INTRODUCTION

Benzydamine hydrochloride (BHC) (CAS nr 132-69-4) (Figure 1) is a local anti-inflammatory and analgesic active ingredient. Since mid 1960 preparations containing BHC have been marketed worldwide for symptomatic treatment of oropharyngeal and gynaecological conditions [1]. BHC toxic exposures have been mainly associated to oral use of vaginal preparations caused by confusion about the correct administration route and by their being mistaken for oral antiseptic preparations [2]. A few reports on abuse have been also reported [3].

In Italy, between 1977 and 2009, BHC containing vaginal preparations had been classified as prescription medicines and consequently supervised by the Italian pharmacy profession. In mid 2009, these restrictions were switched to the category over-the-counter (OTC), allowing for direct to consumer advertising (DTCA).

Between December 20, 2009 and January 2, 2010, the producer launched a first intensive TV advertising campaign, followed by a second one, launched from January 17 to 23. Immediately after the first campaign, the national Poison Control Centre of Milan (PCCM) observed a sharp increase in the number of consultations referred to cases of unintentional oral ingestion of BHC containing gynaecological preparations [4]. Taking into account this observation, the Italian Ministry of Health required a revision of the TV spot in order to improve the information concerning the topical use of the preparations. A new campaign was launched between February 21 and 27, 2010, and in this case the spot included a statement on the topical use of the medicine. TV advertising was voluntarily stopped by the producer since December 2010.

RESULTS

Altogether, 216 cases exposed to BHC containing vaginal preparations were identified. Among them, 87 occurred in the five year pre-advertising period, 67 in the advertising and post-advertising periods, respectively. In the pre-advertising period, the total number of exposures were between 0 and 4 cases/month. A sharp increase in the absolute number of cases was observed immediately after the launch of the first advertising campaign (Figure 2), with 20 cases occurred between December 20-31, 2009, and 31 cases in January 2010. In February, 12 cases were observed, 7 of which occurred during the last TV advertising campaign (February 21-27). Twelve cases were also identified in March, of which occurred within the first 6 days of the month, also included in the advertising period. In the following months, the number of cases ranged between 3 and 11. In the pre-advertising period, 67 cases occurred in women, accounting for 0.04 cases/day, 95% confidence intervals 0.03 to 0.05, and 20 cases occurred in men (0.01 cases/day, 0.01 to 0.02). According to those rates, in the advertising period about three women and one man were expected, while the observed cases were 64 (95% CI 22.9 to 29.2) and three (95% CI 0.8 to 11.0), respectively. In the post-advertising period the expected cases were about 11 in women and 3 in men. The observed cases were still significantly higher than expected in women (n=56, 95% CI 3.8 to 6.6), but close to the expected number in men (n=5, 95% CI 0.5 to 3.5) (Table 1).

The distribution of cases by gender and exposure period showed an increased percentage of women in the advertising and post-advertising period (92%, respectively) in comparison to those reported in the pre-advertising one (72%, Pearson’s χ² = 6.29, P=0.043). Focusing the attention on women, in the pre-advertising period, the proportion of cases treated at hospital (52%) was slightly higher in women (n=11, 95% CI 0.5 to 3.5) than men (n=1, 95% CI 0.5 to 3.5) (Table 1).

METHODS

An interrupted time series design with data routinely collected by the National Poison Control Centre of Rome (NPCCR) was used. The study was conducted between December 2009 and June 2010. During this period, the absolute number of cases and the exposure rates per 1000,000 population were calculated. The proportion of cases treated at hospital in the pre-advertising and post-advertising periods, respectively, in comparison to those reported in the pre-advertising one (2%, 95% CI 0.5 to 3.5), was slightly higher in the post-advertising period (69%, 95% CI 6.2 to 11). In particular, the post-advertising period was characterized by a predominance of subjects aged 20-49 years (72% vs. 43%). The proportion of cases treated at hospital (50%) was close to the expected number (n=3, 95% CI 1.1 to 2.3) (Table 1).

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REFERENCES