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Resident and nurse reports of potential adverse drug reactions

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Abstract (word count: 240)

Purpose

Nursing home residents are at high risk for adverse drug reactions (ADR). To improve pharmacotherapeutic care for individual residents, health care professionals need to be aware of ADRs. In nursing homes, nurses have a central role in monitoring residents' health and informing physicians on the presence of ADRs. The aim of this study was to evaluate the value of nursing home residents' ADR reports.

Methods

Residents of a convenient sample of two nursing homes were included if their mental status and understanding of Dutch enabled them to report ADRs. In a cross-sectional design, residents and nurses were questioned about 17 potential ADRs. Reports of residents and nurses were consequently compared. Medication use was studied to describe the risk for ADRs per resident.

Results

Residents had a mean of eight different chronic medication prescriptions. Over 90% of the residents used medications which increase the risk of feeling somnolent/tired/sedated, arrhythmias and abdominal pain. The median number of potential ADRs reported by nurses was significantly lower compared to the number of resident reports (median [range] respectively 1 [1-10] and 4 [1-10]). In

general, residents reported the presence of more ADRs than nurses, except for confusion. The correspondence between nurse and resident reports ranged from 43% (dry mouth) till 88% (arrhythmia).

Conclusions

Nurses and patients reported a lot of potential ADRs. The type of ADRs they reported, was different and complementary. Questioning residents about specific potential ADRs may increase the awareness of ADRs.

Key words

Patient Reported Outcome

Adverse effects

Drug monitoring

Nursing Home

Older Persons

Introduction (manuscript word count: 2587)

Background

In pharmacovigilance, direct patient reporting of adverse drug reactions (ADR) has been introduced in many European countries in the last decade. In the USA, patients have been able to report ADRs since the 1960s [1]. In 2012, Inch e.a. systematically reviewed literature comparing patient and healthcare professional spontaneous ADR reporting. They concluded that, within the limited evidence available, some ADRs were more frequently reported by patients and the seriousness of the reports differed [2]. In a cross-national evaluation of direct patient reporting of ADRs, the value of patient reports of ADRs in pharmacovigilance was confirmed [3].

In evaluating pharmacotherapeutic care of individual patients, health care professionals need to be aware of patients' ADRs. Therefore, in practice, patient reports of ADRs can be very valuable to tailor pharmacotherapeutic care for the patient. The diagnosis of an ADR in practice is based on pharmacovigilance information, patient reporting of ADRs, targeted ADRs assessments, clinical examinations and laboratory results of patients, in combination with data on drug use, diseases and therapy changes in the patients. Targeted ADR assessments can be used by professionals and patients to identify ADRs [4-6].

Due to multi-morbidity, polypharmacy and changed pharmacokinetics and -dynamics in old age, residents of nursing homes are at high risk for ADRs. Nurse reports of ADRs in nursing homes have proved to help physicians in evaluating pharmacotherapeutic care. Supporting nurses to screen for ADRs and to report their observations to physicians, resulted in a high detection rate of ADRs, confirmed by physicians [7,8]. The value of nursing home resident reports of ADRs, however, has not been evaluated [9].

The study

Aim

The aim of this study was to evaluate the value of nursing home resident reports of ADRs in daily clinical practice through a paired analysis of resident and nurse reports of ADRs.

Design

In a cross-sectional design, nursing home residents and nurses were questioned by an independent research assistant about 17 potential ADRs in older persons. Reports of residents and nurses were consequently compared. Medication use was studied to describe the risk for ADRs per resident.

Sample/Participants

A convenience sample of two nursing homes with at least 60 beds and minimum 50% nursing beds (high care dependency) , of two different Belgian provinces, was selected. Residents were included if their mental status and understanding of Dutch enabled them to answer the questions. Residents with a score of 3 or 4 on the items disorientation in place or time on the Katz-scale were excluded [10], as well as residents whose general practitioner did not consent to the use of the residents' medication data.

Data collection

Structured interviews

In December 2009 two research assistants (bachelors in nursing with research training) visited the residents. During a structured interview residents were questioned about the presence of 17 potential ADRs (table 1) in the last week or month. When a potential ADR was reported by a resident, the resident was asked how often the problem occurred. Under supervision of the research assistant, head nurses completed a similar questionnaire for each resident on the presence and the frequency of the ADRs. The head nurse was allowed to consult team members or patient files, yet, not to question the residents at the moment of the data collection. The data collected ought to represent nurses information on the health problems in usual care situations.

