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Naturopathic Management of Females with Cervical Atypia: A Delphi Process to Explore Current Practice

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Abstract

Background: Human papillomavirus is the most significant factor contributing to cervical cancer. Naturopathic doctors (NDs) implement an integrative approach to treat cervical atypia. This study explored practice consensus and variance among NDs.

Methods: A purposefully selected panel of six NDs participated in a modified Delphi study to validate practice. Three electronic web-based surveys were completed over nine months.

Results: Local and systemic treatments were included in all ND protocols. Six protocols included cervical cancer screening guidelines, green tea suppositories, and oral folic acid. Five protocols included oral green tea, diindoylemethane (DIM), and cartenoids. Four protocols incorporated Vitamin C. Two NDs considered escharotics when managing cervical atypia. All NDs included health behavior management in their protocols.

Conclusion: Naturopathic management of cervical atypia varies across practitioners. However, in general, elements of management include (1) cervical cancer screening guidelines, (2) local and systemic treatments, (3) health behavior/lifestyle recommendations, and (4) immune system support.

Keywords: naturopathic medicine, cervical atypia

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Introduction

Cervical cancer remains a significant world health problem as the second most common cancer in women worldwide.[1,2] Research has identified human papillomavirus (HPV) as the most common sexually transmitted infection worldwide and the most significant factor contributing to the development of cervical cancer.[3] From an epidemiological perspective, HPV infection meets the criteria of a causal agent for atypia and ultimately cervical cancer.[4,5] However, it is known that HPV infection alone is not sufficient to cause invasive cervical cancer.[6–10] Most likely, several environmental and host comorbid factors determine host infectivity and susceptibility for the progression from persistent HPV infection to cervical carcinogenesis, although the role of host and environmental factors in the predisposition of cervical cancer remains unclear.[8,9,11] In particular, naturopathic doctors (NDs), or naturopaths, acknowledge the role of the host as a factor in the predilection of cervical cancer and offer an integrative approach to managing both abnormal Papanicolaou (Pap) results and cervical epithelial neoplasia.[12]

Naturopathic medicine is grounded in the belief that the human body has an innate healing ability and is a distinct system of primary health care that emphasizes prevention and the self-healing process through the use of natural therapies.[13] Naturopaths blend centuries—old knowledge and a philosophy that nature is the most effective healer with evidence regarding the optimization of health and human systems.[14] Generally, the modalities used by NDs include diet and nutrition, physical medicine, phamacotherapeutics, minor surgery, and lifestyle changes, along with botanicals and natural therapies to help the body ward off and combat disease. Specifically, the naturopathic management of cervical atypia incorporates local, systemic, and constitutional treatments, implementing a variety of immune-enhancing, antiinflammatory, and antiviral botanicals.[7]

Outcomes related to screening and treatment of cervical atypia vary across health care delivery systems and across health care practitioners. The literature reveals that the utilization of naturopaths as practitioners is associated with statistically significant higher rates of Pap testing in comparison with conventional care exclusively,[7] and it is known that cervical cancer screenings decrease the incidence of cervical cancer while decreasing morbidity and mortality.[6] Increasingly, more women in the United States are including naturopaths as practitioners to meet their primary health care needs.[15]

Naturopathic doctors manage clinical cases of cervical atypia; yet, there are limited published reports on the outcomes of comprehensive naturopathic management of cervical atypia. What is known comes from three published papers providing preliminary evidence for the efficacy of a naturopathic approach to the management of cervical atypia.[12,16,17] The first, a consecutive case study research report of the naturopathic management of cervical carcinoma in situ, describeed the incorporation of local, systemic, and constitutional therapies featuring escharotic treatments. Of the seven subjects in the study, treatment was moderately effective with three subjects and totally effective with four subjects.[16]

