

COMPARISON OF VERBAL CLAIMS FOR NATURAL HEALTH PRODUCTS MADE BY HEALTH FOOD STORES STAFF VERSUS PHARMACISTS IN ONTARIO, CANADA

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ABSTRACT

Background

This study tested the hypothesis that while there are no written medical claims existing for many NHP, such claims are made verbally, giving a false impression that these are proven medical products.

Objective

To compare the number and type of verbal claims for NHP made by pharmacists to those made by health food stores personnel.

Methods

Randomly selected Canadian pharmacies selling NHP and health food stores were visited and the staff was asked to recommend natural health products for the treatment of hypertension.

Results

All health food stores (n=20) but only 4 out of 38 pharmacies (p< 0.001) recommended NHP for the treatment of hypertension. A majority of health food store staff (70%) stated that NHP are superior or equal to medicinal drugs in treating hypertension based on efficacy.

Conclusion

Unlike pharmacy practice, verbal claims are common practice in health food stores, despite the lack of either written claims and/or proof of efficacy for most of them. These may be a very effective approach given that 30-40% of North American adults are functionally illiterate. These verbal claims are often inappropriate and not evidence-based.

Keywords: *Natural health products, verbal claims, pharmacy, natural health stores, pharmacists, garlic, calcium, magnesium, hypertension.*

Medicinal drugs are regulated in virtually all countries of the world in terms of both the quality of their chemical production as well as the clinical indications. In order for a drug to be indicated for a certain condition it must be shown to be effective through clinical trials. This is the basis for the “claim” which is written in the product monograph and is approved by the regulatory authorities. In contrast, a large

proportion of the world’s population is using natural health products (NHP), such as herbal preparations. Typically, these have not been regulated as drugs but rather as foods, and as such are not allowed or supposed to present a “medical claim”.¹⁻⁵

In Canada, new regulations no longer regard NHP as foods, but rather in their own class, allowing three types of claims: therapeutic claims,

risk reduction claims, and structure-function claims.² Hence, amendments to regulations governing natural health products will allow advertising of these products to consumers for the prevention and treatment of disease. Yet, when reading the product inserts of most NHP, one will not find a medical claim of ameliorating or curing a medical condition for most of them.

The problem leading to the present study is a widespread human experience suggesting that, in many cases when no regulated written claims are made for NHP, such claims are made verbally. It has been estimated that up to 30% of individuals in North America are functionally illiterate, making verbal claims a potentially powerful and effective means to affect people's views and consumption.

The present study was aimed at determining whether verbal claims are made for NHP by pharmacists and by health food stores personnel, and to compare the rates of such claims made by these two groups.

To examine whether verbal claims are made for natural health products, we deliberately chose to target hypertension treatment. The World Health Organization (WHO) and the International Society of Hypertension (ISH) have targeted the treatment of mild or borderline hypertension as a critical health care issue.⁶ Garlic, magnesium (Mg), and calcium (Ca) are among the herbs and nutritional supplements that have been suggested to reduce high blood pressure.

METHODS

Two researchers approached a random list of retail pharmacies or health food stores which sell NHP in London and Toronto, Ontario, Canada. The pharmacist or sales person was asked a standard question for a recommendation of a natural health product for hypertension following the script in Appendix 1. The sales persons and pharmacists were not aware that their responses were recorded. To minimize suboptimal recall, the interviewer recorded the responses immediately after the interview was completed. The effectiveness of this method is proven by extensive written narratives of what was said. The responses of the sales person or pharmacist were recorded, along with other pertinent information (Appendix 1).

Subsequently, the responses by pharmacists were compared to those of health food store sales persons. Rates and nature of advice were compared between the pharmacies and health food stores by chi square or Student t-test, as appropriate. The study protocol was approved by The University of Western Ontario Health Sciences Research Ethics Board.

RESULTS

A total of 38 retail pharmacies selling complementary products (17 in Toronto, 21 in London ON) and 20 Health Food stores (8 in Toronto and 12 in London ON) were visited.