The questionnaire was developed for the purposes of this study and needed to contain the most important ADRs, taking into account prevalence, severity and hindrance. To our knowledge, a list with the most important ADRs in nursing homes did not exist. Therefore, frequent ADRs of the top 20 of active ingredients most prescribed in nursing homes were listed [11]. ADRs of these active ingredients were extracted from the website of the Belgian Centre for Pharmacotherapeutic Information [12]. Afterwards, the list was discussed in an expert panel with a nurse, a pharmacist, a general practitioner and a geriatrician. The experts were asked to judge the prevalence of the ADRs in nursing homes, the severity and the hindrance for residents. ADRs not observable by nurses were not considered. Related ADRs were clustered to result in 16 (clusters of) ADRs understandable by nurses and residents to create a targeted and practicable instrument. Dry mouth was added by the experts because of the high expected prevalence and hindrance. (See table 1)

Medication charts

Medication charts of the participating residents were copied to collect data about residents' medication use. Active ingredients were coded using the Anatomical-Therapeutic-Chemical classification on 5th level [13].

Ethical considerations

General practitioners were informed about the study by the coordinating and advising physician of the institution and could refuse to copying the medication charts of their patients. Nurses and eligible residents received study information and signed informed consent before participation. The study was approved by the ethics committee of the Antwerp University Hospital (reference 9/45/243).

Data analysis

Data were analyzed using SPSS 22.0. Kolmogorov-Smirnov and Shapiro-Wilk tests showed non-normality of the distributions of age, care dependency and medication use in the sample.

Differences between residents who participated and who did not participate in reporting ADRs, were calculated using non-parametric statistics (Mann-Whitney for continuous and chi-square tests for discontinuous variables). The Katz score for care dependency consists of eight items (washing, dressing, toileting, incontinence, mobility, eating, disorientation in place and in time)[10]. The score on each item can range from 0 to 4. A higher score represents a higher level of dependency. Paired analyses were performed to compare nurse and resident reports of ADRs, using McNemar statistics. Finally, the number of reports was compared between residents with and without a theoretical risk (based on medication use) for each of the 17 potential ADRs, using chi-square tests.

Results

The research population

The nursing homes, with a capacity of 90 and 93 beds, were both divided in three nursing units. Data on medication use and nurse reports of potential ADRs were collected from 164 residents. Due to mental deterioration (34%) or not willing to report ADRs (24%), resident reports of potential ADRs were obtained from 68 residents. (figure 1)

The mean age of the residents was 86 years [51-101] and 78% were women. The group of residents who reported on potential ADRs for the means of this study, had the same age but was significantly less care dependent in comparison with those who did not participate. (see table 2)

Residents had a mean of eight different chronic medication prescriptions. Most prescriptions were written for the nervous system (up to eight per resident), followed by the cardiovascular system (up to seven per resident). The group who reported on potential ADRs had significantly more chronic prescriptions in general and for cardiovascular problems specifically. (see table 2)

Potential adverse drug reactions

In table 3, for each of the 17 selected potential ADRs, we described how many residents took drugs with the potential to cause the potential ADR. Furthermore, the mean number and range of drugs taken per resident with the potential to cause the potential ADR are presented. Over 90% of the

residents used medications increasing the risk for feeling somnolent/tired/ sedated, of arrhythmias and abdominal pain. Some residents took up to 8 different medications with a risk for the same potential ADR. Based on their medication use, all 17 potential ADRs studied were a theoretical risk to over 50% of the residents. Residents were at risk for a median of 14 potential ADRs of the 17 which were selected in this study (see table 3 and figure 2).

Resident and nurse reports of potential ADRs

The median number of potential ADRs reported by nurses was significantly lower compared to the number of resident reports (median [range] respectively 1 [1-10] and 4 [1-10]). Except for confusion and depression or feeling down, every potential ADR was reported more often by residents than by nurses. The difference in reports was statistically significant for dry mouth, anxiety/agitation, skin rashes/itching, feeling somnolent/tired/sedated, muscle pain/weakness and headaches. Most potential ADRs were reported by nurses and residents as daily or weekly problems. The reported frequencies were equally distributed by nurses and residents. Dry mouth was reported as a daily problem by 31% of the residents, while only 1.5% of the residents had problems of a dry mouth according to the nurses. (Table 4)

Figure 3 shows the results of the paired analysis on agreement or disagreement in reports per resident. The agreement between nurses and residents ranged from 43% (dry mouth) to 88% (arrhythmia). Residents reports of ADR, not recognized by a nurse, were most frequent on dry mouth (57%), being tired/somnolent/sedated (31%), skin rashes/itching (29%) and anxiety/agitation (28%). Nurses reports of ADRs, not recognized by the resident, were most frequent on confusion (15%), depression/feeling down (13%), obstipation (12%) and nausea/vomiting (7%).

