

Current Awareness in Clinical Toxicology

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CURRENT AWARENESS PAPERS OF THE MONTH

Systematic review: prognostic tests of paracetamol-induced acute liver failure

Craig DG, Ford AC, Hayes PC, Simpson KJ. *Aliment Pharmacol Ther* 2010; 31: 1064-76.

Background

Paracetamol toxicity remains the leading cause of acute liver failure (ALF) in the developed world. In the UK, the recently modified King's College Criteria (KCC) are used to list patients for emergency liver transplantation, but these criteria have been criticised for their low sensitivity and for spectrum bias in their application. Aim: To critically evaluate existing prognostic criteria for predicting death without transplantation in paracetamol-induced ALF.

Methods

MEDLINE, EMBASE and CINAHL were searched to identify studies containing adult patients with paracetamol-induced ALF. Selected studies were evaluated, and data were pooled if appropriate, to calculate sensitivity, specificity, and diagnostic odds ratios (DORs) of applied prognostic tests.

Results

Of 6507 studies identified, 14 were eligible for inclusion, evaluating 1960 patients. The original KCC had a pooled sensitivity of 58.2% and specificity of 94.6%, with a DOR of 27.7. Addition of arterial lactate to the KCC reduced the DOR to 26.1. Several other clinical and laboratory variables had higher DORs than the KCC, but were only evaluated in single studies of limited quality.

Conclusion

The original KCC remain well validated criteria with high prognostic accuracy. Other potential prognostic variables should be prospectively assessed in multi-centre studies to further refine the criteria.

What is the role of lidocaine or phenytoin in tricyclic antidepressant-induced cardiotoxicity?

Foianini A, Joseph Wiegand T, Benowitz N. *Clin Toxicol* 2010; 48: 325-30.

Introduction

Tricyclic antidepressant (TCA) poisoning is a relatively common occurrence and remains a

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significant cause of mortality and morbidity. Deaths from TCA toxicity are typically due to cardiovascular events such as arrhythmias and hypotension. Cardiovascular toxicity may be multifactorial. However, the primary mechanism is a TCA-induced membrane-depressant or "quinidine-like" effect on the myocardium resulting in slowing down of phase 0 depolarization of the cardiac action potential and subsequent impairment of conduction through the His-Purkinje system and myocardium. This effect is manifest as QRS prolongation on the EKG, atrioventricular (AV) block, and impairment in automaticity leading to hypotension and ventricular dysrhythmia. Primary treatment strategies include sodium bicarbonate, hypertonic saline, and correction of any conditions that may aggravate this toxicity such as acidosis, hyperthermia, and hypotension. In cases of severe TCA toxicity, administration of sodium bicarbonate may be insufficient to correct the cardiac conduction defects. Use of lidocaine or phenytoin, both Vaughan Williams Class IB antiarrhythmic agents, has been reported as an effective adjunctive therapy in cases of severe cardiotoxicity.

Methods

Thirty articles of interest were identified by searching PubMed, abstracts from meetings, and the reference sections of related primary and review articles and toxicological texts.

Role of lidocaine and phenytoin

Lidocaine and phenytoin also cause sodium channel blockade, but unlike Class IA or IC agents do not depress phase 0 depolarization in healthy cardiac tissue. Lidocaine and phenytoin dissociate relatively quickly from cardiac sodium channels. Sodium channels have faster recovery times after exposure to lidocaine (1-2 s) and phenytoin (0.71 s), than with some TCAs such as amitriptyline (13.6 s), but not others (e.g., imipramine at 1.6 s). In experimental models of amitriptyline poisoning, lidocaine co-administration resulted in decreased sodium channel blockade compared to amitriptyline alone. This correlated with clinical improvement, including normalization of QRS interval, improved hypotension, and decreased mortality. It is postulated that lidocaine's rapid binding to the sodium channel may directly displace slower acting agents from the channel, leaving more channels unbound, and therefore be able to facilitate cardiac conduction. Phenytoin may act through a similar mechanism as lidocaine, although experimental studies suggest that it does not compete directly for the same sodium channel binding site as TCAs. Allosteric modulation of the TCA binding site may occur in the setting of phenytoin use. The evidence for using phenytoin in treating TCA-induced sodium channel blockade is less convincing than that for lidocaine. Human trials are limited to case series and, in most human exposures in which there appeared to be efficacy, the toxicity was not severe.

