

**5PSQ-081** **Δ-9-TETRAHYDROCANNABINOL (SATIVEX) FOR THE TREATMENT OF MULTIPLE SCLEROSIS SPASTICITY: EVALUATION OF EFFECTIVENESS AND SAFETY**

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**Background** Spasticity is a common and disabling symptom of multiple sclerosis (MS). The management of MS spasticity is centred around relief and functional improvement, evaluated with the Expanded Disability Status Scale (EDSS). Sativex oromucosal spray is a cannabinoid-based medicine used for adult MS patients with moderate to severe spasticity who do not respond adequately to first-line antispasticity medications. The patients who responded to Sativex showed an improvement from baseline in spasticity  $\geq 20\%$ – $30\%$  evaluated with a numerical rating scale (NRS) scores.<sup>1</sup>

**Purpose** The aim of the study was to review the use of oromucosal spray Sativex in patients with moderate to severe MS.

**Material and methods** A retrospective cohort study was conducted in patients who began using Sativex between January 2016 and June 2018. The data was retrieved from the web-based register of the Italian Medicines Agency. The primary endpoint was the change in the degree of severity of spasticity assessed by the NRS scale and the evaluation of adverse effects in order to assess safety. The efficacy of Sativex was established by a medium reduction of 20%, according to the NRS scale, from the value at the baseline to the value of the last re-evaluation of the disease. The adverse effects were evaluated during the whole period considered.

**Results** Thirty-seven patients were evaluated, 70.27% of these were female. The medium age was  $56 \pm 9$  years, the mean NRS and the mean EDSS score before treatment was  $7.86 \pm 1.00$  and  $5.95 \pm 1.47$ , respectively. A medium correlation was found between NRS and EDSS score ( $R=0.669$ ;  $F=29.903$ ;  $p<0.0001$ ). The NRS score after treatment was  $5.66 \pm 1.04$  ( $\Delta = -2.20 \pm 0.68$ ), with a statistical significance ( $Z=-5.829$ ;  $p<0.00001$ ). All patients obtained a reduction  $>20\%$  of the NRS score. The adverse effects detected were fatigue (8.1%), nausea (5.4%), headache (5.4%) and vertigo (2.7%).

**Conclusion** The symptomatic relief of spasticity led to quantifiable benefits in the ability to perform daily activities and it improved the patients' quality of life. These findings are in line with other studies, which show the use of Sativex as effective and well tolerated for the management of the spasticity of patients with MS with moderate to severe grade symptoms.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

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No conflict of interest.

**5PSQ-082** **ABSTRACT WITHDRAWN**

**5PSQ-083** **DEVELOPMENT AND VALIDATION OF QUALITY INDICATORS FOR BENZODIAZEPINE USE IN GENERAL AND MENTAL HEALTH HOSPITALS: SHORTCOMINGS OF AVAILABLE REIMBURSEMENT DATA**

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**Background** Quality of care monitoring is an important aspect in healthcare and depends on the availability of valid quality indicators (QI), easily obtainable from available data sources. This is important particularly for benzodiazepines and Z-drugs (BZD) given their important side effects, so good QIs are needed.

**Purpose** To develop QIs for BZD use in general and mental health hospitals, based on available reimbursement data (RD).

**Material and methods** First, QI were selected through a literature review and expert meetings within the network for healthcare institutions (Zorgnet-ICURO). Next, these QIs were assessed for content validity in two separate datasets. The first dataset was obtained from national RD (year 2017, collected from all Belgian health care insurers). The second dataset comprised facturation data (FD) from two test hospitals: one general hospital psychiatry ward (GHP) and one mental health hospital (MHH).

**Results** Four QIs were selected allowing in-depth evaluation of BZD use (Table). For the MHH, reimbursement data corresponded well with local facturation data (719 vs. 710 patients with  $\geq 1$  BZD use) but not in the GHP (161 vs. 206 patients). Upon analysis, it emerged that three-quarters of QIs could not be calculated as RD does not provide for a valid nominator at different times during hospitalisation. A subsequent survey among hospitals showed high variability in how RD are reported to insurers, explaining information loss.

