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Research Article

Captagon Abuse: Analysis for its Constituents in Drug Rehabilitation in the UAE

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ABSTRACT

Stimulants in the form of Amphetamine Type Stimulants (ATS) are the most commonly abused drug class in the UAE and the wider Middle East region and has been reflected in the National Rehabilitation Centre (NRC) drug trend data for many years. The NRC is the major center in the United Arab Emirates (UAE) for drug addiction prevention, treatment and rehabilitation.

Of the (ATS) the most commonly abused drug is Fenethylline (Captagon®) a stimulant drug that has been banned worldwide since 1986. Counterfeit Captagon produced illicitly in the region contains mainly amphetamine, the-ophylline and/or caffeine among other chemicals, rather than fenethylline itself. Production is fueled by conflicts and instability in the region. Fenethylline breaks down in the body to produce amphetamine and theophylline and unlike drug seizure analysis, this poses a problem for biological fluid analysis to determine the exact constituents of Captagon consumed.

Aim: In order to study whether ATS-positive patients' samples contain counterfeit Captagon, as part of routine diagnostic immunoassay, LC-MS/MS and GC-MS testing, urine samples from the 2021 NRC patient cohort were analysed for the presence of possible Captagon counterfeit constituents such as amphetamine and/or metham-phetamine with ephedrine, theophylline and/or caffeine.

Results: A total of 992 ATS positive patient samples were analyzed with the most frequently detected combination being (methamphetamine + amphetamine with caffeine and theophylline) representing 29% of all ATS-positive cases, followed by (methamphetamine + amphetamine with caffeine) representing 15.6%. All other combinations were less than 1.5%, with only two cases where only amphetamine was detected along with ephedrine, caffeine and/or theophylline.

Conclusion: The data support the wide use of amphetamines and whilst caffeine and theophylline can be present due to intake of certain foods and beverages, their presence with amphetamines could be due to their presence in counterfeit Captagon.

Keywords: Captagon; Fenethylline; Amphetamine; Methamphetamine; Counterfeit medicines; UAE

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INTRODUCTION

Substance misuse is a global issue of concern. The Middle East region is no different and it is imperative for all countries to understand the scale of the problem. Services providing care for patients suffering from substance use disorders need to educate themselves about the prevalence, health and social consequences of drug use. In United Arab Emirates (UAE), this task has been allocated to the National Rehabilitation Centre (NRC) as the national response center for drug addiction prevention, treatment and rehabilitation of both inpatients and outpatients [1].

At the NRC, medical care is supported by state-of-the-art clinical laboratory services, including toxicology for the detection of drugs in patients' samples, in-house, maximizing confidentiality and patient trust. The results of these tests have allowed the NRC to detect the drugs within the substance-using patient population and monitor trends to provide an evidence-based assessment of drugs within the UAE area applicable to the wider Middle East region [2].

These data have shown a rapid increase in Amphetamine Type Stimulants (ATS) over the period 2013-2021. Specifically, ATS in the form of amphetamine is the most commonly abused drug in year 2021 in the region. Whilst this may represent use of amphetamine itself, there has been a growing trend of counterfeit Captagon[®] tablets being available in the Near and Middle East often containing amphetamine along with theophylline and/or caffeine and are sourced from South-East Europe and from within the region [3].

Captagon contains the active drug Fenethylline, also known as amphetaminoethyltheophylline and amfetyline [4]. This co-drug breaks down in the body to produce amphetamine and theophylline, and acts as a prodrug to both aforementioned drugs [5]. In one study, fenethylline was found to produce amphetamine (24.5% of oral dose) and theophylline (13.7% of oral dose) [6]. Whilst amphetamine is a well-known central nervous stimulant drug, theophylline is a member of the xanthine family with structural and pharmacological similarity to theobromine and caffeine. It is mainly used for the treatment of pulmonary conditions, including apnoea. Theophylline also increases cardiac contractility and heart rate; as a positive inotropic and chronotropic agent, increasing blood pressure, increasing renal and cerebral blood flow [7].

Fenethylline was marketed as a psychostimulant under the brand names Captagon, Biocapton, and Fitton. It became known as Abu Hilalain (meaning two crescents in Arabic) in the Arabic speaking countries, the term borrowed from the logo on the tablets [8]. It was first synthesized by the German Degussa AG in 1961 as a part of an investigational program on side effects of theophylline derivatives and particularly on the cardiovascular, pulmonary and central nervous system. Three years later, a strict prescription only status was required [4].