Conclusions

Although there appears to be more evidence for the use of lidocaine than phenytoin as adjunctive treatment for TCA-associated cardiotoxicity, specific clinical indications and dosing recommendations remain to be defined. We recommend the use of lidocaine in cases in which cardiotoxicity (arrhythmias, hypotension) is refractory to treatment with sodium bicarbonate or hypertonic saline, or in which physiological derangement (e.g., severe alkalosis or hypernatremia) limits effective use of these primary strategies.

Electrocardiographic effects of methylphenidate overdose

Hill SL, El-Khayat RH, Sandilands EA, Thomas SHL. Clin Toxicol 2010; 48: 342-6.

Objectives

Stimulants used in the management of attention-deficit hyperactivity disorder have been associated with an increased risk of sudden cardiac death. One mechanism could involve drug-induced repolarization delay, reflected as prolongation of the QT interval on the electrocardiogram, which has been described in some recipients of methylphenidate in therapeutic doses. Because QT prolongation is usually dose-related, this study was performed to investigate effects of methylphenidate overdose on the QT interval.

Methods

Adults with methylphenidate overdose identified retrospectively were matched for sex and heart rate with a control subject with overdose of a noncardiotoxic substance, mainly acetaminophen.

Notes were reviewed for clinical details and coingestants. Admission 12-lead electrocardiograms were individually calibrated and analyzed using a manual digitizer in a blinded manner by a single investigator. Mean QRS and QT intervals were calculated and differences between groups were analyzed.

Results

Twenty-three cases of methylphenidate overdose (median reported dose 120 mg, range 40-1,500 mg) were identified (10 males, 13 females, mean age 27.8 years). There were multiple coingestants. Level of consciousness and mean hemodynamic variables were within normal limits for all cases. Symptoms recorded in cases included anxiety (32%), dilated pupils (20%), abdominal pain (16%), vomiting (12%), palpitations (12%), and chest pain (8%). No arrhythmias were recorded. Mean heart rate was 92.4/min in methylphenidate cases and 93.8/min in the heart rate-matched controls. There were no significant differences between the groups in mean QRS (cases 86.1, controls 86.2, mean difference 0.1, 95% confidence interval = -5.1 to 5.0 ms) or mean QT intervals (cases 354, controls 355, mean difference -0.8, 95% confidence interval = -10.7 to 9.2 ms).

Conclusions

Methylphenidate overdose is unlikely to have substantial effects on the QRS or QT intervals.

Activated charcoal for acute poisoning: one toxicologist's journey

Olson K. J Med Toxicol 2010; online early: DOI: 10.1007/s13181-010-0046-1:

Summary

Activated charcoal can effectively bind a wide variety of drugs and poisons with a few notable exceptions (e.g., iron, lithium, potassium, and ethanol).

Animal and human volunteer studies, as well as case reports, have shown that AC can prevent systemic absorption of drugs when given within 1-2 h of ingestion and perhaps longer after ingestion of sustained-release preparations. The optimal dose is probably a 40:1 ratio (by weight) of charcoal to drug, higher than the conventional 10:1 ratio. Randomized, controlled trials have failed to demonstrate improved clinical outcome in overdose patients treated with AC, and there are risks with its use – most importantly, pulmonary aspiration of gastric contents. But there are important flaws in the RCTs reported to date, and they have not yet cast charcoal into the ash heap of toxicology.

