

Review

The Ethical Implications of Complementary and Alternative Medicine in Systemic Lupus Erythematosus

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REZUMAT

Implicațiile etice ale medicinei complementare și alternative în lupusul eritematos sistemic

Lupus eritematos sistemic (LES), s-a dovedit a fi o boală greu de înțeles și una chiar mai greu de controlat. LES reprezintă un obstacol major pentru comunitatea medicală, deoarece etiologia și evoluția bolii sunt insuficient înțelese. Medicina convențională se apropie de boală prin diferitele scheme de terapie medicamentoasă. Cum medicina convențională nu a făcut progrese semnificative, este atât necesar cât și rațional să stabilim dacă medicina complementară și alternativă pot aduce contribuții pentru a umple golul. Medicina complementară și alternativă este frecvent folosită dar problemele etice pe care le implică aplicarea ei sunt rareori discutate. Pentru clinician practicarea și utilizarea terapiei medicale complementare și alternative pot crea o serie de dileme etice. Medicii au datoria de a respecta autonomia pacienților lor și prin urmare, să permită libertatea de a alege conform dorinței lor de a căuta tratamente alternative. Buna practică medicală obligă toți medicii în a conștientiza pacienții lor cu privire la riscurile posibile, dar multe dintre riscuri sunt teoretice și tratamentele complementare și alternative pot să fie benefice. Medicii trebuie să fie pregătiți să acorde atât asistență juridică cât și să consilieze pacienții cu privire la toate opțiunile terapeutice disponibile, oferindu-le mai bune dovezi disponibile. Pentru un număr tot mai mare de pacienți "toate opțiunile disponibile" vor însemna integrarea medicinei complementare și alternative în îngrijirea sănătății lor. Acesta implică că pacientul și medicul vor explora împreună toate opțiunile de tratament, atât convenționale și alternative, într-o încercare de a controla cel mai adecvat manifestările de LES cu aplicare individuală pentru fiecare pacient în parte.

Cuvinte cheie: medicină complementară, medicină alternativă, lupus eritematos sistemic, etică, medicină integrativă

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ABSTRACT

Systemic lupus erythematosus (SLE) has proven to be a difficult disease to understand and even harder to control. SLE poses a major obstacle to the healthcare community because of the poorly understood etiology and progression. Conventional medicine approaches the disease with various forms of drug therapy. With conventional medicine failing to make any significant breakthroughs, it is both appropriate and rational to determine if complementary and alternative medicine can make contributions to fill the void. Complementary and alternative medicine is popular, but ethical issues are rarely discussed. For the practicing clinician, the use of complementary and alternative medical therapy might create a number of ethical dilemmas. Physicians have the duty to their patients to respect their autonomy and allow freedom of choice as to their desire to seek alternative treatments. Good medical practice obliges all physicians to make their patients aware of the possible risks but many of the risks are theoretical and treatments may still be beneficial. Physicians must be prepared to counsel and advise patients about all available options with the best available evidence. For an increasing number of patients “all available options” will mean incorporating complementary and alternative medicine into their healthcare. It is up to the patient and his physician to explore all treatment options, both conventional and alternative, in an attempt to appropriately control the manifestations of SLE in an individual patient.

Key words: complementary medicine, alternative medicine, systemic lupus erythematosus, ethics, integrative medicine

Lupus erythematosus is an autoimmune disease with multiple symptoms and each patient presents a particular clinical and immunological-biological profile. The cause of the disease remains unknown. Lupus erythematosus embraces three clinical forms: chronic, subacute and systemic. Events in the three clinical forms range from skin involvement (chronic form) to serious systemic implications, affecting patient's health and life (as a systemic disease).

The systemic form – systemic lupus erythematosus – has a wide range of immunological abnormalities that cause inflammation in various organs and systems. The inflammation occurs as a result of excessive production of autoantibodies, that are directed against self structures that are no longer recognized. In systemic lupus, cutaneous manifestations are often accompanied by renal, cardiac, osteoarticular, neuropsychiatric disorders.

Taken together, these events cause deterioration of the quality of life.

