SMOKER COMPLAINT SCALE (SCS): FACTORIAL STRUCTURE

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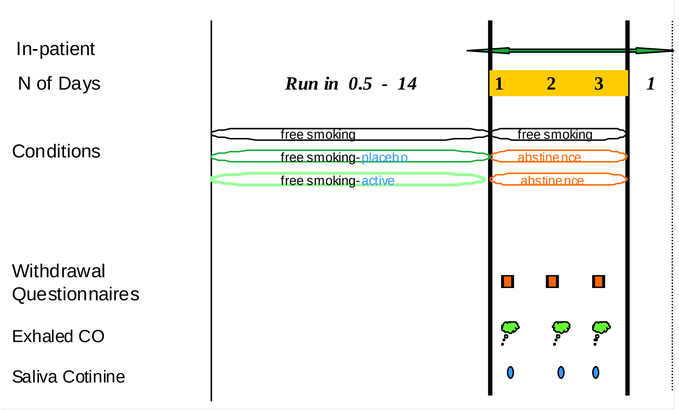
Study Design

We pooled data from 4 double blind, randomised, 3-period, crossover studies, in healthy volunteers. Subjects went through three periods of: free smoking, enforced abstinence with an active treatment (different in each study) and enforced abstinence with placebo. Each period consisted of 3 days (72 hours) of observation. The Smoker Complaint Scale (SCS) [1] was self-administered at predefined times, over the 3-day periods, for smoking withdrawal symptoms assessment. The 3-day of abstinence corresponding to placebo or active treatments were preceded by a run in period of placebo/active administration, ranging from half a day to 14 days (figure 1). There was a wash-out of at least 10 days between each treatment period. We report methods and results to explore if a factorial structure could be identified in the SCS and if this could lead to a further strengthening of this questionnaire.

Figure 1 Study Diagram



Methods

A total of 113 healthy subjects not intending to quit smoking were recruited from the panel of volunteers of the Clinical Pharmacology Unit of GlaxoSmithKline in Verona (Italy). *Main inclusion criteria* were: at least 18 years old; have smoked an average of 15 cigarettes or more a day for the past year; have a Fagerström Tolerance Questionnaire (FTQ) scores of at least 7; have signed and dated a written informed consent prior to study participation. *Main exclusion criteria* were: drug or alcohol abuse; use of long term medication; use of any drug within the previous 4 weeks; current use of any nicotine replacement therapy. Ethical committee approval was obtained before the start of each study, which was conducted in accordance with the Declaration of Helsinki.

Procedure Subjects that received active or placebo treatment quitted smoking abruptly at 7:30 am of day 1 of observation.

Measurements and Evaluations Time zero (0), around 8 am, was the beginning of abstinence, 30 minutes after the subject's last cigarette allowed. The SCS was self-administered at 0, 3, 6, 12, 24, 30, 36, 48, 54, 60 and 72 hours to evaluate cigarette withdrawal symptoms (figure 2). The SCS consists of 20 items scored on a likert scale from 1 (very definitely not) to 7 (very definitely). These are summarised by means of a Sum Total Score, ranging from 20 to 140, where higher scores represent higher levels of withdrawal symptoms. Each item captures a different smoking withdrawal symptom (table 1). Breath Carbon Monoxide (CO) and Saliva Cotinine were assessed at 0, 6, 12, 24, 30, 36, 48, 54, 60 and 72 hours to evaluate subjects' smoking status and abstinence compliance (figure 2).

