Psychiatria Danubina, 2013; Vol. 25, No. 3, pp 261-265 *Brief report*

PRELIMINARY DATA ON VALIDITY OF THE DRUG ADDICTION TREATMENT EFFICACY QUESTIONNAIRE

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received: 2.10.2012; revised: 14.5.2013; accepted: 29.7.2013

SUMMARY

Background: *This study describes the validation process for the Slovenian version of the Drug Addiction Treatment Efficacy Questionnaire (DATEQ).*

Subjects and methods: *DATEQ was constructed from the questionnaires used at the Centre for the Treatment of Drug Addiction, Ljubljana University Psychiatric Hospital, and within the network of Centres for the Prevention and Treatment of Drug Addiction in Slovenia during the past 14 years. The Slovenian version of the DATEQ was translated to English using the 'forward-backward' procedure by its authors and their co-workers. The validation process included 100 male and female patients with established addiction to illicit drugs who had been prescribed opioid substitution therapy. The DATEQ questionnaire was used in the study, together with clinical evaluation to measure psychological state and to evaluate the efficacy of treatment in the last year. To determinate the validity of DATEQ the correlation with the clinical assessments of the outcome was calculated using one-way ANOVA.*

Results: *The F value was 44.4, $p<0.001$ (sum of squares: between groups 210.4, df=2, within groups 229.7, df=97, total 440.1, df=99). At the cut-off 4 the sensitivity is 81% and specificity 83%. Conclusion: The validation process for the Slovenian DATEQ version shows metric properties similar to those found in international studies of similar questionnaires, suggesting that it measures the same constructs, in the same way and as similar questionnaires. However, the relatively low sensitivity and specificity suggests caution when using DATEQ as the only measure of outcome.*

Key words: *drug addiction - opioid substitution treatment - treatment efficacy - evaluation questionnaire*

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INTRODUCTION

It is reported that some 185 million people worldwide – 3.1% of the global population or 4.3% of people aged 15 years and above – were consuming drugs in the late 1990s (Bearn 2004). There are an estimated 13.2 million injecting drug users worldwide, and at least 10% of all cases of HIV infection worldwide result from unsafe injecting behaviour, and up to 90% in countries in Eastern Europe and Central Asia (Bearn 2004). Opioid dependent users constitute a small proportion of the world population (less than 1% of those aged 15 years or over, but globally the regular and sustained use of heroin accounts for a substantial proportion of drug related problems (World Health Organization 2004). In addition, addiction to heroin is accompanied by increased criminal activity (Kinlock et al. 2003, Nurco 1998), risk of human immunodeficiency virus (HIV) infection (Centers for Disease Control 2006), hepatitis B and C infections (Centers for Disease Control 2006, Hagan et al. 2002), overdose death (Weatherburn et al. 1999) and re-incarceration (Hanlon et al. 1999, Substance Abuse and Mental Health Services Administration 2000). Therefore, the development, implementation and evaluation of effective drug abuse treatment programmes for heroin addiction treatment is needed (Kinlock 2002).

There are many types of opioid dependence treatment, but they basically fall into two categories: substitution treatment and abstinence-based programmes (Kastelic 2007). Research has shown that substitution therapy is the most effective way to treat opioid dependence, reduce the risk of HIV and hepatitis C transmission, and reduce the risk of overdose. The prescription for substitution therapy and administration of opioid agonists to persons with opioid dependence – within the framework of recognized medical practice approved by the competent authorities – is in line with the 1961 and 1971 Conventions on Narcotic Drugs and Psychotropic Substances (Kastelic et al. 2007).

All forms of drug dependence treatment have the potential to influence the risk of HIV and hepatitis C transmission, but substitution treatment programmes have the greatest potential to reduce injecting drug use and the resulting risk of spread of infection (Kastelic et al. 2008).