The association between residents' potential ADRs and medication use

To evaluate whether the potential ADRs reported by the residents corresponded to their risk profile, based on their medication use, the percentage of positive reports was compared between residents at risk and residents not at risk (figure 4). Because of the high theoretical risk profile for ADRs (table 3) the group of residents not at risk was often very small. Because of the limited reliability and

relevance, analyses with groups smaller than 10 residents were excluded. No significant differences were found in the percentage of positive reports of potential ADRs between groups with and without a theoretical risk. Nurses and residents did not report significantly more potential ADRs in residents who used medication, for which the ADR has been described in pharmacotherapeutic information resources. Although the results were not significant, depression/ feeling down and obstipation were reported by relatively more residents (respectively 19% and 15%) in the group without medication for which these potential ADRs have been described. Dry mouth, muscle pain/ weakness and drowsiness were reported more in the group with medication for which these potential ADRs have been described.

Discussion

Residents and nurses were asked to report potential ADRs on a list of 17 selected ADRs. Based on pharmacotherapeutic information resources, the theoretical risk profile for ADRs for nursing home residents was very high. Residents' medication use was related to a median of 14 out of the 17 selected ADRs. Residents reported positive on a median of 4 potential ADRs and nurses on a median of 1 potential ADR. Nurse – resident agreement per potential ADR ranged from 43% (dry mouth) to 88% (arrhythmia). Dry mouth, anxiety/agitation, skin rashes/ itching, feeling somnolent/ tired/sedated, muscle pain/ weakness and headaches were significantly more reported by residents. Only confusion was reported more by nurses.

Also in pharmacovigilance research both similarities and differences in reports have been described between patient and healthcare professional ADR reports [2,14]. Research comparing patient and healthcare professional ADR reporting in daily clinical practice is very limited. In Thailand, patient reporting of potential ADRs of non-steroidal anti-inflammatory drugs, using a checklist, showed that out-patients were able to contribute to drug monitoring [15]. In a tertiary teaching hospital in Thailand, most ADRs reported by patients were not reported by physicians. Of the patient reports 76% were assessed probable or possible ADRs by a pharmacist [16].

Taking into consideration the differences in reports between nurses and residents, questioning residents on the presence of potential ADRs is of added value to obtain a more complete view on residents' responses to pharmacotherapy. Residents can report on different ADRs, which may be missed otherwise [17,18]. Also less threatening ADRs, such as dry mouth, which can be uncomfortable to residents can be detected. It is advisable to question how often the resident suffers from the potential ADRs, to avoid unnecessarily taking into account very rare complaints.

An evaluation of all resident reports of potential ADRs will be required. Most residents do not have the competences to distinguish between ADRs and clinical problems not related to medication use. Thai patients who reported on potential ADRs of statins, assessed their symptoms as medication-related based on timing relationships, information received, seeing similar symptoms in others and diagnosis through blood tests [19]. They experienced, however, a lack of information and knowledge to attribute the symptoms in case of concomitant medication use and disease [19]. Nurses too may find it hard to define the difference. An evaluation of resident reports by physicians or (clinical) pharmacists would have given extra information on the validity of the resident reports. However, since resident reports can complement on health care professionals reports as in pharmacovigilance, also physician and (clinical) pharmacist reports cannot be considered as the only golden standard. Assessing ADRs in older persons is often difficult [20]. By questioning residents on ADRs every month or in case of medication changes, residents and nurses will increase their awareness and knowledge on ADRs. After the first sound evaluations of the observations with physicians, evaluations of repeated reports without major changes can be minimized. Earlier research has shown the valuable contribution of nurse reports on ADRs in nursing home residents for physicians to improve pharmacotherapeutic care [7,8]. When nurses are systematically involved in interdisciplinary medication review and nurses structurally incorporate drug monitoring in caring for the residents, nurses can provide essential information to tailor pharmacotherapy. Resident reports can be used to complete the information required in structural interventions, such as the Pharmeducation intervention in which drug monitoring is supported by computer generated, individualized ADR checklists [7].