It was used for many years in the treatment of attention-deficient-hyperactivity disorder, and to a lower extent, in narcolepsy, epileptic absences and depression [4]. Fenethylline does not cause a noticeable rise in the blood pressure of the subjects being treated as opposed to amphetamines [4]. In 1986, fenethylline was included in Schedule II of the United Nations (UN) Convention on Psychotropic Substances 1971 [3]. Following this, signatory countries moved to prohibit production and use. However, in some countries a few specific medical uses continued to be allowed for some time. For example, until 2013, the ANSM (the French National Agency for Medicines and Health Products Safety) still allowed small quantities of Captagon[®] to be used for patients presenting with narcolepsy, making France one of the 5 countries in the world (with Belgium, Germany, Luxembourg, and the Netherlands) that reported the use of fenethylline for medical purposes at that time. However, fenethylline was never approved for medical use in the United States, as no investigational new drug application was submitted to the Food and Drug Administration [3-8].

As a prodrug, fenethylline is well-liked with street chemists as the method of manufacturing is relatively easy and readily available on the Internet. Thus, the amphetamine-containing product purported to be "Captagon" is extremely popular in the Middle East region and some parts of southern Europe [3-8] (Figure 1).

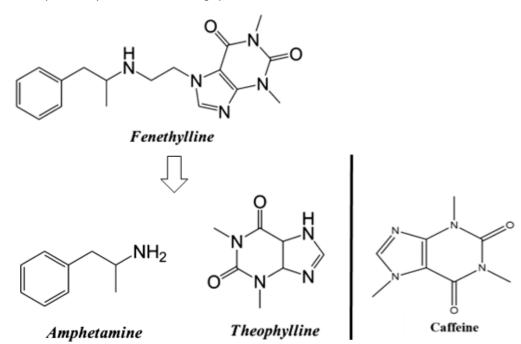


Figure 1: Chemical structure of fenethylline, amphetamine, theophylline and caffeine

In a study in Jordan, Gas Chromatography-Mass Spectrometry (GC-MS) analysis of counterfeit Captagon tablets from 124 seized batches confirmed the absence of fenethylline but detected the following in order of frequency based on representative sample sets: caffeine; amphetamine; methamphetamine, ephedrine, quinine; theophylline; chlorphenamine, procaine; metronidazole, trimethoprim, chloroquine [9]. The counterfeit nature of Captagon tablets seized in Europe was also confirmed by the analysis of seizures between 2008 and 2011, which indicated that it no longer contained fenethylline but amphetamine in combination with caffeine and other substances [10]. Virtually all the contemporary information available suggests that the tablets seized on the drug market in recent years are not diverted Captagon® tablets but clandestinely manufactured tablets that do not contain fenethylline. It should be noted however that there has been only limited forensic analysis of seized illicit Captagon tablets. However, the information available suggests that amphetamine and often caffeine are the psychoactive substances most likely to be present, although it should also be noted that tablet content appears highly variable [3-11].

The aim of this work was to further review the available data on analysis of seized Captagon in the Middle East region, as well as analyse the NRC patient cohorts for potential constituents such as amphetamine, methamphetamine, theophylline and/or caffeine. Information about the chemical purity of the available types of Captagon in the region has been summarized through:

- Literature review gathered from a detailed search of PubMed and the Internet using the terms of 'Fenethylline' or 'Captagon', 'counterfeit Captagon' and 'counterfeit amphetamine'.
- Analysis of the NRC patient samples presumptively positive for ATS (amphetamine along with theophylline and/or caffeine; along with methamphetamine and ephedrine derivatives).

MATERIALS AND METHODS

Materials and Reagents

All calibration, quality control and internal standards were prepared from reference materials of 99% purity purchased from Cerilliant (Sigma-Aldrich, St. Louis, USA). All solvents and reagent were of HPLC or LCMS grade and purchased from Fisher Scientific (Loughborough, UK), Merck (Darmstadt, Germany) or Sigma-Aldrich (St. Louis, USA). The enzyme used for hydrolysing the urine samples was ß-glucuronidase from Helix pomatia Type HP-2 aqueous solution \geq 100,000 units/mL (Sigma-Aldrich, USA). Derivatization reagent used was Selectra SIL BSTFA with 1% Trimethylsilane (TMS) (United Chem, USA). All the reagents used for immunoassay presumptive screening were from Abbott (USA).

Equipment

Initial screening of the patient urine samples was performed by Abbott Alinity Immunoassay. For LC-MS analysis patient urine sample extractions were performed using an automated Biotage Extrahera[™] system (Biotage, Sweden) in a 24 position configuration. Biotage EVOLUTE[®] EXPRESS CX 150 mg/6 mL columns were used for solid phase extraction. Samples were eluted to glass test tubes and dried under nitrogen flow using Biotage TurboVap LV evaporator [11].

