an important advance in the treatment of a neoplastic disease

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'Alkeran' brand Melphalan is the L-phenylalanine derivative of nitrogen mustard, also known as Compound CB 3025 and L-Sarcolysin, is useful in the treatment of multiple myeloma by oral route. Although there is no cure for multiple myeloma, 'Alkeran' brand Melphalan is considered by leading authorities to be a real advance which provides substantial benefit to one-third to one-half of the patients treated.

Warning: As with other nitrogen mustard drugs, excessive dosage will produce marked bone marrow depression. Frequent blood counts are essential to determine optimal dosage and to avoid toxicity. The drug should be discontinued or the dosage reduced upon evidence of abnormal depression of the bone marrow.

Contraindications: 'Alkeran' brand Melphalan should not be given if other similar chemotherapeutic agents or radiation has been administered in the recent past, or if the neutrophil and/or platelet counts are depressed. The drug should not be administered concurrently with radiation.

Precautions: If the leukocyte count falls below 3,000 cells/cu. mm., or the platelet count below 100,000/cu. mm., the drug should be discontinued until the blood picture has had a chance to recover. Whenever possible, use of the drug should be avoided during the first trimester of pregnancy.

Adverse reactions: Nausea and vomiting have followed the use of high doses of 'Alkeran' brand Melphalan.

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because it's the safety zone for the patient on oral anticoagulants. To prevent the formation of another thrombus, anticoagulants slow the enzyme reactions of coagulation, by depressing the activity of certain clotting factors. As enzyme activity is reduced, the patient's plasma becomes far more sensitive to minor defects in the test system. Such defects (e.g., smudged glassware or a few degrees difference in temperature) are more apt to cause longer times than shorter ones. (An erroneously long time reported to the clinician may result in the patient's dosage being reduced to a dangerously low level.) To reveal defects, the control plasma must react with the same sensitivity as the anticoagulated patient's plasma. If it does not, it will not detect a falsely prolonged prothrombin time.

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Papers are accepted for publication on condition that they are contributed solely to this Journal. Manuscripts must be typewritten, in good English, double or triple spaced, on good quality bond paper with at least one inch margins, the original and one duplicate submitted (figures and tables should also be submitted in duplicate). Brief Reports of not more than 4–5 double spaced, typewritten pages, and especially of new or preliminary work, Letters to the Editor, Hypotheses and Brief Reviews may be submitted for prompt publication, subject to editorial review.

References to literature, both text and bibliography, should conform with this Journal's usage. Contributors are advised to examine issues of the Journal so that their manuscripts will conform to the Journal's style as to table and figure references, citations of the literature in the text, preferred spellings, abbreviations, and so forth.

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Academic and/or hospital affiliations of each author, and an address for mailing proofs should be submitted with the article.

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before the deadline of September 25.

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AMICAR controls excessive bleeding by blocking one of the first crucial events in the chain of chemical reactions leading to clotting-failure: it inhibits the activation of plasminogen to prevent the formation of plasmin, and to a lesser extent, inhibits plasmin itself.1,2

**Hyperfibrinolysis — a major cause of excessive bleeding**

In normal blood-clotting, fibrinogen is converted to fibrin monomers which polymerize to form larger groups; these later undergo gelation to produce the clot. But when the plasminogen-plasmin enzyme system is disturbed, so that there is excessive plasmin, the normal blood-clotting mechanism goes awry. With fibrinogen lysed by plasmin, disorganized and unstable clots are formed that dissolve spontaneously. The result is excessive bleeding. Such hyperfibrinolysis may be associated with various surgical procedures, hematological disorders, neoplastic diseases, hepatic cirrhosis, and abruptio placentae.

**References:**

AMICAR®
Aminocaproic Acid

Effective control of hyperfibrinolytic hemorrhage in open heart surgery

Hemorrhage on the increase in cardiac operations
The spectacular success of open heart surgery in recent years has led to a steady increase in the number of operations to correct cardiac defects. Impressive as the results have been, many of these operations have been accompanied by life-threatening hemorrhage because of the use of the pump oxygenator. Incoagulable blood and generalized oozing and bleeding may occur quite suddenly late in the operation, or in the early postoperative period.