A second study reported on the treatment of 48 subjects with a naturopathic protocol that included escharotic treatment for all degrees of cervical atypia and dysplasia. Results showed regression to a normal status in most subjects (n = 38), with partial regression in a few subjects (n = 3), persistence in a couple of subjects (n = 2), and progression in no subjects.[18] Third and most recently, a clinical case outcome report describeed the case of a woman with progressive and recurrent cervical dysplasia four years after cervical conization. The report illustrateed outcomes following naturopathic management for cervical dysplasia. Follow-up Pap results at four months, 10 months, and five years after the initiation of treatment revealed negative cervical cytology for intraepithelial lesion or malignancy.[17]

Based on this limited evidence, exploring current practice among a convenience sample of naturopaths can provide preliminary data to further define the gap between current research and naturopathic practice in the management of cervical atypia. The aim of this study was to explore practice variance and possible consensus among NDs for the management of cervical atypia.

Materials and Methods

Recruitment, sample, and design

Naturopathic doctors in the United States who were managing care of women with a diagnosis of cervical atypia were identified for potential inclusion into this

study by investigators in consultation with an expert in integrative women's health from the University of Arizona (Low Dog, written communication, January, 2011). The Delphi technique was used to structure ND group opinion and discussion, to generate consensus, and to quantify the judgment of a convenience sample of NDs.[19] Consistent with the Delphi method, a heterogeneous, minimally sufficient number of panel members were considered during study participant recruitment.[19]

Initially, six NDs were contacted by email and then by telephone. Information on the study purpose and a brief description of the study process was included in the email. The telephone contact allowed for detailed discussion and clarification of the Delphi process and explanation of the National Institute of Child Health and Human Development (NICHD) Clinical Trials Database (CTDB) survey. The CTDB is a secure, web-based application that supports protocol design, clinical data collection, and reporting. It automated the processing and monitoring of data collected for the study. The CTDB permitted design of data collection questionnaires, data capture, data import and export, data analysis, and reporting. The study and associated data were housed on a dedicated server protected by two firewalls. Internal security measures prevented one researcher from seeing another researcher's data. Only the principal investigator and preauthorized research team members could access the CTDB.

Following initial communication, all panelists were emailed a standardized cover letter that identified the purpose and procedure of the study and included an Internet web link to access the survey website. Agreement to participate in the study was implied by accessing the Internet website and initiating participation in the study. Panelists were instructed that their participation was voluntary and that they could opt out of the study at any time. Panelists who initiated participation were assigned a unique study code for electronic information management. This study including the use of CTDB was reviewed and approved by the National Institutes of Health, Office of Human Subjects Research Protection (#11-NR-5849).

Measures

The Delphi survey results submitted by panelists were collated after each round. Three iterations of electronic sequential surveys were completed over nine months, with the results of the third round presented to the panelists for final consensus.

In the first round of the Delphi survey, the participants were asked to provide demographic information and to respond to two open-ended questions: (1) What are your current clinical practices for the management of the female patient seeking care for HPV? and (2) Is there any other information pertaining to the management of the female patient with HPV? The first round demographic information and open-ended questions served as a platform for soliciting specific information on treatment options from the panel members.[19]

In the second round, each panel member was asked to review the treatment options based on the information provided and summarized by the research team from the first round. The panel members were asked to use a five-point Likert scale (1, "very unlikely" to 5, "very likely"; and 0, no response) to rank how likely or unlikely they were to use any of the 23 treatment options identified in the first round. The panel members were asked to provide preferred dose, range, route, and frequency for each treatment they identified. The NDs used the same five-point Likert scale to indicate how likely they were to implement the cervical cancer screening guidelines delineated by The American Society for Colposcopy and Cervical Pathology (ASCCP), The American Congress of Obstetrics and Gynecologists (ACOG), or American (National) Comprehensive Cancer Network (ACCN). A text box was available for panelists to state the rationale for their rankings or to contribute open-ended, narrative responses.