In all cases (100%), health food store personnel recommended NHP as effective treatment for hypertension, as compared to only 4 out of 38 (10.5%) pharmacies ($p < 0.001$). These 4 recommendations were made by pharmacists. In the majority of pharmacies, the pharmacists insisted that the patient in question must take his antihypertensive medication or risk his life. The pharmacists who made a recommendation for NHP recommended garlic (2), a B complex, BP Essentials, herbal diuretic formula (Buchu leaf, uva ursula, juniper berries, celery seeds, parsley root), calcium, and magnesium. Among health food stores, a variety of claims were made, with garlic being the most common recommendation (Table 1). In the health food stores, 13 staff claimed that NHP are as effective as medicinal drugs in treating hypertension, 1 claimed that they are superior, and 2 said that they were inferior. Three pharmacists stated that NHP are equivalent in efficacy to medicinal drugs, but two out of those three stated that it is only the case for mild hypertension.

In response to the question on potential unwanted effects, only heartburn due to garlic was mentioned in 4 health food stores. No pharmacist mentioned any unwanted effects of NHP. In response to the question what is known about particular health products that were recommended, 8 health food retailers quoted "literature", and 2 health food store sales persons and 1 pharmacist answered "tradition". When asked for materials to read, 15 health food retailers offered brochures, and 2 health food retailers and 1 pharmacist offered the Internet.

TABLE 1 Summary of Results

	Pharmacy staff (n=38)	Health food stores staff (n=20)
Gender	24 Male 13 Female 1 Not documented	3 Male 18 Female (total of 21 = 2 salesperson assisted customer at one store)
Qualifications	34 Pharmacists 1 Pharmacy assistant 3 Not documented	16 Salespersons 3 "Other" 2 Not documented
Number (%) that made claims	4 (10.5%)	20 (100%)
Number (%) that made recommendations	2 Garlic (5.3%) 1 B complex (2.6%) 1 Dr. J. Whitaker BP Essentials®(2.6%) 1 Diuretic Formula® (2.6%) 1 Calcium, Magnesium (2.6%)	11 Garlic (Kyolic)® (55%) 9 Omega oil (fish oils) (45%) 6 B complex (30%) 6 as per the book "Prescription for Nutritional Healing" Balch & Balch (30%) 5 CoQ10® (25%) 4 Hawthorn (20%) 4 Calcium (20%) 3 Magnesium (17%) 3 Dr. J. Whitaker BP Essentials®(17%) 2 Potassium (10%) 2 Strauss' Heart drops® (10%) 2 Mega-Vitamins (10%) 2 Cayenne (10%) <i>1 each for (5%):</i> Garlic/Cayenne mix Melatonin Rhodiola Olive leaf Vitamin C Calada (Otigh) Purple corn C3G Lipoguard Greens + multi BP formula (Ridgecrest)® Sea Salt® Wet grains
Is the natural/herbal product as effective as prescription medications? (out of those who made verbal claims)	Yes: 3* No: 0 No answer: 1 (* 2 out of those 3 said yes but for mild hypertension only)	Yes: 13 Better: 1 No: 2 Unknown / No answer: 4

DISCUSSION

Our study documents experimentally, that, explicit medical claims are made regarding NHP, for most of which no claims have been established.

Although garlic is believed to have health-promoting benefits, there is insufficient evidence to support a role for garlic in reducing blood pressure.⁷⁻¹⁰ Similarly, the majority of clinical trials on magnesium and hypertension have shown inconsistent findings. A meta-analysis found that the pooled net estimates of blood pressure change with magnesium were only -0.6mmHg for systolic blood pressure and -0.8mmHg for diastolic blood pressure. There was an apparent dose-dependent effect of magnesium, with reductions of 4.3 mm Hg systolic blood pressure and 2.3 mm Hg diastolic blood pressure for each 10 mmol/day increase in magnesium dose.¹¹ Although it is debated as to what constitutes a clinically significant reduction in blood pressure¹², magnesium supplementation results in only a small overall reduction in blood pressure.¹¹ There are several studies suggesting that oral calcium reduces blood pressure in patients with hypertension. Meta-analysis of randomized controlled trials of calcium supplementation showed a reduction in systolic blood pressure of 1.44 mm Hg and in diastolic blood pressure of 0.84 mm Hg. The authors concluded that the modest response in systolic and diastolic blood pressure reduction does not justify the use of calcium supplementation as the sole treatment for patients with mild hypertension.¹³

