

Research article

Health food store recommendations: implications for breast cancer patients

Edward Mills^{1,2}, Edzard Ernst³, Rana Singh¹, Cory Ross¹ and Kumanan Wilson⁴

¹Department of Research, Canadian College of Naturopathic Medicine, North York, Ontario, Canada

²University of Oxford, Oxford, UK

³Department of Complementary Medicine, University of Exeter, Exeter, UK

⁴Department of Medicine, University of Toronto, Toronto, Ontario, Canada

Corresponding author: Edward Mills (e-mail: emills@ccnm.edu)

Received: 29 Apr 2003 Revisions requested: 17 Jun 2003 Revisions received: 20 Jun 2003 Accepted: 8 Jul 2003 Published: 7 Aug 2003

Breast Cancer Res 2003, 5:R170-R174 (DOI 10.1186/bcr636)

© 2003 Mills et al., licensee BioMed Central Ltd (Print ISSN 1465-5411; Online ISSN 1465-542X). This is an Open Access article: verbatim copying and redistribution of this article are permitted in all media for any purpose, provided this notice is preserved along with the article's original URL.

See related Commentary: <http://breast-cancer-research.com/content/5/6/300>

Abstract

Background: Many breast cancer patients use complementary and alternative medicine (CAM). We aimed to determine what advice health food store employees present to individuals seeking treatment options for breast cancer.

Methods: Eight data gatherers asked employees of all retail health food stores in a major Canadian city, what they recommended for a patient with breast cancer. The data gatherers inquired about product safety, potential drug interactions, costs and efficacy. They also enquired about employee training related to the products.

Results: Thirty-four stores were examined. A total of 33 different products were recommended, none of which are supported by sufficient evidence of efficacy. The average cost of the products they recommended was \$58.09 (CAD) (minimum \$5.28, median \$32.99, maximum \$600) per month. Twenty-three employees (68%) did not ask whether the patient took prescription medications. Fifteen employees (44%)

recommended visiting a healthcare professional (naturopaths (9), physicians (5), nutritionists (1)). Three employees (8.8%) discussed potential adverse effects of the products. Eight employees (23.5%) discussed the potential for drug interactions. Two employees (5.9%) suggested a possible cure with the products and one employee (2.9%) suggested discontinuing Tamoxifen. Four employees (11.8%) recommended lifestyle changes and three employees (8.8%) recommended books for further reading on the products.

Conclusion: This study draws attention to the heterogeneity of advice provided by natural health food stores to individuals seeking treatments for breast cancer, and the safety and cost implications of some of the products recommended. Physicians should enquire carefully about the use of natural health food products by patients with breast cancer. Regulators need to consider regulations to protect vulnerable patients from incurring significant costs in their purchasing of natural health food products lacking evidence of benefit and of questionable safety.

Keywords: breast cancer, complementary and alternative medicine, consumer product safety/standards, natural health products, risk

Introduction

The use of natural health products (NHPs) is increasing [1]. Reasons for the increased public use of NHPs vary from individual involvement in health decisions to distrust in medical organisations [2,3]. With increasing research in complementary and alternative medicine (CAM) comes an increase in public health awareness of social and safety concerns [4,5]. This is particularly true in terminal diseases, in which patients may seek out marketed cures and treatments based on folklore [6].

Breast cancer patients might be particularly vulnerable to the use of NHPs because women are large consumers of them [7]. Several public health concerns arise about the use of NHPs. The potential for drug interactions with chemotherapy might reduce or exacerbate the effectiveness of prescription drugs [8,9]. The potential for harm increases when large doses of products are used chronically and when multiple NHPs are used simultaneously [10]. Additionally, patients might delay or discontinue orthodox treatment at the advice of a CAM practitioner

because the discussion of CAM use with physicians is limited [11]. NHPs and CAM usage might also prove to be an expensive treatment option for breast cancer patients.

Methods

We conducted a field study to determine what health food store employees recommended to individuals seeking treatments for breast cancer. We focused on identifying what products were recommended and the cost of these products. We also examined the education of these employees and their knowledge of drug interactions and adverse effects.