In round 3, each panelist received an email containing a word document summarizing the items from round 2. The panelists also were asked two questions: (1) Do you agree with the consensus for ranking of the naturopathic modalities for clinical management of females with HPV? (2) Is there any other information that you would like to contribute? These questions offered the panelists an opportunity to revise judgments, specify reasons for judgments, and offer clarifications for both information and judgments.[19] The principal investigator invited the panelists to provide their round 3 responses through an email that included an attached Microsoft Word document summarizing the results of all three rounds and inviting any final comments. One final email was sent to the panelists announcing the completion of the study.

Analysis

Raw data were exported from the CTDB survey into a Microsoft Excel file. Descriptive statistics were used to present panelist demographics. Thematic analysis was conducted of the practice elements within round 1 panelist responses. Frequencies were calculated for round 2 responses, and practice elements were evaluated using a five-point Likert-type scale. Round 3 responses were evaluated by confirmatory email.

Results

Round 1

There were six panelists recruited to participate in this study. All six panelists enrolled in and completed the study. All panelists reported caring for women with atypia and having practiced as an ND for more than 5 years (Table 1). All panelists were white females over the age of 40. One panelist reported limited experience managing women with HPV.

Round 1 revealed a consensus for the incorporation of cervical cancer screening guidelines for detection, prevention, and risk reduction into protocols for management of cervical atypia. All six NDs acknowledged following the cervical cancer screening guidelines defined by ACOG, ASCCP, or ACCN (Table 2). The Bethesda System (TBS) was referenced explicitly by four of the panelists as a determinant for management of cervical atypia.

All round 1 panelists identified a combination of local and systemic treatments in cervical atypia protocols. The time, dose, and route of administration for specific systemic and oral treatments varied among panelist responses (Table 2). All panelists identified suppositories as a route for local administration. Two of the panelists reported considering local treatment with escharotics in their management plans. Two panelists were neutral about considering escharotics in their management plans. The specific compound or protocol for escharotic treatment was not defined in round 1. One panelist reported considering incorporating HPV typing methods into the management protocol. One panelist described the significance of treating the "whole body, not just the abnormal cervical cells" when managing HPV. Two panelists were more descriptive with their inclusion of individual needs into management plans including diet, lifestyle (exercise and smoking cessation), immune support, and "motivation for seeking naturopathic treatment." Further delineation of treatment, dosage, and route for all local and systemic treatments and the establishment of priorities among items were the impetus for round 2.

Table 1. Panelist characteristics (n = 6).

Characteristic	n
Provide direct patient care	
Yes	6
Location of practice	
Washington state	3
Hawaii	1
Arizona	1
Oregon	1
How long practicing naturopathy?	
6–10 years	1
11–15 years	1
16–20 years	2
>20 years	2
How long providing care to women?	
6–10 years	1
11–15 years	1
16–20 years	2
>20 years	1
Age	
40–49	3
50–59	2
Gender	
Female	6
Race or ethnicity	
White or caucasian	5
Missing	1

Round 2

Round 2 (Table 3) defined treatment, dose, and route for the local and systemic treatments that were identified in round 1. Partial missing item responses in round 2 (Table 3) were noted for two of the six panelists due to a CTDB data capture system error. All panelists selected the cervical cancer screening guidelines implemented in their management plan. Again, combinations of local and systemic treatments were identified in all management plans. Green tea suppositories were reported to be the most commonly used local treatment. Sloughing was identified by one panelist as an untoward outcome of using green tea suppositories as a treatment plan component. Vitamin A suppositories of varying doses were identified as a protocol component by four panelists in round 2. One panelist noted implementing thuja suppositories, and one other panelist identified vaginal irritation as an

Table 2. Panelists' in-depth responses on their cervical atypia practice from, round 1.

