P0316

Phytotherapy and psychiatry: A bibliometric study during the period 1986-2006

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Objectives: In different areas of Therapy, included Psychiatry, herbal medicine has had an increasing interest during the last years. Plants are traditional uses, but only a few have been approved therapeutically. However, we do not know any bibliometric analysis about herbs that are used in Psychiatry.

Methods: We have conducted a bibliometric study regarding scientific publications related to phytotherapy in the Psychiatry area during 1986-2006 period. Using the platform Embase.com (Elservier, Amsterdam), including EMBASE and MEDLINE database, we selected those documents whose included the descriptors plant, herb, phytotherap, and psychiatr (with all diagnostic criteria). Plants' indications had been selected according to PDR for Herbal Medicines. As bibliometric indicator of the production, Price's Law was applied.

Results: A total of 21.409 original documents were obtained. Our data confirm a fulfilment of the Price' Law related to scientific production about medicinal plants in Psychiatry. We had observed it after carring out a lineal adjustment (y=135,08x-466,38 r=0.92) an another adjustment exponential curve (y=132,26e0.1497x; r=0.99). The plants more mentioned in the psychiatric literature have been St. John's Wort (Hypericum perforatum; n=937) and Ginkgo (Ginkgo biloba; n=694). The countries with more percentage of documents were the Unites States (29,44%), Germany (9,41%) and Japan (8,75%), and the country with highest Index of Participation (number of documents per country / number of documents in our repertory) was India (IPa= 0,935) and China (IPa=0,721).

Conclusion: Productivity medicinal plants in the Psychiatry area increased during the period 1986-2006. Nevertheless, documents about therapeutic herbs in this field are rather little.

P0317

Psychosocial factors in development of non-psychotic mental disorders in diabetes mellitus of type 2

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Objective: To study role of psychosocial factors in formation of mental disorders (MD) in patients with diabetes mellitus (DM).

Material and Methods: We examined 210 patients (age 48.57±8.65 years) with DM of type 2 and glucose tolerance disturbance (GTD) at Borderline States Department.

Results: DM patients were diagnosed as having neurotic, stress-related (44%), and affective (14%), organic (35%), personality (7%) disorders. Method of logistic regression has identified totality of prognostic signs in values (Concordant; Somers'D) of Hosmer and Lemeshow's test (0,7-0,9). We studied significance of psychogenic factors (life events, medical, working, family-housing ones) in formation of mental disorders. Predictors were as follows: level of glycemia (p=0.0001), body mass index (p=0.0001), diabetic retinal angiopathy (p=0.02), family history (p=0.044). Psychosocial predictors: duration of MD (p=0.0001), age of onset of MD (p=0.0001), ratio of age of onset and duration of MD and DM (p=0.0001), disorders of neurotic and affective level (p=0.0001). Anosognosia DM was combined with anxiety, fears and fear of death, inappropriate assessment of their abilities, hypothymia, anxiousness, and vegetative dysfunctions.

Two-factor disperse analysis has identified relationship between level of glycemia on an empty stomach, MD (p=0.0001; p=0.007) and DM (p=0.003). Instability of blood glucose (4.63-19.3 mmol/l) was observed in 40% of patients with leading syndrome of depression. Depressive disorders contributed to quicker development or decompensation of DM 2 for the first six months.

Conclusions: High risk of complications of DM was associated with influence of psychostressors and depressive disorders. Treatment of patients requires interaction of therapist (endocrinologist), psychiatrist, and psychotherapist.

P0318

Early arousing effects of caffeine and decaffeinate coffee

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Background and Aims: Some previous studies have demonstrated an early effect of caffeine administration on subjective state, but none of them has explored its existence after the administration of decaffeinate coffee, nor the possible differences according to the gender. The aim of the present work was to investigate, using a realistic design (non-research settings and naturalistic administration of the drug), the early effects (10-30 min post-consumption) of a single low-moderate dose of caffeine (100 mg) and decaffeinate coffee on sleepiness and subjective activation.

Methods: A random double-blind informed placebo controlled procedure was applied to a group of 688 healthy undergraduate volunteers (238 men) mean age 22.03 ± 2.21 years. Measures were recorded in two experimental sessions: morning 11:00-13:00h or afternoon 16:00-18:00h, in three moments before (30, 20 and 10 min.) averaged as a stable baseline, and three after (10, 20 and 30 min.) consumption.

Results: Caffeine administration induces fewer somnolence (F= 159.776, p<0.0001) and greater activation (F= 43.516, p<0.0001) in all post-consumption records, while the decaffeinated drink only induced arousing effects in the 10 min. post-consumption record. Caffeine effects were greater in men and the decaffeinated beverage produced greater effect in women (sleepiness: F= 14.893, p<0.0001; activation: F= 4.229, p=0.038).

Conclusion: Future works should study more accurately the early effect of caffeine and decaffeinate coffee and the influence of gender, using other parameters which have proven to be sensitive to their administration, as well as several caffeine doses.

P0319

A systematic review of the contra-indications in the summary of product characteristics for drugs licensed for ADHD in the UK

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Background and Aims: The Summary of Product Characteristics (SPC) specify how to use a medicinal product safely and effectively. They are mandatory documents approved by the regulatory authority (EMEA). The content is compiled based on available evidence and is

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updated as new information becomes known. The safety of paediatric medicines is of paramount importance and the SPC's specify where a treatment should not be used through the contra-indications section. ADHD is a condition affecting 4-8% of the paediatric population and medicinal treatments are commonly used.

