Clinical efficacy and health implications of inconsistency in different production batches of antimycotic drugs in a developing country

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Objective: This study aimed at evaluating the in vitro efficacy and health implications of inconsistencies in different production batches of antimycotic drugs. Materials and Methods: In vitro susceptibility profiles of 36 Candida spp. – C. albicans (19.4%), C. glabrata (30.6%), C. tropicalis (33.3%), and C. pseudotropicalis (16.7%) – obtained from human endocervical and high vaginal swabs (ECS/HVS) to two different batches (B1 and B2) of six antimycotic drugs (clotrimazole, doxycycline, iconazole, itraconazole, metronidazole and nystatin) was determined using modified agar well-diffusion method. Results: None of the Candida strains had entirely the same (100%) susceptibility / resistance profiles in both batches of corresponding antimycotic drugs; while, different multiple antifungal susceptibility (MAS) rates were also recorded in batches 1 and 2 for corresponding antifungals. Only 14.3%, 27.3%, 16.7–33.3%, and 8.3–25.0% of C. albicans, C. glabrata, C. pseudotropicalis, and C. tropicalis strains, respectively, had similar susceptibility/resistance profiles toward corresponding antifungal agents in both batches; while up to 57.1% of C. albicans, 45.5% of C. glabrata, 66.7% of C. pseudotropicalis, and 50.0% of C. tropicalis strains were susceptible to one batch of antifungals but resistant to corresponding antifungals in the second batch. As high as about 71.4% (C. albicans), 73.0% (C. glabrata), 50.0% (C. pseudotropicalis), and 66.74% (C. tropicalis) strains had differences of ≥10.0 mm among corresponding antimycotic agents. Conclusions: Candida strains exhibited different in vitro susceptibility / resistance patterns toward two batches of corresponding antimycotic agents, which has clinical implications on the efficacy of the drugs and treatment of patients. The findings of the present study will be of benefit in providing additional information in support of submission for drug registration to the appropriate regulatory agencies.

KEY WORDS: Antifungal agents, candidosis, clinical efficacy, production batch, public health