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HRT use in 2001 and 2004 in The Netherlands—A world of difference

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Abstract

Objective: Did the publication of the Women Health Initiative (WHI) trial in 2002 and the Million Women Study (MWS) in 2003 lead to changes in prescription rates of hormone replacement therapy (HRT). Therefore, we compare the prescribing of HRT in 2004 (after) with that of 2001 (before the publications) in The Netherlands.
Method: Community pharmacy dispensing data from a population of approximately 500,000 patients in The Netherlands. Women aged 40–74 years to whom at least one HRT prescription was dispensed in 2001 or 2004 were included. Annual prevalences of HRT in 2001 and 2004 and the percentage change (2004 versus 2001) were calculated for overall HRT (excluding vaginal products) and per HRT category (combined estrogens and progestagens, estrogens only, tibolon and vaginal preparations) and age category.
Results: In 2001, 5.64% of the women aged 40–74 used HRT and this percentage declined to 2.39 in 2004. The use of vaginal products among these women did not change, 1.76% in 2001 and 1.65% in 2004. The percentage change was highest in the opposed HRT group (66% decrease) and in women aged 50–54 (64.4% decrease). In 2004, compared with 2001, the proportion of long-term users (>3 year) increased with 12.7%.
Conclusions: In The Netherlands, after publication of the WHI study and the MWS the prescribing of HRT fell dramatically whereas the prescribing of vaginal products did not change. Future patterns of HRT use should be monitored to know whether this decrease will be sustained.

Keywords: Hormone replacement therapy (HRT); Change in prescribing; Low potency estrogens/vaginal products; Opposed HRT; Unopposed HRT; Tibolon

1. Introduction

In The Netherlands, hormone replacement therapy (HRT) is licensed for the alleviation of climacterial symptoms and the prevention of osteoporosis, however in daily practice, it was mainly prescribed for treatment

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of vasomotor symptoms. HRT preparations used for this purpose are either combined estrogens and progestagens (opposed) or estrogens alone (unopposed) or tibolon. Vaginal applications, containing estriol or dienestrel, are licensed for the relief of urogenital symptoms.

Before 2002, HRT had been regarded as an intervention with great potential benefits in terms of cardiovascular disease prevention and osteoporosis treatment [1–3]. The publications of the Women Health Initiative (WHI) trial results [4–6] and the results of the observational Million Women Study (MWS) [7] reported increased rates of breast cancer, coronary heart diseases, stroke, dementia and venous thromboembolism and decreased rates of hip fractures and colorectal cancer in postmenopausal women using long-term HRT. Both studies led to much attention and debate in the medical and the lay press.

As a consequence, shortly after the publication of the MWS the Dutch associations of gynaecologists and general practitioners clearly stated that HRT should be prescribed only in women with severe vasomotoric complaints in the lowest effective dose and for a short period. According to the general practitioners this period should not exceed 6 months and the recommendations of the gyneacologists stated that the treatment should be evaluated every 6–12 months [8,9]. The European Medicines Agency for Drug Safety (EMEA) stated in a position paper that for the initiation and continuation of HRT, the minimum effective dose for the shortest duration should be used. And in all cases, a careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as benefits overweighs risks [10].

The aim of this report is to compare the use of HRT in The Netherlands in 2004, after publication of the WHI trial and the MWS results, with the use in 2001, the year before these publications. In addition, we compared the duration of use among HRT-users before and after publication of both studies.

2. Methods

This study was performed with the InterAction Database (IADB), which contains prescription drug dispensing data from community pharmacies in the northern and eastern part of The Netherlands. The IADB covers all prescriptions from an estimated population of approximately 500,000 since 1999 [11,12]. Each prescription record contains among others name of the drug, ATC-code, date of dispensing and amount dispensed. Each patient has a unique, though anonymous identifier. Date of birth and gender of patients are available. Due to a high patient–pharmacy commitment in The Netherlands and sophisticated pharmacy software, the medication records for each patient are virtually complete [13]. This database comprises all prescriptions, regardless of insurance or reimbursement status, apart from drugs dispensed during hospitalisations. Note that almost all HRT preparations are fully reimbursed. Only for transdermal oestrogen/progestagen preparations a patient's copayment is required.

2.1. Study population and design

All women aged 40–74 years, to whom at least one HRT prescription was dispensed in 2001 or in 2004 were selected from the IADB. Women who received HRT prescription were classified into four categories: (I) those who received conjugated estrogens or estradiol and progestagens either in a fixed combination or separately (opposed), (II) those who only received estrogens (conjugated estrogens or estradiol) (unopposed), (III) women who got tibolon and (IV) women who received low potency estrogens (estriol or dienestrel) mainly a vaginal application for vulvar vaginal atrophy. Tibolon is a synthetic steroid with weak estrogenic, progestogenic and androgenic properties [14]. Prevalence of HRT prescribing was estimated per year (2001 and 2004) and was defined as the number of women (aged 40–74) to whom any HRT prescription was dispensed per 100 women in the population covered by the IADB. Annual prevalence was stratified per HRT category and 5-years age categories. The percentage change, defined as: [(prevalence 2001 minus prevalence 2004) divided by prevalence 2001 multiplied by 100], was calculated and stratified per HRT category.

For calculating the duration of use, we selected in 2001 as well as in 2004 all HRT-users with at least 3-year medication history in the database before the first prescription in 2001 or 2004. Of these HRT-users we calculated the differences in proportion (2004 compared to 2001) in relation to duration of use, being: less