Methods: A systematic review of the contra-indications for the licensed treatments for ADHD in the UK was undertaken. Data was extracted from the Electronic Medicines Compendium. Categorisation of contra-indications was done using relevant body systems. Where appropriate, language was reported verbatim. Atomoxetine is defined as a non-stimulant, methylphenidate and dexamfetamine as stimulants.

Results: There are eight licensed treatments (1992-2007) falling into two categories; non-stimulants and stimulants.(1:7) Most SPC's (75%) have been amended from February to July 07.

Numbers of contra-indications; all treatments 3-20, all stimulants 9-20, methylphenidate formulations 10-20. There are inconsistencies in the specific contra-indications between the various formulations of methlyphenidate. The only contra-indication common to all treatments is glaucoma. All forms of methylphenidate are contra-indicated in marked anxiety/tension, diagnosis/family history of Tourettes, severe angina, arrythmias and hyperthyroidism. Atomoxetine is the only treatment with no cardiac or neurological contra-indications.

Conclusions: The contra-indication section (4.3) of the SPC is a valuable tool when assessing the safety of comparative ADHD medications.

P0320

OROS®-MPH in adolescents with ADHD transitioning from Atomoxetine or ER-MPH (medikinet retard®) - a post-hoc analysis

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Objectives: To explore changes in quality of life (ILC) in adolescents with attention-deficit/hyperactivity-disorder (ADHD) transitioning from Atomoxetine (ATX) or ER MPH (Medikinet retard) onto OROS MPH.

Methods: Post hoc analysis. 12 week, open label non-interventional trial in adolescents (ADHD; ICD-10 criteria) transitioning from ER MPH or Atomoxetine onto flexible dose of OROS MPHs. Effectiveness parameter were changes in IOWA Conners' parent rating scale, C-GAS, ILC adolescents and parents and questions focusing on afternoon activities.

Results: 57 adolescents were analyzed (median age 14 years, 84.2% male). Insufficient efficacy (77.2%), adverse events (3.5%) or a combination of both (19.3%) led to transition to OROS MPH. Mean dose of ER MPH prior was 34,3mg±19,3 and mean dose of atomoxetine was 53,2mg±17,9. Eight patients terminated the study prematurely. Median dose of OROS MPH at endpoint was 54mg/day. "Playing with other children", "doing household chores", "doing homework", "going to bed in the evening", and "ability to visit or receive visitors" improved (all $p<0.001$) as well as C-GAS ($p<0.00001$), Conner's parent rating scale, ILC parents and adolescent's (all $p<0.001$).

Adverse events (AE) with under OROS MPH treatment were reported in 45.6% of patients. AE ≥5% were involuntary muscle contractions not further specified (5.3%), insomnia (5.3%), and ineffective medication (5.3%).

Conclusion: Transitioning from ER MPH or ATX to OROS MPH in adolescents with ADHD was associated with an improvement in quality of life in adolescents and their parents and in daily functioning. Improved symptom control during late afternoon and early evening activities was apparent.

P0321

Changes in quality of life in ADHD-patients treated with extended-release Methylphenidate (OROS®-MPH) - results from an open-label naturalistic study

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Objectives: To explore changes in daily functioning (C-GAS) and quality of life (ILC) in children and adolescents with ADHD OROS®-MPH and their parents.

Methods: Full analysis. Open label non-interventional trial in children & adolescents with ADHD (ICD-10 criteria) treated with flexible dose OROS MPH for 3 months (42603-ATT-4001). Effectiveness parameter were C-GAS, ILC adolescents and parents and IOWA Conners' parent rating scale at baseline and endpoint.

Results: 598 patients with ADHD (ICD-10 criteria; Ø age 10.4 years ± 2.6; 84.8% male) were documented. 81.6% completed the observation. Mean OROS MPH dose at last observation was 33.5 mg/day (SD ± 13.3). Patients improved on C-GAS from 58.9±14.7 to 71.2±15.1 ($p<0.001$). IOWA Connors Symptoms decreased from 29.0 ± 10.5 to 18.5 ± 10.6 ($p<0.0001$). ILC improved from 18.8 ± 4.0 to 20.8±3.8 in children and adolescents ($p<0.0001$) and from 17.2±3.9 to 19.7±3.9 in parents ($p<0.001$). At endpoint, 76.8% of patients showed at least minimal improvement on CGI-C. Adverse events were reported in 28.8% of patients. AEs listed in ≥2% of patients were insomnia (7.7%), anorexia (3.9%), ineffectiveness (2.8%), headache (2.3%), nervousness (2.2%) and involuntary muscle contractions (2.2%). There were no significant changes in blood pressure or pulse.

Conclusion: Treatment with OROS®-MPH was associated with a clinically relevant improvement in daily functioning in patients with ADHD and Qol improved significantly in patients and their parents. Treatment with OROS®-MPH was well tolerated.

P0322

Truth in psychiatry: Need for a pluralogue

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Background and Aims: In order to assist in ameliorating suffering and improving health, psychiatrists engage with patient's experiences and behaviors and the social milieu within which these experiences and behaviors emerge and are expressed. How can psychiatric illnesses (complex biopsychosocial entities) be classified, comprehended, and treated?

Method: Pluralogue.

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