Panelist	Question 1: Current clinical practices?	Question 2: Other information you would like to share?
1	I follow ACOG guidelines for evaluation and follow-up. If cervical HPV only, I use regimens that include green tea suppositories, vitamin A suppositories, folic acid, DIM, selenium, carotenoids, and green tea.	If the patient has CIN, I determine when they might need cryo, LEEP, cold knife cone, or the supplements and suppositories above along with an herbal escharotic treatment.
2	Immune support with nutritional and herbal supplements, dietary and lifestyle changes, and if appropriate a topical escharotic treatment directly to the cervix.	It is critical to the success of HPV management to treat the whole body, not just the abnormal cervical cells associated with HPV infection.
3	When a patient presents with a diagnosis of high grade HPV I would take a thorough current medical history including recent pap results, pathology, treatments, sexual history, motivation for seeking naturopathic treatment, medication and supplements currently used, past medical history, family medical history, and social history. I follow conventional guidelines of ASCCP for testing and for referral for colposcopy. If the patient has had an abnormal pap, ASCUS, LGSIL, HGSIL, etc., I would refer for colposcopy and biopsy. Often the patient is referred to me for adjunctive care by their health care provider after they have had colposcopy. The suggested treatment is based on their pathology and previous treatment.	I used the following basic plan and vary it based on the patient's individual situation: Vaginal suppositories: Calendula/Vitamin A suppositories for 6 nights alternating with herbal suppositories that contain Hydrastis, Commiphora, Echinacea, Usnea, Althea, Geranium and Achilliea suppository for 6 nights. In between the two types of suppositories, I have the patient take one night without a suppository. Oral botanical formula: Taraxacum root, glycyrrhiza root, hydrastis and trifolium or ligusticum. Dose: one half teaspoon. Vitamin C 3000 mg PO qd. Folic acid 2 gms PO qd. Green tea: 12–16 oz per day or green tea capsules. Adequate vitamin D to maintain a vitamin D level between 40–60 ng/mL. If a patient only has high grade HPV and normal pap smear, I will recommend the following until the next pap: If next pap is normal continue oral supplements until following pap. Vitamin C 3000 mg PO qd. Folic acid 2 gms PO qd. Green tea: 12–16 oz per day or green tea capsules. Adequate vitamin D to maintain.
4	I follow the guidelines as per ASCCP regarding management of abnormal cytology and histology. Care and treatment of the effect of HPV in terms of dysplasia depends of the extent of the dysplasia and how it is affecting the cervix.	ASCUS + HR HPV +, LSIL, HSIL, CIS I refer all these patients for colposcopy. CIN I and CIN II, I may treat with folic acid, DIM and or green tea suppositories if there is a negative ECC. CIN III, I refer for LEEP.
5	Follow ACCN guidelines for testing. Use topical products including green tea, Vit. A and thuja suppositories. Use TCA, Aldara for topical condyloma. Use oral supportive nutrients such as green tea, folic acid, carotenes, DIM/calcium-d-glucarate, zinc. Refer for escharotic treatment or LEEP as appropriate and following patient preferences/ insurance coverage.	Limited patient numbers for HPV management.

(*Continued*)

Table 2. (*Continued*)

Panelist	Question 1: current clinical practices?	Question 2: Other information you would like to share?
6	If a patient is HPV high risk positive, I run genotyping with MDL to determine the specific high risk strain. If it is 16 or 18, I am more aggressive in my treatment than if it is not 16 or 18. I start with a 3 month oral protocol consisting of; Folic acid 10 mg/day Beta carotene 180,000 IU/day B12 2,500 mcg/day Vitamin C 3–4 grams/day Anti-viral herbal tincture (echinacea, ligusticum, lomatium, licorice, and thuja) Green tea extract 1,650 mg/day Indole-3-carbinol 400 mg/day Coriolus versicolor 3,000 mg/day Plus a one month herbal suppository protocol of; week one—a suppository containing Myrrh, echinacea, goldenseal, marshmallow, geranium, and yarrow. Week two—green tea compounded suppository. Week three—repeat week one. Week four—repeat week two.	This is a very successful protocol for HPV high risk alone or with cervical dysplasia including ASC-US, CIN I and CIN II. If it is CIN III the treatment is a little different. I don't use suppositories and instead do 8 escharotic treatments to the cervix. Obviously this includes proper work-up and following ACOG guidelines for colposcopy.