I can think of several lines of future inquiry including the use of a higher dose ratio of AC to drug (up to 40:1 by weight), the combination of multiple doses of AC with whole bowel irrigation for massive ingestions, and late decontamination after overdose involving sustained-release drugs. Meanwhile, there is enough evidence from in vitro data, volunteer studies, and case reports to justify the use of oral AC in selected overdoses.

Gamma-hydroxybutyrate (GHB) for treatment of alcohol withdrawal and prevention of relapses

Leone MA, Vigna-Taglianti F, Avanzi G, Brambilla R, Faggiano F. Cochrane Database Syst Rev 2010; 2: CD006266.

Background

Chronic excessive alcohol consumption may lead to dependence, and to alcohol withdrawal syndrome (AWS) in case of abrupt drinking cessation. Gamma-hydroxybutyric acid (GHB) can prevent and suppress withdrawal symptoms, and improve the medium-term abstinence rate. A clear balance between effectiveness and harmfulness has not been yet established.

Objectives

To evaluate the efficacy and safety of GHB for treatment of AWS and prevention of relapse

Search strategy

We searched Cochrane Drugs and Alcohol Group' Register of Trials (October 2008), PubMed,

EMBASE, CINAHL (January 2005 - October 2008), EconLIT (1969 to February 2008), reference list of retrieved articles

Selection criteria

Randomized controlled trials (RCTs) and controlled prospective studies (CPS) evaluating the efficacy and the safety of GHB vs placebo or other pharmacological treatments.

Data collection and analysis

Three authors independently extracted data and assessed the methodological quality of studies.

Main results

Thirteen RCTs were included. Eleven studies were conducted in Italy. For withdrawal syndrome, comparing GHB 50 mg with placebo, results from 1 study, 23 participants favour GHB for withdrawal symptoms: WMD -12.1 (95% CI, -15.9 to -8.29) and side effects were more frequent in the placebo group: RR 16.2 (95% CI, 1.04 to 254.9). In the comparison with chlormethiazole, for GHB 50 mg, results from 1 study, 21 participants favour GHB for withdrawal symptoms: MD -3.40 (95% CI -5.09 to -1.71), for GHB 100 mg, results from 1 study, 98 participants favour anticonvulsants for side effects: RR 1.84 (95% CI 1.19 to 2.85). At mid-term, comparing GHB with placebo, results favour GHB for abstinence rate (RR 5.35; 1.28-22.4), controlled drinking (RR 2.13; 1.07-5.54), relapses (RR 0.36; 0.21-0.63), and number of daily drinks (WMD -4.60; -6.18 to -3.02). GHB performed better than NTX and disulfiram on abstinence (RR 2.59; 1.35-4.98, RR 1.66; 0.99-2.80 respectively). The association of GHB and NTX was better than NTX on abstinence (RR 12.2; 1.79-83.9), as well was the association of NTX, GHB and escitalopram versus escitalopram alone (RR 4.58; 1.28-16.5). For Alcohol Craving Scale results favour GHB versus placebo (WMD -1.90; -2.45 to 1.35) and disulfiram (WMD -1.40; -1.86 to -0.94).

Authors' conclusions

GHB 50 mg is effective compared to placebo in the treatment of AWS, and in preventing relapses in previously detoxified alcoholics at 3 months follow-up, but the results of this review do not provide sufficient evidence in favour of GHB compared to benzodiazepines and chlormethiazole for AWS prevention. GHB is better than NTX and disulfiram in maintaining abstinence and it has a better effect on craving than placebo and disulfiram. Side effects of GHB are not statistically different from those with BZD, NTX or disulfiram. However, concern has been raised regarding the risk of developing addiction, misuse or abuse, especially in polydrug abusers.

