

Evidence Report

Chapter 1. Introduction

Purpose

Complementary and alternative medicine (CAM) is commonly tried by patients with cancer. However, evidence is lacking for the effectiveness of most CAM therapies for cancer. One of the challenges confronting the Cancer Advisory Panel on Complementary and Alternative Medicine (CAPCAM) is to identify promising CAM therapies that may have received insufficient consideration by the cancer research community. These include therapies that have not been subjected to a controlled trial, as well as those that have been subjected to a controlled trial but whose outcomes have either never been published or have been published only as a case study or a case series. As part of its mission, CAPCAM, in conjunction with the Office of Cancer Complementary and Alternative Medicine (OCCAM), provides a forum for practitioners to report on the outcomes of therapies and provides a resource for them to obtain technical assistance in developing best-case series studies. In best-case series studies, a provider chooses those cases that represent the best outcomes for a given form of treatment, and these cases are then reviewed by experts to determine if the evidence is sufficient to warrant further study. To assist in this effort, NCI has developed a set of criteria for creating a best-case series. For CAM therapies, CAPCAM has been charged with facilitating more rigorous investigation of therapies that show sufficient promise. Despite CAPCAM's efforts to publicize this forum, few case series have yet been presented to the panel. It was therefore decided that a proactive approach might be more productive in generating best-case series. Thus, the purpose of this study was to use the resources of the Southern California Evidence-Based Practice Center (SCEPC) to create best-case series for therapies identified by the National Center for Complementary and Alternative Medicine (NCCAM).

Our purpose was to abstract patient records of a selected CAM provider and then to create a best-case series by evaluating each of the cases against a set of defined criteria. In addition, we report on the method, effort, and resources required to complete a best-case series and the practicality and feasibility of this method.

Specific Aims

The project had four specific aims, established by the National Center for Complementary and Alternative Medicine (NCCAM) and the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM):

1. To create best-case series for two CAM providers treating cancer patients.
2. To determine if there is sufficient evidence for recommending further study of these therapies.
3. To recommend the type of future study, if any.
4. To describe the technical challenges and difficulties in creating this kind of best-case series.

A Brief Review of the Use of CAM for Cancer Treatment

In the United States, the general public has increasingly sought out CAM therapies; about 40 percent of patients recently reported using some form of CAM (Eisenberg, Davis, Ettner, et al., 1998; Astin, 1998). Between 1990 and 1997, the prevalence of CAM use in the United States increased from 33.8 percent to 42.1 percent, and the number of visits to CAM practitioners increased from 427 million to 629 million visits per year (Eisenberg, Davis, Ettner, et al., 1998).

Among cancer patients, increasing interest in CAM has also been reported. Recent surveys of cancer patients in the United States estimated that 65 to 83 percent have tried some form of CAM therapy for their cancer (Richardson, Sanders, Palmer, et al., 2000; Boon, Stewart, Kennard, et al., 2000; Sparber, Bauer, Curt, et al., 2000). These figures exceed previously reported estimates (Burstein, Gelber, Guadagnoli, et al., 1999; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984; Beckrow, Wyatt, Given, et al., 1999; Faw, Ballentine, Ballentine, et al., 1978; Adler and Foskett, 1999). A systematic review of 26 surveys across 13 countries concluded that the mean prevalence of CAM use by cancer patients in these countries was 31.4 percent (range, 7 percent to 64 percent) (Ernst and Cassileth, 1998).

The typical cancer patient using CAM in the United States is reported to be Caucasian, more affluent and better educated than average, 30 to 50 years of age, and suffering from advanced disease (Richardson, Sanders, Palmer, et al., 2000; Paltiel, Avitzour, Peretz, et al., 2001; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984; Cassileth, 1986). National surveys of cancer patients found that dietary supplements (including vitamins, herbs, and substances that affect metabolism), electronic treatments, and mind/body approaches were the most popular (Richardson, Sanders, Palmer, et al., 2000; Lerner and Kennedy, 1992; Cassileth, Lusk, Strouse, et al., 1984). Studies report that most cancer patients (60 – 80 percent) who engage in CAM practices are simultaneously receiving conventional treatments (Cassileth, Lusk, Strouse, et al., 1984; Richardson, Sanders, Palmer, et al., 2000; McGinnis, 1991; Lerner and Kennedy, 1992; Bourgeault, 1996).