Conventional treatment of lupus disease is based on systemic corticosteroids, antimalarials, immunosuppressants, anti-inflammatory drugs and new biological therapy agents. These drugs, according to disease stage and form, may be administered alone or in combination. Even if good therapeutic results are obtained, these results are often accompanied by side effects. Corticosteroids may cause musculo-skeletal complications such as avascular necrosis and Cushing syndrome. NSAIDs may produce gastro-

intestinal bleeding. Immunosuppressive drugs and biologic medication is burdened by adverse effects such as cytopenia, liver disease, nausea, vomiting, neuropsychiatric disorders, opportunistic infections. By trying to improve their health status, patients with lupus - particularly systemic form (SLE) - use methods more or less accepted by the physician, specifically complementary and alternative medical methods. Complementary and Alternative Medicine refers to a wide variety of systems and methods of healthcare, which currently are not considered part of conventional medicine, and have obvious medical limitations [6,7]. Romanian patients with SLE certainly resort to such methods but there is insufficient data concerning the use of complementary and alternative medicine. What are the reasons for the existence of insufficient or inaccurate data? First, patients do not always recognize that they resort to alternative medicine [3], and on the other hand, medical institutions have not conducted national multicenter studies to determine the extent of the use of complementary and alternative medicine. In countries like England, Canada, USA, for over 10 years, studies on the use of alternative medicine have been carried out [2,3,7]. The trigger behind these studies is medical and socio-economic status. How many patients use complementary and alternative medicine? What are the most common in practice? How profitable is to use these practices and procedures? What is the cost of these practices?

Can they reduce medical costs of conventional therapy? - These are some of the questions that the studies have tried to answer [2,3].

In starting to use complementary and alternative medicine, experts raise new issues and dilemmas related to ethics and the ethics of using these methods [8,9,10]. The purpose of this paper is to highlight both the positive and the negative aspects of the use of complementary and alternative medicine, with an overview of the main techniques and practices of complementary and alternative medicine usually encountered in medical literature [26], applied to lupus erythematosus.

As an example, we present the following table summarizing the results of a multicenter study [2], on patients with SLE who used alternative and complementary medicine. (Table 1)

The procedures and techniques specified in the table were the most frequently used by patients of the three countries that have conducted these studies. Aware of specific items, doctors in our clinic began to ask patients about the use of complementary methods and techniques.

We encountered reluctance from the patients to give us information. If they initially denied having

used the complementary and alternative medicine, while, after 4-5 visits, after the physician has earned the confidence of the patient (that is not abandoned or rejected if resort to alternative), patients admitted they used, out of curiosity or intrigued by non medical articles from magazines, various remedies. Meanwhile, they have not abandoned conventional medication and medical controls, but have tried to diminish, on their own initiative, the side effects of corticosteroids or cytostatics through herbal remedies. Acupuncture and massage were used by our patients to a lesser extent due to higher direct costs, but also due to indirect costs (absenteeism from work, leave without pay, etc.).

Investigating our patients, without being able to make a rigorous statistic, we learned that spiritual healing, pilgrimage to places of prayer and fasts, were used more than procedures involving human manipulation or increased financial costs.

A description of all these procedures and methods used as alternative treatments in systemic lupus is not subject to this article. In this article we bring attention to ethical issues, financial implications on complementary and alternative medicine with application in SLE. (Table 2)

Table 1. Use of complementary and alternative medical therapy in patients with SLE in England, Canada and USA. The total refers to all patients using at least one alternative therapy and numbers in brackets are the percentage (%) of patients in each category [2]