We identified all health food stores in a major Canadian city through the local business pages and yellow pages of telephone directories. Further stores were located through word of mouth. In total, 34 stores met our inclusion criteria of being a retail NHP sales outlet. We specifically excluded Asian herbal stores because of language difficulties.

This study received ethical approval by the Canadian College of Naturopathic Medicine Ethical Review Board and approved with reference to Office for Protection from Research Risks Regulations under section 46.116(d).

Procedure

Eight research assistants (six female, two male) of various ages and appearances were recruited and trained to portray customers ('participants-as-observers'). The participants entered individually into assigned stores; they had been informed to browse in the store until approached by an employee. At this time the participants would declare that their mother has breast cancer. The participants disclosed information on their mother's condition, use of chemotherapy (Tamoxifen) and physician visits, only if asked. The participants would then ask what the employee recommended for this condition. All participants followed a structured, memorized, pretested questionnaire that asked about product usage, dosage, cost, employee education and product safety or potential for drug interactions. No further information about the condition was divulged.

The data gatherers recorded which products were recommended by natural health food store employees, along with the recommended dose and price per product as well as price per month. Data gatherers inquired about safety issues and drug interactions with each recommended product. Additionally, they inquired about where the employee had obtained information on the recommended products. They also noted whether the employees referred them on to CAM specialists or recommended that they consult further with a physician. Additional suggestions by the employees were recorded.

Full notes on the encounters were recorded immediately after leaving the store. All data were transcribed according

to the research questions. The research assistants specifically recorded the various products recommended, including their costs and dosage. We summarised the data with descriptive statistics. We have disclosed the results of our audit to each health food store.

Results

Of the 34 stores that met our inclusion criteria, 27 recommended NHPs; a total of 33 different products were recommended (see Table 1). The mean cost of product per month was \$58.09 (CAD) (minimum \$5.28, median \$32.99, maximum \$600). Twenty-three employees (68%) did not ask whether the patient took prescription medications. Fifteen (44%) employees recommended visiting a healthcare professional; these included: naturopaths (9), physicians (5) and nutritionists (1). Health food store employees relied on a variety of sources of information. Twelve employees (35%) received their information from books, 5 (15%) from a supplier, 3 (9%) had a formal education in CAM, 2 (6%) had in-store training and 12 (35%) did not disclose their sources of information.

Potential adverse effects of recommended products were discussed by three employees (8.8%). The potential for drug interactions was discussed by eight employees (23.5%). Two (5.9%) suggested that the products might offer the potential for cure. One employee (2.9%) suggested discontinuing Tamoxifen. Four employees (11.8%) suggested lifestyle changes and three (8.8%) recommended books for further reading on the products.

Discussion

Several important messages emerge from this analysis of advice provided to breast cancer patients in health food stores. These stores are recommending a variety of products, none of which is supported by evidence of benefit. In many instances the stores do not discuss the potential for adverse effects of these products or the possibility of drug interactions. In addition, in at least one instance in this study, an employee recommended that a conventional medical therapy (Tamoxifen) be discontinued. The findings of our study are consistent with previous reports on the practice of natural health food stores [12–19]. Other studies examining advice provided about CAM on the Internet, another readily available source, find that this advice can also be misleading and could seriously harm consumers [20].

All these findings highlight the importance of physicians' awareness of the possibility that their breast cancer patients are seeking advice and treatment from alternative medical sources such as natural health food stores. Patients might not disclose this information to their traditional health care providers. However, the advice they seek could have a negative effect on their response to medical treatment and be the source of unexplained reac-

Table 1**Frequency, dosage and monthly cost of products recommended by 34 natural health food store employees**

