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D-DIMER AND SERUM FDP IN GYNAECOLOGICAL SURGERY AND DIC PATIENTS

C. Legnani, G. Palareti, M. Maccaferri, B. Bianchini, O. Boggian, M. Poggi, S. Coccheri. Dept of Angiology and Blood Coagulation, Hospital S. Orsola, Bologna, Italy.

We carried out in parallel plasma D-Dimer (Dimertest Latex assay, kindly supplied by Ortho Diagnostic Systems, Milan) and serum FDP measurements (ThromboWellcotest, Wellcome) in: 1) 35 gynaecological patients (Gyn. pts) pre and post- operatively (8th day); pts were treated with low dose heparin for thromboembolic prophylaxis and controlled with I125- fibrinogen leg scanning (L.S.); 2) 20 pts from the intensive care unit (ICU) with DIC diagnosed by means of standardized laboratory criteria (DIC pts); tests were performed at admission to the ICU and 1 week later in the 15 survivors.

In all Gyn. pts both D-Dimer and serum FDP tests were negative pre- operatively. At the 8th post-op. day 16 pts (45.7%) had a positive Dimertest, 8 of which had also positive, even if transient, leg scanning (out of 10 L.S. positive pts).Serum FDP were present in 5 pts (14.3%), 2 with negative Dimertest and 2 with positive l.s.. All the 20 DIC pts showed at first observation positive Dimertest and 19 had also serum FDP. After 1 week Dimertest was still positive in 12 and serum FDP in 10 pts. Considering five range levels of results (from normal to highly positive for both tests) we found a significant ($p<0.05$) correlation (Kendall's τ non parametric test) between the results of the two tests in all observations (35 samples). In conclusion, Dimertest, but not serum FDP, seemed to be highly sensitive to post-operative hypercoagulability, with a specificity of 50% for subclinical fibrin deposition as detected with L.S.. No relevant differences were appreciated in the usefulness of the two tests in DIC pts.

DEFIBROTIDE

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DEFIBROTIDE VS. HEPARIN IN ACUTE THROMBOFLEBITIS THERAPY.

Palmieri G.,Palmieri R.,Ambrosi G.,Ferraro G.,Bucci L. Agrati A.M. Department of biomedical sciences and technologies,I School of Internal Medicine,University of Milan- Italy.

Defobrotide(D),a natural polydeoxyribonucleotide of mammalian lung origin,is a new substance with no anticoagulant or hemodinamic effects;it has shown considerable profibrinolytic and antithrombotic activities. The ability of (D) to increase generation of prostaciclin(PGI2) from vascular tissue has been demonstrated; this substance also promotes substantial release from vascular tissues of a plasminogen activator factor which plays an important role in preventing thrombotic occlusion of vascular segments.Widely accepted therapies in deep venous thrombosis and Acute Thromboflebitis (A.T.) are based on anticoagulant treatments (heparin and/or oral anticoagulant agents). We have evaluated the efficacy of (D) in (A.T.) vs. heparin in 40 pts.(28 females,12 males;mean age=50) with an open randomized study.Group A:20 pts.have been administered (D) 200mg.four times a day i.m. for 10 days.Group B: 20 pts.have been administered Sodic Heparin 30000 U.I. intravenously,with successive dosage based upon APTT values.Both groups have been treated with an oral anticoagulant agent(acenocoumarol) after the tenth day. No clinical differences between the treatments have been observed and in no pts. treated with (D) we noted significant changes in laboratory parameters evaluated: complete blood count,glycemia,BUN,creatinine,ALT,AST, LDH.Clinical efficacy was excellent in both groups, also supported by augmented fibrinolysis and instrumental improvement(strain-gauge plethismography). The absolute safety of (D) therapy shows its possible alternative role when compared to heparin treatment in (A.T.) of any origin.

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EFFECTIVENESS OF DEFIBROTIDE IN THE TREATMENT OF ACUTE MYOCARDIAL INFARCTION

Milazzotto F., Carelli M., Citone C., Di Marco Tullio G., Gambelli G.C., Giampaolo P., Malinconico U.,Polizzi C.,Cornelli U.*
Cardiology - S. Camillo Hospital - Rome - Italy
* Crinos - Medical Dept. - Como - Italy

Defibrotide (D) is an extractive polydesoxyribonucleotide. In preclinical studies the product was shown to be active as a pro - fibrinolytic, antithrombotic and thrombolytic agent while completely devoid of anticoagulant activity. In animal models, D was found to afford striking protection from the effects of acute lethal and non lethal myocardial ischemia as well as from myo - cardial injury following reperfusion. In this open single - blin trial, D was administered to patients with acute myocardial infa ction (AMI) for the prevention of complicating arrhythmias; thro bus formation, pericarditis, etc.

Sixty patients with AMI were divided randomly into two group of 30 patients each. One group was treated with D by 6-hour drip infusion for 3 consecutive days (2.8 g on the first day, then 2.4 g daily). The other group was treated with equal volumes of physiological salt solution. All patients received conventional treat ment for AMI. The two trial groups were sufficiently homogeneous in terms of AMI type, age and sex distribution, PCT, Forrester index, Holter, and Peel index. D treatment proved effective in reducing the incidence of severe arrhythmia ($p < 0.05$), thrombus formation ($p < 0.05$), and pericarditis ($p < 0.01$). CPK, TT and PTT readings were not modified by the treatment; the incidence of post-AMI angina and the number of deaths (4 in each group) were similar in the two groups. The results of this pilot study are encouraging; further clinical trials are currently in pro - gress to assess D activity in larger groups of patients treated with the product at higher dosages.