Strengths and limitations

This study has investigated the role of engaging residents and nursing staff in reporting adverse events in nursing homes, an important aspect of guiding patient centered care. Research on the topic is very exceptional because of the major challenges for researchers to differentiate between symptoms related to medicines or changes in comorbid health conditions and to guarantee the validity of the resident reports. In our study we attempted to correct for comorbid health conditions by relating residents reports to their medication use. Dry mouth, muscle pain/weakness and drowsiness were reported more by residents at risk for the ADR, which can be a first indication of the validity of the resident reports on these ADRs. The opposite was true for depression/feeling down and obstipation. The confrontation between the reports and the risk profile should, however, be interpreted with caution, since theoretical risk profiles were very high, resulting in small groups for comparison and statistically insignificant results. The confrontation between the reports and the risk profile can only be a first indication of the validity of the reports and does not suffice to draw strong conclusions on the validity. Furthermore, the use of closed ended questions of 17 common ADRs can increase the chance of residents to report one of the ADRs in comparison with open ended questions, with the potential to over-estimate the frequency and limit the causality. The researchers deliberately chose to use the prompt list of common ADRs. When generating ADR lists based on residents' individual medication use, ADR-lists tend to be too long for residents to consider and comparison between reporters would have been less accurate. The list was created based on the medication use in nursing homes and was validated in a multidisciplinary panel. However, other ADRs such as urinary incontinence and hypotension are important for health care professionals to be aware of.

Conclusions

Resident reports of potential ADRs complement the existing awareness of ADRs of nurses. Targeted information and questioning of residents can be valuable to improve pharmacotherapy in daily clinical practice. Additional research covering more potential ADRs and comparing resident, nurse

and physician reports in a larger sample can further extend the knowledge and insights in the value of patient reported outcome on ADRs in a nursing home population.

Contribution of the authors statement and acknowledgements

TD – conception or design of the work, acquisition, analysis and interpretation of data for the work; drafting the work; final approval of the version; agreement to be accountable for all aspects of the work. BVR- contribution to the conception of the design; revising the work critically for important intellectual content; final approval of the version; agreement to be accountable for all aspects of the work. PVB- contribution to the conception of the design; revising the work critically for important intellectual content; final approval of the version; agreement to be accountable for all aspects of the work. ME - conception or design of the work, acquisition, analysis and interpretation of data for the work; revising the work critically for important intellectual content; final approval of the version; agreement to be accountable for all aspects of the work.

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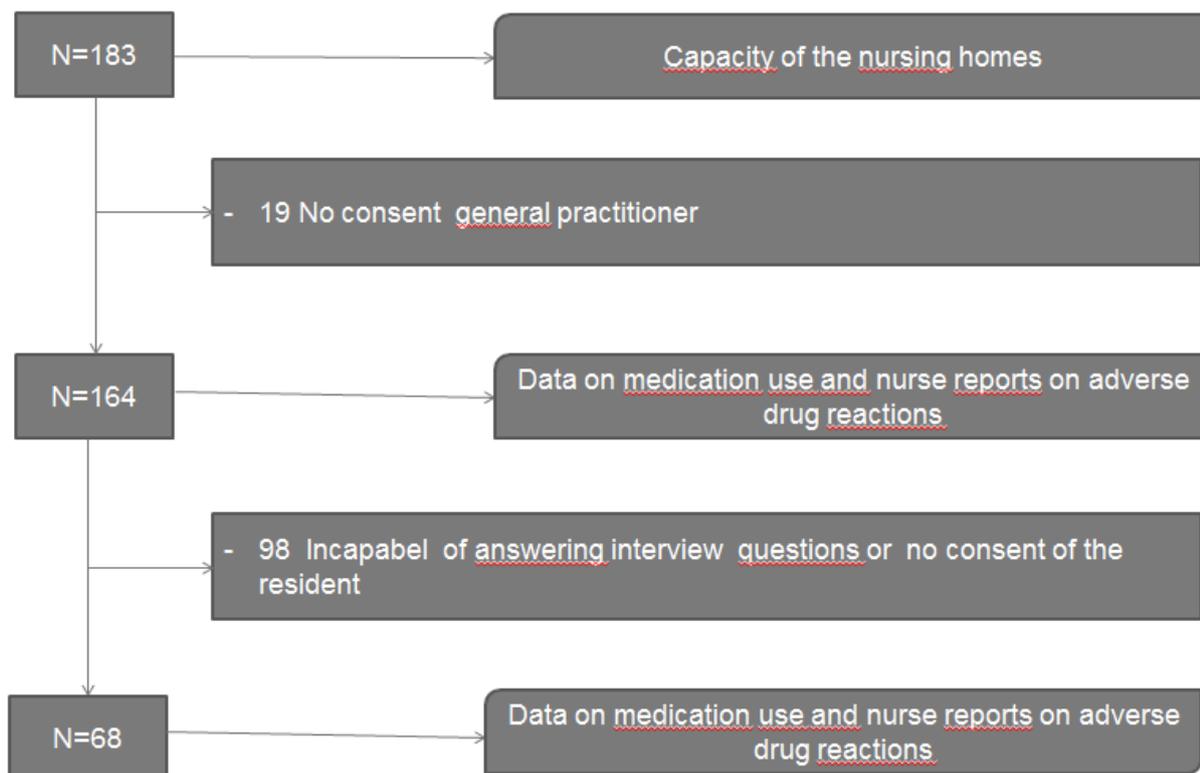