The two differential conformational analysis (LC-MS and GC-MS) were performed using Shimadzu QP 2010 Ultra GCMS system and

Shimadzu Nexera LCMS-8040 system (Shimadzu Corporation, Kyoto, Japan). A Raptor Biphenyl 2.7 μm 100 mm \times 2.1 mm column (Restek, Bellefonte, USA) was used for LC-MS. A Restek Rxi-5Sil MS 30 m 0.25 mmID 0.25 mm similar to 5% diphenyl/95% dimethyl poly (Restek, USA) column was used for GC-MS analysis.

Sample Preparation and Analysis

Sample hydrolysis: To 3 mL of urine sample, 2 mL of pH 5.0 100 mM acetate buffer, 50 μ L or 100 μ L internal standard solution (depending on the analyte) and 100 μ L ß-glucuronidase (100,000 units/mL) were added. The samples were briefly vortex mixed, then incubated at 60°C for 2 hours. After cooling down to room temperature, the samples were then extracted by automated solid phase extraction technique for LC-MS analysis and liquid-liquid extraction for GC-MS analysis.

Liquid-Liquid extraction and GC-MS analysis: After cooling down at room temperature, the samples for GC-MS analysis were pH adjusted to 7-8 by using ammonia solution and acetic acid then thoroughly mixed with 6 mL extraction solvent (Chloroform: Ethyl acetate: Ethanol 90:30:30 by volume) and centrifuged. The separated organic lower layer was transferred into glass test tubes and dried under nitrogen flow. The samples were then derivatized by 100 μ L BSTFA solution (BSTFA: Ethyl acetate 1:1 v/v) and 1 μ L injected on GC-MS. For mass spectrometry detection, the MS instrument was operated with an El ion source in SIM/SCAN mode at a scanning range from 45 m/z to 600 m/z.

Solid phase extraction and LC-MS analysis: After sample cooling at room temperature, 500 μ L of 10% H₃PO₄ was added and centrifuged at 2000 rpm for 3 minutes. The samples were then extracted by automated Biotage Extrahera system with preconditioned EVOLUTE[®] EXPRESS CX 150 mg/6 mL columns. Each column was washed with 6 mL of 4% phosphoric acid and 6 mL of Methanol:Water (1:1 v/v) with positive pressure applied. Finally, analytes were eluted by elution solvent (Dichloromethane:Isopropanol:Ammonium hydroxide solution 78:20:2) with gradient positive pressure. After extraction, 100 μ L of methanolic HCl was added and vortex mixed prior to evaporation to dryness under nitrogen flow using a Biotage Turbovap evaporator at 40°C for approximately 15 minutes. The residue was reconstituted in 500 μ L 1:1 Methanol:Water, vortex mixed and analyzed by LC-MS-MS (Table 1).

 Table 1: Compound table with retention time and m/z for amphetamine, methamphetamine, caffeine, theophylline and ephedrine

Compound	Retention time (mins)	Target Ion (m/z)	Qualifier lons (m/z)
Amphetamine TMS	10.3	116	91, 192
Methamphetamine TMS	11.5	130	91, 206
Caffeine	17	194	109, 165
Theophylline TMS	17.6	237	252, 223
Ephedrine 2TMS	13.7	130	294, 147

Analytes were eluted from a Raptor Biphenyl analytical column at 30°C with a flow rate of 0.3 ml/min. The mobile phases consisted of Mobile Phase-A (2 mM ammonium formate with 0.002% formic acid in water) and Mobile Phase-B (2 mM ammonium formate with 0.002% formic acid in methanol) using a gradient programme. For mass spectrometry detection, the MS instrument was operated with an ESI probe in positive and negative modes depending on the analyte. Each analyte was optimised for appropriate collision en-

ergy and associated parameters for Multiple Reaction Monitoring (MRM) of precursor and product ions for sensitivity and selectivity and has been previously published [12].

