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Authors: BRYANT CM, DOWELL CJ, FAIRBROTHER G
Institution: Prince of Wales Hospital & Community Health, Royal North Shore Hospital & Community Health
Title: FINAL RESULTS OF A RANDOMISED TRIAL OF A CAFFEINE REDUCTION INTERVENTION AND DESCRIPTIVE ANALYSIS OF CAFFEINE BEHAVIOURS

Aims:

To report the effect of a caffeine reduction intervention on urinary frequency, urgency and urge incontinence and to describe trial subjects' caffeine related behaviours. Despite scant trial evidence about caffeine's effect on urinary frequency, urgency and urge incontinence ⁽¹⁾, there is a wide spread international practice of routinely recommending reduction of caffeine as a treatment component for people with these urinary symptoms^(2,3,4), however the scientific basis for this, has up to now been taken for granted. Surprisingly there is relatively little published information about any mediating role of caffeine usage, pattern, history and demographics relating to urinary dysfunction.

Methods:

A prospective randomised trial among consecutive patients presenting to two experienced nurse continence advisers at community continence clinics. All adult patients with symptoms of urinary urgency, frequency and/or urge incontinence and who routinely ingested 100mg or more of caffeine per day were invited to join the trial. Patients with significant cognitive impairment, pregnancy and symptoms of urinary tract infection were excluded.

Patients were randomised to 2 groups; group 1 received bladder training and a request to continue their normal caffeine intake during the four-week study period. Group 2 received bladder training and an educational intervention to reduce caffeine < 100mg day. All subjects completed a caffeine usage history and a three-day time/volume/caffeine chart at trial entry. Subjects were enrolled in the trial for 30 days and completed time/volume/caffeine charts for three days each week. All subjects gave informed consent to the study, which was approved by the Ethics Committee and patients received no remuneration for their participation.

Results:

Effect of caffeine reduction intervention: 95 subjects enrolled in the study and of those: 21 (22%) withdrew. Mean years with urinary problem: urgency 12.25 (SD 7.93) frequency 6.67 (SD 3.51), urgency + frequency 15.14 (SD 16.58), urge incontinence 12.03 (SD 3.51). A comparison of key baseline data is set out in table 1:

Table 1

| Variable | Intervention | Control |
|------------------|--------------|---------|
| Age (mean years) | 56 | 58 |
| Sex (% female) | 94 | 87 |
| Weight (mean kg) | 69 | 68 |

| | | |
|---------------------------------|------|------|
| Daily caffeine intake (mean mg) | 239 | 272 |
| Frequency (mean voids/24hrs) | 11.4 | 11.4 |
| Urgency (mean occasions/24hrs) | 4.8 | 4.7 |
| Leakage (mean occasions/24hrs) | 2.8 | 3.2 |

The following results summarise findings for the 74 subjects who completed the study. Outcomes were measured by calculating change per 24 hours in voids, occasions of urgency and leakage. Comparative results are set out in table 2:

Table 2

| | Intervention group N=36 (mean reduction) | Control Group n=38 (mean reduction) | F | Sig. |
|-----------------------------------|--|---|------|----------|
| Caffeine intake per 24 hours | 58% | 11% | 64.6 | <0.0001* |
| Voids per 24 hours | 35% | 23% | 2.1 | 0.037* |
| Occasions of urgency per 24 hours | 61% | 12% | 0.5 | 0.002* |
| Occasions of leakage per 24 hours | 55% | 26% | 1.1 | 0.219 |

P<0.05*

Stepwise multiple regression procedures (SPSS 9.0) confirmed a nil confounding effect of demographic variables and clinical characteristic variables on the three outcome results measures. Change in occasions of urgency per 24hrs in the control group was analysed further to explore whether caffeine intake level was related to urgency. Results are evident of a trend, though non-significant(p=0.0516): with a 23% reduction in the low users (100-200mg), a 5% reduction in the medium users (201-300mg) and a -4% reduction in the high users (>301mg).

Caffeine Behaviours: analysis of caffeine behaviour revealed; change in caffeine intake over the past five years: decrease 31 (33%), increase 19 (20%) and no change 45 (47%). Main reasons for increase (in order of prominence); caffeine enjoyment; workplace; social pressure. Main reasons for decrease (in order of prominence); health; social pressure; pregnancy; insomnia; workplace. Forty subjects (42%) reported caffeine effects; of those the most prominent was urinary symptoms (20%).

Conclusions:

The decrease in caffeine intake in the intervention group has established that a caffeine reduction education intervention was successful in generating meaningful caffeine reduction (<0.0001*). Outcome comparisons between the two groups show a substantial beneficial effect among those who received the intervention. Significant improvements in occasions of urgency per day (p=0.002*) and number of voids per day (p=0.037*) were found and a beneficial trend is evident in occasions of leakage per day, though significance was not established (p=0.22), on the basis of this evidence we can advise our patients that caffeine reduction to <100mg per day is likely to reduce their symptoms of urgency and frequency. The findings on caffeine behaviours shed light on what drives our patient's caffeine use. Urinary symptoms figure prominently as a reported effect but less so as a driver of caffeine reduction, this suggests a window

of educational opportunity for practitioners seeking improved outcomes for their caffeine using patients.

References:

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