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Australian Journal of Herbal and Naturopathic Medicine

The *Australian Journal of Herbal and Naturopathic Medicine* is a quarterly publication of the NHAA. The Journal publishes material on all aspects of Western herbal medicine and is a peer-reviewed journal with an Editorial Board.

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The NHAA is a peak professional association representing appropriately qualified naturopathic and Western herbal medicine practitioners. A foundation member of the World Naturopathic Federation and founded in 1920, it is a member-based association, the oldest professional association of complementary therapists in Australia and the only national professional association specifically concerned with the practice and education of Western herbal medicine (WHM) in Australia. Our mission is to support naturopaths and Western herbal medicine practitioners to deliver excellence in healthcare in Australia and our vision is naturopathy and Western herbal medicine for the health of Australia.

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The *Australian Journal of Herbal and Naturopathic Medicine* (*AJHNM*) is Australia's leading herbal publication. A thoroughly modern, peer-reviewed and clinically relevant journal, the *AJHNM* can trace its origins back to publications issued by the Association as long ago as the 1930s. Issued quarterly, the *AJHNM* publishes material on all aspects of herbal medicine including philosophy, phytochemistry, pharmacology and the clinical application of medicinal plants.

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A global perspective brings new opportunities for naturopaths and herbalists

Susan Arentz

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Health and medical care systems influence the type of health care that people use around the world. In some countries, such as the UK and Australia, most people have access to Western medicine through universal health care, funded by taxpayers, providing essential care at low cost when needed. In these countries, other types of health and medicine systems run parallel to Western medicine in a mainstream, pluralistic approach and people are able to choose and use the types of health and medicine they wish. This contrasts with remote situations and places where Western medicine can be expensive, and not always available or accessible. In these circumstances, traditional herbal medicine and natural health practices, which are embedded in culture, are more readily available, reasonably priced and therefore often used as the main form of medical treatment. They are not considered part of a pluralistic system but instead as first-line, and potentially the only form of treatment.

Taxpayer-funded research is another contrasting feature of countries with developed economies. Funded academic research programs for the sake of research in itself is a hallmark characteristic. In these countries, research outcomes have a transparency that is not always feasible in developing economies. The High costs and commercial agendas can influence the design (method), value and dissemination of research findings. The same is true for investigations embedded in industry. Studies with positive outcomes are held in higher esteem, with foundational research costs factored into the next medicine to market.

A surge of funding for research of herbal and naturopathic medicine is on the horizon in Australia that may help transition traditional medicines into mainstream Western health care. The introduction of the new 'assessed' category AUSTL(A)¹ of the Therapeutic Goods Administration (TGA), is intended to enable consumers to identify complementary medicines that may prevent, cure or alleviate non-serious forms of disease, ailments, defects or injuries. This category is touted as filling a gap between the AUSTL and AUSTR categories and enables consumers' recognition of complementary medicines for which there is evidence of efficacy for particular conditions. Traditional evidence is included in this category; examples of which include Western herbal

medicine and others that have traditional use in excess of three generations (75 years).

There is a caveat on citing traditional evidence however, in that it requires additional scientific evidence to confirm efficacy for specified conditions. This is due to several reasons including historical and local indications for herbal medicine not necessarily being aligned with the health needs of health consumers. An example is the case of women: women's health needs have changed over 75 years due to having fewer children and at older ages². Traditional indications for Western herbal medicine may not be as applicable as they once were; and forgotten remedies may find a new valued place. Another reason for scientific support is variation of health needs on the ground, at local levels. The capacity of human beings to adapt to their environments has led to health variations being determined by local physical, cultural and social settings³, in much the same way as species of plants grown in different regions have different chemical structures. Variations in the expression and prevalence of human health and disease (or conditions) can be altered in response to external stimuli, determined in part by the local environment.

The importance of transparent investigations to support traditional claims cannot be overstated. Transparency may prevent monopolised exploitation of traditional knowledge. It can also ensure that negative outcomes are presented so that consumers' opportunities of effective care are not lost. The new category of products are intended for over-the-counter retail sales, potentially provided without any expert advice. Labels citing traditional use and transparent research are more likely to prevent adverse outcomes for retail consumers. Our ability to undertake research and interpret its meaning in the context of traditional application for use in contemporary health care defines our unique professional expertise, forming a bridge between traditional and contemporary health care. As the NHAA's 100-year anniversary conference approaches, we will have an opportunity to share our expanding knowledge and evidence for naturopathy and herbal medicine with our traditional herbal-using friends and explain appropriate methods for transparent evaluation.

In this issue, which shaped up to being somewhat *international*, I am pleased to present an immersive

traditional herbal experience by Christine Thomas and friends who explored the herbal practices of Sri Lanka. This follows on from her conference coverage of Tradmed International Sri Lanka 2017, reported in the December 2017 issue⁴, and presents a pictorial tour of rich, traditional herbal medicine culture and practice. In addition, it is with pleasure I present two case studies of perplexing women's health issues: recurrent bacterial vaginosis and recurrent pregnancy loss. One of these articles from naturopaths in Canada reflects the new broader wings of the NHAA as part of the World Naturopathic Federation. We welcome a global perspective of naturopathic practice and look forward to cross-pollination, sharing knowledge and experiences.

Jodie Tester has again summarised the evidence in MedJourn and MedPlant. She reports on a Cochrane Systematic Review authored by naturopath Josh Goldenberg and colleagues about probiotics for the prevention of *Clostridium difficile*-associated diarrhoea, research investigating the efficacy of intermittent fasting and associations between air pollution and respiratory diseases. There is also a collection of reviewed women's health studies, including post-partum maternal sleep, implications of coeliac disease on reproduction and PCOS, which are fitting topics for this issue. Herbal medicines covered in MedPlant include *Ginkgo biloba* with Metformin, *Withania somnifera* with antipsychotics, *Crocus sativus* and *Rhodiola rosea* for depression,

Ginseng on cognition, a review update of herbal medicines for psychiatric conditions and a Cochrane Review of cannabis-based medicines for chronic neuropathic pain. Enjoy.

Thank you Jodie Tester

Please join me in thanking Jodie for her great work on MedPlant and MedJourn and writing the CPE questions for NHAA members. Jodie has decided to dedicate her time to her medical studies, which take her all around the country and she has resigned — weaning us off her wonderful work, starting with MedPlant and finishing with MedJourn in the December issue. Thank you, Jodie, you really have been wonderful in this role. On behalf of the NHAA and our members, we wish you all the best.

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President update

Natalie Cook

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Spring is such a positive time — leaves return to deciduous trees, plants blossom and fresh, green, leafy growth brings new life to even the weeds in our gardens. However, if you are anything like me, you are actually cultivating some of those ‘weeds’ as dear and valuable allies (hello tarax, my old friend)! Likewise, time is no less busy for the NHAA board and office team as we head full steam ahead towards our next international conference as well as many other activities contributing to the growth of our profession in Australia.

NHAA international conference

The theme *Traditional Wisdom, Future Practice* has been deliberately chosen to allow a celebration of our valuable traditions, whilst maintaining an eye on the future as our profession evolves. The event will be in Melbourne on 29–31 March 2019 and early-bird registrations are now open. Abstract submissions are now also open and we invite students, clinicians and academics alike to forward your proposal for a presentation at the conference. If you are unsure, please reach out as we really want to encourage new faces as well as those already admired and respected in our profession — everyone starts somewhere! The 2019 conference is a particularly important one as we mark our 100th year as an association, the oldest in Australia. In addition, we are proud to host the World Naturopathic Federation and their biennial General Assembly, so the event will be culturally rich and historically important. Details at www.nhaaconference.org.au.

Arbutin scheduling

The NHAA led a team of experts who contributed to our response to this recent issue impacting herbs, including Damiana (*Turnera diffusa*) and Bearberry (*Arctostaphylos uva-ursi*). A member update was released that clarified the situation and provided a clear understanding for practitioners and legislators alike. Clear, fact-driven and professional responses to important issues are a hallmark of the NHAA and I am proud of the work the volunteers on our Professions Subcommittee did in our response to this issue.

The work is ongoing, but here is a snapshot of the response (extract from NHAA Member Alert, Original release 18 June 2018, updated 24 June 2018):

Has there been a recent change to the Scheduling of arbutin and arbutin-containing herbs?

No. The change occurred in 2010. There is a TGA administrative follow-through on previous Scheduling decisions about the chemical substance hydroquinone and related substances found in certain herbs. Arbutin is included as a cross-reference to hydroquinone in the Appendices to the Poisons Standard and is affected by this follow-up. Both hydroquinone and preparations containing above 10 parts per million (10 ppm) of the component arbutin were included as Schedule 4 Prescription Only in 2009. This means that arbutin, when present in herbal preparations at a level above 10 ppm, is effectively captured by Schedule 4 and therefore restricted for general sale and supply. Herbs containing less than 10 ppm arbutin are not affected and can still be included in herbal preparations.

What is arbutin and hydroquinone?

Hydroquinone is used as a photographic developer, antioxidant, stabiliser (in paints, fuels, oils and polymers), as a chemical intermediate and in pharmaceuticals. Hydroquinone is also used as a skin depigmenting agent and in hair preparations. The National Drugs and Poisons Schedule Committee 2009 reported that “although the general toxicological assessment of arbutin suggests that the substance may be safe, the bioavailability of hydroquinone under conditions of intended use of the substance is of concern.”

Arbutin is a glycoside of hydroquinone, is stable in gastric acid and can be absorbed by the human intestinal sodium/glucose co-transporter (SGLT2). After being absorbed from the small intestine, arbutin is transported to the liver, where it is deglycosylated to yield hydroquinone (HQ) and glucose. The HQ immediately undergoes phase II glucuronidation and sulfation, resulting in HQ-glucuronide and HQ-sulfate, respectively. Arbutin itself has not been detected in urine, suggesting complete metabolism.

What has been done so far?

As the main concern is with free hydroquinone, not directly with arbutin, Complementary Medicines Australia (CMA) has written to the TGA requesting that the level of arbutin in permissible herbs within listed complementary medicines be increased to a level of 25 ppm (according to the molecular weight of arbutin, 25 ppm is equivalent to 10 ppm of hydroquinone). We have been informed that this new level has been

accepted, and will be reflected in the upcoming TGA documentation changes. The NHAA continues to work with all interested industry bodies and associations to represent this issue with one clear and focused voice.

Board elections 2018

Each year elections are held to allow members to nominate and vote for the people they would like to have representing them on the NHAA board. The NHAA constitution enshrines transparent and democratic processes and each year half the board is up for re-election. As part of this process, some members stand for re-election, while others complete their term so there is generally some turnover at this point. To be a member of the NHAA board does not require specific experience; however, passion for advancing the profession and some time to devote to this are needed. Please encourage your peers or nominate yourself to be in the running at the October AGM. The AGM will again be held online (with technical glitches from last year being ironed out) to allow members to participate and vote, no matter where they are. As the saying goes, you've got to be in it to win it.

Thanks, as always, for your support of the NHAA. The association is nothing if not the sum of its members and I thank you for the privilege of representing you.

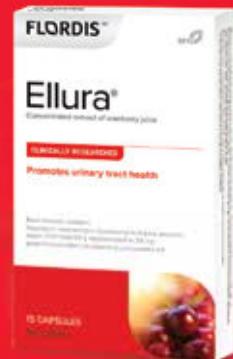
Cheers, Natalie

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Cochrane review, 2012



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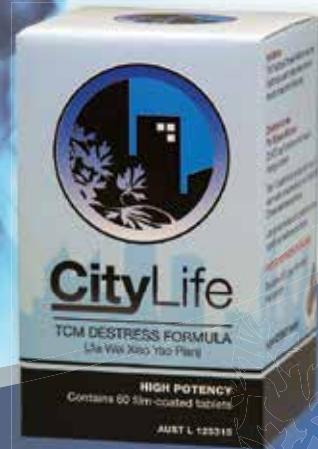
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The I Love Herbs Sri Lanka excursion

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Abstract

An intrepid group of eight passionate herbalists had the ultimate Sri Lankan herbal medicine immersion experience in March 2018, where they witnessed traditional herbal medicine in action in the 21st century. The majority of the excursion was set in an enchanted sanctuary of exceptional beauty in Sri Lanka's heartland. The tour included Ayurvedic healing practices taking place in a traditional working village, including soothing massages and oil applications, medicated steam baths, herbal saunas, medicine making classes with an acclaimed Ayurveda practitioner, a visit to the oldest planted tree in the world in the ancient city of Anuradhapura, a personal tour of a working Ayurveda hospital and manufacturing facility, but mostly just surrendering to Mother Nature herself.

Keywords: Sri Lanka, traditional medicine, indigenous medicine, herbal medicine, Ayurveda, herb manufacturing.

"It seems to me that we all look at nature too much and live with her too little." Oscar Wilde

For more than two years now I have been living in Sri Lanka, working as the technical writer for The Herbal Extract Company of Australia (HEC). During my time in this biological hotspot I have been impressed by the depth of medicinal plant knowledge within the local community. Ayurveda is the dominant traditional medicine here and it forms part of the national health services provided by the government, including a separate ministry for indigenous medicine. Scattered across the country are 62 Ayurvedic hospitals and 208 central dispensaries and more than three million people seek treatment at these hospitals annually. In addition, there are 230 dispensaries administered by local government authorities, which offer services free of charge to a large number of people. Along with the 1424 Ayurveda medical practitioners employed by the government at these hospitals there are about 20,000 traditional medical practitioners on the island registered under the Sri Lanka Ayurveda Medical council. Up to 70 per cent of the rural population relies on traditional and natural medicine for their primary health care. Herbal medicine is an essential component of this, with about 2000 species of plants used for Ayurvedic herbal preparations for the treatment of diseases. Plants used in the local Ayurveda system have been botanically described and many of these have been investigated for their biological activities by scientists at the local universities and research institutes^{1,2}.

The unique, indigenous Sri Lankan traditional medical system is known as Deshiya Chikitsa and it uses about 500 plant species. Along with the registered physicians at the Ayurveda Medical Council there are more than 8000 Deshiya Chikitsa practitioners, who are descendants of reputable families with secret formulae. Some of their traditional knowledge has also been recorded in palm

(*ola*) leaf manuscripts and ancient books. The community relies on this system for many treatments, including for eye diseases, fractures and dislocations, burns and scalds, boils and carbuncles, and cancers. Some of the practitioners specialising in fractures and dislocations are held in such high regard that they are often the first choice for treatment even by sections of the community accustomed to allopathic medicine^{3,4}.

This compelled me to share with other plant enthusiasts the botanical treasures I have discovered on this lush tropical island. In this era of evidence-based medicine, I am passionate about keeping traditional herbal medicine alive. In line with this, I believe the secret of herbalism lies in the sensory experience. Traditional practitioners don't use scientific studies or books to learn about herbs, they experience the herb. This empowers them to learn about herbs through their senses and not solely through passive learning. If you have only ever learned about herbs from books or lecturers, and never seen them grow, it is very difficult to remember them and all the lists of their actions and indications become confusing. This is the inspiration, sentiment and driving force behind the hands-on excursion I curated.

On 16 March 2018, eight curious globetrotters, including seven from Australia and one from the Seychelles, landed in the spice isle ready for some herbal immersion as part of the 12-day I Love Herbs Sri Lanka excursion. On our first day, we had a mental decluttering session with Verity Mace, a life coach from Evolve in Sri Lanka, to harness the holiday mindset magic and use it as a catalyst for creating real and sustainable change. We were encouraged to 'unpack' and become present, explore with curiosity what is important to us and then decide what we wanted to take home with us and what 'baggage' we wanted to leave behind, so we could return home lighter with more clarity and peace of mind.

The excursion group then spent 18–25 March at Ulpotha, an internationally renowned yoga and Ayurveda retreat, where we got our green on and took a pharmacological dose of wilderness tonic. Ulpotha is very much a traveller's experience rather than a tourist's. We were off the grid for the week, living in a traditional working village in open-sided mud huts cradled on one side by rocky outcrops and a lotus-ringed ancient reservoir (or tank), and on the other by verdant paddy fields. Jungle bathing was high on the agenda — the medicine of simply being with the ocean of trees and plants in their natural habitat and breathing the fresh air.

When you enter magical Ulpotha you fall down the rabbit hole. It is a cross between the pages of a child's fairytale book, a psychedelic experience, time travel and a commune. Like the garden of Eden, it is an earthly paradise. It is a party of the five senses and a place to entertain your inner child.

Ulpotha is first and foremost an oasis of nature. As such, it is a self-sustaining, biodiverse organic farm that

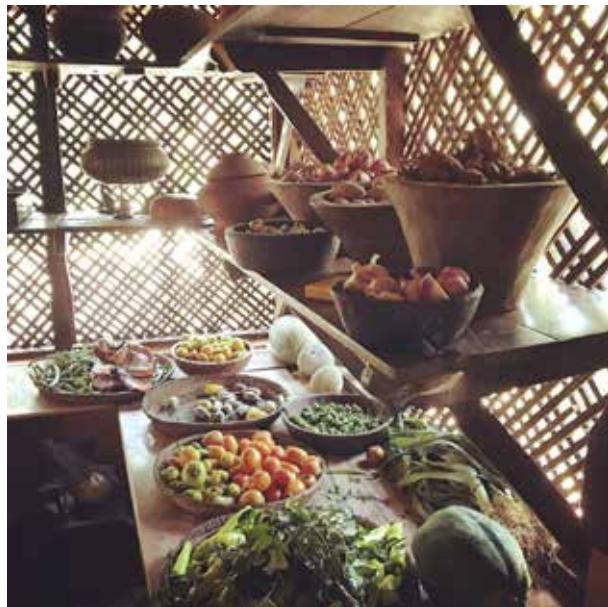


Welcome to the jungle: The entrance to Ulpotha, an internationally renowned yoga and Ayurveda retreat.

works with the environment. In order to protect the natural habitat, water buffaloes are used in place of tractors to plough the fields and thresh the rare varieties of high-nutrient heritage red rice. Rice, vegetables, fruit, timber trees and medicinal plants are grown in the garden and no artificial fertilisers or pesticides are used, hence why there are plentiful butterflies. Instead, crops are protected from bugs and pests using traditional and biological methods such as powdered *Azadirachta indica* (neem) seeds and sap from *Artocarpus heterophyllus* (jackfruit). So,



Vibrant: The main house (*walaawwa*) entrance at Ulpotha, with the beautiful fresh flower bowls that are dotted all over the property and greet you daily.



Tantalise your taste buds: The kitchen shelves at Ulpotha, full of organic, fresh food, ready to be prepared and cooked in clay pots over wood fires.

imagine the delicious feasts, mostly curries, using recipes handed down for generations. It is a detox without fuss because you are eating simple, healthy, vegetarian and naturally wheat-free food. Our rice and curry lunches and dinners were finished off with tropical fruit or buffalo curd (made from the local buffalo milk) and coconut treacle (*kithul* in Sinhala), served in coconut shell bowls.

Breakfast usually consisted of tropical fruit, fresh coconut water from *Cocos nucifera* (king coconut or *thambili* in Sinhala), *Coriandrum sativum* (coriander seeds or *koththamalli* in Sinhala) and *Zingiber officinale* (ginger or *inguru* in Sinhala) tea and *kola kanda*, a nutritious herbal porridge (Sri Lanka's version of a green smoothie) made from red rice, fresh coconut, *Allium sativum* (garlic), *Piper nigrum* (pepper) and salt and a blend of green leaves, which could include *Centella asiatica* (gotu kola), *Cardiospermum halicacabum* (balloon plant or *wepenela* in Sinhala), *Hemidesmus indicus* (hemidesmus or *iramusu* in Sinhala), *Asparagus racemosus* (shatavari or *hatawariya* in Sinhala), *Aerva lanata* (*polpala* in Sinhala), *Murraya koenigii* (curry leaf or *karapincha* in Sinhala) or *Senna auriculata* (*ranawara* in Sinhala). As there's no electricity, all the food is cooked fresh (there are no fridges to keep 'unfresh' food) over open fires in clay pots, which all make for rich and vivid flavours. It is eaten communally in the *ambalama*, a meeting house, or the *kade* (corner shop) hut for breakfast.

Ulpotha literally means water spring in Sinhala and it is a rare treat to be able to drink the spring water from the taps anywhere on the property. Guests can swim in the tank, which could have been built 2500 years ago (the date is unknown), and it is still used to irrigate the surrounding rice paddy fields. It's a twitcher's dream, as the surroundings are home to a vast array of colourful birdlife, including milky statuesque egrets and the blue flash of kingfishers. There is nothing quite like the smell and feel of fresh water. Gliding through its pure, velvety



Wonderland: The *kade* hut, where breakfast at Ulpotha is eaten, decorated with *Cocos nucifera* (king coconut or *thambili*) used for fresh coconut water.

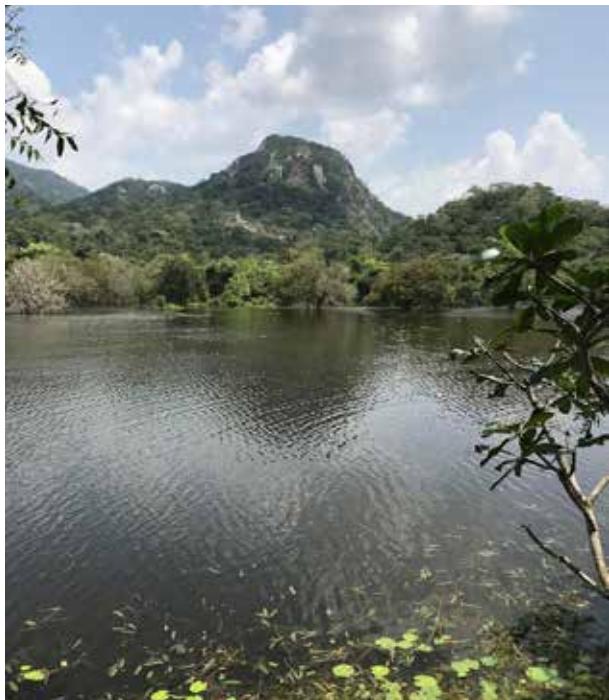


Oasis of nature: In order to protect the natural habitat at Ulpotha, water buffaloes are used in place of tractors to plough the fields and thresh the rare varieties of high-nutrient heritage red rice. They also provide milk to make buffalo curd, a treat eaten after meals.

mass, with its sun-warmed surface and refreshing cool depths, one feels baptised into nature. Burdens are delicately washed away and you are born again. The tragedy of modern life is a sense of discontinuity with nature. Ulpotha is the elixir to this affliction. A balm to the soul.

One of the founders of Ulpotha, the late Mudasinghe Tennakoon, said it is a place for leisure, pleasure and rest and it is true, when you arrive at Ulpotha you leave the ordinary world behind. It is a portal to a deeper connection with nature for those of us whose lives are marred by rampant consumerism. In Ulpotha's warm embrace, you live life at a less frenetic pace and feel a heightened state of consciousness, leaving you on a natural high when you depart.

While Ulpotha is a place of leisure, pleasure and rest it is not for the faint-hearted. You surrender to Mother Nature herself. Ancient elephant paths criss-cross through the village. On our first night, we were warned there were 14 elephants on the perimeter and we should leave lanterns burning outside our huts at night to deter them and we were not allowed to walk beyond the village. Tragically, three villagers had been killed prior to our arrival, including the 59-year-old next door neighbour three days before we arrived. She had been walking alone following warnings and it is thought she startled an elephant. We had Bob, the 'harmless' rat snake, and huge spiders in our outdoor bathrooms. There were monkey and grey langur families everywhere, inquisitively watching us do yoga under the banyan tree, or on Monkey Rock, in the mornings and evenings. The tank where guests can swim is brown and although safe — there were no crocodiles, we were assured — it is off-



Leisure, pleasure and rest: The lotus-ringed ancient tank (reservoir) at Ulpotha, where guests can swim. Just one of the many ways Ulpotha makes the mundane world sublime.



Tranquil: The adventurous and romantic can row to the tree house by the lake at Ulpotha and spend a warm night.

putting for some. Despite this, there is a certain symbiosis that exists and humans and animals can live side by side as long as they respect each other. It wasn't all ferocious beasts, though. Ulpotha is teeming with kaleidoscopes of butterflies by day, entrancing fireflies by night and frogs a go-go. Not to mention the humans, the villagers with their perpetual smiles, who are some of the most genuine,

wisest, kindest, gentlest people on the planet. There is a rare synergy at Ulpotha that can only be experienced.

With no electricity or mod cons you become in-tune with the cycles of nature and are able to disconnect and become present, or reconnect. The soft light of dusk and dawn eases you into the transition of night and day. At nightfall, Ulpotha transforms into its own galaxy. The paths and accommodation are illuminated by lanterns and the meals are eaten communally in this flickering, romantic light. It is like an intimate dinner party every night, where you can lounge and converse with the myriad of spellbinding people from all over the globe. In the balmy, tropical evenings we drank magical blue tea from *Clitoria ternatea* (the butterfly pea flower or *katarolu* in Sinhala) and *Cymbopogon citratus* (lemongrass or *sera* in Sinhala) as a digestive after our meals. There was no buzz or humming of electronic devices, but rather our lullabies were electric pulsing fireflies and a cacophony of frogs. Despite all this, there isn't a sanctimonious attitude, in fact quite the opposite. A feeling of *la dolce vita*, barefoot hedonism and pleasure seeking pervades the air. There is the odd party night where the local arrack (made from the fermented sap of coconut flowers) comes out and there is music and dancing for those in the mood. People can bring coffee and chocolate if they want. It is about having fun.

During our whimsical experience in the jungle we met Dr Srilal Mudunkothge, who embodies the spirit of traditional herbal medicine. He is Ulpotha's resident Ayurveda physician, who is carrying on a rare heritage in the tradition of his illustrious teachers, Dr Sooriya Arachchige Amaratunga and Dr Ven Dehiwela Dhammaloka Thero. Dr Srilal's unique practice of indigenous medicine sees him treating not only Ulpotha's guests but offering a free clinic, where he diagnoses and dispenses free medicines, to more than 100 local villagers



Elegant simplicity: A dinner feast eaten communally by lantern light in the wooden-pillared pavilion (*ambalam*).



Traditional healer: Dr Srilal Mudunkothge in his clinic dispensary, a mud hut with a thatched roof, where he diagnoses and dispenses free medicines to over 100 local villagers weekly. Many of the medicinal herbs are grown in the compound surrounding the clinic.

each week. This is the way traditional Ayurveda was practised, where instead of paying cash, patients would make a symbolic offering of *Piper betle* (betel) leaves at the time of consultation and offer their services in kind. The villagers will often travel long distances to get to the clinic so they are welcome to stay overnight, especially when there is danger due to elephants. Dr Srilal said the most common ailment he treats is arthritis due to all the hard work the villagers do in the rice fields. He will often prescribe herbal teas for his patients and they will collect the plants from the jungle themselves. They might also be given a massage oil to relieve the pain. The clinic is sustained by the money raised from the Ayurveda treatments paid for by Ulpoltha's guests.

We undertook the five-day *Ashinsanaya* (benediction) package with Dr Srilal. During our consultation, in Dr Srilal's wattle and daub consultation room, our pulse was taken and we were told what our body type, or *dosha*, was (a combination of *vata* — air, *pitta* — fire or *kapha* — earth). This, in turn, allowed Dr Srilal to give us advice on what eating and living habits we need to live a healthy, balanced life. The primary aim of Ayurveda is to balance the body's energy and thus restore health. Because we only had a short time — anything less than three weeks is considered short by Ayurveda standards — most of our detoxifying treatments were similar, concentrating on preparatory and elimination therapies. These are known as oleation and fomentation therapies.



Payment in kind: A patient at the free clinic at Ulpoltha holding her symbolic offering of *Piper betle* (betel) leaves.



Medicine man: Dr Srilal Mudunkothge in his consultation room at Ulpoltha. Photo credit: Jennifer Webster <http://www.traditionalherbs.com.au/index.htm>

Our oleation therapies were administered with the intent of dislodging toxins from the body's tissues and moving them towards the pores. These toxins are extracted through the fomentation therapies, which consist of medicated baths, steam baths and herbal saunas. The oleation therapy consisted of a superficial *Sesamum indicum* (sesame) oil application for the first layer of the body (*abyanga*), a deeper tissue oil application with *pinda* oil (*hemidesmus*, *Vateria copallifera* and *Rubia*



Herbal immersion: The herbal bath with *Azadirachta indica* (neem) leaves. Photo credit: Ulpotha.



Sweat it out: The sauna at Ulpotha is in a traditional round hut with an open fire underneath. Each of the small compartments in the floor is filled with different herbs. Photo credit: <http://talkwellness.at/ayurveda-in-sri-lanka/>

cordifolia (Indian madder) are incorporated into sesame oil with bees wax) for the second layer of the body (*angamarda abyanga*), a detoxifying herbal paste (*pattu*), which included *Curcuma longa* (turmeric), *Phyllanthus emblica* (Indian gooseberry or *nelli* in Sinhala) and bees' honey, dripping of oil on the whole body (*sarvangadara*), application of oil with a milk–rice poultice (*pindasweda*) or oil pouring to the forehead on the third eye (*shirodara*), following which you wear a headscarf for two days. The oil applications were followed either by a sauna in a traditional round hut with an open fire underneath and small compartments in the floor filled with different herbs and flowers such as *Syzygium aromaticum* (clove) and *Myristica fragrans* (nutmeg), steam baths in a wicker basket fuelled by a wood fire while covered in the herbal paste or infused herbal baths, which included neem, *Justicia adhatoda* (adhatoda) and *Vitex negundo* (*nika* in Sinhala) leaves. Some guests received elimination therapies such as inhalation with herbal oil. Following treatments, we scrubbed ourselves with ground *Vigna radiata* (mung beans) and had a rinse by ladling warm water over our heads from the copper kettle, which had been filled with water heated in a large cauldron. This was a treat because it was the only time we had warm

water for bathing due to the fact there is no electricity at Ulpotha. According to Dr Srilal, simply being at Ulpotha, with the climate, nature and diet, helps to correct 90% of any imbalances in doshas. The therapies and treatments, which help expel toxins, add the final 10% to wellness.

Dr Srilal introduced us to a selection of plants growing in the vicinity of the clinic and we revelled in the sensory experience. The plants included *Cinnamomum verum* (Ceylon cinnamon or *kurundu* in Sinhala), *Ixora coccinea* (*rathmal* in Sinhala) whose red flowers are used in babies' baths, *Saraca indica* (*ashoka* in Sinhala, which means one that is used for the pain and grief of women) the bark of which is used for leucorrhoea, *Cassia fistula* (*ahela* in Sinhala), whose leaf is used for arthritis, cardiotonic



Double double toil and trouble: A large cauldron used to heat water for a warm rinse after treatments at Ulpotha.

Terminalia arjuna (arjuna or *kumbuk* in Sinhala) and shatavari, the famous female tonic. One of the many highlights of Ulpotha was making an Ayurveda head massage oil with Dr Srilal and his team from the juice of *Sesbania grandiflora* (*katuru murunga* in Sinhala or hummingbird tree) leaves, a herbal paste (*kalka*), which included hemidesmus, nutmeg, garlic and onion, and freshly pressed coconut oil. The oil is used for catarrh, rhinitis and runny noses.

Sri Lanka's traditional medicine system has more than 3000 years of tested and demonstrated efficacy. It is a way of life and, as mentioned above, is generally the first approach for disease control by locals. Dr Srilal's wife Dr AH Shirani Gunawardana is also an Ayurveda doctor who works at the Provincial Ayurveda Hospital of Anuradhapura, which, incredibly, is a free service run by



Therapy: The wicker basket steam bath, fuelled with a wood fire used as part of our fomentation therapy.



