[1]杨春松,张伶俐,林芸竹,等.国内儿童应用托吡酯安全性的文献分析[J/CD].中华妇幼临床医学杂志(电子版),2014,(05):609-615.
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国内儿童应用托吡酯安全性的文献分析(PDF)

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Title: Literature Analysis of the Safety of Topiramate for Domestic Children

作者: 杨春松; 张伶俐; 林芸竹; 王芳
610041 成都，四川大学华西第二医院药学部

Author(s): Yang Chunsong; Zhang Lingli; Lin Yunzhu; Wang Fang.
Department of Pharmacy,West China Second University Hospital,Sichuan University,Chengdu 610041,Sichuan Province, China.

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摘要: 目的 了解国内儿童应用托吡酯的不良反应(ADR)发生情况及其相关因素。 方法 计算机检索中国知网（CNKI）文献数据库，收集国内关于抗癫痫药物托吡酯用于儿童的临床研究文献，由2位研究者采用统一的资料提取表格，提取纳入文献中ADR病例的原患疾病，托吡酯用药剂量，ADR 病例的性别及年龄，ADR出现时间、类型、处理及转归等资料。对儿童应用托吡酯导致的ADR及其相关因素采用SPSS 16.0统计学软件进行数据分析。 结果 经文献检索，最终符合本研究纳入标准的关于儿童托吡酯ADR的研究文献共计22篇，关于托吡酯疗效的研究文献共计110篇，共计纳入13 011例患儿，其中2 771例发生ADR，ADR发生率为21.3%。关于托吡酯ADR的研究中，55.1%的ADR涉及神经及精神系统(泌汗障碍、影响自主神经功能等)，34.5%涉及内分泌系统(影响骨代谢及生长发育等)；关于托吡酯疗效的研究文献报道的ADR中，35.2%涉及神经及精神系统(出汗减少、记忆力下降、注意力不集中、头昏等)，27.1%涉及消化系统(食欲下降、胃肠道反应等)，19.5%为全身反应(体质量下降、发热等)。99 6%的儿童应用托吡酯发生的ADR的严重程度为Ⅲ～Ⅳ级，多数在降低托吡酯剂量或停药后症状减轻。 结论 本研究纳入的132篇关于儿童应用托吡酯发生ADR的研究文献中，均未提示重大ADR发生，但由于受到研究设计和样本量局限，同时，纳入本研究的关于ADR的文献，均存在关键信息不完整、研究报告质量欠佳等情况，因此建议进一步对儿童应用托吡酯开展上市后循证再研究及再评价，以确保临床用药安全。儿童应用托吡酯治疗导致的ADR及药物安全性问题，有待以后高质量、大样本、多中心的随机对照研究进一步证实。

Abstract: Objective To assess the adverse drug reaction （ADR） and related factors of topiramate in the treatment of domestic children. Methods Clinical studies of topiramate in the treatment of various diseases for domestic children were

searched from China National Knowledge Infrastructure (CNKI) database. The relevant information such as primary diseases of ADR cases, dosage of topiramate, the age and gender of ADR cases, and the emergence time, category,treatment and prognosis of ADR were collected and analyzed using a standardized data collection form by two reviewers independently.Collected data were analyzed by SPSS 16.0 statistical software. Results We included 22 ADR reports and 110 clinical studies of efficacy evaluation which met the inclusion criteria,involving 13 011 patients,a total of 2 771 ADR cases were reported,the ADR incidence rate was 21.3%.For ADR reports,55.1% of ADR were related to neurological and mental systems (such as sweat secretion disorder, effecting autonomic nervous system function,etc.), 34.5% were related to endocrine system (such as effecting bone metabolism, growth and development,etc.).For clinical studies,35.2% of ADR were related to neurological and mental system (such as decreased sweating,memory decline,inability to concentrate,dizziness,etc.),27.1% were related to digestive system(such as decreased appetite,gastrointestinal reactions,etc.), 19.5% were systemic reactions (such as weight loss,fever,etc.).The severity of 99.6% ADR cases were III to IV class.Most symptoms of ADR relieved when reducing the dose of topiramate or withdrawal it. Conclusions Serious ADR of topiramate did not occur in 132 researches which were included in our study. Due to the limitations of the research design and small sample size,key information in ADR reports and clinical studies were incomplete,and poor quality of research reports,it is recommended to carry out evidence based research and evaluation of topiramate to ensure the safety of clinical practice.It deserves to confirm the safety of topiramate by further high quality, large sample and multi center randomized controlled research of ADR.

参考文献/REFERENCES

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