Recreational use of mephedrone (4-methylmethcathinone, 4-MMC) with associated sympathomimetic toxicity

Wood DM, Davies S, Puchnarewicz M, Button J, Archer R, Ovaska H, Ramsey J, Lee T, Holt DW, Dargan PI. J Med Toxicol 2010; online early: doi: 10.1007/s13181-010-0018-5: 1-4.

Introduction

Cathinone is a pharmacologically active alkaloid that can be extracted from the leaves of the khat plant (*Catha edulis*). There are synthetic derivatives of cathinone entering the recreational drug market, including mephedrone (4-methylmethcathinone, 4-MMC). There are discrepancies in the legal status of both the khat plant and its extracted alkaloids between the UK and the USA.

Case report

A 22-year-old man purchased 4 g of mephedrone powder over the Internet from a chemical supplier based in China. He initially ingested 200 mg of the mephedrone orally, with no perceived clinical effects, and thereafter injected the remaining 3.8 g intramuscularly into his thighs. Shortly after the injection, he developed palpitations, "blurred tunnel vision," chest pressure, and sweating and felt generally unwell; he presented to hospital with continuing features of sympathomimetic toxicity. His symptoms settled over the next 4 h after a single dose of oral lorazepam. Qualitative analysis of the urine and serum sample was undertaken using gas chromatography with mass spectrometric (GC/MS) detection, both positive for the presence of 4-methylmethcathinone. Quantitative analysis of the serum sample was undertaken by liquid chromatography with tandem

mass spectrometric detection; the estimated mephedrone concentration was 0.15 mg/l. Routine toxicological analysis of the serum and urine specimens using a broad GC/MS toxicology screen did not detect any other drugs or alcohol.

Discussion

This is the first case of isolated 4-MMC toxicity, with confirmatory analytical findings. It is important that clinical toxicologists and emergency physicians work together to ensure a better understanding of the toxicity of novel/emerging drugs such as 4-MMC.

Intravenous lipid emulsion does not augment blood pressure recovery in a rabbit model of metoprolol toxicity

Browne A, Harvey M, Cave G. J Med Toxicol 2010; online early: doi: 10.1007/s13181-010-0049-y: 1-6.

Abstract

Intravenous lipid emulsion (ILE) has been demonstrated to be an effective treatment for systemic toxicity associated with local anaesthetics and increasingly non-local anaesthetic agents of high lipophilicity. Effect for ILE has been demonstrated in animal models of propranolol poisoning; however, any benefit for ILE in more hydrophilic beta-blockers remains uncertain. We determined to examine the effect of ILE on haemodynamic recovery following induction of hypotension with the relatively hydrophilic beta-blocker, metoprolol.

Twenty sedated, invasively monitored and mechanically ventilated adult New Zealand white rabbits underwent metoprolol infusion to mean arterial pressure (MAP) 60% baseline. Intravenous rescue was given according to the following groups: 6 mL/kg 20% lipid emulsion or 6 mL/kg 0.9% saline solution over 4 min. Haemodynamic parameters were obtained in 15 min. MAP was 70 (interquartile range (IQR), 58-82) mmHg saline group and 79 (IQR, 72-89) mmHg ILE group at baseline, and 38 (IQR, 33-40) mmHg saline group and 41 (IQR, 40-43) mmHg ILE group, respectively, following metoprolol infusion.

No statistically significant difference between ILE and saline-treated groups was observed in MAP, or pulse rate, at any time point following rescue therapy. ILE was not effective in reversal of metoprolol-induced hypotension in this rabbit model.

These findings lend inferential support for the 'lipid sink' as principal mechanism for the beneficial effect observed with ILE administration in other models of lipophilic beta-blocker-induced toxicity.

Octreotide's role in the management of sulfonylurea-induced hypoglycemia

Dougherty PP, Klein-Schwartz W. J Med Toxicol 2010; online early: doi: 10.1007/s13181-010-0064-z: 1-8.

Abstract

The objective is to evaluate the evidence regarding octreotide's efficacy as a treatment for sulfonylurea-induced hypoglycemia.