Prominent among the coagulation defects observed after cardiac bypass of the circulation is considerable plasminogen-activation, which is frequently related to the duration of the bypass procedure. While there are many factors responsible for uncontrollable bleeding, experience with AMICAR Aminocaproic Acid indicates that excessive fibrinolysis is a major contributing cause.6

Gans and Krivit7 investigated the effect of AMICAR on a group of patients undergoing open heart surgery, and the results were compared with those in a similar group of patients not receiving this drug. While fibrinolytic activity was absent in the plasma of patients pre-treated with AMICAR, there was considerable fibrinolytic activity in the plasma of patients not receiving the drug—proof that this agent was an effective inhibitor of plasminogen-activator in patients undergoing open heart surgery. On several occasions it was noted that with this drug in patients with post-cardiac-bypass hemorrhage, there was normal clot formation, which had been absent before the administration of the drug.

Kirklin6 treated approximately 25 patients with AMICAR after cardiac surgery. In all these patients, bleeding—either in the operating room or in the postoperative period—was so substantial as to be a grave threat to survival. Three-fourths of the patients treated benefited from this drug.

Rodenbaugh8 described the dramatic effect of AMICAR in a man who developed an extreme degree of circulating fibrinolysin during aortic surgery. In spite of vigorous local methods of control, hemorrhage was continuing at a rapid rate, with lysis of the whole-blood clot occurring within ten minutes. Five grams of AMICAR were given rapidly, five grams over the next two hours, and another five grams over the next twelve hours. Fibrinolytic activity and hemorrhage ceased within fifteen minutes after this regimen was initiated.

References:
Official Brochure

**AMICAR** Aminocaproic Acid; 6-Aminocaproic Acid: Intravenous, Syrup, and Tablets.

**Warning**

This drug is offered for use only in acute life-threatening situations where hemorrhage results from an overactivity of the fibrinolytic system.

**AMICAR** Aminocaproic Acid has a very specific action in that it inhibits both plasminogen activator substances and, to a lesser degree, plasmin activity. The drug should not be administered without a definite diagnosis, and/or laboratory findings indicative of hyperfibrinolysis (hyperfibrinemia).*

Animal experiments indicate particular caution should be taken in administering **AMICAR** Aminocaproic Acid to patients with cardiac, hepatic or renal diseases.

Demonstrable animal pathology in some cases have shown endocardial hemorrhages and myocardial fat degeneration. The use of this drug should thus be restricted to patients in whom the benefit hoped for would outweigh the hazard.

Rapid intravenous administration of the drug should be avoided since this may induce hypotension, bradycardia and/or arrhythmia.

One case of cardiac and hepatic lesions observed in man has been reported. The patient received 2 grams of aminocaproic acid every 6 hours for a total dose of 26 grams. Death was due to continued cerebral vascular hemorrhage. Necrotic changes in the heart and liver were noted at autopsy.

If it is accepted that fibrinolysis is a normal process, potentially active at all times to ensure the fluidity of blood, then it must also be accepted that inhibition of fibrinolysis by aminocaproic acid may result in clotting or thrombosis. However, there is no definite evidence that administration of aminocaproic acid has been responsible for the few reported cases of intravascular clotting which followed this treatment. Rather, it appears that such intravascular clotting was most likely a result of the fibrinolytic disease being treated.

It has been postulated that extravascular clots formed in situ with incorporated aminocaproic acid may not undergo spontaneous lysis as do normal clots. However, it is the consensus of experts that the few reported cases of extravascular clotting could have occurred in the absence of aminocaproic acid treatment.