Product name	No. of stores providing recommendation	Cost for a monthly supply (\$CAD)	Recommended daily usage	Type of product
Essiac	10	57.50 ± 18.07	1 cup	Herbal tea combination
Floressence	9	46.47 ± 18.50	1 cup	Herbal tea combination
Coenzyme Q ₁₀	4	34.24 ± 6.12	100 mg/day	Antioxidant
Ip6 (Inositol hexaphosphate)	4	60	12 caps/day	Antioxidant
Moducare	4	45.99 ± 18.38	As directed on bottle	Sterols/sterolins
MGN	3	433.33 ± 152.75	12 caps/day	Mushroom extract
Pau D'arco	3	20	As directed on bottle	Herb
Multivitamin	3	6.74 ± 3.17	1 cap/day	Vitamin
Ester-C	2	5.75	1 cap/day	Vitamin
Pycnogenol	2	33.99	1 cap/day	Antioxidant
Grape seed extract	2	43.50	1–3 caps/day	Seed extract
Vitamin C	2	5	5000 mg/day	Vitamin
Astragalus	2	14.99	As directed on bottle	Herb
Greens+	1	10.59	1 cup/day	Herbal combination
Breast Health Combination	1	126.00	6–12 caps/day	Herbal combination
Beta-carotene	1	2.00	10,000 mg/day	Antioxidant
Shark Cartilage	1	104.00	8 caps/day	Cartilage of shark
Cat's claw	1	24.89	As directed on bottle	Herb
RM-10	1	210.00	4–6 caps/day	Mushroom and herbal combination
Oregano oil	1	5.28	2 g/day	Herbal extract
Proanthocyanidin	1	24.99	1–2 caps/day	Antioxidant
Cancer-go	1	69.00	2 caps t.i.d.	Herbal combination
Collagen slim	1	69.00	15 ml q.i.d.	Herbal combination
Mega B	1	9.66	1 cap/day	Vitamin
Oncolyn	1	115.50	3 caps/day	Botanical extract
Venus fly trap	1	N/A	N/A	Herb
Garlic	1	5.00	2–3 caps/day	Botanical
Vitamin A	1	6.00	50,000 mg/day	Vitamin
Vitamin E	1	6.00	400 IU/day	Vitamin
Mushroom extract	1	24.99	As directed on bottle	Mushroom extract
Maitake mushroom	1	75.00	As directed on bottle	Mushroom extract

N/A, not applicable. ±, where shown, are standard deviations.

tions [21]. This study also highlights the vulnerability of patients with breast cancer to potentially misleading information from health food employees. Advice presented by health food employees was authoritative and could be misconstrued by patients as evidence-based, particularly when books are consulted or literature is provided on the products. This was illustrated by the two employees who

suggested that their recommended products could cure the patient of cancer. It is important to note that, with the exception of small trials examining the efficacy of coenzyme Q₁₀ [22,23] and vitamin C [24], there is no evidence from clinical trials to support the use of the recommended products by patients with breast cancer [25–27]. The distrust of conventional medical treatments by individuals

who seek CAM might also be reinforced by dispensers of CAM [28,29]. This was illustrated in our study by the single employee who suggested that the patient discontinue her chemotherapeutic drug (Tamoxifen) because it was 'poisonous'.

Many patients are attracted to NHP use because it is natural, which is suggestive that this is less toxic than prescription medication. Recent reports on adverse effects of NHPs identify that several products once considered safe might be harmful [5,10,30]. These risks are increased when the products are used in large doses or chronically. The heterogeneity of information about dosages increases the likelihood for misuse. Recommendations such as 'immune-boosting' and 'cleansing' can be misleading to patients as to the aetiology of their disease. The education of employees about NHPs was also variable, with several employees indicating that formal education was unnecessary. Others considered that working in the health food environment for several years was experience enough.

Breast cancer patients are susceptible not only to adverse health effects owing to advice and treatments provided by natural health food stores but also to incurring significant costs from purchasing natural health food products. The monthly cost of products ranged from \$5.28 (CAD) to \$600 (mean \$58.09). The products that were most expensive, such as the herbal teas and mushroom extracts, rely on insufficient or questionable research and evidence based on folklore.

Our study has some important limitations. The consistency of data might be limited by approaching only one employee at each store; however, we believe that this is the closest to a real-life situation that can be replicated for a study. It is difficult to measure employees' knowledge of cancer through a brief encounter, and the quality of informative literature varies substantially. It is possible that the responses from employees varied according to each data gatherer. It might be that gatherers presenting themselves as breast cancer patients would have elicited different recommendations. Although this study was conducted in one city in Canada, we believe that the results could be widely transferable, because several of the stores were national chains. All research assistants were trained and had followed a structured questionnaire; they had completed the questionnaire immediately after leaving the store, to avoid inter-observer variation in collection and recall.

