Homeopathy (2011) 100, 95–100

doi:10.1016/j.homp.2011.02.013, available online at http://www.sciencedirect.com

ORIGINAL PAPER

Adjunctive homeopathic treatment in patients with severe sepsis: a randomized, double-blind, placebo-controlled trial in an intensive care unit☆

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Background: **Mortality in patients with severe sepsis remains high despite the development of several therapeutic strategies. The aim of this randomized, double-blind, placebo-controlled trial was to evaluate whether homeopathy is able to influence long-term outcome in critically ill patients suffering from severe sepsis.**
Methods: **Seventy patients with severe sepsis received homeopathic treatment (*n*=35) or placebo (*n*=35). Five globules in a potency of 200c were given at 12 h interval during the stay at the intensive care unit. Survival after a 30 and 180 days was recorded.**
Results: **Three patients (2 homeopathy, 1 placebo) were excluded from the analyses because of incomplete data. All these patients survived. Baseline characteristics including age, sex, BMI, prior conditions, APACHE II score, signs of sepsis, number of organ failures, need for mechanical ventilation, need for vasopressors or veno-venous hemofiltration, and laboratory parameters were not significantly different between groups. On day 30, there was non-statistically significantly trend of survival in favour of homeopathy (verum 81.8%, placebo 67.7%, *P*=0.19). On day 180, survival was statistically significantly higher with verum homeopathy (75.8% *vs* 50.0%, *P*=0.043). No adverse effects were observed.**
Conclusions: **Our data suggest that homeopathic treatment may be an useful additional therapeutic measure with a long-term benefit for severely septic patients admitted to the intensive care unit. A constraint to wider application of this method is the limited number of trained homeopaths.** *Homeopathy* (2011) **100**, 95—100.

Keywords: APACHE II; homeopathy; critically ill patients; intensive care unit; sepsis; survival; double-blind; randomized prospective; placebo-controlled study

Introduction

The incidence of severe sepsis is 70,000 to 300,000 patients in the United States each year.[1] Septic shock is associated with mortality rates ranging from 40% to 90%.[2] Several new therapeutic approaches have failed during the last decades. Recent guidelines[1] recommend use of goal directed therapy, low-tidal ventilation, administration of recombinant Protein C (aPC), close monitoring of blood glucose with a target value of 80—100 mg/dl, and administration of hydrocortisone. Despite these therapeutic strategies, mortality has remained almost unchanged during the last few years.

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☆This article is a reprint of a previously published article. For citation purposes, please use the original publication details; *Homp* 2005; **94**: 75—80.
DOI of original item: 10.1016/j.homp.2005.01.002.
Received 3 August 2004; revised 11 January 2005; accepted 26 January 2005

Homeopathic medicine has been used for about two centuries. Several studies describe its superiority above placebo.[3–5] Experimental studies demonstrate the effect of high dilutions[6,7] even beyond Avogadro's number.[7] There are several case reports on the beneficial effect of homeopathy in critically ill patients.[8] We initiated this study to investigate the effect of homeopathy on the outcome of critically ill patients. The aim of this prospective, randomized, double-blind, placebo-controlled trial was to evaluate at two time points (30 and 180 days) whether homeopathy can influence outcome in patients suffering from severe sepsis.

Materials and methods

Patients

The Ethical Committee of the University of Vienna approved the study. Seventy patients admitted to a Medical Intensive Care Unit (MICU) of the University of Vienna were assessed for eligibility, all were included in the study. All were randomized and treated, three had to be excluded because of incomplete data, all of the latter survived. Written informed consent was obtained from all participants or their authorized representatives. The criteria for severe sepsis of Bone *et al*. were used.[9] Patients with a known or suspected infection on the basis of clinical data at the time of screening and three or more signs of systemic inflammation (temperature $\leqslant 36$ or $\geqslant 38\,^{\circ}C$, respiratory rate $\geqslant 20$/min, heart rate $\geqslant 90$/min, leukocytes $\leqslant 4 \geqslant 12$ G/L) and sepsis-induced dysfunction of at least two organ systems that lasted no longer than 48 h were included. Treatment with homeopathy or placebo started within 48 h after the patients met the inclusion criteria (Fig. 1).

Randomization process

Within 24 h after meeting the criteria for sepsis, all eligible patients were sequentially randomized into two groups, receiving either the homeopathic medicine or placebo, according to a computer-generated code provided by a member of the Department of Medical Computer Sciences. An independent physician not involved into the study held the code. A person not involved in the decision and/or application process for the study prepared the medication for each patient.

Start of therapy and sublingual administration of the globules

Within 12 h after meeting the criteria for sepsis, homeopathic treatment started. A person not involved in the randomization process poured five globules into the lid of the tube containing the globules, then the globules were poured from the lid directly underneath the patient's tongue. In patients with endotracheal tubes, the globules were administered just aside the endotracheal tube. Globules were given twice daily at an interval of 12 h until sepsis was resolved or until death. Patients were treated for the duration of their stay in the intensive care unit. Treatment stopped on transfer to the general ward. Fifteen minutes before and after administration of the globules, no oral fluid or food intake or oral hygiene was allowed to avoid any potential interference with the globules. The homeopathic doctors were free to decide which homeopathic medicine should be applied. All medicines were prepared as a 200c (Rote Krebs Apotheke, Vienna, Austria).

Evaluation of patients

Patients were followed for 180 days after the start of treatment unless death occurred earlier. Base-line characteristics including demographic information and information on pre-existing conditions, organ function, markers of disease severity (APACHE II),[10] and infection were assessed within the 24 h before starting treatment. Adverse effects were recorded during the treatment period.

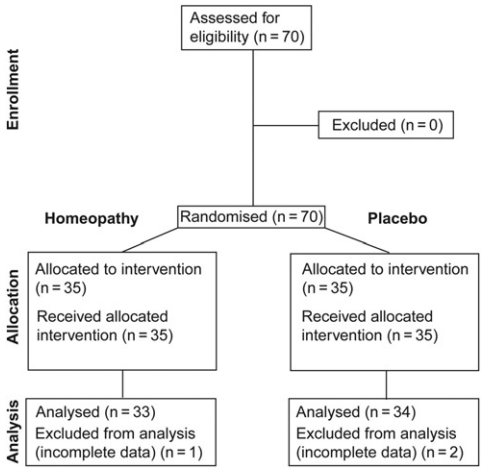

Figure 1 Flow of patients through the study.