Figure 2 Study Measurements

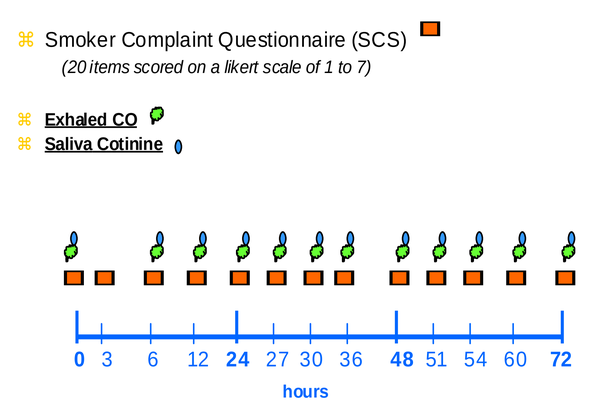


Table 1 SCS* Questionnaire

Q1	I feel anxious
Q2	I have experienced a sense of panic at times today
Q3	I am experiencing some irritability
Q4	I am experiencing fluctuations in mood today
Q5	I find myself craving cigarettes more than usual
Q6	Do you miss a cigarette ?
Q7	Do you have an urge to smoke a cigarette right now ?
Q8	I am concerned about my weight today
Q9	Are you hungry right now ?
Q10	Last night I had trouble sleeping
Q11	I am feeling a little disoriented
Q12	I can't seem to concentrate clearly today
Q13	Do you feel slowed down ?
Q14	Do you feel lightheaded ?
Q15	I am feeling depressed
Q16	I am experiencing a feeling of being "left out"
Q17	I am restless
Q18	I am experiencing some hostility
Q19	I seem to be easily annoyed today
Q20	I am frustrated today

* Smoker Complaint Scale

Statistics

The score of each SCS item was at first summarised over the 72 hours for each subject by the weighted mean. This was calculated as the area under the measurement-time curve, using the linear trapezoidal method, divided by the time over which the measurements were taken.

The pooled set of 72-h weighted mean for each SCS item was randomly split into 2 subsets. One, consisting of 159 observations, was used for the Exploratory Factor Analysis (EFA) to identify a Factors structure of the SCS. The other, of 158 observations, was used for the Confirmatory Factor Analysis (CFA) to examine the validity of the hypothesized Factors previously identified [2-3]. EFA consisted of Principal Component Analysis. Decisions regarding the number of factors to extract were based on the results of the Scree test.

CFA was performed by means of Structural Equation Models (SEM) analyses, also called LISREL. Different Factor models were tested, on the basis of a variety of fit measures, with the aim of achieving the model that provides the best fit to the observed data. Finally, both Reliability and Validity (Convergent and Discriminant) of the new Factors were assessed.

All analyses were performed using SAS Version 8.02 for Windows System and Procedures.

Results

Relevant study population characteristics are reported on table 2. The **EFA** recognised 4 main Factors accounting for 95% of the total variance (table 3). **Factor 1,** clustered by 9 items ("anxious" Q1, "irritability" Q2, "fluctuations in mood" Q4, "depressed" Q15, "left-out" Q16, "restless" Q17, "hostility" Q18, "annoyed" Q19, "frustrated" Q20), represents the broadest feature of "***Nervousness***". **Factor 2**, clustered by 4 items ("disoriented" Q11, "concentrate" Q12, "slowed down" Q13, "light-headed" Q14), captures the concept of "***Confusion***". **Factor 3**, clustered by 3 items ("craving cigarettes" Q5, "miss a cigarette" Q6, "urge to smoke" Q7), relates to cigarettes ***"Craving"***. **Factor 4**, clustered by 2 items ("weight" Q8, "sleeping" Q10) identifies ***concern*** for ***weight increase*** and ***positive attitude to sleep***.

The CFA analysis showed that the best fit model (Comparative Fit Index >0.90) is the one built on Factors: 1) Nervousness, 2) Confusion and 3) Craving, without Factor 4). Furthermore this analysis confirmed the improvement in the Model fit after the extraction from Factor 1 of a relevant clustering of 3 items ("depressed" Q15, "left-out" Q16, "frustrated" Q20) which may relates more specifically to the concept of ***Depression*** (figure 3). All these 4 Factors (***Nervousness, Confusion, Craving*** *and* ***Depression***) showed significant levels of reliability (Cronbach's α and Index of Composite Reliability > 0.90) (table 4) and construct validity (convergent: Factor Loadings p<0.001; discriminant: $r^2 \leq 0.90$) (figure3).