A search of PubMed for articles published from 1965 to 2008 using combinations of the terms octreotide, antidote, sulfonylurea, overdose, poisoning, and toxicity was performed. References from identified articles were reviewed for additional sources. Animal studies, case reports, case series, and randomized controlled trials were evaluated.

An animal model of sulfonylurea overdose demonstrates that octreotide reduces the number of refractory sulfonylurea-induced hypoglycemic episodes. Published case reports describe the use of octreotide to prevent recurrent hypoglycemia after sulfonylurea overdose. A retrospective case series demonstrates that administration of octreotide decreases the need for supplemental dextrose boluses as well as hypoglycemic events. Two prospective, controlled trials determined that octreotide and supplemental dextrose increase blood glucose concentrations with fewer

hypoglycemic events.

Based on animal and human data, there is sufficient evidence to recommend the use of octreotide with supplemental dextrose for the treatment of sulfonylurea-induced hypoglycemia.

Evidence-based, multidisciplinary approach to the development of a crotalidae polyvalent antivenin (CroFab) protocol at a university hospital

Weant KA, Johnson PN, Bowers RC, Armitstead JA. Ann Pharmacother 2010; 44: 447-55.

Background

Several thousand people are bitten annually by venomous snakes in the US. While the development of ovine Crotalidae polyvalent immune Fab antivenin (FabAV) for Crotalinae snakebite envenomations has greatly changed the way this clinical presentation is treated, multiple issues complicate its use. From patient assessment and evaluation, to medication preparation and administration, to the management of adverse drug reactions, the use of this antidote carries with it multiple points of possible medication variances. The inappropriate use of this agent can result in adverse patient consequences and a significant financial burden for both the hospital and the patient.

Objective

To describe an evidence-based, multidisciplinary approach that was taken to ensure optimal, safe, and cost-effective treatment of patients with FabAV.

Methods

Following an analysis of the available literature, a multidisciplinary committee was formed to construct a protocol for use of FabAV. This group included clinical pharmacists, pharmacy administrators, emergency medicine physicians who specialized in wilderness medicine and pharmacy residents.

Results

A multidisciplinary FabAV usage protocol was constructed and implemented to ensure appropriate patient evaluation, FabAV use and preparation, monitoring, and follow-up. This protocol was based on the available literature and the expert opinion of the committee. Through the use of a 24-hour in-house pharmacy resident on-call system, clinical pharmacy services were provided to ensure a multidisciplinary approach to the care of these patients emergently. Although limited, initial data show that this approach is effective and may result in substantial cost savings.

Conclusions

Initial results from implementation of a protocol for use of FabAV have limited inappropriate use, reduced medication wastage, and decreased costs.

Lung cancer risk in painters: a meta-analysis

Guha N, Merletti F, Steenland NK, Altieri A, Cogliano V, Straif K. Environ Health Perspect 2010; 118: 303-12.

Objective

We conducted a meta-analysis to quantitatively compare the association between occupation as a painter and the incidence or mortality from lung cancer.

Data sources

PubMed and the reference lists of pertinent publications were searched and reviewed. For the meta-analysis, we used data from 47 independent cohort, record linkage, and case-control studies (from a total of 74 reports), including > 11,000 incident cases or deaths from lung cancer among painters.

Data extraction

Three authors independently abstracted data and assessed study quality.

Data synthesis

The summary relative risk (meta-RR, random effects) for lung cancer in painters was 1.35 [95% confidence interval (CI), 1.29-1.41; 47 studies] and 1.35 (95% CI, 1.21-1.51; 27 studies) after controlling for smoking. The relative risk was higher in never-smokers (meta-RR = 2.00; 95% CI, 1.09-3.67; 3 studies) and persisted when restricted to studies that adjusted for other occupational exposures (meta-RR = 1.57; 95% CI, 1.21-2.04; 5 studies). The results remained robust when stratified by study design, sex, and study location and are therefore unlikely due to chance or bias. Furthermore, exposure-response analyses suggested that the risk increased with duration of employment.