Table 3. Naturopathic management of cervical atypia: results from Delphi round 2.

Management plan	Panelist					
	1	2	3	4	5	6
Guidelines						
ASCCP	5	4	5*	5*	0	4
ACOG	2*	4	3	4	0	4*
ACCN	2	4	1	3	0*	1
Suppositories						
Green tea	5*	4	4	5*	0*	5
Vitamin A	5*	4	1*	4	0*	5
Thuja	5	1	0	3	0*	1
Calendula	1	4	5*	4	0	1
Myrrh	5	5	0	3	0	5*
Oral						
Folic acid	5*	5	5*	5*	0*	1*
DIM	5*	5	2	5*	0*	5
Selenium	5*	4	0	2	0	1
Carotenoids	2*	5	0	5	0*	4*
Green tea	5*	1	5*	5	0*	5*
Zinc	1	1	0	2	0*	1
Taraxacum root	1	1	0*	2	0	1
Glycyrrhiza root	1	1	0*	3	3	1
Hydrastis	1	1	0*	3	2	5
Vitamin D	1	5	0*	3	5	1
Vitamin C	3	5	0*	3	4	5*
Vitamin B12	1	1	0	3	3	1*
Echinacea	1	1	0	3	2	5*
Usnea	1	1	0	3	2	3
Althea	1	1	0	3	1	1
Geranium	1	1	0	3	1	1
Achilliea	1	1	0	3	1	1
Escharotic treatment						
Herbal escharotic (eg, *sanguinaria canadensis*)	3*	4*	1	1	3*	5*

Notes: *Item identified in Round 1 as included in management plan; 1 = very unlikely; 2 = unlikely; 3 = neutral; 4 = likely; 5 = very likely; 0 = missing data.

untoward outcome of thuja suppositories. Three panelists consider using calendula suppositories to manage cervical atypia. There was no rationale or untoward outcome identified as a justification for not including calendula suppositories. The use of escharotic treatments in management plans varied. Respectively, the panelists were "very likely" (n = 1), "likely" (n = 1), "neutral" (n = 1), and "not likely" (n = 2) to employ the treatment. Time, expense, and patient comfort were identified as challenges to implementing escharotics into management plans.

Systemic treatments are delivered by oral route of administration (Table 3). The dosages of oral systemic treatments are similar and within the recommended amounts. The highest variation in dose range

was noted with the administration of Vitamin D and Vitamin C. Folic acid was identified by five panelists as "highly likely" to be included in a management plan. One panelist identified implementing oral folic acid in round 1, yet the data were missing in round 2. Green tea and carotenoids emerged again as oral systemic components of five management plans. Five panelists reported that they were likely to incorporate diindoylemethane (DIM) into management plans for cervical atypia, while one panelist reported they were not likely to do so. As in round 1, the consideration of individual immune support and health behaviors including diet, exercise, and smoking was incorporated into the development of management plans.

Round 3

Round 3 validated the responses reported in round 2. Following the distribution of round 2 results to the panelists and the solicitation for revision of responses, two panelists provided additional feedback. One panelist confirmed vaginal sloughing as a significant deterrent for the use of green tea suppositories. One panelist confirmed the challenge of managing HPV positive cervical atypia versus non-HPV cervical dysplasia. As in round 1, it was identified that the consideration of current HPV type-specific management of cervical atypia should continue to be incorporated into ND protocols for cervical atypia.