Technical / process	England (n = 211)	Canada (n = 229)	U.S. (n = 267)
Relax	45 (21.3%)	51 (22.3%)	71 (26.6%)
Massage and reflexology	40 (19%)	36 (15.7%)	52 (19.5%)
Natural plant extracts	32 (15.2%)	28 (12.2%)	28 (10.5%)
Diets	27 (12.8%)	26 (11.4%)	41 (15.4%)
Spiritual healing through prayer / meditation	14 (6.6%)	16 (7%)	39 (14.6%)
Weight loss pills	14(6.6%)	8(3.5%)	18(6.7%)
Homeopathy	13(6.2%)	14(6.1%)	6(2.2%)
Multivitamins	10(4.7%)	14(6.1%)	14(5.2%)
Support groups	10 (4.7%)	21 (9.2%)	29 (10.9%)
Acupuncture	8 (3.8%)	7 (3.1%)	3 (1.1%)
Imaging	7 (3.3%)	18 (7.9%)	26 (9.7%)
Healing energy (bioelectromagnetic)	6 (2.8%)	11 (4.8%)	6 (2.2%)
Folk remedies	4 (1.9%)	18 (7.9%)	10 (3.7%)
Chiropractic techniques	4 (1.9%)	15 (6.6%)	13 (4.9%)
Hypnosis	3 (1.4%)	3 (1.3%)	3 (1.1%)
Biofeedback	0 (0%)	8 (3.5%)	10 (3.7%)
(cognitive therapy, behavioural and stress reduction)			
Other	13 (6.2%)	10 (4.4%)	8 (3%)
Total	102 (48.3%)	116 (50.7%)	134 (50.2%)

Defining complementary and alternative medicine

National Centre for Complementary and Alternative Medicine (NCCAM) of the U.S. defined alternative and complementary medicine as: „a group of different systems, practices and medical products not currently considered part of conventional medicine. While scientific evidence exists regarding some therapies of alternative and complementary medicine, there are key questions, which must still be answered by well reasoned scientific evidence, whether the procedures are safe and are suitable for diseases or medical conditions for which they are used” [19]. The term “complementary” refers to those practices used together with conventional therapies, while the term „alternative” applies to practices used in place of conventional.

Even the term alternative and complementary medicine shows the difficulties of defining the concept itself, as well as the difficulties to accept the terminology, procedures and its efficiency.

Patients who use complementary and alternative medicine are not generally supervised by the practitioner in applying these methods, although

especially these patients require close supervision and careful guidance the most [15]. Complementary and alternative medicine includes therapies whose effectiveness has been proven, together with procedures without scientific basis or insufficiently documented [12].

Complementary and alternative medicine areas include: 1. Alternative medical systems: homeopathy, naturopathy and cultural-based systems such as traditional Chinese medicine and Indian Ayurvedic; 2. ”Mind-body” interventions: yoga, meditation, prayer; 3. Systems based on biological therapies such as diet and various plants / herbs; 4. Handling body therapies such as massage, Chiropractic treatments; 5. Energy treatments such as Reiki, Qigong, magnets, quartz crystals [19].

Doctor - patient relation on complementary and alternative medicine

Although complementary and alternative medicine is used by patients, there is a gap of communication and mutual understanding between patients and practitioners. There are specific studies that show that communication regarding complementary and alternative medicine is poor or absent. The most common reasons given by patients are: 1. The patient does not consider important to inform his doctor

Table 2. Classification of complementary and alternative modalities and therapies in SLE [26]

Fields of Practice	Alternative modalities therapies	Examples
Diet, nutrition and lifestyle changes	Studies on the effect of food, vitamins and minerals in acute and chronic disease, with particular attention to health maintenance and disease prevention	Essential fatty acids Vitamins A and E Selenium Green tea Food restrictions
Herbal medicine	Natural products derived from European tradition, Asian and American	Uncaria tomentosa Uncaria guianensis
Movement therapy	Biofeedback, relaxation, meditation, hypnosis, psychotherapy, prayer, dance, music, yoga	Meditation Hypnosis Cognitive behaviour therapy Physical exercise Aromatherapy
Alternative methods of medicine	Oriental Medicine	Acupuncture Moxibustion
Manual healing methods	Osteopathy, massage, chiropractic	Massage Reflexology
Bioelectromagnetic	Explore living organisms interact with electromagnetic fields	Electro-magnetic field devices
Pharmacological and biological interventions	Medicines and vaccines that have not yet entered into clinical practice	Diet

about alternative and complementary procedures (61% of answers); 2. The doctor did not ask the patient if he uses / wants to use alternative and complementary medicine practices 3. „It is not doctor's business"; 4. The doctor could not understand why I use alternative and complementary medicine" [7,13]. 14% of patients admitted openly that the doctor would disapprove and would discourage the use of alternative and complementary medicine [7].