Conclusion

These results support the conclusion that occupational exposures in painters are causally associated with the risk of lung cancer.

Relationship between mercury levels in blood and urine and complaints of chronic mercury toxicity from amalgam restorations

Eyson J, House I, Yang YH, Warnakulasuriya KA. Br Dent J 2010; 208: E7-3.

Aim

To determine whether patients complaining of oral and medical symptoms perceived to be associated with chronic mercury toxicity have elevated mercury levels in their blood and urine.

Methods

The study group in this audit were 56 patients presenting to an oral medicine unit with complaints perceived to be related to chronic mercury toxicity. Their symptoms and co-morbidity were charted and mercury levels in blood and urine were biochemically tested by atomic absorption spectrophotometry.

Results

None had elevated mercury levels in blood or urine above the normal threshold level. Subgroup analysis showed subjects with oral lesions, autoimmune disorders and multiple sclerosis had relatively and significantly higher mercury levels within this cohort, but within the threshold values. When tested by multiple logistic regression adjusted for age and gender, mercury levels in blood or urine, numbers of amalgams were not significant for multiple sclerosis or previously diagnosed autoimmune disease.

Conclusion

Mercury levels in blood and urine of this cohort of patients with perceived chronic mercury toxicity were within the normal range in accordance with a national laboratory threshold value.

Melamine related bilateral renal calculi in 50 children: single center experience in clinical diagnosis and treatment

Wen JG, Li ZZ, Zhang H, Wang Y, Zhang RF, Yang L, Chen Y, Wang JX, Zhang SJ. J Urol 2010; 183: 1533-7.

Purpose

We investigated the clinical diagnosis and treatment features of bilateral renal calculi in young children who ingested melamine tainted infant milk formula.

Materials and methods

We retrospectively analyzed clinical data on 50 children (mean \pm SE age 23.4 \pm 3.1 months) with a history of ingesting melamine tainted infant milk formula and suffering from bilateral renal calculi. All patients underwent ultrasound and renal function evaluation. Treatment included cessation of melamine tainted formula consumption, hydration, urine basification and hemodialysis if necessary.

Results

Bilateral renal calculi peaked in 6 to 18-month-olds (58% of cases). The male-to-female ratio was

3.1:1.0. Calculi ranged in diameter from 4 to 10 mm in 33 patients (66%) and 2.5 to 4 mm in 17 (34%). Of the 11 patients with renal failure 8 underwent 1 to 4 sessions of hemodialysis. Of the 9 bilateral obstruction cases with renal failure 8 did not require surgical intervention but 1 required ureteral catheterization to drain the renal pelvis. All children experienced a good outcome and were discharged home after a mean \pm SE hospitalization of 8.1 ± 0.7 days.

Conclusions

Melamine related urinary calculi were most often seen in patients 6 to 18 months old. Conservative management has been sufficient in most cases. However, these children need to be monitored for long-term effects of melamine tainted milk formula consumption.

Clinical profile and outcome of aluminum phosphide-induced esophageal strictures

Kochhar R, Dutta U, Poornachandra KS, Vaiphei K, Bhagat S, Nagi B, Singh K. J Med Toxicol 2010; online early: doi: 10.1007/s13181-010-0082-x: 1-6.

Abstract

Aluminum phosphide (AIP) is a lethal solid fumigant pesticide which has been recently linked to esophageal stricture formation. This paper aims to study the clinical profile and response to treatment of AIP-induced esophageal strictures.

Data on all patients of AIP-induced strictures seen between January 2004 and June 2008 were retrieved and analyzed for clinical parameters and response to endoscopic dilation. Each patient underwent barium swallow to define the site and length of stricture and then was dilated endoscopically.