Table 2 Relevant Characteristics of the Study Population

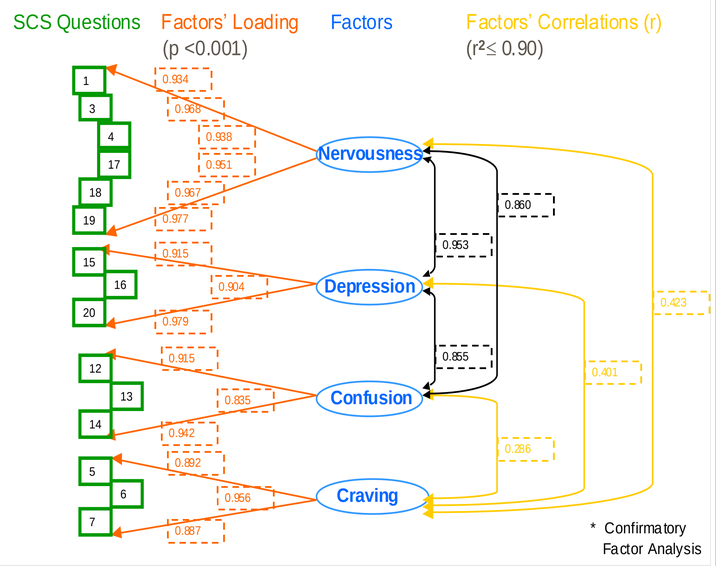
	N of subjects	(%)	Mean (± SD)	Range
N Enrolled	113			
Male / Female	63 / 50	(56% / 44%)		
White / Black	112 / 1	(99% / 1%)		
Age (years)			35.7 (±13.3)	19-63
Smoking Duration (years)			18.4 (±13.7)	1-47
N daily Cigarettes			23.2 (±6.8)	15-50
FTQ score			8.0 (±0.9)	7-10
7	40	(35%)		
8	45	(40%)		
9	20	(17%)		
10	8	(8%)		

Table 3 Loadings of the 20 SCS items on the 4 extracted Factors from PCA*

	Factor 1	Factor 2	Factor 3	Factor 4
Q1	**0.75594**	0.41552	0.20432	-0.06217
Q2	0.51240	0.33523	0.17873	0.24372
Q3	**0.87624**	0.29069	0.26827	-0.08079
Q4	**0.80368**	0.41395	0.16758	0.09740
Q5	0.18951	0.08065	**0.86212**	-0.06817
Q6	0.13806	0.06141	**0.93257**	-0.03134
Q7	0.18521	0.05767	**0.91743**	0.02750
Q8	0.26147	0.06751	0.02549	**0.41087**
Q9	0.20718	0.32836	0.01179	0.05664
Q10	0.18531	0.25567	0.15317	**-0.37504**
Q11	0.53473	**0.76546**	0.14058	-0.01237
Q12	0.34777	**0.84469**	0.06369	-0.02530
Q13	0.37041	**0.77321**	0.06633	-0.25678
Q14	0.40147	**0.80658**	0.06581	0.00327
Q15	**0.69475**	0.58054	0.13204	0.05122
Q16	**0.71481**	0.38821	0.08567	0.16906
Q17	**0.81317**	0.32129	0.24131	-0.11376
Q18	**0.85101**	0.33984	0.14717	0.08686
Q19	**0.82891**	0.40714	0.17541	0.06051
Q20	**0.75797**	0.48334	0.11437	0.11236
Variance explained	**62.7%**	**21.7%**	**6.8%**	**3.4%**

* Principal Component Analysis

Figure 3 Final CFA* Model



* Confirmatory Factor Analysis

Table 4 Reliability for each Factor

Factor	Composite Reliability	Cronbach alpha
Nervousness	0.985	0.984
Depression	0.926	0.961
Confusion	0.961	0.925
Craving	0.938	0.936

The 4 SCS-Factors show different average scores during smoking abstinence (as during free smoking) contributing differently to the whole smoking abstinence syndrome (figure 4).

Figure 4 Mean of 72hour weighted mean Factors during Free Smoking and Placebo-Abstinence conditions

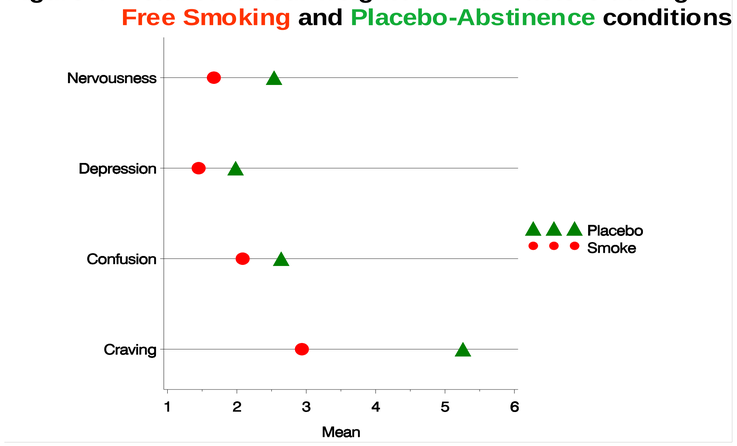
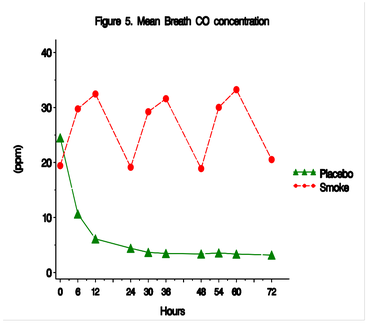
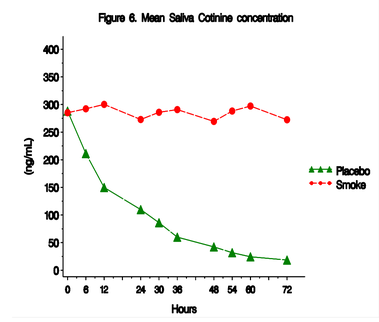


Figure 5 shows that, during placebo abstinence, as expected, levels of breath CO (mean concentration at repeated times across days) dropped to very low levels (< 8ppm) after 12 hours of abstinence. Figure 6 shows that during placebo abstinence, as expected, also the cotinine levels (mean concentration at repeated times across days) dropped with a progressive reduction to very low level (<40 ng/ml) after 54 hours of abstinence. Thus breath CO and saliva cotinine levels proved to be good indicators of cigarette /nicotine abstinence.





Discussion/Conclusions

A consensus on specific signs of smoking/nicotine withdrawal symptoms is difficult to reach. For example the two most mentioned sources, the Surgeon General's Report (USDHHS 1988) [4] and the American Psychiatry Association with its Diagnostic and Statistical Manual (DMS IV, 1994) [5], in part differ. In a recent review of the literature up to 29 subjective effects of smoking abstinence were reported [6]. The different methodology used to investigate the effect of smoking abstinence is considered the cause of the discrepancy of findings. Among these methodological discrepancies, relevance is given to the assessment of abstinence symptoms by means of single-items measures. In fact single-item may be not able to capture varied aspects of abstinence symptoms experienced by individuals in different stages of drug dependence and under different environmental conditions. Moreover, single-item questions may not reflect the theoretical perspectives of the nature of that specific symptom [6,7,8]. The SCS is a questionnaire widely and reliably used to assess smoking withdrawal symptoms[9]. However, as outlined above, the improvement of existing scales, the generation of new ones and the achievement of a consensus in the definition of withdrawal symptoms, is a constant objective in the field of smoking dependence [10,11]. In the light of these needs we explored if a factorial structure could be identified in the SCS and if this could lead to a further strengthening of the questionnaire. Our results show, for the first time, that the 20-items of the SCS might be summarised by a 4-Factor Model, comprising dimensions of ***Nervousness, Depression, Confusion*** *and* ***Craving***. In our view, the recognition of these 4 Factors can increase the strength of the SCS for three main reasons: 1) the specific dimensions of the smoking withdrawal syndrome can be easily captured; 2) the impact of each individual dimension on the overall abstinence syndrome (Sum Total Score) can be detected; 3) differentiated changes over time of each factor could be recognised.

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