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## Heat exposure of Cannabis sativa extracts affects the pharmacokinetic and metabolic profile in healthy male subjects

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### Abstract

The most important psychoactive constituent of CANNABIS SATIVA L. is Δ (9)-tetrahydrocannabinol (THC). Cannabidiol (CBD), another important constituent, is able to modulate the distinct unwanted psychotropic effect of THC. In natural plant extracts of C. SATIVA, large amounts of THC and CBD appear in the form of THCA-A (THC-acid-A) and CBDA (cannabidiolic acid), which can be transformed to THC and CBD by heating. Previous reports of medicinal use of cannabis or cannabis preparations with higher CBD/THC ratios and use in its natural, unheated form have demonstrated that pharmacological effects were often accompanied with a lower rate of adverse effects. Therefore, in the present study, the pharmacokinetics and metabolic profiles of two different C. SATIVA extracts (heated and unheated) with a CBD/THC ratio > 1 were compared to synthetic THC (dronabinol) in a double-blind, randomized, single center, three-period cross-over study involving 9 healthy male volunteers. The pharmacokinetics of the cannabinoids was highly variable. The metabolic pattern was significantly different after administration of the different forms: the heated extract showed a lower median THC plasma AUC (24 h) than the unheated extract of 2.84 vs. 6.59 pmol h/mL, respectively. The later was slightly higher than that of dronabinol (4.58 pmol h/mL). On the other hand, the median sum of the metabolites (THC, 11-OH-THC, THC-COOH, CBN) plasma AUC (24 h) was higher for the heated than for the unheated extract. The median CBD plasma AUC (24 h) was almost 2-fold higher for the unheated than for the heated extract. These results indicate that use of unheated extracts may lead to a beneficial change in metabolic pattern and possibly better tolerability.

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