Randomized-Controlled Trial (NCT04772755) (Poster 1)

Monday, May 1, 2023 1:00 PM – 2:30 PM ET

Location: Convention Center: 204 C

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Disclosure(s):

Michael J. Smith, MD, MSCE: Pfizer (Ongoing) (Products/Services: Research Support including clinical trials & the principal or named investigator)

KAREN R. BRODER, MD: I do not have any relevant financial / non-financial relationships with any proprietary interests.

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Michael M. McNeil, MD MPH: I do not have any relevant financial / non-financial relationships with any proprietary interests.

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Andrew T. Kroger, MD, MPH: I do not have any relevant financial / non-financial relationships with any proprietary interests.

Emmanuel Walter, MD, MPH: Clinetic (Ongoing) (Products/Services: Research Support including clinical trials & the principal or named investigator); Iliad Biotechnoligies (Terminated, February 28, 2022) (Products/Services: Consultant); Pfizer (Ongoing) (Products/Services: Research Support including clinical trials & the principal or named investigator); Sequiris (Terminated, August 31, 2022) (Products/Services: Research Support including clinical trials & the principal or named investigator); Vaxcyte (Ongoing) (Products/Services: Advisory Committee)

Background: There are no evidence-based recommendations for the primary prevention of post-vaccination syncope, a rare but sometimes serious adverse event following immunization. Presyncope is more common than syncope, and has served as a syncope surrogate in blood donation and vaccine prevention studies. A previous study identified anxiety and pain as risk factors for post-vaccination presyncope.

Objective:
To assess the efficacy and acceptability of two simultaneously administered interventions to prevent post-vaccination presyncope, and by extension, syncope.

Design/Methods: Adolescents 10-14 years-old receiving ≥1 intramuscular vaccine were randomized 1:1 to a combined intervention group including Buzzy® (vibration/cool pack device to reduce injection site pain) and video game (distraction) or a standard of care control group. Baseline assessments included generalized anxiety (PROMIS), needle phobia (APA), and prior syncope/presyncope history. Post-vaccination presyncope (Modified BDRI - Table 1), injection-site pain (Wong-Baker Faces Pain Score), state anxiety (Youth Momentary Anxiety), and acceptability were assessed.

The primary outcome was efficacy, reported as the percent decrease in presyncope in the intervention group compared to the control. Secondary outcomes included differences in pain and anxiety between the groups and acceptability of the intervention. Between-group differences were assessed using $\chi 2$ tests. Factors associated with presyncope were identified using logistic regression.

Results: 332 participants were included in the modified intent-to-treat population (Table 2). 59/165(36%) participants in the intervention group reported presyncope versus 80/167(48%) in the control group (p=0.025), a 25% (95% confidence interval: 3% – 42%) decrease. The mean injection-site pain score was lower in the intervention group (2.51 vs 3.26, p=0.006) 1-3 minutes post-vaccination. The proportion of participants with a pain score ≥ 4 was also lower (32% vs 46%. p= 0.009). There was no difference in post-vaccination state anxiety between the 2 groups. The interventions were viewed favorably: 79% of participants would use Buzzy® again, and 81% would play a video game.

In the model, pain at 1-3 minutes post-vaccination, baseline anxiety, baseline thirst, and number of vaccines received were associated with presyncope (Table 3).

Conclusion(s): The combination of Buzzy® and a video game decreased the risk of post-vaccination presyncope by 25%, likely due to a decrease in pain. These data suggest that the combination intervention was well-tolerated and may be useful in settings where adolescents receive vaccines.

Table 1: Modified Blood Donations Reaction Inventory (BDRI)*

	Not at all	Very little	Some	A lot
Feeling like you might "pass out" or faint				
Feeling dizzy, like the room is spinning				
Feeling weak				
Feeling like your face is getting red and warm (or hot), like blushing or flushing				
Experiencing ringing in your ears, decreased hearing, or sounds seem far away				
Feeling lightheaded				
Feeling like your heart is beating fast or hard or pounding				
Feeling hot or sweaty				
Feeling cold or "clammy"				
Feeling like you are breathing fast or hard				
Feeling like you might throw up (nausea)				

*Participants were asked if they had felt any of the above symptoms since being vaccinated. A response of "some" or "a lot" to one or more item met the study definition of presyncope

Table 2: Demographic and Clinical Characteristics

	Buzzy N=165	Control N=167	Total
	N (%*) or Mean (Range)	N (%*) or Mean (Range)	
Gender: Male	78 (47.3%)	81 (48.5%)	159
Gender: Female	87 (52.7%)	86 (51.5%)	173
Age in Years	11.8 (10 - 14)	11.9 (10 - 14)	332
Race: Black Only	52 (31.5%)	60 (35.9%)	112
Race: Other	26 (15.8%)	15 (9%)	41
Race: White Only	87 (52.7%)	92 (55.1%)	179
Ethnicity: Hispanic or Latino	15 (9.1%)	11 (6.6%)	26
Ethnicity: Non-Hispanic or Non-Latino	150 (90.9%)	156 (93.4%)	306
Insurance: Only Public	52 (31.5%)	50 (29.9%)	102
Insurance: Any Private	113 (68.5%)	115 (68.9%)	228
PROMIS T-Score	45.0 (33.5 - 76.0)	45.9 (33.5 - 81.1)	332
Average Total Phobia Score	0.70 (0 - 3)	0.72 (0 - 3)	332
History of Presyncope or Syncope	43 (26.1%)	47 (28.5%)	332
Thirst: A Little to A Lot	108 (49.8%)	109 (50.2%)	217
Hunger: A Little to A Lot	87 (47.5%)	96 (52.5%)	183
Vaccines Received: 1	77 (46.7%)	76 (45.5%)	153
Vaccines Received: 2	44 (26.7%)	34 (20.4%)	78
Vaccines Received: 3	40 (24.2%)	52 (31.1%)	92
Vaccines Received: 4	4 (2.4%)	5 (3.0%)	9

*Column percentages

Participants were enrolled between March 2021 and June 2022

Table 3: Factors Associated with Presyncope in Stepwise Logistic Regression*

	Odds Ratio (95% CI)	p-value
Injection Site Pain (Faces Pain Score)	1.24 (1.12, 1.39)	<.0001
General Anxiety (PROMIS T-score)	1.04 (1.01, 1.07)	0.0024
Thirsty - Little to A Lot vs Not at All	2.10 (1.29, 3.41)	0.0029
2 or more Vaccines vs 1 Vaccine	1.81 (1.11, 2.94)	0.0173

*The model included the following variables: treatment group, gender, ethnicity, race, health insurance (public versus private), PROMIS T-score, tiredness, hunger, thirst, injection site pain, average phobia score, number of vaccines, and history of syncope/prescyncope.