Other studies support the perception of patients that doctors would have no information on complementary and alternative medicine, such as plants (44% of patients in one study) [4].

In addition, over half of patients in the same study [4], although they knew that the plants proved to be ineffective, continued to use them, claiming that they feel the health benefits using food supplements or plant. This seems to be more than the therapeutic placebo effect and helps supplementing the diet.

Complementary and alternative medicine evolution towards integrative medicine

Integrative Medicine differs fundamentally from complementary and alternative medicine being a combination of safe medical procedures and high quality scientific therapies with complementary and alternative therapies [21].

Integrative Medicine is a term recently promoted by complementary and alternative medicine supporters. NCCAM defines integrative medicine as a combination of well defined conventional medical therapies, and efficient and safe alternative and complementary medicine methods [19]. Applied to lupus disease, we can mention the use of complementary therapies (massage, acupuncture, herbal supplements) with conventional therapy (corticosteroids, chemotherapy, gene therapy, biological). These combinations of therapies may be part of an open patient-physician relationship, as the application of these therapies can have a positive impact or on the contrary, negative on the mental state of the patient, throughout the disease. The integration of these therapies would require a collaborative patient-physician- alternative and complementary medicine provider relationship [22]. The specialist is the one who has to coordinate them altogether for the benefit of the patient. This encompasses the finding of a balance and of a way of approaching individual and medical problems of the patient. Where conventional therapies are combined with alternative /

complementary, the aim is to ensure an optimal patient wellness, covering, if possible, all patient needs. Assimilation of complementary and alternative medicine therapies involve recognition of complementary principles of treatment that are safe and beneficial to patient health. The physician should convey the message that these therapies are not curative and that complementary and alternative medicine is not an alternative to conventional therapies, when traditional medical treatment is effective and available for the patient. Proper use of all conventional and alternative therapies, along with empathic physician-patient relationship, gives the premise that the overall needs of the patient are provided [16]. These practices can be integrated into a professional model of healthcare and regular medical responsibilities, including malpractice [14]. Limits of conventional medicine and complementary and alternative medicine are still flexible and still remain to be defined.

Doctors who want to practice integrative medicine must ensure that: 1. They are well qualified to practice alternative medicine; 2. Alternative therapy is safe; 3. They have taken measures to ensure that alternative treatment modality is not contraindicated in conventional medicine; 4. They are aware of the side effects of alternative practices, and studied relevant literature; 5. They respect medical ethics code [25].

Informed consent

Informed consent is the key to good practice.

Informed consent involves three components: 1. Truth about the patient's condition (providing the patient with relevant information on diagnosis and treatment and making sure that the patient understands them); 2. Patient's ability of decision (refer to the patient's ability to understand data provided to him, the selection or rejection of a certain intervention, communicate consent, acceptance and appreciation of the consequences of proposed treatment); 3. Voluntary (independent decision relating to the patient's right to freely decide on his treatment, without constraint or manipulation) [18]. More synthetically, these issues could be tackled by applying five principles: 1. Free choice of the patient on treatment followed; 2. Patient should be informed by the physician / supplier of medical practice regarding treatment or medical procedures; 3. Patient's ability to understand the information received; 4. Clear information for patients; 5. Patient's ability to decide

[18]. Informed consent can be offered explicitly (orally or in writing) and hence [5].

Input from patients who use alternative and complementary medicine (patients who are in our clinic records) revealed that these patients have resorted to such practices and procedures within complementary and alternative medicine centres and did not sign any form. They just simply spoke about their suffering and they were recommended complementary and alternative medical procedures. None said that written consent was required. They were asked only whether they had already followed procedures that they had been sent to and where they had learned about these procedures. Patients said that only a small part of complementary and alternative medicine providers were interested to read the tickets out of hospital, medical letters or official medical documents certifying basic medical condition.

