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Analysis of off-label use of drugs among pediatric inpatients of a tertiary care teaching hospital

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Introduction: Off-label use of drugs refers to use of approved drugs in a situation that is not mentioned in the product information. As considerable risks are involved to the children and the extent of "off-label" drug use among children in India is largely unknown due to limited studies, this study was planned to determine the extent of off-label drug use in children admitted in a pediatric wards of a tertiary care teaching hospital.

Material & Methods: This was a prospective, observational exploratory study in which data were collected from prescription records of all patients admitted between June and August 2014, in pediatric wards of Government Medical College, Nagpur.

Results: Data were collected from 200 patients admitted in pediatric wards; all of them received at least two or more drugs. Of 1188 prescriptions, 524 (44.10%) were found off-label. The anatomical therapeutic chemical classes most involved in off-label prescriptions were anti-infectives for systemic use (45.03%), alimentary tract and metabolism (17.55%), Nervous system (13.74%) and Blood and blood forming organs (9.92%). The highest rate of off-label drug prescriptions was observed in the age range of 1-30 days (36%) followed by age range of 1-12 months (22.51%).

Conclusions: The study found a high percentage of off-label use of drugs in the Pediatric inpatients. We identified inappropriate prescriptions for specific drug classes. The findings emphasize a need for further clinical studies as well as compilation of existing clinical experience and scattered evidence, particularly for drug treatment in pediatric population.

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Salvigenin and Eupatorin greatly improved therapeutic index of Doxorubicin in human colon cancer cell line

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Many of dietary flavonoids have been known to possess beneficial effects in the human body due to their antioxidative and tumor growth inhibitory activities. Natural agents could be a useful strategy to reduce the dose of hazardous chemotherapy drug. In this study, SW948 and HT-29 human colon cancer cells were treated with IC50 dose of salvigenin and eupatorin for 24 h with or without doxorubicin presence. The extent of proliferation was assessed by MTT test. To determine apoptotic cells morphologically, DAPI staining done by fluorescent microscopy. Cell cycle analysis, Annexin V-FITC/PI staining and western blot analyses were measured too. It was shown in cell cycle analysis that, these cell lines which were treated with salvigenin or eupatorin with non-effective dose of doxorubicin, arrested in G1 phase were about 40 and 30% more than doxorubicin treated cells, respectively. Moreover G2 arrest was induce by flavonoids too. On the other hand, Annexin V-FITC/PI staining confirms that combination of salvigenin or eupatorin with lower dose of doxorubicin induce greater apoptosis in colon cancer cell lines compared to doxorubicin treated cells. In addition, caspase-3 and PARP expression increased significantly in these groups to confirm that flavonoids enhanced apoptotic feature of doxorubicin in colon cancer cell lines. Synergistic effect was calculated by computer software. Natural therapeutic flavonoids regimens such as salvigenin and eupatorin, were able to potentiate doxorubicin effects in lower doses, with protecting non-tumoral cells that are needed to improve treatment of colon cancer patients, because, most colon cancer patients treated with combination therapies have only temporary responses to treatment, associated with the side effects of the therapies.

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