In the past two decades, there were huge advances in the availability of substitution treatment programmes in most Central and Eastern European countries, including South Eastern Europe. Different strategies have been developed, but without appropriate evaluation studies to confirm their effectiveness. In some of these countries, the majority of the programmes are office based treatments provided by general practitioners (Croatia), while in others they are mostly done in specialised treatment centres (Albania, Bosnia and Herzegovina, Bulgaria, Macedonia, Montenegro, Greece, Romania, most of Serbia) or administered as a combination of

both modalities (Slovenia, Vojvodina in Serbia, partly Croatia).

There is an ongoing debate regarding justifications for the use of opioid substitution therapy. However, this debate is more present in unscientific communities than in scientific ones. The fundamental question is whether psychopharmacotherapy can be justified by the patients' best interest, cost effectiveness, risk to benefit ratio and patient preference (Jakovljević 2012). This question is obviously not limited only to the treatment of addiction but is also relevant to other treatments. Not only lay public but also many physicians and policy makers have adopted a moral point of view and have serious problems accepting evidence based data. The South Eastern European Adriatic Treatment Network (SEEA net) is a regional NGO of treatment professionals trying to develop and scale up good quality treatment. A decision was done to develop a short and comprehensive method for measuring and comparing treatment efficacy in different programmes in the region. Many of the recent evaluation strategies are time consuming and require complicated procedures to be comparably introduced in different cultural environments (Gerevich et al. 2005).

The Drug Addiction Treatment Efficacy Questionnaire (DATEQ) was thus developed and tested with the intention to partially fill the gap in the availability of short questionnaires that include regional culturally specific questions. As DATEQ is a new research tool, validity and reliability of the DATEQ have not been evaluated in the existing literature.

SUBJECTS AND METHODS

The study protocol was approved by the Slovene National Medical Ethics Committee, Ljubljana. DATEQ was constructed from the questionnaires used at the Centre for the Treatment of Drug Addiction, Ljubljana University Psychiatric Clinic, and within the network of Centers for the Prevention and Treatment of Drug Addiction (CPTDA) in Slovenia in the past 15 years during the clinical evaluation of treatment efficacy. The Slovenian version of the DATEQ questionnaire was translated to English using the 'forward-backward' procedure by its authors and their co-workers. The DATEQ consists of 7 items for assessing the efficacy of addiction treatment. Each item is rated 0 or 1. The items are as follows:

- Abstinence or quitting the use of heroin;
- Abstinence or quitting the use of other illicit drugs;
- Participating in psychosocial and/or medical treatment;
- Better social integration/inclusion;
- Improved well-being;
- Employment, education;
- Suspension/reduction of criminal behaviour.

The maximum score on the DATEQ questionnaire is 7. Scores of 4 or more are considered to indicate successful treatment of patients with known addiction to opioids in different treatment programmes, while scores of 2-3 represent partially successful treatment ('borderline'). A score of 1 or 0 is considered unsuccessful treatment. The DATEQ only takes 2 to 5 minutes to complete. It has been shown to be acceptable to the population for which it was designed.

Eligibility/exclusion criteria

Patients must have met the following criteria: (i) history of heroin dependence meeting the criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV); (ii) inclusion in opioid substitution treatment (OST) for at least twelve months (iii) willingness to enrol in the study. All patients with dual diagnoses were excluded.

Participant screening and recruitment

The participants were recruited from May till October 2009 inclusive, from among 1026 patients in seven CPTDAs within the Republic of Slovenia and from the Centre for the Treatment of Drug Addiction at the Ljubljana University Psychiatric Hospital who had been treated for at least one year with OST. The participants were recruited in group orientation sessions and through word of mouth. Those patients who were willing to enrol were screened individually for participation by the study personnel. The eligible patients then met with the research staff to provide informed consent for their participation in the study, which was done immediately prior to the assessment. The consent form also provided prospective participants with specific information about the potential risks and benefits of participation in the study. The final decision on study enrolment was made by the treating psychiatrist following an examination.