The tone adopted by complementary and alternative medicine suppliers was to reassure the patient, that nothing bad can happen, that just everything is natural, or harmless. Patient's trust in accepting these natural methods is very high. Moreover, the patient was the one who tried to convince the specialist that he had been diagnosed with the disease (through expensive medical and scientific investigations covered by health insurance) with benefits and lack of risks of complementary and alternative medicine practices. In many cases, the doctor could not find the component of the natural cure. Undoubtedly that cure had some benefits for the patient, but until proven otherwise, specialist has the right to be cautious [24]. The patient is generally confident when alternative and complementary medicine centre/office is visited by many people, and he tells his doctor that there were many people there and every one was happy with the prescriptions or the methods offered by alternative and complementary medicine provider. This approach is however unethical, involving a violation of ethical principles.

It is true that there are many physicians with expertise in homeopathy, applying the principle of "primum non nocere" but we have not met an interdisciplinary consultation request from them yet.

We cannot neglect the fact that the centre/office of complementary and alternative medicine did not diagnose lupus disease, despite that all complementary and alternative procedures are based on this diagnosis!

Ethical implications of complementary and alternative medicine

The use of alternative medical methods is unclear and represents an ethical dilemma. Ethical issues arise when the patient has unrealistic expectations or when alternative methods for conducting the alternative procedures are inappropriate [17].

Patient informed consent requires knowledge concerning both the possible adverse effects and toxicity and setting of clear therapeutic objectives proposed by alternative and complementary medicine. Patient's disappointments about alternative procedures are the real problem, but not necessarily unethical [17].

Equally true is that the patient may be disappointed with conventional therapies and that is why he is using the complementary methods or seek harmony by using both [3].

Patients are seeking other methods of healing clearly different from the conventional ones, even if these methods are questionable, disapproved or less effective.

What urges them to use these alternatives? The reasons may be many: 1. Pragmatic pursuit of better health status; 2. Preference for self-medication; 3. Distrust and disappointment in conventional therapies; 4. Divergence of opinion on disease or its evolution; 5. Trying to avoid/minimize the adverse effects of conventional medication; 6. A certain resignation and return to the spiritual side, a healing of the body by faith [23].

Financial implications of complementary and alternative medicine in SLE

For accurate analysis, large-scale studies [2] conducted in countries with well developed health-care system (England, Canada, United States) took into account both the direct and indirect costs.

Annual direct costs per patient using complementary and alternative medicine have shown that they are higher in patients who used, than in those who have not used the complementary and alternative medicine. The real cost benefits of using complementary and alternative medicine to treat systemic lupus erythematosus is higher in patients who use complementary and alternative medicine, even if health status is not improved compared to those who do not use it.

Clinical examination and various indicators of

personal well-being, regarded by patients were considered as relevant. In principle, it showed that any medical therapy that is clinically ineffective is unprofitable. The same study [2] showed that those alternative and complementary medicine users pay on average four times more specialist doctor visits than the non users. The family doctor was less requested by the users of alternative therapies, but the specialist doctor appointments were common.

The person who certified if the patient's health status using complementary and alternative medicine is better/worse was the specialist rather than the person who performed the alternative procedure! These studies [26] showed that although there are many non-conventional procedures and medical techniques, the persons who provide these for patients with SLE were not able to appreciate the real evolution of the disease or the risk. When the patient demanded to know whether the disease has improved or worsened, complementary and alternative medicine providers guide them to conventional medicine! Therefore the number of specialist visits was higher than that of complementary and alternative medicine provider visits, which again shows that these people spent more money and time than non-users, just because they use the double medical counting, conventional and alternative.

CONCLUSION

Doctors should ask their patients about self-medication or drugs/complementary and alternative techniques and encourage them to seek expert advice if there is doubt about the complementary and alternative medicine [11]. Gradually, it could go toward integrative medicine. The physician should instruct patients to seek licensed providers such as those for massage or acupuncture. Patients who want to use herbal remedies should know their exact composition and preparation from reliable sources [1]. Patient autonomy is essential [13] and the doctor should be able to advise patients about all options - conventional medical methods or complementary and alternative ones, because the patient has the right to know their benefits and risks.

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