Figure 1: Flow of the research population

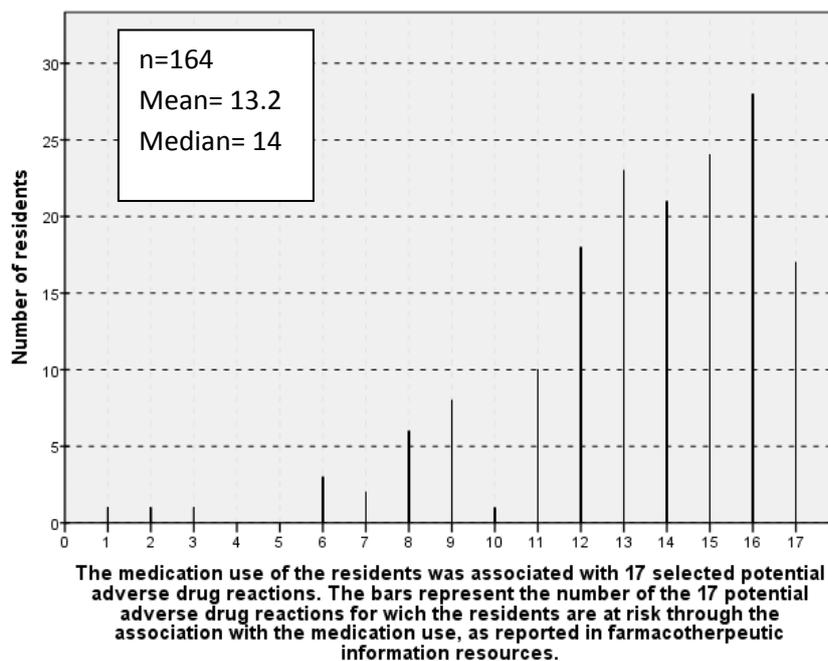


Figure 2: Frequency distribution of the number of potential adverse drug reactions related to the residents' medication use. (denominator= 17 selected ADRs)