Subjects

In Slovenia, a total of 1026 patients were treated in seven CPTDAs included in the study, out of 3324 patients treated in substitution treatment programmes in all 18 CPTDAs in 2009. 120 consecutive patients from May till October 2009, treated at respective seven CPTDAs, and 29 from the Centre for the Treatment of Drug Addiction at the Ljubljana University Psychiatric Hospital were asked to participate in the process of DATEQ validation. Patients with dual diagnoses were not asked to participate in the study. 49 of those who had been asked (out of 149) were unwilling to participate, nearly all of them stated that was because they did not have enough time or were simply not willing to take part. From among those patients, 100 males and females with known addiction to illicit drugs were included in the validation process after receiving their consent. They all completed the DATEQ questionnaire and all of them went through the clinical evaluation done by psychiatrists. The validation study

was presented to the Slovene National Medical Ethics Committee. The Committee confirmed that this research was in line with its ethical requirements and approved it (No. 1390509).

Statistical analysis

The data obtained by clinical evaluation were compared with the data gathered by the DATEQ. Chi square and the C coefficient were calculated.

RESULTS

Through clinical evaluation, 48 (48%) patients were classified by the treating psychiatrist in the group with successful response to treatment, 33 (33%) were classified in the group with partial response and 19 (19%) were classified in the group having unsuccessful response to treatment. These three groups of patients were compared by one-way ANOVA regarding the scores achieved on the DATEQ (Table 1). Tukey procedure was used for the post hoc test.

The F value was 44.4, $p<0.001$ (sum of squares: between groups 210.4, df=2, within groups 229.7, df=97, total 440.1, df=99). The mean score of participants' ratings on the DATEQ was 3.79 (SD 2.2). The average scores on the DATEQ in the group of patients classified by the physician as having successful response to treatment was 5.1 (SD 1.7), in the group with only partial response it was 3.4 (SD 1.8) and in the group with unsuccessful response to treatment it was 1.1 (SD 0.9) (Figure 1). Post hoc test reviled differences between all groups compared ($p<0.001$ for each comparison).

The clinical evaluation of outcome gave three groups: successful, partially successful, and unsuccessful. To determine the sensitivity and specificity of the DATEQ only the successful group was considered as positive, and the rest two groups (partially successful, unsuccessful) as negative. At the cut-off 4 the sensitivity is 81% and specificity 83% (Table 2). Because of methodological limitations of present research reliability was not calculated.

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Table 1. Distribution of DATEQ scores for patients with successful, partially successful or unsuccessful response to treatment according to physician's classification

	Sum of DATEQ scores (number of patients per answer - frequencies)								
DATA scores	0	1	2	3	4	5	6	7	SUM
Successful	0	0	4	5	11	5	8	15	48
Partial success	0	3	7	14	2	1	1	5	33
Unsuccessful	4	11	2	2	0	0	0	0	19
SUM	4	14	13	21	13	6	9	20	100

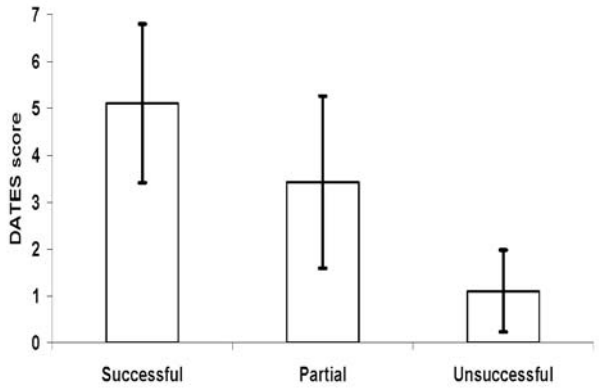

Figure 1. The average DATEQ scores in the group of patients classified by the physician. The first column represents the group of patients having successful response to treatment, the second column represents those with partial response to treatment and the third one represents those who responded to treatment unsuccessfully. The average scores and the SD are depicted

Table 2. Distribution of true positive, false positive, false negative and true negative cases. Cut-off point is set at DATEQ score 4. Number of cases for each subgroup are depicted

Cut-off < 4	Successful	Partially successful Unsuccessful
DATEQ 4 - 7	True positive 39	False positive 9
DATEQ 0 - 3	False negative 9	True negative 43

