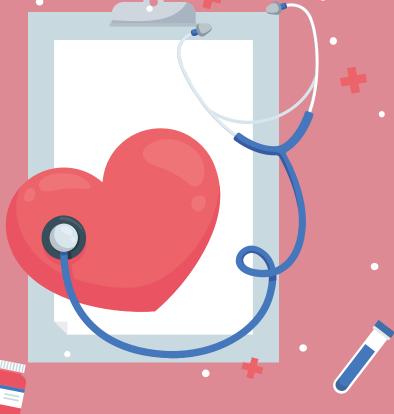


### Libyan International Medical University

Faculty of Pharmacy
Second year

Impact of High Volume Energy
Drink Consumption on
Electrocardiographic and
Blood Pressure Parameters: A
Randomized Trial

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# Introduction

Research has been done that the energy drinks are a growing industry with a market value predicted to reach \$61 billion by 2021, it is also estimated that about 30% of teenagers between the ages of 12 through 17 years in the United States consume energy drinks on a regular basis.

Although commonly promoted as supplements that can boost performance and cognition, these drinks have also been reported to have numerous detrimental side effects, particularly cardiovascular and neurological in nature.

So, the overall goal of this random trail was to determine the impact of energy drinks on electrocardiographic and hemodynamic parameters in young healthy volunteers.

This study was approved by the Institutional Review Board (IRB) at University of the Pacific (Stockton, CA).



This random trail was conducted at a university campus setting (July 2017 to December 2017). There were healthy volunteers between the ages of 18 and 40 years who were willing to avoid ingestion of caffeine and energy drinks for 48 hours before each study day were eligible for enrolment. Any participants with any known medical condition (confirmed through participant interview) were excluded, also, who were taking any chronic prescription or over-the-

sunter medications were excluded too.

what was required of the volunteers? What did the drinks contain?



How was the process of the trial?



#### So, what was required of the volunteers?

- An overnight fast (with allowance for water only) every study day.
- No food was allowed during the study monitoring period.







#### How was the process of the trial?

- The participants were randomized into 1 of 3 intervention phases using a computergenerated code.
- They received two 16-oz bottles of a commercially available caffeinated energy drink brand drink (drink A), another brand of a caffeinated energy drink (drink B), or a placebo-drink (placebo).
- they were separating on 3 days with a minimum 6-day washout period in-between.
- The beverages were consumed within a 60-minute period but no faster than 1 bottle in 30 minutes.

#### What did the drinks contain?



Based on the package labelling, both **drink A and drink B** contained:

Caffeine (304–320 mg/32-fl oz), taurine, glucuronolactone, and vitamins along with other

proprietary ingredients. There were some differences between the 2 energy drink brands include the presence of carnitine, guarana, and panax ginseng.

On the other hand, the placebo drink contained: carbonated water, lime juice, and cherry flavouring.

All drinks were packaged in identical, masked containers prepared within 24 hours of administration and stored in a refrigerator before administration.

## **End Point Measurement**

- The primary end point was QTc interval.
- Secondary end points included the QT interval (QT), PR interval (PR), QRS duration (QRSd), heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), central systolic blood pressure (cSBP), and central diastolic blood pressure (cDBP).
- Augmentation index (AI) adjusted to an HR of 75 bpm was also measured and will be reported in a separate analysis. All end points were measured at baseline and at 30, 60, 90, 120, 150, 180, 210, and 240 minutes on each study day. Participants began the study at approximately the same time each study day to account for circadian rhythm changes.

# **End Point Measurement**

 Blood pressure measurements were obtained in the seated position after an initial rest period of 8 minutes using an automated blood pressure device (SphygmoCor XCEL PWA, AtCor Medical). SphygmoCor provides automated brachial Clinical Perspective.

#### What Is New?

• The class of energy drinks, rather than one particular product affect the QTc interval and blood pressure.





# End Point Measurement &

#### What Are the Clinical Implications?

- Individuals with acquired or congenital long QT syndrome and those with hypertension should be more vigilant and limit their energy drink intake blood pressure as well as noninvasive analysis of the central aortic blood pressure waveform and related hemodynamic parameters.
- Two measurements were taken at each time point 2 minutes apart on the right arm and averaged.