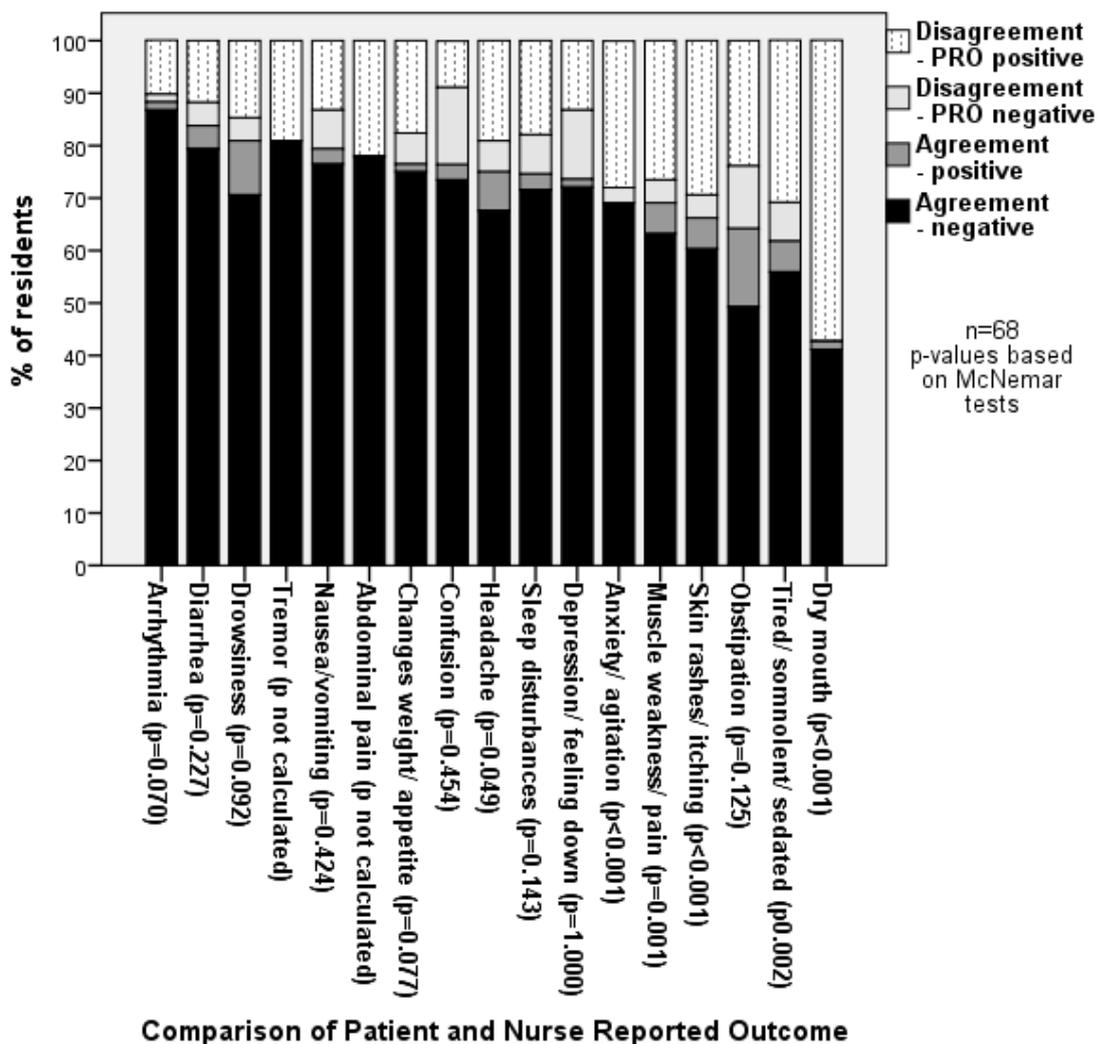


Figure 3: Agreement and disagreement between nurse and resident reports.

Agreement: The resident and the nurse report were the same.
 Disagreement: The resident and the nurse report were different.
 PRO: Patient Reported Outcome – The report of the resident.
 Positive: The potential adverse drug reaction is present.
 Negative: The potential adverse drug reaction is not present.

