

AN INVESTIGATION OF THE EFFECT OF DRINKING CAFFEINATED VERSUS DECAFFEINATED FLUIDS ON SYMPTOMS OF OVERACTIVE BLADDER SYNDROME: A FEASIBILITY TRIAL.

Hypothesis / aims of study

The negative effect of caffeine on overactive bladder (OAB) is largely anecdotal with conflicting results reported; hence the foundation of evidence upon which this advice is based is far from robust and is largely based upon widespread clinical experience and international expert opinion. The primary aim of this feasibility study was to investigate the effect of drinking caffeinated versus decaffeinated fluids on symptoms of overactive bladder (OAB) in adult women. The protocol and research methodology used was tested for use in a future multi-centre randomised control trial.

Study design, materials and methods

An eight week double-blinded randomised cross-over study design was adopted at a single centre. Adult women were recruited through professional referrals and local advertisements and were invited to take part if they had been newly diagnosed with OAB. Inclusion criteria were >18 yrs, experiencing 7+ voids per day and 2+ episodes per night, self-rated urgency and/or UUI with or without SI symptoms, and consuming 2+ caffeinated drinks per day (minimum 60 mgs caffeine per 24 hours). Main exclusion criteria included: SI only, smoking, taking oestrogen and/or medications containing caffeine or interfere with caffeine metabolism, post-void residual < 100mls, history of frequent (>3/6 months) UTIs, pregnant, or unable to undertake a bladder diary.

Fourteen participants (mean age 52.07 yrs; range 27 to 79 yrs) were recruited from 47 women who met the initial eligibility criteria and were randomised into Group A or Group B via a random number generator. All participants underwent periods of caffeinated and decaffeinated fluid intake with the order randomly assigned as caffeinated first (Group A) or decaffeinated first (Group B). Before starting their assigned Group participants took part in a Run-In period of caffeine withdrawal, during which they were requested to reduce their caffeine intake by substituting one cup of caffeinated tea or coffee with decaffeinated every other day. The Two study periods (Period 1 and Period 2) were separated by a 14 day Washout Period.

Data were analysed by the Sign test using SPSS version 17.0 for Windows. The primary outcome variables of episodes of urgency, frequency, volume per void, and incontinence were obtained from a 3-day bladder diary recorded towards the end of each period. These were analysed on day 1, 2, 3 (of the bladder diary) and overall for each 2 week intervention period. Secondary outcome measures were assessment of symptom severity and QoL as measured by the ICIQ-OAB and ICIQ-OABqol tools completed towards the end of each period. The effects of caffeine reduction on the participants QoL were measured on a caffeine withdrawal VAS completed twice a day. Comparisons were made between Periods 1 and 2. Participant compliancy was determined by caffeine levels from saliva samples.

Results

Eleven participants completed both periods of the study. Three participants withdrew giving a drop-out rate of 21.4%; this is comparable to a larger study on 95 adults (1) who reported a 22% drop-out rate. Two participants did not comply with caffeine substitution.

A significant decrease in the mean number of urgency episodes (8.73 vs. 7.54; $P \leq 0.01$) and the mean number of urinary voids (8.82 vs. 8.36; $P \leq 0.05$) was found on day 3 during the period of caffeine substitution vs. caffeine exposure. No other differences were found from the 3-day bladder diary.

A significant improvement was found in the ICIQ-OAB total score (Figure 1a) with a greater mean value obtained during the period of caffeine exposure compared to caffeine substitution (6.55 vs. 4.64; $P \leq 0.01$). The frequency of getting up to urinate during the night (2.09 vs. 1.44; $P \leq 0.05$) and episodes of urgency (2.00 vs. 1.27; $P \leq 0.05$) were also both significantly increased; furthermore the latter symptom was significantly more bothersome when drinking caffeinated fluids (6.87 vs. 3.82; $P \leq 0.01$). The ICIQ-OABqol shows that significantly greater mean scores were recorded during the period of caffeine exposure for how regularly bladder symptoms interfered with the ability to get a good nights rest (4.09 vs. 2.64; $P \leq 0.01$), how often bladder symptoms caused anxiety or worry (2.64 vs. 1.73; $P \leq 0.05$), and how much bladder symptoms interfered with everyday life overall (5.64 vs. 3.73; $P \leq 0.01$). Although total scores for the ICIQ-OABqol indicated better QoL during caffeine substitution (53.91 vs. 68.36) (Figure 1b) the difference was not significantly different between periods ($P = 0.065$).

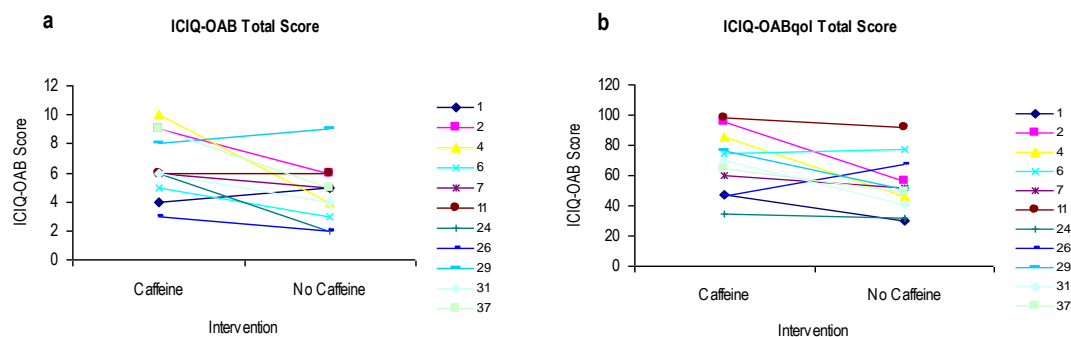


Figure 1: Total score for the ICIQ-OAB (a) and ICIQ-OABqol (b) for each participant.

No significant differences were found for symptoms of caffeine withdrawal between both periods, meaning participants experienced similar symptom severity whether drinking caffeinated or decaffeinated beverages. Moreover this relationship is supported by participant subjective reports which confirmed that 63.6% of the participants could not identify between the two periods.

Interpretation of results

Despite the small sample size, this feasibility study has demonstrated that reducing caffeine intake by replacing caffeinated beverages with decaffeinated beverages may significantly alleviate the severity of some symptoms and QoL factors associated with OAB. A significant reduction in the number of urinary episodes and frequency of urinary voids on day 3, mean total score for the ICIQ-OAB, and directional change in favour of caffeine substitution for the total ICIQ-OABqol score support these findings. Although the existence of a caffeine withdrawal syndrome is well established we did not find any of the caffeine withdrawal symptoms to be significant; therefore it may be concluded that caffeine substitutes were well tolerated.

Concluding message

This small cross-over study of caffeine substitution is the first to be carried out on women with OAB and indicates that the abstinence of caffeine may alleviate OAB symptoms. Although a modest effect size is likely, caffeine substitution is a relatively easy, low risk and painless intervention to implement and appears to be well tolerated and interchangeable as a lifestyle intervention. It is recognised that future larger trials are needed to demonstrate these findings more robustly. The primary issues of recruitment, drop-out rate and non-compliance are likely to be important factors to consider in future trials.

References

1. Bryant CM, Dowell CJ, Fairbrother G (2002) Caffeine reduction education to improve urinary symptoms, Br J Nurs 11:560-565

Specify source of funding or grant	Burdett Trust for Nursing, UK
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	Yes
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Royal Devon and Exeter Foundation NHS Trust and NHS Devon Research ethics committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes