A Double-blind, Controlled Clinical Trial of Homeopathy and an Analysis of Lunar Phases and Postoperative Outcome

Josef Smolle, MD; Gerhard Prause, MD; Helmut Kerl, MD

Objective: To use scientific methods to evaluate 2 claims made by practitioners of alternative medicine.

Design: A placebo-controlled, double-blind study of homeopathy in children with warts, and a cohort study of the influence of lunar phases on postoperative outcome in surgical patients.

Setting: Outpatients of a dermatology department (homeopathy study) and inpatients evaluated at an anesthesiology department (lunar phases).

Subjects: Sixty volunteers for the homeopathy study and 14,970 consecutive patients undergoing surgery under general anesthesia for the lunar phase study.

Interventions: Treatment of children with warts with individually selected homeopathic preparations (homeopathic study); surgical procedures including abdominal, vascular, cardiac, thoracic, plastic, and orthopedic operations and assessment of the lunar phase at the time of operation (lunar phase study).

Main Outcome Measures: Reduction of area occupied by warts by at least 50% within 8 weeks; death from any cause within 30 days after surgery.

Results: Nine of 30 subjects in the homeopathy group and 7 of 30 subjects in the placebo group experienced at least 50% reduction in area occupied by warts ($\chi^2 = 0.34; P = .56$); the mortality rate was 1.20% in patients operated on during waxing moon and 1.33% in patients operated on during waning moon ($\chi^2 = 0.49; P = .50$).

Conclusions: Statements and methods of alternative medicine—as far as they concern observable clinical phenomena—can be tested by scientific methods. When such tests yield negative results, as in the studies presented herein, the particular method or statement should be abandoned. Otherwise one would run the risk of supporting superstition and quackery.

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In recent years, methods of alternative medicine have gained increasing importance both in public opinion and among physicians. Paradoxically, the critical approach to scientific medical measures often seems to be accompanied by an approach on faith to alternative methods, even when basic data on the alternatives’ clinical effectiveness and potential risks are lacking.1

The main reason many alternative methods are rejected by representatives of scientific medicine is that often there are few or no sound studies supporting the claims of a particular alternative method. Discussion between practitioners of scientific and alternative medicine is further hampered by the view of some representatives of alternative medicine that clinical studies are inappropriate tools to test alternative medical methods.

In this article we briefly summarize and discuss 2 studies of alternative medicine methods performed under the stringent criteria of scientific evaluation. These studies show that scientific criteria are applicable to the methods of alternative medicine; scientific methods are valuable tools for distinguishing helpful alternative medical methods from superstition and quackery.

HOMEOPATHY IN THE TREATMENT OF COMMON WARTS

Supporters of homeopathy claim that highly diluted preparations that are chemically identical to pure water contain properties that produce beneficial effects in the treatment of various diseases. Opponents of homeopathy consider all eventual clinical benefits of

From the Departments of Dermatology (Drs Smolle and Kerl) and Anesthesiology (Dr Prause), University of Graz, Graz, Austria.
homeopathic treatment to be placebo effects. In order to evaluate the efficacy of a drug beyond the placebo effect, randomized, double-blind, placebo-controlled trials should be performed. As a drawback in homeopathic trials, there is usually not a single homeopathic preparation to be tested against the placebo; rather, depending on the totality of symptoms of a patient, particular preparations are individually selected by the homeopathic physician.

We performed a double-blind, placebo-controlled study in collaboration with the Boltzmann Institute of Homeopathy, Graz, Austria. In this specially designed study of children with common warts, the homeopathists prepared a list of those remedies most commonly used in treating children with warts. They arrived at a total of 12 different homeopathic preparations. For each preparation, an ordered sequence of bottles with globuli was prepared, with the true homeopathic preparation randomly alternated with pure placebo preparations. After informed written consent was obtained from appropriate subjects and their parents, the subjects were carefully examined by a homeopathic physician, and the best homeopathic preparation—as determined by the particular physician—was selected. When 1 of the 12 preselected preparations was chosen, the subject entered the study and was treated with the next bottle of the particular preparation. Neither the physician nor the subject knew whether the bottle contained the homeopathic preparation or pure placebo. When a homeopathic preparation was selected that was not in the predefined list, this patient did not enter the study. Thus, the study design guaranteed that the subject received either optimal homeopathic treatment or placebo.

The area occupied by the warts on the hands was drawn on transparent sheets and measured with a digitizer board before and after 8 weeks of treatment. Fifty percent reduction of the area involved was chosen as the primary outcome variable at the beginning of the study, and subjects demonstrating this 50% reduction qualified as responders.

Of the 70 subjects who signed up for the study, 3 were rejected prior to treatment (2 because the homeopathic preparation required was not on the preselected list and 1 because the subject’s symptoms did not allow for a homeopathic diagnosis). Of the remaining 67 subjects, 7 withdrew from the study (3 from the placebo group and 4 from the remedy group). The reasons for withdrawal were exacerbation of warts in 2 cases (1 in each group), thrombosis of a capillary hemangioma in 1 case (placebo), and unavailability for follow-up in 4 cases (1 placebo and 3 active treatment). There were a total of 16 responders: 9 of 30 subjects in the homeopathic therapy group and 7 of 30 subjects in the placebo group (χ² = 0.34; P = .56). Obviously, there was no significant difference in efficacy between pure placebo and the homeopathic remedy in the context of this study.

RELATIONSHIP OF LUNAR PHASES AND POSTOPERATIVE OUTCOME

Potential influences of lunar phases on human behavior and incidence of disease have been discussed for a long time. During the last few years, several reports have been published, albeit most of them negative or inconclusive, concerning the moon’s influence on suicides,3,4 psychiatric crises,5 car crashes,6 and childbirths.7 More recently, much attention has been paid in the lay press to lunar phases, particularly the full and waxing moon, as potential risk factors for postoperative complications.8 While these claims have led to serious concern among patients and to some extent also among physicians, in a pilot study9 no relationship between lunar phases and complications was found.

We examined the clinical records of 14,970 patients who underwent surgery under general anesthesia from 1990 to 1996 at the Department of Surgery, University of Graz, and who had had preoperative evaluation at the Department of Anesthesiology.10 Surgical procedures included abdominal, vascular, cardiac, thoracic, plastic, and orthopedic operations. Postoperative mortality was defined as death from any cause within 30 days after surgery. Based on scientific tables of moon phases,11 each operation was labeled as having been done at waxing, waning, or full moon. Potential relationships of lunar phases and outcome were tested by x² statistics.

Of 14,970 patients, 189 (1.26%) died within 30 days after surgery. Mortality rate was 1.20% for patients operated on during waxing moon and 1.33% for patients operated on during waning moon (χ² = 0.49, P = .50). At full moon, mortality rate was 1.16% compared with 1.27% at other lunar phases (χ² = 0.04; P = .85). These data strongly indicate that postoperative mortality does not depend on lunar phases. Previous claims of a greater risk inherent in operations performed during a full or waxing moon can be disregarded as superstition, at least as far as lethal complications are concerned.

COMMENT

There seems to be a clear-cut difference between scientific and alternative medicine. While scientific medicine judges the truth of a given statement on observation, alternative medicine often bases its judgment solely on a philosophical model or a certain paradigm. This does not prevent scientific medicine from making errors, but it does prevent it from creating philosophical systems that have no relationship to the real world.

Supporters of alternative medical concepts often accuse representatives of scientific medicine of adhering strictly to physical facts and measurable phenomena and neglecting all other aspects of human life. Because this accusation is sometimes used to reject clinical studies like those presented herein, it should be carefully evaluated. However, we have provided 2 examples of clinical studies on aspects of alternative medicine that yielded negative results. Both studies deal with statements of alternative medicine that directly concern observable facts: homeopaths claim that children with warts will experience improvement when treated with a homeopathic remedy compared with pure water, and physicians believing in the power of lunar phases claim that the moon affects postoperative outcome. Each of these statements has proven itself subject to scientific refutation.
In conclusion, methods and statements introduced by supporters of alternative medicine should be scientifically tested whenever possible. If independent tests repeatedly support the alternative methods or statements, scientific medicine should gratefully accept this enrichment of therapeutic modalities. When, however, as here, the findings are unambiguously negative, the alternative medicine methods or statements should be abandoned.

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Corresponding author: Josef Smolle, MD, Department of Dermatology, University of Graz, Auenbruggerplatz 8, A-8036 Graz, Austria.

REFERENCES