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Research Methods

Development and validation of the scale to assess satisfaction with medications for addiction treatment – Buprenorphine-naloxone for heroin addiction (SASMAT-BUNHER)

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ABSTRACT

Background: Until now, no specific tool has been available to measure heroin-dependent patient satisfaction with buprenorphine-naloxone as a medication. The purpose of the present study was to develop the Scale to Assess Satisfaction with Medications for Addiction Treatment–Buprenorphine-Naloxone for Heroin addiction (SASMAT-BUNHER) and to examine its validity and reliability.

Methods: The SASMAT-BUNHER was developed from a pool of 44 self-administered items grouped into nine theoretical domains, as follows: Overall Satisfaction, Pharmacotherapy, Initiation, Anti-Addictive Effect on Heroin, Mental State, Physical State, Personal Functioning, Acceptability, and Anti-Addictive Effect on Secondary Substances. The Treatment Satisfaction Questionnaire for Medication 1.4 version (TSQM 1.4) was used for convergent validation. Participants were 316 heroin-dependent patients in maintenance treatment with buprenorphine-naloxone sublingual tablets at 16 different treatment centres.

Results: Principal component analysis of the SASMAT-BUNHER revealed a 5-factor structure that accounted for 65.1% of total variance. Based on similarities between empirically-obtained factors and theoretical domains, Factors 1 through 5 were named 'Mental and Physical State' (10 items), 'Anti-Addictive Effect on Other Substances' (5 items), 'Anti-Addictive Effect on Heroin' (4 items), 'Personal Functioning' (3 items), and 'Acceptability' (4 items). All factors showed acceptable internal consistency (Cronbach's alpha coefficients: 0.744–0.925) and test-retest reliability (intraclass correlation coefficients: 0.704–0.895). Correlation between SASMAT-BUNHER and TSQM 1.4 total scores was moderate (Pearson $r = 0.552$). Moreover, SASMAT-BUNHER total scores of patients reporting absence of buprenorphine-naloxone side effects were higher than those of their counterparts.

Conclusion: These results support the validity and reliability of the SASMAT-BUNHER.

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Introduction

Buprenorphine (alone or in combination with naloxone) maintenance treatment is a key intervention to treat heroin dependence. A meta-analysis of randomized clinical trials (RCT) concluded that buprenorphine, in comparison with placebo, is effective in retaining patients in treatment and in reducing heroin use (Mattick, Breen, Kimber, & Davoli, 2014). In regard to the use of non-opioid substances, two placebo-controlled RCTs did not find buprenorphine effective in reducing cocaine or benzodiazepine use in heroin-dependent patients (Fudala et al., 2003; Johnson et al., 1995). However, another placebo-controlled RCT involving participants who presented both heroin and cocaine dependence found that buprenorphine reduced cocaine use (Montoya et al., 2004).

Patient satisfaction with treatment is largely the result of the perceived match between expectations and actual experience (Shikiar & Rentz, 2004). Patients can draw a unique impression about their whole experience with treatment (Smith, Schüssler-Fiorenza, & Rockwood, 2006), but the construct "satisfaction with treatment" is considered multidimensional (Allemann Iseli, Kunz, & Blozik, 2014; Crow et al., 2002) since it includes a wide variety of different experiences. Some examples of these experiences are accessibility to the treatment centre, the convenience of the treatment process, the skills and manners of the various professionals (doctors, psychologists, nurses or social workers), the availability of different types of psychosocial treatment, and the perceived safety and effectiveness of medications.

The multidimensional assessment of treatment satisfaction with each particular facet of the patient experience, such as satisfaction with medication, is also advisable because patient dissatisfaction is difficult to detect with single-item instruments (Ruggeri, Dall'Agnola, Agostini, & Bisoffi, 1994; Sitzia & Wood, 1997). Moreover, multidimensional assessment is the only way for researchers and clinicians to identify unambiguous sources of dissatisfaction in order to plan targeted interventions to improve the patients' treatment experience. In addition to the multidimensional assessment of satisfaction, we assume that patients must be asked specific questions about the treatment experience in order to better detect treatment dissatisfaction. For example, using a specialized instrument (such as the one developed in the present study) that specifically asks patients if they are dissatisfied with buprenorphine-naloxone in terms of its possible ineffectiveness in reducing opioid withdrawal is more likely to detect dissatisfaction than by using a generic tool such as the Treatment Satisfaction Questionnaire for Medication 1.4 version (TSQM 1.4; Atkinson et al., 2004), which does not specifically assess this question.