RESULTS AND DISCUSSION

In the literature, few studies that explored the composition of Captagon tablets in the region were identified, across multiple decades. In 1993, Al-Gharably and Al-Obaid examined tablets seized by the General Directorate of Drug Control in Riyadh [13,14]. They found that 84% of the confiscated tablets contained fenethylline, while the remainder (16%) was composed of caffeine and quinine [13]. Conversely, Al-Hussaini examined confiscated Captagon tablets between 1986 and 1993, only to find that none of them contained fenethylline [14]. The tablets examined contained mixtures of other adulterants such as acetaminophen and ephedrine (10%), ephedrine and amphetamine (13%), and caffeine and quinine (16%) [14]. In 2020, Alshehri et al examined 60 Captagon tablets collected from several agencies in the Saudi Arabia [15]. They found 100% of all 60 tablets contained amphetamine and caffeine with 15 out of 60 tablets (25%) contained theophylline. Methamphetamine was present in 41 (68%) of tablets and no tablets contained fenethylline. Non-stimulant drugs frequently detected were dextromethorphan (88%), acetaminophen/paracetamol (73%) and tramadol (42%) [15]. In 2011, officials from the Saudi Ministry of Health examined the content of 98 stimulant tablets that were seized by law authorities as Captagon tablets [16]. Fenethylline was not found in

any of these tablets. Instead, 38.8% of the tablets contained considerable amounts of amphetamine, 49% contained trace amounts of amphetamine and 12.2% did not contain any amphetamine. Additionally, the most frequent adulterants identified in these tablets were caffeine (96.9%) and theophylline (93.9%) [16]. Most recently, in October 2021, Captagon tablets seized in Saudi Arabia were analyzed and found to have an amphetamine content of 16%-41%, along with significant levels of additives such as caffeine, lidocaine, diphenhydramine and 8-chlorotheophylline [11]. All these findings further agree with the study from Jordan that showed that most Captagon tablets obtained by authorities did not contain fenethylline, but were rather composed of amphetamines and caffeine [9]. These reports supports the perception that most Captagon tablets worldwide are "fake" and rarely contain fenethylline, especially in more recent decades [15]. Furthermore, amphetamine seems to be the active substance in most of these counterfeit tablets along with caffeine and theophylline [9-14].

In terms of the analytical toxicology testing of NRC rehabilitation patients, in the year 2021 the major substance class abused was Amphetamines, specifically amphetamine itself and methamphetamine. As shown by the NRC data for the period of 2013 to 2021 (Figure 2), there has been a pronounced shift towards more frequent use of amphetamine-like stimulants from 2016 onwards, despite a downward trend in absolute numbers in the last few years which could be related to the COVID-19 pandemic.

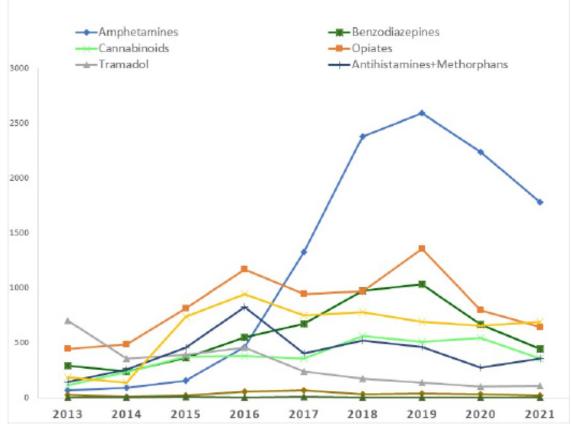


Figure 2: Drug trends in NRC patient samples from 2013 to 2021 (The reduction of patient numbers in 2019/2020 was due to changes in the patient cohort at the NRC and also COVID-19 pandemic.)

For this Captagon study, data included all patients assessed and admitted to the NRC from January 2021 to December 2021. All data were collected confidentially and evaluated anonymously with no personal identifiers 39% of all the 2021 positive cases were ATS. In total, there were 992 ATS-positive cases (where amphetamines or other stimulants were detected, irrespective of the presence or absence of other drugs). Table 2 shows the breakdown of positive case frequency of the various specific potential Captagon constituents (including combinations). The most frequently detected combination was methamphetamine + amphetamine with caffeine and theophylline representing 29% of all ATS-positive cases, followed by methamphetamine + amphetamine with caffeine representing 15.6%. All other combinations were less than 1.5%, with only two cases where only amphetamine was detected along with ephedrine, caffeine and/or theophylline. It should be noted that the presence of methamphetamine could be due to use of a product sold as and consumed as methamphetamine, rather than Captagon. It should also be noted that as amphetamine is a metabolite of methamphetamine, it is not unexpected that amphetamine would be present in urine even if methamphetamine itself had been consumed. Therefore, based on the positive detections alone, it is not possible to determine if amphetamine and/or methamphetamine had been consumed in those cases where both drugs are found. Even in the cases where amphetamine only was detected (along with caffeine and theophylline), this could be due to previous methamphetamine use, but amphetamine use itself cannot be excluded.