**Description**

**AMICAR** Aminocaproic Acid Lederle is a monaminocarboxylic acid which acts as an effective inhibitor of fibrinolysis.

**Site and Mode of Action**

The beneficial fibrinolysis-inhibitory effects of **AMICAR** Aminocaproic Acid appear to be mediated principally via inhibition of plasminogen activator substances and, to a lesser degree, through antiplasmin activity. The drug is absorbed rapidly following oral administration. Whether administered by the oral or intravenous route a major portion of the compound is recovered unmetabolized in the urine. The renal clearance of **AMICAR** Aminocaproic Acid is high (about 75 per cent of the creatinine clearance). Thus the drug is excreted rapidly. After prolonged administration **AMICAR** Aminocaproic Acid distributes throughout both the extravascular and intravascular compartments of the body and readily penetrates human red blood and other tissue cells.

**Indications**

**AMICAR** Aminocaproic Acid has proved useful, in many instances, in the treatment of excessive bleeding which results from systemic hyperfibrinolysis and urinary fibrinolysis. In life-threatening situations, fresh whole blood transfusions, fibrinogen infusions, and other emergency measures may be required.

Systemic hyperfibrinolysis, a pathological condition, may frequently be associated with surgical complications following heart surgery (with or without cardiac bypass procedures) and portacaval shunt; hematological disorders such as aplastic anemia; abruptio placentae; hepatic cirrhosis; neoplastic disease such as carcinoma of the prostate, lung, stomach, and cervix.

Urinary fibrinolysis, usually a normal physiological phenomenon, may frequently be associated with life-threatening complications following severe trauma, anoxia, and shock. Symptomatic of such complications is surgical hematuria (following prostatectomy and nephrectomy) or nonsurgical hematuria (accompanying polycystic or neoplastic diseases of the genitourinary system).

**Contraindications**

**AMICAR** Aminocaproic Acid should not be used when there is evidence of an active intravascular clotting process. The effect of **AMICAR** Aminocaproic Acid on the fetus and transplacental passage of this drug is unknown. Therefore its use during the first and second trimesters of pregnancy should be confined to instances where need outweighs possible hazards.

**Side Effects**

Occasionally nausea, cramps, diarrhea, dizziness, tinnitus, malaise, conjunctival suffusion, nasal stuffiness, headache, and skin rash have been reported as results of the administration of aminocaproic acid. Only rarely has it been necessary to discontinue or reduce medication because of one or more of these effects.
Thrombophlebitis, a possibility with all intravenous therapy, should be guarded against by strict attention to the proper insertion of the needle and the fixing of its position.

**Dosage Forms**

**AMICAR Aminocaproic Acid Lederle Intravenous.** Each 20 cc. vial contains 5.0 Gm. of Aminocaproic Acid (250 mg. per cc.) as an aqueous solution, with 0.08% methylparaben and 0.02% propylparaben as preservatives.

**AMICAR Aminocaproic Acid Lederle 25% Syrup.** Each cc. of syrup contains 250 mg. of Aminocaproic Acid with 0.1% Sodium Benzoate and 0.2% Potassium Sorbate as preservatives.

**AMICAR Aminocaproic Acid Lederle Tablets.** Each tablet contains 500 mg. of Aminocaproic Acid.

**Administration and Dosage**

**Initial Therapy:** An initial priming dose of 5 grams of AMICAR Aminocaproic Acid administered either orally or intravenously followed by 1 to 1¼ gram doses at hourly intervals thereafter should achieve and sustain plasma levels of 0.130 mg./ml. of the drug. This is the concentration apparently necessary for the inhibition of systemic hyperfibrinolysis. Administration of more than 30 grams in any 24-hour period is not recommended.

**Intravenous:** AMICAR Aminocaproic Acid Intravenous is administered by infusion utilizing the usual compatible intravenous vehicles (e.g., Water for Injection, physiologic saline, 5% dextrose or Ringer’s Solution). **RAPID INJECTION OF AMICAR AMINOCAPROIC ACID INTRAVENOUSLY UNDILUTED INTO A VEIN IS NOT RECOMMENDED.**

For the treatment of acute bleeding syndromes, it is suggested that 16 to 20 cc. (4 to 5 grams) of AMICAR Aminocaproic Acid Intravenous be administered by infusion during the first hour of treatment, followed by a continuing infusion at the rate of 4 cc. (1.0 gram) per hour. This method of treatment would ordinarily be continued for about 8 hours or until the bleeding situation has been controlled.