A potential concern to the conduct of this study relates to its ethical implications. In essence, this was an investigation on human subjects without consent. Informed consent is the cornerstone of research ethics [31]. However, there are situations in which informed consent is not a necessary precondition. This study might be such an exception: first, there is little conceivable harm in not obtaining

consent in this particular setting; second, with informed consent the investigation would not have been possible; third, our aim was to investigate an area of potential harm to consumers, which can be viewed as overriding concerns about the potential of harm to shop assistants in this setting. We therefore feel that, on balance, the study was ethically justifiable, a judgement shared by the review board that approved it.

Conclusion

Governing bodies should consider health food stores as commonly used, yet unregulated, sections of the health care system. Educational interventions aimed at employees might help to facilitate cooperation rather than stimulate antagonism [12]. Education about safety and drug interactions as well as regulations about the extent of advice might best help to coordinate a move towards a safer and more evidence-based health food business. Concerned physicians and regulating bodies should be aware of the variety of advice that breast cancer patients receive about NHP use. Discussions about efficacy, safety and cost should be initiated to be consistent with the health beliefs and expectations of the patients and providers.

Competing interests

None declared.

Acknowledgements

We thank Cinzia Genuardi, Laura Imola, Orest Szczerko, Andrea Kenny, Stella Nonis, Tina Konstantinow, Camille Nghiem-Phu and Sarah Dash-Arbuckle for participation in data gathering.

References

- Berger E: *Berger Population Health Monitor*. Toronto: Hay Associates; 2002.
- Alferi SM, Antoni MH, Ironson G, Kilbourn KM, Carver CS: **Factors predicting the use of complementary therapies in a multi-ethnic sample of early-stage breast cancer patients.** *J Am Med Womens Assoc* 2001, **56**:120-123.
- Jonas WB: **Alternative medicine - learning from the past, examining the present, advancing to the future.** *JAMA* 1998, **280**:1616-1618.
- US Food and Drug Administration: **Risk of drug interactions with St. John's Wort.** *JAMA* 2000, **283**:1679.
- Cassileth BR: **Evaluating complementary and alternative therapies for cancer patients.** *CA Cancer J Clin* 1999, **49**:362-375.
- Ernst E, Cassileth BR: **The prevalence of complementary/alternative medicine in cancer: a systematic review.** *Cancer* 1998, **83**:777-782.
- Morris KT, Johnson N, Homer L, Walts D: **A comparison of complementary therapy use between breast cancer patients and patients with other primary tumor sites.** *Am J Surg* 2000, **179**:407-411.
- Mathijssen RH, Verweij J, de Bruijn P, Loos WJ, Sparreboom A: **Effects of St. John's wort on irinotecan metabolism.** *J Natl Cancer Inst* 2002, **94**:1247-1249.
- Spaulding-Albright N: **A review of some herbal and related products commonly used in cancer patients.** *J Am Diet Assoc* 1997, **97**:S208-S215.
- Izzo AA, Ernst E: **Interactions between herbal medicines and prescribed drugs: a systematic review.** *Drugs* 2001, **61**:2163-2175.
- Adler SR, Fosket JR: **Disclosing complementary and alternative medicine use in the medical encounter: a qualitative study in women with breast cancer.** *J Fam Pract* 1999, **48**:453-458.

