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ORIGINAL ARTICLE

Magistral drugs in hospitalized newborns and children

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Abstract
Objective: Study the use of magistral oral solutions and suspensions in infants and children at a university hospital.
Methods: This is a descriptive study based on the analysis of the assessed hospital's magistral drug request forms regarding the patients in the neonatal ICU, Obstetrics, Pediatrics and Pediatric Emergency from January 2012 to December 2013. The frequency of drug requests and dispensation was evaluated and the consumption of each active ingredient of the preparations was expressed as number of ''infant defined daily dose'' (iDDD) and of iDDD/100 bed-days.
Results: A total of 657 forms were analyzed–a monthly average of 27 pediatric preparations. The neonatal ICU accounted for 69.6% of these requests. Twenty-one drug items were used, of which the most common were folinic acid (88 requests), sulfadiazine (85) and captopril (73). The consumption of the active principle in these preparations varied in number of iDDD, from 7.5 (hydralazine) to 16,520.0 (folic acid), and in number of iDDD/100 bed-days in the neonatal ICU, from 0.1 (zinc sulfate) to 146.1 (folic acid).
Conclusions: The constant consumption of magistral oral solutions and suspensions by newborns and children of the assessed hospital indicates the need for such preparations as a pediatric therapeutic alternative in this hospital.

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PALAVRAS-CHAVE
Uso de medicamentos;
Medicamentos pediátricos;
Medicamentos fracionados;
Medicamentos não licenciados

Medicamentos magistrais em recém-nascidos e crianças hospitalizados

Resumo

Objetivo: Estudar o uso de soluções e suspensões orais magistrais em recém-nascidos e crianças de um hospital universitário.

Métodos: Foi feito um estudo descritivo a partir da análise dos formulários de solicitação de manipulação do hospital estudado referentes aos pacientes da UTI-neonatal, obstetrícia, pediatria e emergência pediátrica de janeiro de 2012 a dezembro de 2013. As frequências das solicitações e dispensações desses medicamentos foram avaliadas e o consumo de cada princípio ativo das preparações foram expressos sob a forma de número de *infant defined daily dose* (iDDD) e de iDDD/100 leitos-dia.

Resultados: Foram analisados 657 formulários–média mensal de 27 preparações pediátricas. A UTI-neonatal foi responsável por 69,6% dessas solicitações. Foram usados 21 itens de medicamentos, destacou-se o uso de ácido folínico (88 solicitações), sulfadiazina (85) e captopril (73). O consumo de princípio-ativo nessas preparações variou, em número de iDDD, de 7,5 (hidralazina) a 16.520 (ácido fólico) e em número de iDDD/100 leitos-dia da UTI-neonatal, de 0,1 (sulfato de zinco) a 146,1 (ácido fólico).

Conclusões: O consumo constante das soluções e suspensões orais magistrais pelos recém-nascidos e crianças do hospital estudado indica a necessidade dessas preparações como opção terapêutica pediátrica nesse hospital.

Introduction

Newborns and children go through physiological changes throughout their development, which interfere with the pharmacokinetics and, consequently, the safety and effectiveness of drug treatment in the pediatric age group. Therefore, studies are needed in each pediatric subpopulation for which their use is intended aiming at safety and efficacy assessment of pediatric drugs.[1]

However, there is a shortage of pediatric drugs in the pharmaceutical industry, which can be explained by economic, ethical and technical issues. This fact makes the magistral preparations advantageous options for obtaining medications with appropriate pharmaceutical form for pediatric use, as they allow dose flexibility and easy drug administration.[1,2]

In Brazil, the preparation of compounded drugs must comply with the rules of the Collegiate Board Resolution (RDC) 67/2007, which provides for Good Compounding Practices of Magistral and Compounded Drugs for Human Use in pharmacies.[3] To obtain magistral solutions and oral suspensions, the first choice is the compounding of the active principle; however, these can also be obtained by diluting a liquid formulation (e.g., an injectable dilution), provided it is compatible with oral administration, by pulverizing tablets or removing the powder from the capsule.[4]

This study aims to evaluate the use of magistral oral solutions and suspensions in hospitalized newborns and children.

Method

A descriptive, retrospective study was carried out based on the analysis of request forms for compounding of oral liquid preparations for newborns and children admitted at Hospital Universitário Antônio Pedro (HUAP) of Universidade Federal Fluminense (UFF), related to the period of January 2012 to December 2013. This is a tertiary and quaternary hospital, has 287 beds and serves the population of the Metropolitan Region II of the State of Rio de Janeiro.

The pediatric oral liquid preparations mentioned in this study were prepared at the pharmacy of the UFF, under the responsibility and guidance of a pharmacist, with formulations being based on scientific literature, with adequate validity and packaging, as well as correct storage recommendations, quality control procedures and medication traceability.

The frequencies of requests for pediatric compounded oral liquid formulations in relation to: the month of request; their active principle; their Anatomical-Therapeutic-Chemical (ATC) classification,[5] and requesting sectors were calculated.

The administration frequency of magistral oral solutions and suspensions was analyzed for total oral use liquid pharmaceutical forms dispensed by the hospital pharmacy to the neonatal intensive care unit and Pediatrics in 2013.

The annual consumption of infant defined number of daily dose (iDDD), which corresponds to 1/10 of the defined daily dose (DDD), was calculated for each active principle of these preparations, assuming the complete consumption of the compounded product. The number of iDDD/100 bed-days was also calculated for patients in the NICU.[6] The total occupation of beds in this sector was considered to calculate the number of beds in the NICU.

Descriptive statistics tools such as mean, standard deviation and frequency distributions were used for data analysis.

This study was approved by the Institutional Review Board of the UFF (n. 765.880 de 08/08/2014).

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