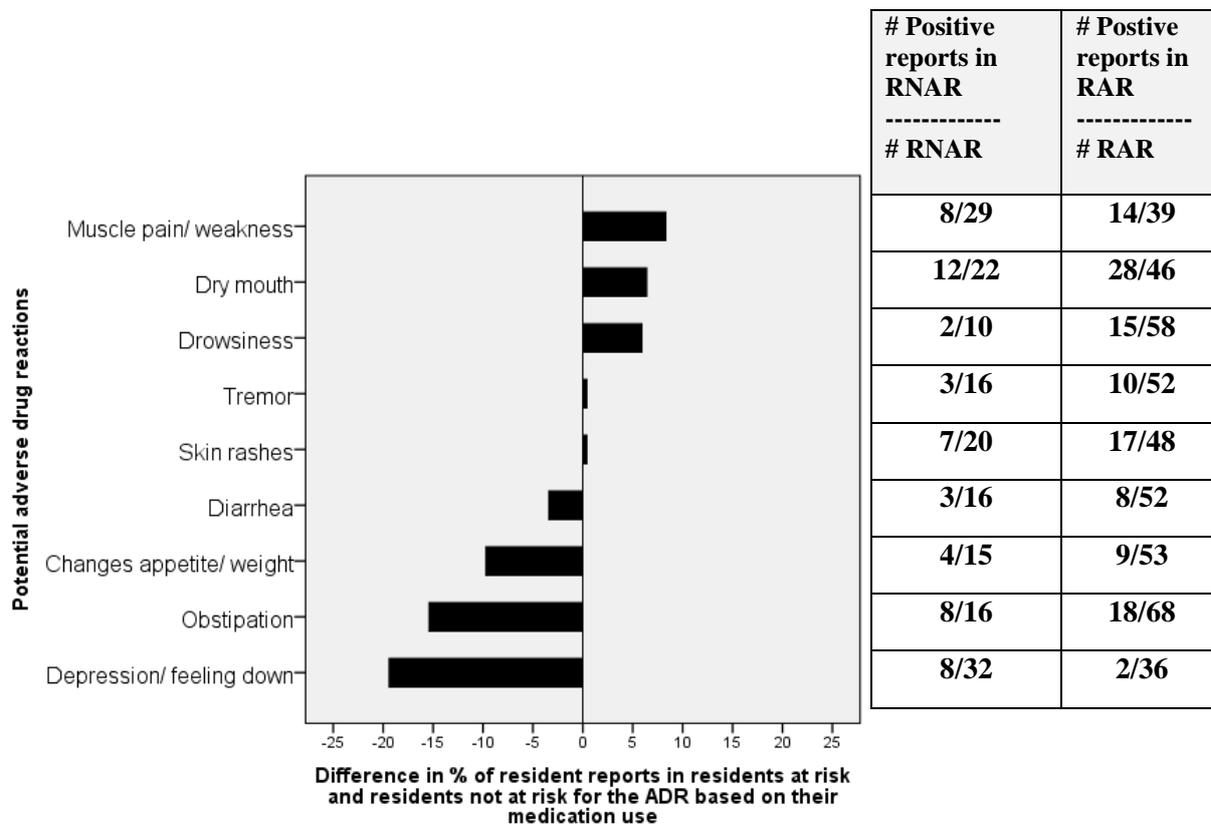


Figure 4: differences in % of reports of potential adverse drug reactions in residents with hand without a theoretical risk for the adverse drug reactions, based on their medication use.

None of the differences was significant (chi-square). Analyses with groups <10 residents were excluded. The size of the remaining groups ranged [10, 68].

RNAR= Resident Not At Risk for the adverse drug reaction, based on the residents' medication use.

RAR= Resident At Risk for adverse drug reaction, based on the residents' medication use.

Adverse drug reactions of the top 20 most prescribed active ingredients in Belgian nursing homes [11]	Decision by experts – ADRs included in the study
Nausea or Vomiting	Nausea/vomiting
Gastro intestinal problems	Abdominal pain
Irritation of the gastric mucosa / gastric bleeding	
Bowel cramps	
Obstipation or obstruction	Obstipation
Diarrhea	Diarrhea
Weight gain	Changes in appetite/weight
Weight loss	
Anorexia	
Confusion	Confusion
Sedation	Tiredness/ somnolence/ sedation
Tiredness and somnolence	
Headache	Headache
Sleep disturbances	Sleep disturbances
Anxiety	Anxiety/agitation
Agitation	
Depression	Depression/feeling down
Drowsiness	drowsiness
Extrapyramidal effects	Tremor
Dystonia	Muscle pain / weakness
Falls	Muscle weakness/ drowsiness
Arrhythmia	Arrhythmia
Skin eruptions	Skin rashes/ itching
	Dry mouth
Hypotensia	
Gynaecomastia	
Tolerance or dependence or hang-over	
Hyperprolactinemia	
Electrolyte imbalance	
Liver problems	
Convulsions	
Hallucinations	
Flatulence	
Increased risk for diabetes	
Maligne neuroleptic syndrome	
Hyperglycemia	
Libido alterations	
Impotence	
Erectile dysfunction	
Irritation of the rectal mucosa	

Table 1: Selection of adverse drug reactions (ADRs) to assess the presence of ADRs in nursing home residents;