# Statistical Analysis

# **Statistical Analysis**

- An intention-to-treat analysis was performed using the last-observation-carried-forward methodology to account for missing data.
- A repeated-measures analysis of variance, which assumes a compound symmetry covariance structure, was performed with the main effects of intervention, time, and an interaction of intervention and time one for their data.
- Results of this analyses called for a 2-way analysis of variance for each end point (baseline-adjusted) at each time point, with a post hoc Tukey Honestly Significant Difference (HSD), to assess for differences between the 3 interventions.
- In addition, the maximum value for each end point within each time frame (30–240 minutes) was identified (referred to as the "maximum" time point).
- The data were also analysed using the Bonferroni adjustment, which did not change the interpretation of the study.

# Results

- Forty-four participants were screened, 40 were randomized, and 34 ultimately included for analysis.
- None of the participants were on any medications other than 3 who were on oral contraceptives.
- 3 participants had received drink A, 4 had received drink B, and 1 had received placebo.





# **Table 1. Patient Characteristics**

Characteristic	Total
Age in y, mean (SD)	22.1 (3.0)
Sex, n (%)	
Male	17 (50)
Female	17 (50)
BMI, n (%)	
<18	1 (2.9)
18 to 24	20 (58.8)
25 to 29	9 (26.5)
>30	4 (11.8)
Race, n (%)	
White	4 (11.8)
Asian	22 (64.7)
Other	8 (23.5)
Caffeine consumption, n (%)*	
Rarely	5 (14.7)
Occasionally	7 (20.6)
Frequently	16 (47.1)
Daily	6 (17.6)

- BMI indicates body mass index.
- Rare caffeine consumers were defined as <1 caffeine containing drink per month.
- occasional caffeine consumers were defined as
   1 to 3 drinks per month.
- frequent caffeine consumers were defined as 1 to 6.
- caffeine containing drinks per week.
- Daily caffeine consumers were defined as ≥1 caffeine containing drink per day.

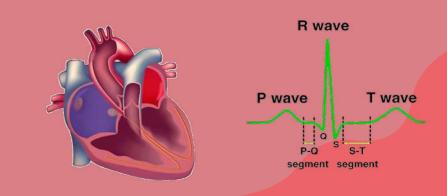
# Table 2. Describes ECG and blood pressure parameters at baseline

Cardiovascular Parameters	Drink A	Drink B	Placebo
HR, bpm	63.5 (8.2)	63.2 (10.0)	62.5 (7.2)
PR, ms	158.0 (17.1)	157.9 (20.2)	156.4 (18.3)
QRSd, ms	92.3 (13.3)	93.1 (14.1)	93.0 (14.2)
QT, ms	403.4 (20.8)	404.5 (20.5)	407.1 (20.3)
QTcB, ms	412.9 (20.9)	412.3 (22.9)	413.7 (18.7)
QTcF, ms	409.8 (16.8)	409.7 (16.1)	411.6 (15.4)
SBP, mm Hg	116.9 (10.0)	118.5 (9.6)	118.2 (9.0)
DBP, mm Hg	73.4 (7.8)	74.2 (8.4)	73.9 (7.9)
cSBP, mm Hg	104.0 (9.4)	105.3 (8.8)	104.8 (7.9)
cDBP, mm Hg	74.4 (8.0)	75.2 (8.4)	74.8 (8.0)

All data reported as mean (SD).

**cDBP** indicates central diastolic blood pressure.

**cSBP:** central systolic blood pressure.



## **Table 3.** Average Maximum Change in

# Cardiovascular Parameters (n=34)

9.8 (4.8)

6.1 (3.8)

6.5 (3.5)

6.7 (3.5)

< 0.001

< 0.001

< 0.001

< 0.001



	Drink A	Drink B	Placebo	P Value*		
ECG parameters <sup>†</sup>						
QTcB, ms	17.9 (13.9)‡	19.6 (15.8)§	11.9 (11.1)	0.005		
QTcF, ms	15.0 (11.8) <sup>‡</sup>	15.2 (11.9)§	6.9 (7.1)	<0.001		
QT, ms	18.4 (17.0)‡	15.8 (13.3)	10.2 (12.2)	0.026		
PR, ms	5.4 (6.5)	6.1 (7.5)	8.6 (6.6)	0.076		
QRSd, ms	6.2 (3.3)	5.9 (3.0)	5.0 (2.9)	0.164		
HR, bpm	7.7 (7.4)	7.2 (6.8)	7.4 (5.9)	0.918		
Hemodynamics	†					