Perfect potion: Making an Ayurveda head massage oil with local plants. Photo credit: Tabitha McIntosh <http://www.awakenyourhealth.com.au/>

the government. It is the largest Ayurveda hospital in the northern province of Sri Lanka. There are nine provinces in Sri Lanka and every one has an Ayurveda hospital. The Anuradhapura hospital is also the second oldest, having been open since 1964. It works in tandem with the general hospital nearby for cases of emergency and lifesaving or when testing facilities, such as x-rays, are needed for investigations. The I Love Herbs Sri Lanka

group felt privileged to be given a tour of this eye-opening facility, which uses ancient methods with local plants in a modern context. Before the tour we were treated to a *helapa*, a delicious, traditional, earthy tasting Sri Lankan sweet made from *Eleusine coracana* (finger millet) flour, red rice flour, grated coconut, coconut treacle, *Elettaria cardamomum* (cardamom) and wrapped in *Macaranga peltata* (*kenda* in Sinhala) leaves to add flavour and to double as a wrapper. There are seven departments including out and inpatients (there are four wards — two male and two female), drug manufacturing (90% of the plant-based drugs are prepared on site), a herbal garden and medicinal plant distribution department and paying wards (eight rooms). More than 300 patients a day come through their doors. There are 12 doctors and 75 staff members. With non-communicable diseases on the rise, it was refreshing to see a ‘developing country’ setting an example for so-called ‘developed countries’ like Australia by bridging the gap between evidence-based and traditional medicine.

Following this insightful morning, it would have been remiss of a bouquet of herbalists not to visit Sri Maha Bodhi, the oldest living human planted tree in the world with a known planting date (288 BC). It has been tended by an uninterrupted succession of guardians for more than 2000 years. This sacred *Ficus religiosa* (bo or fig) tree is said to be grown from a cutting from the Sri Maha Bodhi at Buddha Gaya in India, under which Lord Buddha attained enlightenment. Today it is one of the most sacred relics of the Buddhists in Sri Lanka and is respected by Buddhists all over the world who come to visit the tree



Rich heritage alive and well: A female ward for inpatients at the Provincial Ayurveda Hospital in the ancient city of Anuradhapura.

on their burning bare feet. In the surrounding area is the oldest dagoba (brick stupa) in Sri Lanka Ruwanwelisaya (built in 140 BC and which has been restored), which was considered to be an icon of architectural glory in ancient Sri Lanka and the surrounding wall is decorated

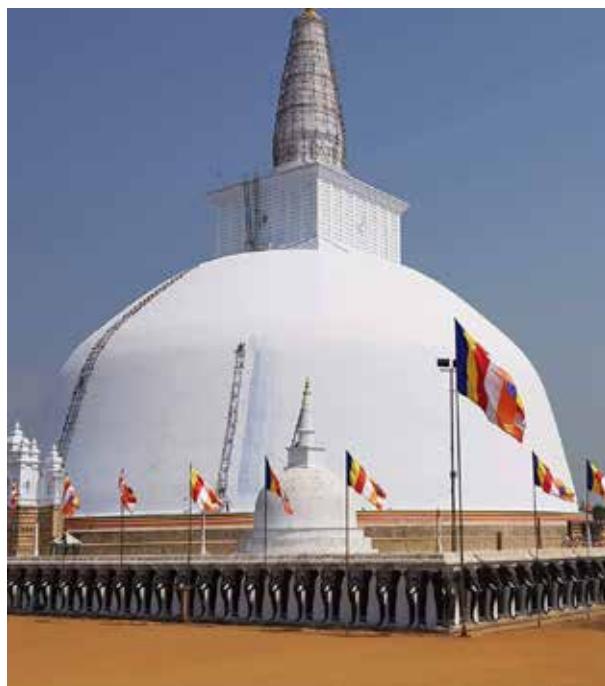
with 1900 figures of elephants. There is also the Jethawanaramaya dagoba, which is the largest stupa in Sri Lanka and the world (originally 122 metres tall) built by a king in 271–303 AD. It may be an ancient city, and you can ‘feel the BC’, but when you are close to these enormous elegant structures, it feels like you’ve landed on another planet.

Basking in the afterglow of Ulpotha, we headed back to Colombo and visited Seth Medura (Blessing House), an Ayurveda medicine manufacturing facility on the outskirts of the nation’s capital. Seth Medura has long and humble beginnings, having been run by the same distinguished Ayurveda family for four generations. The son of a well-known Ayurveda physician, Dr MM Chandrasena is himself a qualified specialist Ayurveda physician. In a similar vein to HEC, Dr Chandrasena has built up the facility over his lifetime with his wife



Relic: Sri Maha Bodhi, a sacred *Ficus religiosa* (bo or fig) tree, said to be the oldest living human planted tree in the world with a known planting date (288 BC).

and daughter Pamodani Marasinghe, who is heading research and development for the company. Seth Medura uses traditional manufacturing methods to make medicated oils over wood fires, ground powders using vintage equipment, ointments, pastes, syrups, extracts, spirits, wines, pills and teas. The raw material is wildcrafted throughout Sri Lanka and India by local villagers. If the plants can’t be harvested from the area surrounding the manufacturing facility they are sent by train after collection. This is a small-scale, home-based operation supporting the local community and a select few Ayurveda doctors, including Dr Srilal. It was one of the highlights of our trip for the traditional herbalists.



Feel the BC: The oldest dagoba (brick stupa) in Sri Lanka, Ruwanwelisaya (built in 140 BC and which has been restored), which was considered to be an icon of architectural glory in ancient Sri Lanka and the surrounding wall is decorated with 1900 figures of elephants.



Functional food: Ayurveda physician Dr MM Chandrasena holding the spiny rhizome of *Lasia spinosa* (*kohila* in Sinhala). With his daughter Pamodani translating, he told us the root and young leaves of this aquatic plant are eaten cooked as a vegetable, used in sambols and curry, which is good dietary fibre for constipation. He makes it into a powder for tablets to be used for haemorrhoids.

After working up our appetite watching cauldrons bubble away, we were treated to a private degustation lunch at Kopi Kade (Coffee House), a sleek, creative and innovative Colombo café offering refined Sri Lankan short eats. The owner, Nimeshan Namasivayam, pays high attention to detail and there is a sophistication behind the simple dishes served in a chic, minimalist setting. This was another excursion highlight. Nim cares deeply about the provenance of the food he plates up. As such, we were given a presentation and tasting session by the owners of two Sri Lankan brands with an ecological



Grass roots: Preparing fresh *Centella asiatica* (gotu kola) for manufacture at Seth Medura.

focus. These were Laa Dhalu kombucha made using organic Sri Lankan black tea with four flavours: original, ginger, turmeric and *Aegle marmelos* (bael flower or *beli mal* in Sinhala, which is a common local herbal tea) and Kimbula (Crocodile) Kithul, a healthy, smoky tasting ancient treacle made from the sap of the *Caryota urens* (fishtail, or jaggery, palm) flower, Sri Lanka's answer to maple syrup. It is a low glycaemic index, natural sweetener. For lunch we had king coconut water with *narang* (a local wild orange that tastes like a sweet lime with the tang of a cumquat) and organic coconut sugar, gotu kola salad, *Tamarindus indica* (tamarind or *siyambala* in Sinhala) and onion flower broth, coconut roti crisps served with *Limonia acidissima* (wood apple or *divul* in Sinhala) jam and sambols, seer (a type of mackerel) fish with spiced eggplant mash and pineapple panna cotta with caramelised coconut sauce.