		All residents (n=164)	Participation in reporting adverse drug reactions		
			No (n=96)	Yes (n=68)	p-value of difference
Demographic Data					
Age	mean [range]	85.6 [51-101]	85.8 [51-101]	85.2 [61-101]	0.688
Women	%	77.9	87.4	64.7	0.001
Katz score	mean [range]	2.08 [0-4]	2.6 [0-4]	1.4 [0-3]	<0.001
Medication Use					
Chronic prescriptions	mean [range]	8.2 [2-17]	7.5 [2-17]	9.2 [3-17]	0.001
Main ATC classes					
	mean [range]				
A (alimentary tract/ metabolism)		1.6 [0-6]	1.7 [0-6]	1.5 [0-4]	0.806
B (blood/ blood forming organs)		0.9 [0-3]	0.8 [0-3]	0.9 [0-3]	0.823
C (cardiovascular system)		2.2 [0-7]	1.9 [0-7]	2.6 [0-7]	0.002
N (nervous system)		2.4 [0-8]	2.4 [0-7]	2.5 [0-8]	0.633

Table 2: Demographic data and medication use of the residents

n=164	Prescriptions per resident* mean [range]	Residents with prescription** %
Somnolent/ tired/ sedated	2.9 [0-8]	95.1
Arrhythmia	2.7 [0-8]	95.1
Abdominal pain	2.4 [0-6]	91.5
Nausea/ vomiting	2.3 [0-6]	88.4
Confusion	2.1 [0-6]	89.6
Sleep disturbances	2.0 [0-7]	87.2
Anxiety or agitation	2.0 [0-6]	87.2
Headache	1.8 [0-6]	87.2
Diarrhea	1.6 [0-5]	76.8
Obstipation	1.5 [0-5]	74.4
Changes in appetite or weight	1.5 [0-6]	78.0
Drowsiness	1.5 [0-6]	81.1
Tremor	1.5 [0-6]	74.4
Dry mouth	0.9 [0-4]	59.1
Skin rashes	0.9 [0-3]	65.2
Depression or feeling down	0.6 [0-2]	51.8
Muscle pain/ weakness	0.6 [0-3]	50.0

Table 3: Medication prescriptions with potential adverse drug reactions

*Example: Residents have a mean of 2.9 prescriptions for which the ADR 'being somnolent/tired/sedated' has been described. Some residents have up to 8 different prescriptions for which the ADR 'being somnolent/tired/sedated' has been described.

** Example: 95.1% of the residents take at least one medications for which the ADR 'being somnolent/tired/sedated' has been described.

	Presence of the adverse drug reactions n=68			Frequency of the adverse drug reactions by resident report n=68		
	Nurse report %	Resident report %	Difference (N-R) %	Daily %	Weekly %	Less %
Somnolent/ tired/ sedated	13.2	36.8	<u>-23.6*</u>	26,5	7,4	2,9
Arrhythmia	3.0	11.8	-8.8	4,4	2,9	4,4
Abdominal pain	0	22.1	-22.1	5,9	4,4	11,8
Nausea/ vomiting	10.3	16.2	-5.9	1,5	5,9	8,8
Confusion	17.6	11.8	5.8	0,0	7,4	4,4
Sleep disturbances	10.3	20.6	-10.3	10,3	7,4	2,9
Anxiety/ aggitation	2.9	27.9	<u>-25.0*</u>	5,9	14,7	7,4
Headache	13.2	26.5	<u>-13.3*</u>	7,4	7,4	11,8
Diarrhea	8.8	16.2	-7.4	2,9	4,4	8,8
Obstipation	26.5	38.2	-11.7	16,2	11,8	10,3
Changes in appetite/ weight	7.4	19.1	-11.7			
Drowsiness	14.7	25.0	-10.3	8,8	8,8	5,9
Tremor	0	19.1	-19.1	7,4	7,4	4,4
Dry mouth	1.5	58.8	<u>-57.3*</u>	30,9	25,0	2,9
Skin rashes	10.3	35.3	<u>-25.0*</u>	23,5	8,8	4,4
Depression/ feeling down	14.7	14.7	0.0	5,9	4,4	2,9
Muscle pain/ weakness	10.3	32.4	<u>-22.1*</u>	20,6	7,4	4,4

Table 4: Resident and nurse reports of adverse drug reactions

* The significance level of the difference between resident and nurse reports of the 17 selected adverse drug reactions, was calculated with McNemar tests. * indicates significance levels <0.05; Exact values are reported in figure 3;