

## USE OF ANTIMUSCARINICS IN NORWAY WITH SPECIAL EMPHASIS ON UPTAKE OF A NEW COMPOUND

### Hypothesis / aims of study

The aim of the study was to investigate the epidemiology of prescriptions for antimuscarinics in Norway in 2004 and 2005. Specifically, we investigated the uptake of solifenacin, a new drug on the Norwegian market, sales starting from pharmacies in November 2004. The other registered antimuscarinics in 2004 and 2005 were tolterodine, oxybutynin and emepronium.

### 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 serial number 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.

### Results

A total of 237,113 prescriptions for antimuscarinics were registered during 2004 and 2005. After excluding prescriptions to unidentified patients (N= 2,986, 1.3%), that is, those with unknown or missing identification, the prescriptions represented 50,132 unique patients, which correspond to 1,088 users per 100,000 inhabitants in the total population. Each patient was prescribed a mean number of 4.7 prescriptions during the two year period. The age range was from 1 year to 108 years.

Table 1 shows the rates of users by gender and age groups for all registered antimuscarinics on the Norwegian market for 2004 and 2005. There was a steady increase in rates by age for both genders, and women had a rate more than double of that of men. Tolterodine dominated the market, being used by 91.1% of the men and 93.2% of the women (Table 2). In November and December 2004 only 133 prescriptions were registered for solifenacin, while the number was 13,643 for 2005.

**Table 1.** Rates of users by gender and age groups per 100,000 inhabitants, for all registered antimuscarinics in Norway for 2004 and 2005

| Age group (years) | Men   | Women | Total |
|-------------------|-------|-------|-------|
| 0 - 20            | 105   | 96    | 101   |
| 21 - 40           | 101   | 274   | 186   |
| 41 - 50           | 272   | 940   | 600   |
| 51 - 60           | 659   | 1,894 | 1,266 |
| 61 - 70           | 1,863 | 3,703 | 2,808 |
| 71 - 80           | 3,499 | 5,018 | 4,350 |
| 81 - 90           | 5,744 | 6,787 | 6,428 |
| 90+               | 7,156 | 7,051 | 7,076 |
| Total             | 684   | 1,485 | 1,088 |

**Table 2.** Distribution of patients prescribed antimuscarinics in Norway for 2004 and 2005. Solifenacin was available after November 2004. Emepronium was not used after the start of 2004

| Drug        | Year 2004 |      |       |      | Year 2005 |      |        |      |
|-------------|-----------|------|-------|------|-----------|------|--------|------|
|             | Men       | %    | Women | %    | Men       | %    | Women  | %    |
| Emepronium  | 0         | 0.0  | 3     | 0.0  | -         | -    | -      | -    |
| Oxybutynin  | 53        | 1.1  | 60    | 0.7  | 173       | 1.6  | 339    | 1.3  |
| Solifenacin | 8         | 0.2  | 20    | 0.2  | 2,080     | 19.3 | 3,933  | 15.4 |
| Tolterodine | 4,777     | 98.7 | 8,923 | 99.1 | 8,551     | 79.1 | 21,212 | 83.2 |

When analysing the uptake of solifenacin, we first identified the 5,962 unique new users of solifenacin in the period. They were then analyzed to see if they were antimuscarinic drug naïve or had switched from another antimuscarinic drug. About 59 % were switchers and 41 % were naïve users. Table 3 shows gender distribution for the naïve users and different switch groups by name of drug. The pattern of starting solifenacin among different age groups was similar to that of the total population (data not shown).

**Table 3.** New solifenacin users. Gender distribution for naïve users and different switch groups by name of drug

| Previous use | Men   | %    | Women | %    | Total | %    |
|--------------|-------|------|-------|------|-------|------|
| None         | 1,367 | 66.1 | 2,131 | 54.7 | 3,498 | 58.7 |
| Emepronium   | 0     | 0.0  | 2     | 0.1  | 2     | 0.0  |
| Oxybutynin   | 20    | 1.0  | 103   | 2.6  | 123   | 2.1  |
| Tolterodine  | 680   | 32.9 | 1,659 | 42.6 | 2,339 | 39.2 |
| Total        | 2,067 | 100  | 3,895 | 100  | 5,962 | 100  |

#### Interpretation of results

Antimuscarinic agents have been prescribed to about 1% of the total Norwegian population in the period 2004 and 2005, increasing to about 7 % in women aged 90+. Tolterodine totally dominated the Norwegian markets and was prescribed almost exclusively until 2005. The introduction of solifenacin in 2005 appears to switch some patients from tolterodine, but the majority of solifenacin users were new users of antimuscarinics.

#### 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 of a new drug on the market.

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**HUMAN SUBJECTS:** This study did not need ethical approval because The data is from a national registry that in itself has ethical approval. This specific study was approved by the Norwegian Data Inspectorate. but followed the Declaration of Helsinki Informed consent was not obtained from the patients.