In summary, it can be concluded that the majority of products recommended by health food store staff have little well designed randomized controlled trial data to support their use in the treatment of hypertension. Thus, we believe that this is an opportunity to assess whether or not patients with elevated blood pressure are offered NHP for this unproven indication. Individuals who have been diagnosed with elevated blood pressure might delay or discontinue conventional treatment and seek natural health products.

Our results are consistent with the findings of a telephone study of health food stores in the Phoenix, Arizona area. Eighty-nine percent of stores offered recommendations for nausea and vomiting and 82% provided recommendations for

migraines during pregnancy. However, 5% of recommendations were for products contraindicated in pregnancy and correct usage information was often not provided.¹⁴ A Canadian study has also documented misinformation by health food store staff, as compared to pharmacists.¹⁵ The pervasive nature of making such claims verbally, in a way that cannot be documented in written records, underscores the fact that verbal recommendations are probably much more powerful than written ones.

Our study did not try to address perceptions, attitudes, and practices by consumers, leading them to accept claims which are invalid. It is very likely that our sample of Canadian pharmacies and health food stores can be generalized to other Western countries. We chose treatment of hypertension because a relatively large body of evidence-based studies exists to show that NHP are not effective in treating this condition.^{7,11,13} Hence, the claim made by health food store staff that those products are as effective or superior to medicinal drugs is misleading. In Canada, regulations already allow for NHP to exist with "traditional" use.² Hence, randomized controlled trials are not required for products with a long history of use for a given disorder.

Our present study demonstrates clearly that even products already approved by the Natural Health Products Directorate may be sold without proof of effect. It is conceivable that soon unfounded verbal claims regarding use of products for serious conditions, including hypertension, will be complemented by advertising that may be allowed by the regulatory body.

In conclusion, unlike pharmacy practice, verbal claims are common practice in health food stores, despite the lack of either written claims and/or proof of efficacy for most of them. Regulatory agencies should monitor not just written claims (or lack of), but also practices of health food stores, to avoid the practice of making unfounded claims.

Acknowledgements

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APPENDIX 1

Questionnaire number: _____
Date and time of visit _____
Name of store: _____
Address: _____
Type of store: pharmacy , health food , other _____
Salesperson: M / F
Estimated age in years: ≤ 24, 25-34, 35-44, 45-54, 55-64, 65+
Professional qualifications: Pharmacist , Pharmacy technician , Other _____

Comments:

Scenario: “My father is 67 year-old and was diagnosed with mild hypertension. His doctor said it should be treated. The problem is that he is not willing to take any prescription medications. He heard that there are unwanted effects. Is there anything else he could do or any other product that he could take?”

1. What would you recommend? **Name:** _____
2. What is it? – Is it natural? **Yes** **No**
3. Is it as effective as a prescription medication? **Yes** **No** _____
4. Does it have any unwanted effects? **Yes** _____ **No**
5. How should he take it? _____
6. Should it be taken with food? **Yes** **No**
7. For how long? **Days** **Week/s** **Month/s** **Year/s** **Other** _____
8. Is it okay to take Tylenol® for pain while taking this product? **Yes** **No**
9. What is known about it? **Literature (studies)** **Tradition** **Other** _____
10. When should he expect the BP to be reduced? **Days** **Week/s** **Month/s** **Year/s**
 Other _____ **No claim**
11. My father is very skeptical. Do you know where I could find some material to read on
 Brochures **Journals** **Internet** **Books** **Other** _____

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