Abstract 5PSQ-083 Table 1

	GHP		MHH	
	FD	RD	FD	RD
Q1: admissions with BZD (%)	93/280 (33.2)	N/A	256/891 (28.7)	N/A
Q2: discharged with BZD (%)	48/280 (17.1)	N/A	179/891 (20.1)	N/A
Q3: continuous BZD use (%)	34/280 (12.1)	N/A	144/891 (16.2)	N/A
Q4: median BZD (DDD)/patient day (IQR)	1.2 (1.5)	1.1 (1.7)	0.4 (0.9)	0.4 (0.9)

**Conclusion** Current RD are not sufficiently detailed to evaluate BZD use within/between hospitals. However, high use of electronic prescribing in Belgian hospitals allows the use of actual prescription and administration data for this purpose but will need additional effort from hospitals.<sup>1</sup> A uniform structure is currently under development to allow standardised data extraction and comparison.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Kadri, B. *et al.* Can clinical practice indicators relating to long-acting benzodiazepine use in the elderly be easily generated in a hospital setting? *Eur J Clin Pharmacol* 2018; **74**:233.

No conflict of interest.

#### 5PSQ-084 RISK OF QT INTERVAL PROLONGATION IN OLDER PATIENTS

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**Background** The QT interval prolongation is a rare adverse effect, but its clinical relevance is very serious, being able to trigger sudden cardiac arrest and death. The drugs most frequently involved in QT prolongation are often used among elderly patients.

**Purpose** The objective was to analyse the interventions carried out regarding the prescription of medications in elderly patients who prolong the QT interval.

**Material and methods** This was a transversal descriptive observational study in which the Access registry of the pharmaceutical interventions performed in the Institutionalized Patient Care Unit of the Emergency Department was reviewed. The

study period was from January to March 2017. Demographic data of the patients attended (age, sex) were analysed, as well as the number and type of interventions carried out and the drugs involved (no drugs/patient and pharmacological group).

**Results** During the study period, the treatment of 134 patients was reconciled and reviewed, of which 105 required some type of intervention in the usual treatment prescribed. The mean age of these patients was 85.7 years (64.17% females, 35.82% males) with an average of 9.5 drugs per patient.

In 18 of the 134 (13.4%) patients, the intervention was related to drugs that prolonged QT, with associations of two or more of these drugs being observed in 83% of the cases.

77.14% of the interventions corresponded with psychotropic drugs (SSRIs, tricyclic antidepressants, duloxetine, anti-psychotics, trazodone); 5.71% with antibiotics (azithromycin, levofloxacin), 2.85% with rivastigmine, 2.85% domperidone; 2.85% with antiarrhythmics (amiodarone) and 2.85% with antihistamines H2 (famotidine). In all of them, caution was recommended in the use of these drugs, especially in three of them due to a cardiovascular history.

**Conclusion** Most drugs involved in QT prolongation are psychotropic drugs, very commonly prescribed in this population. In addition, the polypharmacy of the elderly predisposes to the association of drugs whose profile of adverse effects may be enhanced, as is the case of the prolongation of the QT interval.

It is important to make prescribers aware of the need for periodic re-evaluation of the risk/benefit of these drugs and avoid, as far as possible, these types of drugs in patients with a cardiovascular history.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110870/>  
 No conflict of interest.

#### 5PSQ-085 METABOLIC DISORDERS IN PATIENTS TREATED WITH SECOND-GENERATION ANTIPSYCHOTICS: AN OPPORTUNITY FOR PHARMACEUTICAL INTERVENTION

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**Background** Second-generation antipsychotics (SGAs) have improved the treatment of psychiatric disorders. Nevertheless, their use is associated with the development of metabolic disorders, which increase premature cardiovascular mortality.

**Purpose** To describe the prevalence of metabolic disorders in patients treated with SGAs and analyse if these comorbidities were properly monitored.

**Material and methods** A prospective, observational study was conducted in a tertiary hospital from March to April 2018. Inclusion criteria were: age  $\geq 18$  years, psychiatric patients with chronic treatment with SGAs (clozapine, olanzapine, quetiapine, ziprasidone, paliperidone and risperidone) and admission in a psychiatric ward.

We collected sociodemographic (gender, age, alcohol, tobacco, diagnosis), pharmacotherapeutic (treatment with SGAs, antihypertensive drugs (AD) and lipid-lowering drugs (LLD)) and metabolic variables (body mass index, glucose level