14.4 (4.8)§

9.6 (4.9)§

10.1 (4.8)§

9.8 (5.1)§

 $15.9 (5.0)^{\ddagger}$ 

 $9.6(4.1)^{\ddagger}$ 

11.1 (4.7)‡

 $9.9(4.2)^{\ddagger}$ 

SBP, mm Hg

DBP, mm Hg

cSBP, mm Hg

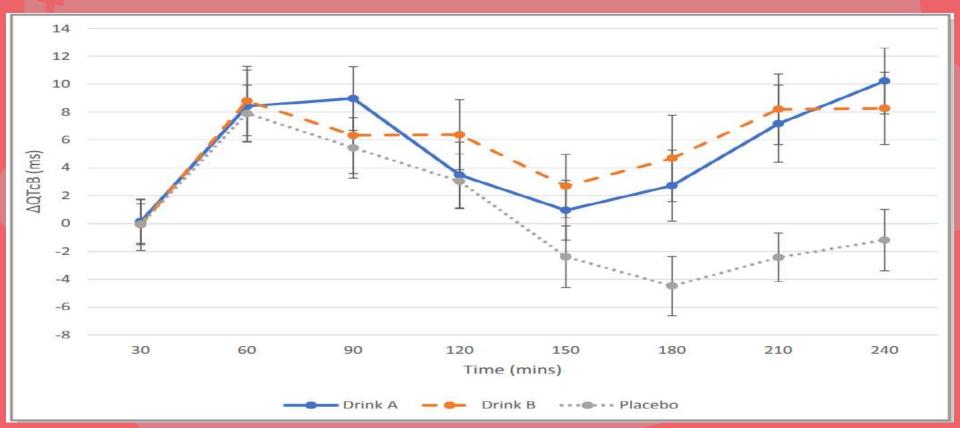
cDBP, mm Hg

- P value for analysis of variance adjusted for subject variability.
- † No statistically significant difference was noted between drink A and drink B for any parameter.
- ‡ Statistically significant difference between drink A and placebo.
- § Statistically significant difference between drink B and placebo.

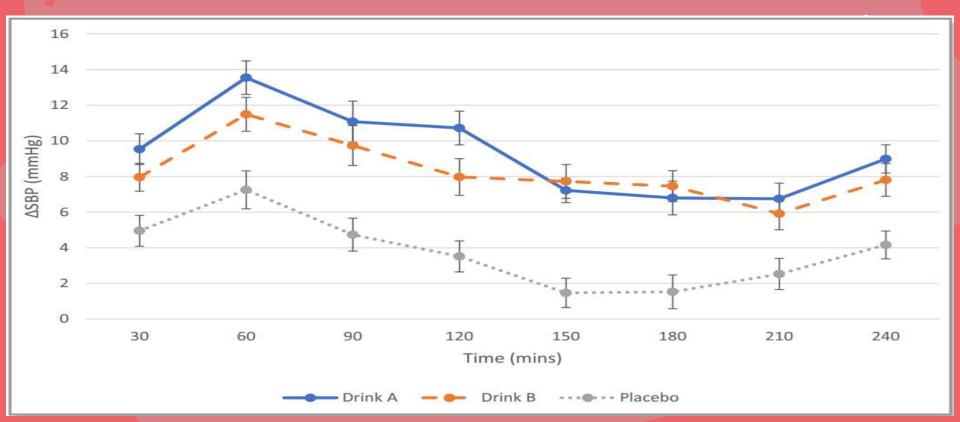


# Discussion

• Figure 1. Change in QTcB from baseline over time. QTcB indicates Bazett's corrected QT interval.



• Figure 2. Change in SBP from baseline over time. SBP indicates systolic blood pressure.



# Discussion

- Both energy drinks had a similar effect on electrocardiographic parameters.
- This study, indicating acute-consumption of 32 oz of a caffeinated energy drink significantly prolongs the QTc interval when compared with placebo.
- QTc prolongation is a well-established risk factor for arrhythmias.
- Individuals with acquired or congenital long QT syndrome and those with hypertension should be more vigilant and limit their energy drink intake.





Further research is required to see if the electrophysiological and hemodynamic changes are caused by a single ingredient or a particular combination of ingredients.

The long-term consequences of energy drink intake are uncertain.



# References

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**Energy Drink Consumption on Electrocardiographic and Blood Pressure** 

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# THANK YOU!