For the final day of the I Love Herbs Sri Lanka excursion, we were given lunch and a grand tour of the recently completed oceanfront property Vingyana at Reefs, a five-star, integrative medical and wellness centre on the outskirts of Colombo. This impressive facility offers treatment plans for the management of cancer, diabetes and clinical detox, combining allopathy, naturopathy, homeopathy, Ayurveda and Chinese medicine. A team of internationally recognised professionals provides assessments, investigations and therapies, which include herbal extracts, nutritional medicine, hyperbaric oxygen

therapy, colonic irrigation, intravenous vitamins and herbs, metronomic chemotherapy (low dose), chelation, hyperthermia, acupuncture, chiropractic, psychotherapy, movement and personalised diets using organic food. It is the only clinic of its type worldwide which also includes wellness elements in a spa village such as oncology massage, salt caves, flotation tanks, music and art therapy, beauty salon and a sensory garden.

And so concluded the I Love Herbs Sri Lanka excursion. I hope I achieved what I set out to do, which was to refresh people's spirits by bringing the world of plants alive.



A bouquet of herbalists: The I Love Herbs Sri Lanka excursion group during the welcome dinner at Tintagel, one of Colombo's prettiest mansions steeped in dark political history. L-R: Gillian Thomas <https://www.facebook.com/gill.thomas.121>; Darryl Lambert, Operations Manager at The Herbal Extract Company of Australia; Annette Lambert, General Manager of The Herbal Extract Company of Australia <http://www.herbalextracts.com.au/>; Jennifer Webster <http://www.traditionalherbs.com.au/index.htm>; Desley Gray <http://www.desleygray.com/>; the author; Tabitha McIntosh <http://www.awakenyourhealth.com.au/>; Catherine Bennett <http://catherinebennett.com.au/>; Pascal Chang Leng <https://www.facebook.com/VitalitySeychelles/>

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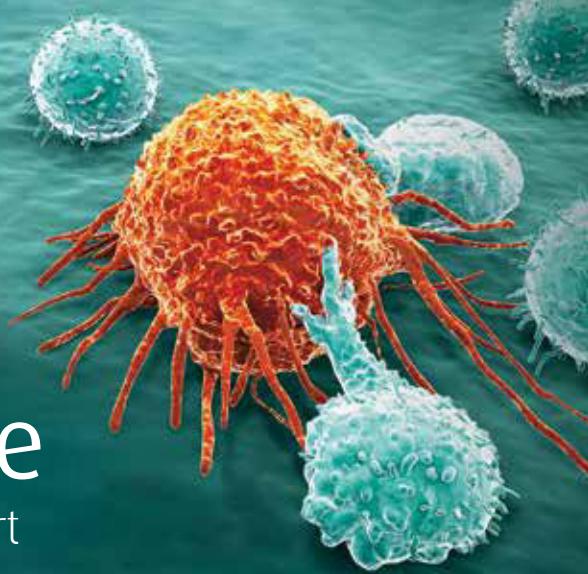
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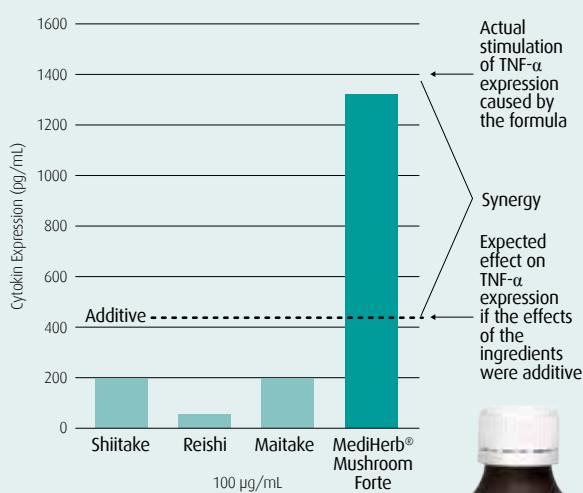
These results indicate synergistic activity. Follow up studies are on-going to further characterise the observed synergistic effect.

Note: Although some of these cytokines are often thought of as being pro-inflammatory, they also play important roles in the immune response. For example, TNF-alpha is an important signaling molecule in the adaptive immune response, with its release from macrophages and monocytes leading to activation of natural killer cells and B cells. Therefore, in this experimental model, increased cytokine production represents an immunostimulatory effect.

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Breaking the cycle of antimicrobial therapy in recurrent bacterial vaginosis. A multifactorial predisposition and risk vaginal dysbiosis case report

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The client's written permission for publication of this case was formally sought and provided.

Abstract

Bacterial vaginosis (BV) and genitourinary disorders associated with vaginal dysbiosis are common in females of all ages. Bacterial vaginosis is characterised by a reduction of *Lactobacillus*-dominant vaginal flora and an overgrowth of facultative anaerobic bacteria. Recurrent infection of BV has a range of implications on the individual, such as psychosexual effects, fertility and pregnancy impacts, possible associations with pelvic inflammatory disease and increased risk of sexually transmitted infections (STI). Antimicrobial pharmaceutical treatment of BV eradicates the active infection but does not offer follow-up treatment to prevent an opportunistic environment for reinfection. In some cases, the treatment of BV predisposes an individual to recurrence as resistant organisms are favoured in an unstable *econiche* environment, and organisms of pathogenicity dominate in a dysbiotic trend. Effective treatment of recurrent BV may be more sustainable if the health of the vaginal micro-environment is rebalanced, whilst reducing risk factors. This may improve natural resistance to pathogenic organisms and break the cycle of this persistent condition.

The following case study is a 32-year-old woman with recurrent BV wanting to conceive. Modification of predisposing and maintaining factors, in association with targeted naturopathic interventions, which included vaginal pessary application, lifestyle modification and dietary change, influenced the vaginal pH and modified the ecology within the vaginal microbiome, providing effective, long-term relief when antimicrobial treatment alone was not able to prevent recurrent symptoms.

Keywords: Bacterial vaginosis, vaginal dysbiosis, *Lactobacilli*, metronidazole, probiotic therapy, lifestyle modification.

Introduction

Bacterial vaginosis (BV) is a common condition in females, with a prevalence of 12–29%¹ in developed nations. The condition carries an array of health risks, ranging from increased sexually transmitted infection (STI) transmission and acquisition, to implications with fertility and pregnancy such as preterm labour and miscarriage². Additionally, recurrent BV impacts on psychosocial aspects in the lives of sufferers³.