Discussion

This study confirms there is variability in practice across naturopathic management of cervical atypia, but management protocols do share common treatment elements. This study recognizes that NDs managing cervical atypia implement protocols that incorporate cervical cancer screening guidelines for prevention and early detection of cervical carcinoma, included local, systemic, and constitutional treatments and consider individual lifestyles and health behaviors. The protocols identified in this study corroborate naturopathic medicine as a distinct system of primary care that emphasizes prevention and self-healing through the use of natural therapies.[13] The assertion that NDs implement a variety of immune-enhancing, antiinflammatory, and antiviral botanical protocols for managing cervical atypia[7] is confirmed, although the treatment components of the protocols vary among NDs. Consistent with current clinical outcomes research, cautious judgment is acknowledged for the incorporation of escharotics in naturopathic practice.[20]

This study also confirms that NDs recognize the host, or individual, as a factor in the predilection of cervical cancer. Thus, treatment regimens offer an integrative approach to managing both abnormal Pap results and cervical epithelial neoplasia.[12] Naturopaths acknowledge host immunity support through the incorporation of green tea[21] and DIM.[22] Vaginal green tea suppositories and oral green tea provide the standardized extract epigallocatechin gallate (EGCG) that is known to inhibit the epidermal growth factor receptor needed for cervical cell growth.[12] Lifestyle and health behavior changes incorporated into management plans further emphasize prevention in the overall naturopathic approach.

The implementation of cervical cancer screening guidelines by all NDs illustrates the incorporation of the current biomedical context and evidence-based practice into naturopathic protocols for managing cervical atypia.[23] One of the evidence-based approaches currently incorporated into practice by some naturopaths includes the addition of folic acid in the prevention of cervical intraepithelial neoplasia, grade I (CIN I).[24] Naturopaths on this expert panel also cited evidence suggesting a significant inverse association between total fruit consumption and the risk of invasive squamous cervical cancer.[25]

One limitation of the study was the use of electronic technology for data collection and data management. Three panelists experienced errors with the system retrieval of their data input. The modified Delphi technique provided an opportunity for panelists to share their opinion without the burden of travel or group bias. However, frustration with the electronic process could pose undue burden on panelists. This panel also represents a small subset of NDs practicing in the United States. Three of the panellists were from the Pacific Northwest, where a significant portion of US naturopaths receive their education. Therefore, it possible that this panel does not represent the NDs practicing in other areas of the United States nor across international practice arenas.

Future directions

It is important to note that in this study as well as others examining contemporary naturopathic practice,

there is an inherent tension between scientific evidence and traditional knowledge gained through naturopathic practice, with science both supporting traditional knowledge and undermining its value.[26] Future research should continue to define the naturopathic approach to management of cervical atypia both nationally and internationally with well-designed efficacy and comparative effectiveness trials. With the incorporation of cervical cancer screening guidelines and local, systemic, and constitutional treatments, naturopaths may contribute a unique approach to the comprehensive care of women. This integrated and comprehensive care may yield positive long-term outcomes for women's health. Escharotic treatments as part of the cervical atypia management plan may play a role in the reduction of undue long-term consequences from invasive procedures.[17] However, more investigation is required to define the benefits, burdens and potential long term risks of escharotic treatments such as Sanguinaria canadensis, which is used in the treatment of all cervical atypia. Additionally, further research remains essential to define the significant contributions of diet and lifestyle to the progression of cervical carcinogenesis.

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Author Contributions
Conceived and designed the experiments: CAL and GRW. Analyzed the data: CAL, CMD, and GRW. Wrote the first draft of the manuscript: CAL, CMD, and GRW. Contributed to the writing of the manuscript: CAL, CMD, and GRW. Agree with manuscript results and conclusions: CAL, CMD, and GRW. Jointly developed the structure and arguments for the paper: CAL, CMD, and GRW. Made critical revisions and approved final version: CAL and GRW. All authors reviewed and approved of the final manuscript.

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Disclosures and Ethics
As a requirement of publication author(s) have provided to the publisher signed confirmation of compliance with legal and ethical obligations including but not limited to the following: authorship and contributorship, conflicts of interest, privacy and confidentiality and (where applicable) protection of human and animal research subjects. The authors have read and confirmed their agreement with the ICMJE authorship and conflict of interest criteria. The authors have also confirmed that this article is unique and not under consideration or published in any other publication, and that they have permission from rights holders to reproduce any copyrighted material. Any disclosures are made in this section. The external blind peer reviewers report no conflicts of interest.

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