To our knowledge, patient satisfaction with buprenorphine as a medication has not been previously assessed using a comprehensive, multidimensional approach. Patient satisfaction with buprenorphine to treat heroin dependence has only been evaluated globally using single-item measures to compare patient preferences between buprenorphine vs. buprenorphine-naloxone (Amato, 2010; Daulouède et al., 2010) or between buprenorphine-naloxone tablets and film (Lintzeris et al., 2013), or partially to examine the coverage of withdrawal symptoms (Montesano, Zaccone, Battaglia, Genco, & Mellace, 2010; Stimolo et al., 2010).

Our experience with the Scale to Assess Satisfaction with Medications for Addiction Treatment–Methadone for Heroin addiction (SASMAT-METHER; (Pérez de los Cobos, Trujols, Siñol, & Batlle, 2014; Pérez de los Cobos, Trujols, Siñol, Duran-Sindreu, & Batlle, 2016) leads us to believe that it would be valuable to develop and use a similar instrument to comprehensively assess patient satisfaction with buprenorphine as a medication. Heroin-dependent patients who receive opioid agonist treatment (e.g., buprenorphine or methadone) are likely to have high expectations that replacing heroin with these medications will substantially improve their general condition. Thus, patient satisfaction may comprise a pivotal treatment outcome: the pre-post treatment change perceived by patients in their mental/physical state and personal functioning. In this sense, it is worth noting that the first factor in the factor structure of the SASMAT-METHER (Pérez de los Cobos, Trujols, Siñol, & Batlle, 2014) is Personal Functioning and Well-Being.

Another reason to assess patient satisfaction with buprenorphine is related to the patient's perception of the anti-addictive effectiveness of the medication. Controlled RCTs have shown that the percentage of urine samples with undetectable levels of opioids obtained thrice-weekly from opioid-dependent patients receiving buprenorphine (Ling et al., 1998), buprenorphine-naloxone (Fudala et al., 2003) or methadone (Strain, Stitzer, Liebson, & Bigelow, 1993) is statistically significantly higher than in opioid-dependent patients receiving placebo (buprenorphine 8 mg/d: 32.9% vs. placebo: 18.5%; buprenorphine 16 mg/d - naloxone 4 mg/d: 17.8% vs. placebo: 5.8%; methadone 50 mg/d: 43.6% vs. placebo: 26.4%). However, the low frequency of opioid non-detection associated with opioid agonist treatment raises the question of whether the patients receiving these medications used heroin more frequently than they had expected. A cross-sectional study found that frequency of heroin use during the last month was negatively associated with scores of the Anti-Addictive Effect on Heroin (the second factor of SASMAT-METHER), a finding that suggests patient dissatisfaction with methadone due to perceived excessive heroin use (Pérez de los Cobos et al., 2016).

The objective of the present study was to develop and validate a comprehensive, multidimensional scale entitled "SASMAT – Buprenorphine-Naloxone sublingual tablets for Heroin addiction (SASMAT-BUNHER)", to assess patient satisfaction. The SASMAT-BUNHER is designed to evaluate the domains of satisfaction with buprenorphine-naloxone most relevant to maintenance treatment from a clinical perspective. The following psychometric properties of the SASMAT-BUNHER were examined: factor structure, reliability (internal consistency and stability over time), and convergent and discriminative validity.

Material and methods

The present study is based on patient satisfaction data for buprenorphine-naloxone obtained through the survey entitled "Patient Satisfaction with medication and dosage adequacy in heroin addiction treatment with buprenorphine-naloxone". The results for buprenorphine-naloxone dose adequacy will be reported elsewhere. This survey was performed in Spain, where buprenorphine-naloxone is the only available buprenorphine formulation for the treatment of opioid dependence. Most Spanish patients receive this medication from publicly-funded addiction treatment centres where methadone maintenance treatment (MMT) is also offered. The main differences between MMT and buprenorphine-naloxone maintenance treatment provided in publicly-funded treatment centres are as follows. Methadone is usually prescribed and dispensed at the centre, and the treatment is fully publicly funded. By contrast, while buprenorphine-naloxone is also prescribed at the centre, patients obtain the medication directly from private pharmacies and they usually self-administer the drug without any nursing supervision or assistance, except when treatment is first initiated. Another difference is that buprenorphine-naloxone is only partially publicly funded, except for unemployed and work-disabled patients, for whom the treatment is fully publicly funded. In both treatments (i.e., MMT and buprenorphine-naloxone maintenance treatment), psychosocial treatment is recommended but not mandatory.

Development of the preliminary version of SASMAT-BUNHER

The SASMAT-BUNHER was developed from the SASMAT (Pérez de los Cobos et al., 2014), a pool of 44 self-administered items designed to assess patient satisfaction with any medication-addiction combination. The domains of SASMAT are as follows (the number of items in each domain is given in brackets): Overall Satisfaction (3), Pharmacotherapy