Twelve patients of AIP-induced esophageal stricture (seven males) with a mean age of 26.83 ± 8.43 years were evaluated. They had consumed one to three AIP tablets, 4-156 weeks before reporting to us. They had onset of dysphagia within 2 to 8 weeks of ingestion of AIP. Of 14 strictures in 12 patients, seven were in upper third, two in middle third, and five in lower third of esophagus with a mean length of 1.96 ± 0.75 cm. Nine patients responded to dilation requiring 5.56 ± 2.65 dilations. Four patients were given intralesional steroids to augment the effect of dilation. Three patients failed and were operated upon. All patients remained symptom free over a follow-up of 3-30 (15.67 ± 9.41) months.

AIP-induced esophageal strictures can be dilated endoscopically in a majority of patients; however, 25% of them require surgical intervention. AIP-induced esophageal strictures, thus, behave like caustic-induced strictures.

Hypothermia and fever after organophosphorus poisoning in humans - a prospective case series

Moffatt A, Mohammed F, Eddleston M, Azher S, Eyer P, Buckley NA. J Med Toxicol 2010; online early: doi: 10.1007/s13181-010-0012-y: 1-7.

Abstract

There have been many animal studies on the effects of organophosphorus pesticide (OP) poisoning on thermoregulation with inconsistent results. There have been no prospective human studies. Our aim was to document the changes in body temperature with OP poisoning.

A prospective study was conducted in a rural hospital in Polonnaruwa, Sri Lanka. We collected data on sequential patients with OP poisoning and analyzed 12 patients selected from 53 presentations who had overt signs and symptoms of OP poisoning and who had not received atropine prior to arrival. All patients subsequently received specific management with atropine and/or pralidoxime and general supportive care. Tympanic temperature, ambient temperature, heart rate, and clinical examination and interventions were recorded prospectively throughout their hospitalization.

Initial hypothermia as low as 32°C was observed in untreated patients. Tympanic temperature

increased over time from an early hypothermia (<35°C in 6/12 patients) to later fever (7/12 patients >38°C at some later point). While some of the late high temperatures occurred in the setting of marked tachycardia, it was also apparent that in some cases fever was not accompanied by tachycardia, making excessive atropine or severe infection an unlikely explanation for all the fevers.

In humans, OP poisoning causes an initial hypothermia, and this is followed by a period of normal to high body temperature. Atropine and respiratory complications may contribute to fever but do not account for all cases.

First trimester diclofenac exposure and pregnancy outcome

Cassina M, De Santis M, Cesari E, van Eijkeren M, Berkovitch M, Eleftheriou G, Raffagnato F, Di Gianantonio E, Clementi M. *Reprod Toxicol* 2010; online early: doi:10.1016/j.reprotox.2010.04.010: 1-4.

Objective

To assess the safety of diclofenac during pregnancy.

Methods

A prospective observational cohort study, evaluating follow-up data of women who contacted Teratology Information Services to get counseling. The exposed group included 145 pregnant women who were exposed to diclofenac between the 5th and the 14th gestational week. A contemporary control group (501 women) was randomly selected from among patients who contacted Teratology Information Services with regard to exposures to agents known not to be teratogenic during a similar period of pregnancy.

Results

Major birth malformations were not more common in the study group than in the control group ($p = 0.07$).

Conclusion

Our study suggests that the use of diclofenac is relatively safe during the first trimester of pregnancy and the studied sample size makes it possible to exclude a risk of congenital malformation higher than 3.3, with a power of 80%.

TOXICOLOGY

General

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Toxicity of chemical mixtures containing similarly and dissimilarly acting compounds: new concepts. Abstract presented at the XII International Congress of Toxicology, Barcelona, Spain, 19-23 July 2010.

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CHEMICAL INCIDENTS AND POLLUTION

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CHEMICAL WARFARE, BIOLOGICAL WARFARE AND RIOT CONTROL AGENTS

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