DISCUSSION

The study was conducted in Slovenia (EU), where the problem of illicit drug use has been estimated at 5.3 problematic drug users aged 15-64 per 1000 inhabitants in 2001 (European Monitoring Centre for Drugs and Drug Addiction 2007). Since 1995, a large network of 18 specialized centres has provided substitution treatment and a broad spectrum of other services, including

counselling and therapy, that are covered by the national health insurance and, therefore, free-of-charge for the patient. Substitution treatment with methadone was introduced in Slovenia in 1990, buprenorphine was registered in 2004, and SROM in 2005 (European Monitoring Centre for Drugs and Drug Addiction 2007). The combination of buprenorphine and naloxone (i.e. Suboxone®) was introduced in 2007. In 2009, there were 3324 patients based in the community substitution treatment programmes, of whom approximately 75% were treated with methadone, 14% with buprenorphine and 11% with slow-release morphine. About 500 patients were treated in custodial settings in substitution treatment programmes for opioid dependency (Kastelic & Kostnapfel 2010).

The clinical evaluation performed by the physicians revealed that 48 (48%) patients were described as having successful response to treatment, 33 (33%) were classified in the group with partial response to treatment and 19 (19%) in the group with unsuccessful response to treatment. On the other hand, patients were grouped on the basis of their DATEQ scores, whereby the score of 4 or more is considered to indicate successful treatment, scores of 2-3 represent partially successful treatment ('borderline') and the score of 1 or 0 is considered to indicate unsuccessful treatment. Based on the results gathered with DATEQ, 48 patients achieved scores of more than 4, 34 had scores from 2 to 3 and 18 patients achieved a score of less than 2. This data indicates that the majority of included patients show at least a small response to treatment.

The need to evaluate the effectiveness of opioid substitution treatment programmes and patient satisfaction has played a prominent role in debates about the cost effectiveness and quality of such programmes in many countries that developed and widely implemented them. To be able to assess the quality and efficiency of OST in any country, some reference standards are needed. This is because certain international questionnaires in use have been found to be too complicated and time consuming for both patients and therapists.

DATEQ was developed from longer questionnaires used in Slovenia to evaluate patient satisfaction with established opioid substitution treatment since 1995. However, those questionnaires were not validated or translated to the English language. Outcome measures are only valid if they have been mutually agreed with the patients, as it is the patient who can best define what recovery means (Agius et al. 2009), so patients were strongly involved in the development of this questionnaire.

We hope that in the future DATEQ might be a useful tool and will be used as a standardised questionnaire to facilitate comparisons of the quality and efficiency of OST in the South Eastern European countries that participate in the SEEA net, as well as in other countries. Further research on larger samples is needed to established questionnaire reliability by performing test-retest procedure. The DATEQ might be a useful ground to develop questionnaires with better metric properties by adding additional questions to existing set of questions. As questions used in DATEQ were selected from longer questionnaire used in Slovenia since 1995 the evaluation of already ruinously fulfilled database from 1995 to present could provide useful data to compare different treatment strategies used in selected time periods.

Limitations

This study has a number of limitations. The Slovenian version of the questionnaire was validated in a relatively small sample population compared to other contemporary studies examining questionnaires for the evaluation of treatment response in groups of patients with addiction. However, the sample size used was not that dissimilar to other questionnaire validation studies in the Slovenian language (Vučko Miklavčič et al. 2008). Finally, although this study demonstrated the usefulness of the Slovenian version of DATEQ in evaluating treatment progress in this specific population, caution is warranted in its ability to detect borderline cases with moderate progress in treatment. The relatively low sensitivity and specificity suggests caution when using DATEQ as the only measure of outcome.

CONCLUSIONS

The validation process for the Slovenian DATEQ version shows metric properties similar to those found in international studies of similar questionnaires, suggesting that it measures the same constructs, in the same way and as similar questionnaires. This validation study of the Slovenian version of the DATEQ questionnaire proved that it is an acceptable and valid measure of the efficacy of treatment programmes for patients with addiction to illicit drugs. However, further research will be needed to evaluate the usefulness of DATEQ in clinical practice and research.

Acknowledgements: None.

Conflict of interest: None to declare.

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