Specifically in relation to Captagon®, as mentioned elsewhere, the challenge to the interpretation of the urine sample results is that as fenethylline itself would not be detectable; the presence of amphetamine and theophylline in such samples does not exclude the use of Captagon[®] or other fenethylline-containing product [17]. Whereas the detection of caffeine along with amphetamine (and/ or methamphetamine) could constitute use of counterfeit Captagon containing methamphetamine/amphetamine and caffeine but could equally be due to the consumption of a caffeine-containing foodstuff in addition to amphetamine and/or methamphetamine use. Overall, as described above and shown in Table 2, instances of amphetamines with caffeine (in the presence or absence of theophylline) were the predominant results group in the patients tested. Of the other drugs detected in the ATS-positive patient urine samples (aside from potential counterfeit Captagon constituents), pregabalin positive cases were the most common, representing 14% of all ATS cases.

Table 2: Shows positive detection of potential counterfeit Captagon constituents in patient substance abuse urine samples

Potential counterfeit Captagon constituents	Total Positive cases	Percentage of total ATS cases
Methamphetamine+Amphetamine with Caffeine	155	15.60%
Methamphetamine+Amphetamine with Theophylline	12	1.20%
Methamphetamine+Amphetamine with Ephedrine	12	1.20%
Methamphetamine+Amphetamine with Caffeine and Theophylline	288	29.00%
Methamphetamine+Amphetamine with Caffeine, Theophylline and Ephedrine	1	0.1
Methamphetamine with Caffeine	4	0.40%
Methamphetamine with Theophylline	1	0.10%
Methamphetamine with Ephedrine	0	0%
Methamphetamine with Caffeine and Theophylline	4	0.40%
Methamphetamine with Caffeine, Theophylline and Ephedrine	0	0%
Amphetamine with Caffeine	0	0%
Amphetamine with Theophylline	0	0%
Amphetamine with Ephedrine	0	0%
Amphetamine with Caffeine and Theophylline	2	0.20%
Amphetamine with Caffeine, Theophylline and Ephedrine	0	0%

Described effects from users of Captagon include a sense of fearlessness, feelings of pleasure, increased energy and alertness as well as a reduced need for sleep and food [18]. They also report feelings of well-being, increased productivity, alertness, intense appreciation of surrounding sounds and colors, and visual distortions; its effects are reportedly intense, long lasting, and slowly released [19,20]. In order to moderate the euphorigenic and activating effects of the drug, Captagon is also taken in combination with cannabis and alcohol but only a few patient urine samples in this study detected cannabinoids (representing 0.04% of all ATS cases). Withdrawal symptoms may include depression and headache [19,20]. A number of adverse effects have also been identified. These include

an increase in heart rate, body temperature, respiration, and blood pressure as well as extreme depression, neurological excitation, lethargy, sleep deprivation, cardiotoxicity, and malnutrition on a longer term. Hazardous adverse effects included: psychosis, visual distortions and hallucinations, acute heart failure, acute myocardial infarction, and epileptic fits [21-24]. Interestingly, whilst amphetamine itself could produce many of the described stimulant effects (e.g. increased energy and alertness, reduced need for sleep, as well as cardiac effects), it would not necessarily account for any audio or visual distortions that would be more associated with hallucinogens. Therefore, further investigation of this may be warranted, especially with the potential wider proliferation of New Psychoactive Substances with hallucinogenic properties but these are not typically identified in amphetamine or related stimulant products [3].

CONCLUSION

The data review and analytical study reinforces the common perception of amphetamines being the most used illegal substance in the UAE, and that a degree of the consumed amphetamines in the country could be in the form of counterfeit Captagon. Due to the challenges associated with interpretation of findings in biological fluid involving methamphetamine, amphetamine, caffeine and theophylline, further work could involve identification of self-reporting users with comparison of results compared to other patient cohorts. Furthermore, potential comparative analysis in relation to the measured urinary concentrations of methamphetamine, amphetamine, caffeine and theophylline (including potential creatinine correction and pH measurement due to known impact on urine drug concentrations) in such patients may assist with interpretation. Additionally, clinical studies could be conducted in order to understand the demographic characteristics of Captagon users (self-reporting or otherwise), and identify potential environmental, medical and psychological risk factors for its use. Conducting this kind of research is crucial for directing law enforcement officials, substance use treatment experts, and other stakeholders toward the best methods to prevent and control the use of counterfeit Captagon in the region.

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COMPETING INTEREST

The authors have no conflict of interest to declare.

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