12. Gotay CC, Dumitriu D: **Health food store recommendations for breast cancer patients.** *Arch Fam Med* 2000, **9**:692-699.
13. Stoffer S, Szpunar W, Coleman B, Mallos P: **Advice from some health food stores.** *JAMA* 1980, **244**:2044-2046.
14. Aigner C: **Advice in healthfood stores.** *Nutr Forum* 1998, **5**:1-4.
15. Haidet JM: **Poor advice plus doubletalk: a probe of 'health food' stores in Central Ohio.** *Nutr Forum* 1992, **9**:6-9.
16. US Food and Drug Administration: *Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace.* Rockville, Maryland: Food and Drug Administration; 1993.
17. Mills EJ, Singh R, Bast L, Kiani P, Hart J, Majlesi A, Kawasaki M, Wilson K: **Emerging issues associated with HIV patients seeking advice from Health Food Stores.** In *International Scientific Conference on Complementary, Alternative & Integrative Medicine Research: April 13, 2002; Harvard Medical School, Boston.* *Can J Pub Health* 2003, in press.
18. Mills EJ, Singh R, Ross CP, Ernst E, Ray JG: **Impact of Federal Safety Advisories of health food store advice.** *CMAJ* 2003, in press.
19. Phillips LG, Nichols MH, King WD: **Herbs and HIV: the health food industry's answer.** *South Med J* 1995, **88**:911-913.
20. Ernst E, Schmidt K: **Health risks over the Internet: advice offered by 'medical herbalists' to a pregnant woman.** *Wien Med Wochenschr* 2002, **152**:190-192.
21. Geyer C, Hammond L, Johnson T, Smetzer L, Coyle J, Drenkler R, Von Hoff D, De Jager R, Rowinsky E: **Dose-schedule optimization the hexacyclic camptothecin (CPT) analog dx-8951f: a phase I and pharmacokinetic study with escalation of both treatment duration and dose [meeting abstract].** *Proc Ann Meet Am Soc Clin Oncol* 1999, A813.
22. Lockwood K, Moesgaard S, Folkers K: **Partial and complete regression of breast cancer in patients in relation to dosage of coenzyme Q10.** *Biochem Biophys Res Commun* 1994, **199**: 1504-1508.
23. Lockwood K, Moesgaard S, Yamamoto T, Folkers K: **Progress on therapy of breast cancer with vitamin Q10 and the regression of metastases.** *Biochem Biophys Res Commun* 1995, **212**:172-177.
24. Babu JR, Sundravel S, Arumugam G, Renuka R, Deepa N, Sachdanandam P: **Salubrious effect of vitamin C and vitamin E on tamoxifen-treated women in breast cancer with reference to plasma lipid and lipoprotein levels.** *Cancer Lett* 2000, **151**:1-5.
25. Kaegi E: **Unconventional therapies for cancer: 1. Essiac. The Task Force on Alternative Therapies of the Canadian Breast Cancer Research Initiative.** *CMAJ* 1998, **158**:897-902.
26. Jain M, Miller AB: **Tumor characteristics and survival of breast cancer patients in relation to premorbid diet and body size.** *Breast Cancer Res Treat* 1997, **42**:43-55.
27. Miller DR, Anderson GT, Stark JJ, Granick JL, Richardson D: **Phase I/II trial of the safety and efficacy of shark cartilage in the treatment of advanced cancer.** *J Clin Oncol* 1998, **16**: 3649-3655.
28. Passalacqua R, Campione F, Caminiti C, Salvagni S, Barilli A, Bella M, Barni S, Barsanti G, Caffo O, Carlini P, Cinquemani G, Di Costanzo F, Giustini L, Labianca R, Mazzei A, Olmeo N, Paccagnella A, Toscano L, Cocconi G: **Patients' opinions, feelings, and attitudes after a campaign to promote the Di Bella therapy.** *Lancet* 1999, **353**:1310-1314.
29. Montbriand MJ: **Abandoning biomedicine for alternate therapies: oncology patients' stories.** *Cancer Nurs* 1998, **21**:36-45.
30. US Food and Drug Administration: *Letter to Health Care Professionals FDA Issues Consumer Advisory That Kava Products May be Associated with Severe Liver Injury.* Rockville, Maryland: US Food and Drug Administration, Centre for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements; 2002.
31. Ernst E, Cohen MH: **Informed consent in complementary and alternative medicine.** *Arch Intern Med* 2001, **161**:2288-2292.

Correspondence

Edward Mills, Department of Research, Canadian College of Naturopathic Medicine, 1255 Sheppard Avenue East, North York, Ontario, Canada M2K 1E2. Tel: 416 498 1255 ext. 324; fax: 416 498 1643; e-mail: emills@ccnm.edu