

PRESCRIPTIONS AND PERSISTENT USE OF DULOXETINE, A NEW COMPOUND FOR STRESS URINARY INCONTINENCE IN WOMEN, IN NORWAY

Hypothesis / aims of study

A new serotonin and noradrenaline reuptake inhibitor, duloxetine, has been shown to significantly improve incontinence and the quality of life of patients with stress urinary incontinence [1, 2]. Although a systematic review found a significant improvement in the median number of incontinence episodes, subjective cure rates were modest [2]. The review also stated that 17% stopped the active treatment during trials, the majority for reasons attributable to duloxetine. This is a higher rate than has been reported in trials of antimuscarinics for overactive bladder symptoms. However, also this group of drugs has a high discontinuation rate in patients from the general population [3].

The aim of the study was therefore to investigate the epidemiology of prescriptions for duloxetine in Norway in 2004 and 2005. Specifically, we investigated the uptake of duloxetine, which was introduced to the Norwegian market in October 2004, and the persistence of use for the first users through the year 2005.

Study design, materials and methods

We used data from the Norwegian Prescription Database (NorPD). The NorPD is a national registry with data from January 1, 2004, maintained at the Norwegian Institute of Public Health. From its inception, all pharmacies have been required by law to submit electronic data of all prescriptions each month. For our purposes, data were available for 2004 and 2005, and included key variables such as patient's date of birth, gender, an encrypted unique identification and date of dispensing. Also included are data on age, speciality of the prescribing doctor, number of packages, ATC-code, defined daily dose (DDD) and more.

To measure the persistence of use of duloxetine we grouped the months of first prescription filled into quarters of a year, from the 4th quarter of 2004 to the 3rd quarter of 2005. We then determined if the patient filled prescriptions for the drug at least once during each of the next quarters until the end of 2005. Duloxetine was sold in packages meant for 1 month use only.

Results

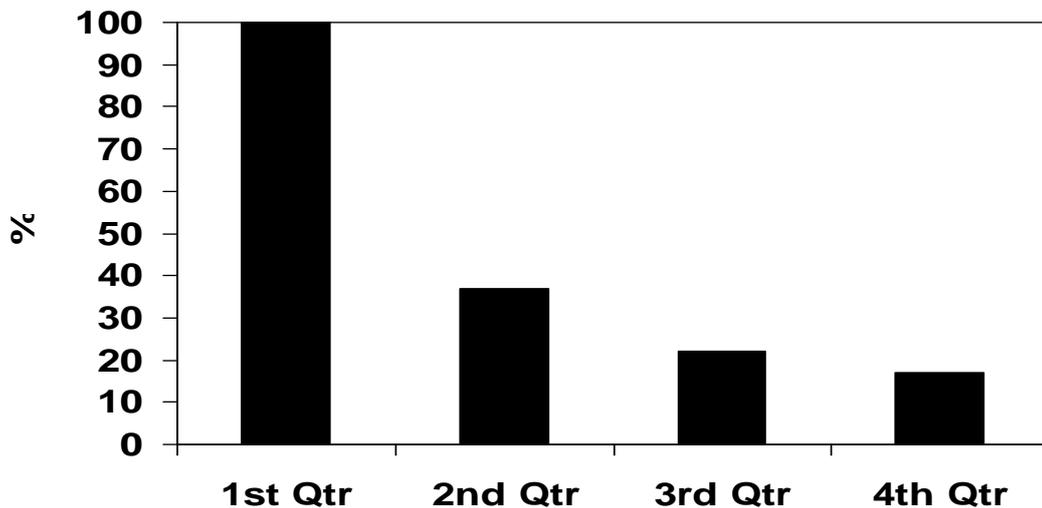
A total of 1,482 prescriptions for duloxetine were registered during 2004 and 2005. After excluding prescriptions for other indications and to men and unidentified patients, that is, those with unknown or missing identification (n= 71, 4.8 %), 1,411 prescriptions were filled for 562 women, which correspond to 24 users per 100,000 women in the total population. Table 1 shows the rates of users by age groups. There was a peak in the 61-80 years age group.

Table 1. Rates of users of duloxetine by age groups per 100,000 women by age group, in Norway for 2004 and 2005

Age group (years)	Rate
0 - 40	5
41 - 60	37
61 - 80	63
80+	43
Total	24

The persistence of use was low already from the 2nd quarter, and further decreased after that (Figure 1). In the 4th quarter only 17% of the original women were still registered with a purchase of at least 1 package of the drug during that quarter.

Figure 1. Percentage of users of duloxetine by 3 month's periods after the first purchase of the drug



Interpretation of results

Only a few women were prescribed and purchased duloxetine in the period 2004 and 2005. Persistence was low during the first year. We do not know whether this is due to lack of effect or to side effects. Costs may also be a factor, as duloxetine is not automatically reimbursed for the patients, as is the case for most other drugs for chronic conditions in Norway.

Concluding message

The Norwegian national prescription database with mandatory data entry from all purchased prescriptions is a useful tool for pharmaco-epidemiological research, including analyses of uptake and persistence of a new drug on the market.

References

1. Am J Obstet Gynecol (2002) 187; 40-48.
2. Eur Urol (2007) 51; 67-74.
3. Int J Clin Pract (2005) 59; 931-937.

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HUMAN SUBJECTS: This study did not need ethical approval because This substudy does not need specific approval. The Norwegian Prescription Database has been approved by the National Ethics Committee and also by the Norwegian Data Inspectorate. but followed the Declaration of Helsinki Informed consent was not obtained from the patients.