The growth in use of CAM in the United States is also supported by figures on expenditures for these treatments: out-of-pocket expenditures for 1997 were estimated at \$34.4 billion (Eisenberg, Davis, Ettner, et al., 1998), compared with a 1984 estimate of \$4 billion spent annually on unproven cancer treatments (U.S. House Select Committee on Aging, 1984). A recent survey of women with breast cancer found that approximately \$45 was spent monthly on CAM products and \$55 was spent monthly on CAM practitioners (Boon, Stewart, Kennard, et al., 2000).

A variety of factors have prompted the increasing utilization of CAM among cancer patients. CAM use has been strongly associated with the belief among these patients that conventional therapy did not meet their needs (Paltiel, Avitzour, Peretz, et al., 2001). Patients have also reported concerns about the toxicity of conventional treatments, viewing CAM therapies as natural and nontoxic (Paltiel, Avitzour, Peretz, et al., 2001; Astin, 1998; Campion, 1993; Lerner and Kennedy, 1992). Despite this finding, another survey showed that approximately 60 percent of cancer patients who used CAM believed that conventional cancer treatments were more likely to cure their cancer than were CAM therapies (Boon, Stewart, Kennard, et al., 2000), and most patients used conventional medicine concurrently (Cassileth, Lusk, Strouse, et al., 1984; Richardson, Sanders, Palmer, et al., 2000; McGinnis, 1991; Lerner and Kennedy, 1992; Bourgeault, 1996). In a recent survey of cancer patients, the most common reason patients cited for using CAM was to boost their immune system (63 percent) (Boon, Stewart, Kennard, et al.,

2000). Patients who use CAM also report feeling more hopeful (Richardson, Sanders, Palmer, et al., 2000). Although cancer patients often turn to CAM with the hope of improving their quality of life (Paltiel, Avitzour, Peretz, et al., 2001), some evidence suggests that users of CAM do not achieve that goal (Paltiel, Avitzour, Peretz, et al., 2001; Burstein, Gelber, Guadagnoli, 1999; Cassileth, Lusk, Guerry, et al., 1991). However, cancer patients who utilize CAM do report feeling more personal control over their situation (Richardson, Sanders, Palmer, et al., 2000), and patients assert that CAM use provides a feeling of control over their lives (Boon, Stewart, Kennard, et al., 2000).

Many patients who use CAM for any illness do not reveal that use to their physicians (Eisenberg, Davis, Ettner, et al., 1998; Adler and Foskett, 1999; Begbie, Kerestes, Bell, 1996). In a recent study of 1,221 breast cancer patients, fewer than half informed their physician of their CAM use (Boon, Stewart, Kennard, et al., 2000). Reasons for not disclosing CAM use include anticipating physician negative response, perceiving that CAM therapies are irrelevant to their conventional medical care, and believing that their physician is unable to contribute useful information about CAM (Adler and Foskett, 1999; Begbie, Kerestes, Bell, 1996). Some CAM users have expressed feeling abandoned by their physicians, and others admit having little faith in them (Cassileth, Lusk, Strouse, et al., 1984). Some patients reported a desire for CAM to be part of conventional cancer treatment (Coss, McGrath, Caggiano, 1998). Other reports indicate that cancer patients want more information about CAM from their medical doctors (Richardson, Ramirez, Nanney, et al., 1999).

Oncologists are becoming increasingly aware that patients use CAM, yet few oncologists discuss these therapies with their patients (Richardson, Ramirez, Nanney, et al., 1999; Neogi and Oza, 1998). This finding may stem from a number of factors. Research shows that the established medical community has been seeking evaluation of CAM therapies through traditional clinical trials (Angell and Kassirer, 1998, Levin, Glass, Kushi, et al., 1997). Without the evidence of efficacy such trials may provide, practitioners may be reluctant to broach the subject. Some physicians have expressed concerns about serious health risks associated with CAM and cite poor outcomes for patients who reject proven conventional cancer treatment in favor of CAM approaches (DiPaola, Zhang, Lambert, et al., 1998; Coppes, Anderson, Egeler, et al., 1998). However, since most cancer patients using CAM are receiving conventional treatments at the same time, it may be critical for oncologists to become more informed about use of CAM, because the effects of those conventional therapies may be influenced by concurrent CAM therapies.