**Oral Therapy:** If a patient is able to take medication by mouth, an identical dosage regimen may be followed by administering AMICAR Aminocaproic Acid Tablets or 25% Syrup as follows: For the treatment of acute bleeding syndromes, due to elevated fibrinolytic activity, it is suggested that 10 tablets (5 grams) or 4 teaspoonfuls of syrup (5 grams) of AMICAR Aminocaproic Acid be administered during the first hour of treatment, followed by a continuing rate of 2 tablets (1 gram) or 1 teaspoonful of syrup (1½ grams) per hour. This method of treatment would ordinarily be continued for about 8 hours or until the bleeding situation has been controlled.


The use of AMICAR Aminocaproic Acid should be accompanied by tests designed to determine the amount of fibrinolysis present. There are presently available (a) general tests, such as those for the determination of the lysis of a clot of blood or plasma and (b) more specific tests for the study of various phases of fibrinolytic mechanisms. These latter tests include both semi-quantitative and quantitative techniques for the determination of pro-fibrinolysin, fibrinolysin, and anti-fibrinolysin.
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Considerable attention is given to 1) sources of error in these methods; 2) how to avoid common errors; and 3) the basic science involved in each. A handy nomogram at the back of the book serves as a guide to measurement of acid-base status.


By Ole Siggaard-Andersen.

1964 134 pp., 26 figs., 14 tables $6.50

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SEPTIC SHOCK: EXPERIMENTAL AND CLINICAL STUDIES

by Hiroshi Hayasaka, Sapporo Medical Coll., Sapporo, Japan, and John M. Howard, Hahnemann Medical College, Philadelphia, Pa. Clinical problems of sepsis in peritonitis, pneumonia, burns, urological infections, gas gangrene, and septic abortion are discussed as they relate to specific bacteria and as they relate to changes in blood volume, capillary permeability, cardiac output and renal failure. Mechanisms by which septic shock develop are described in detail—emphasizing effects of the endotoxin of gram-negative bacteria and the exotoxins of staphylococci, streptococci, and other gram-positive organisms. Blood, plasma, plasma expanders, vasoconstrictors, vasodilators, steroids, anticoagulants, hypothermia, and hyperbaric oxygen—all are evaluated as adjuncts to standard operative and antibiotic therapy.

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THE REDOX POTENTIAL OF THE BLOOD IN VIVO AND IN VITRO

by Ernest Ziegler, Research Laboratories, J. R. Geigy Ltd., Basel, Switzerland, with a guest chapter by J. Rehn, Bochum, Germany, and translated by J. E. Smith, Neu- anstett, BL, Switzerland. The method described in this monograph eliminates the unpredictable interference associated with the presence of oxygen which has been a feature of previous redox potential measurements on blood. This is accomplished by use of a platinum electrode cathodically polarised with the aid of a weak current in place of a "currentless" electrode. With this method it will thus be possible to arrive at clear-cut findings and definite interpretations in this hitherto difficult and obscure field.

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ANTICOAGULANT PROPHYLAXIS AND TREATMENT: The New Emphasis in Management

by G. I. C. Ingram and John Richardson, both of St. Thomas’s Hospital, London, England. The authors present views on anticoagulation, anticoagulant drugs, intravascular coagulation, the relation of anticoagulants and pulmonary emboli, and new techniques for the investigation of the thrombotic process.

October 1964 about 254 pp.
1 il., 12 tables

METABOLISM OF LIPIDS AS RELATED TO ATHEROSCLEROSIS

compiled by Fred A. Kummerow, Univ. of Illinois, Urbana, Ill. (With 23 Contributors) Recent developments in lipid methodology, such as thin-layer and gas chromatography, in combination with the use of radioactive-ly tagged lipids and their metabolites, are much discussed in this symposium which will highly interest the hematologist.

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