Recurrent BV infection is characterised by a reduction in hydrogen peroxide (H_2O_2) and lactic acid-producing *Lactobacilli* spp., and an increase in polymicrobial facultative anaerobic organisms such as *Gardnerella vaginalis*, *Mycoplasma hominis* and *Prevotella species*⁴. Despite reductions of *Lactobacilli* being generally associated with recurrent BV, some species (for example, *Lactobacilli iners*) may be associated with recurrent infections¹. The shift towards anaerobic bacteria dominance and the subsequent pH increase facilitates the proliferation of pathogenic bacteria and perpetuates the host's dysbiotic environment⁵.

Metronidazole, an antimicrobial pharmaceutical agent is standard care for the treatment of BV. Treatment is delivered as either a seven-day course or a single oral dose. Although effective treatment for BV in the short term, recurrence of symptoms is common. The clinical response rate one month post treatment is 71–89%, and the relapse rate of clinical disease after 1 to 6 months is 50–75%⁶. Bradshaw and Morton¹ suggested metronidazole may deplete the active infectious agents responsible for the vaginosis without full eradication. Pharmaceuticals that specifically target *Gardnerella vaginalis*-dominant microbial biofilms may lead to high recurrence rates due to antimicrobial resistance, incomplete eradication and persistent elevation of vaginal pH⁷.

Some sexual behaviour may also contribute to recurrent BV. Enquiry into sexual health may identify behaviours that continually challenge the vaginal homeostasis and eubiosis and contribute to treatment resistance and high recurrence. Sexual activity that involves either digital, oral or penile intercourse has been associated with increased risks of BV due to their impact

on the vaginal microbiome⁸. Semen, saliva and skin may introduce pathogenic microbes and the relative alkalinity of introduced fluids may consequentially increase vaginal pH and provide hospitable conditions for pathogenic bacteria⁸.

In susceptible women who have long-standing dysbiotic trends, the alkaline menstrual bleed can be a recurrent trigger to early-cycle BV flares⁹. Menses can contribute to normal physiological microbial shifts, which are specific to the individual and their microbial colonies⁹. The normal presentation of pathogenic-associated microbes such as *G. vaginalis* at this monthly interval is balanced by the propagation of *Lactobacilli* colonies at cessation of menstruation, which contribute to acidification and environment defence restoration⁹. Exogenously acidifying the vaginal environment in at-risk individuals may theoretically offer a promising intervention.

The following case report outlines the assessment and naturopathic treatment of a recurrent sufferer of BV, for whom standard antimicrobial therapy had been utilised without long-lasting effect.

Presenting concerns

A 32-year-old woman presented to the clinic with watery, grey vaginal discharge and a fishy malodour. She reported approximately seven episodes in the preceding six months with symptoms lasting four to seven days. She reported that her discharge was frequently worse after menstruation.

Previous medical investigation and vaginal swabs six months prior had confirmed BV. Oral metronidazole treatment for seven days was initiated, which resolved symptoms. Subsequent return of symptoms resulted in additional courses of metronidazole and a prescription of a single-dose, two-gram oral metronidazole treatment. All treatment interventions resolved symptoms at time of use. No further vaginal swabs had been performed after the first presentation. The client was sexually active, reporting prior normal pap smears and STI screens.

The client and her male partner had been trying to conceive for the previous 12 months and engaged in sexual activity every second day. The woman reported that sexual intercourse was painful due to low arousal and decreased natural secretions. The use of lubricant assisted with the comfort of frequent sexual activity; however, the emotional impact of the situation became apparent when the client described herself as “feeling unclean” and lamenting the “chore of sex whilst trying to conceive”. The client was also employed in an executive role and reported high levels of stress, often consuming food on the run and a diet high in refined carbohydrates.

Physical examination

Vaginal pH was assessed in the clinic using sterile self-swabbing of the vaginal walls and application of litmus paper when the client returned to the room. The

pH reading was measured at 5.5. Any pH levels over 4.5 indicate a relatively alkaline vaginal environment².

Diagnostic focus and assessment

The client was referred to the local government sexual health clinic to confirm the diagnosis. Results confirmed BV.

The diagnosis of BV, coupled with a history of metronidazole, suggested recurrent infection and vaginal dysbiosis. Other characteristics of the case indicating vaginal microbiome instability and recurrent BV included the increased risk factors of: frequent sexual activity, symptoms worse with menstruation, high glycaemic and nutrient devoid diet, infertility and psychological stress.

Therapeutic focus and assessment

Naturopathic intervention was initially aimed at providing relief of vaginal symptoms. Two different types of vaginal pessaries addressed acidity, microbial balance and local immune defences. Additional treatments were aimed at reducing risks and improving vitality by improving diversity and health of overall microbial colony, tissue integrity and genitourinary microbial eubiosis. Treatment strategies included sexual behavioural modification, psychological support and ingested therapies.

Gelatin pessaries containing 250 mg of ascorbic acid were inserted into the vagina for six days post menses (six menstrual cycles) to promote acidification of the environment. Each cycle was followed by a six-day course of intravaginal *Lactobacilli* probiotic containing *L. reuteri* GR-1 and *L. rhamnosus* RC-14, 2.5 billion colony forming units. The client was instructed to repeat both treatments as required with symptom appearance. During the pessary use the client was instructed to abstain from sexual intercourse (12 days in total a month). The same *L. reuteri* GR-1 and *L. rhamnosus* RC-14 formula was recommended orally. The ingested and vaginal therapy prescription and dosage are outlined in Table 1.

Strategies to minimise disruption of the vaginal ecosystem included the recommendation to abstain from unprotected sex, and use of a personal lubricant with a

Table 1: Table of interventions, application and dosage

Intervention	Application type	Dosage Instruction
Ascorbic acid 250 mg Gelatin capsule	Intravaginally	1 x day, 6 days post menses and again with symptom flare 6 months
<i>L. reuteri</i> GR-1 and <i>L. rhamnosus</i> RC-14	Intravaginally	6 days treatment after ascorbic acid treatment 6 months Additional course if symptoms flared
<i>L. reuteri</i> GR-1 and <i>L. rhamnosus</i> RC-14	Orally	1 capsule daily with food

pH of less than 4.5 and an osmolarity that did not exceed 1200 m0sm/Kg. A lubricant, which met these standards, was anticipated to protect the vaginal environment and tissue integrity, by preventing the introduction of alkaline fluid and cellular osmotic shifts, which may cause damage to vaginal epithelial tissue.

The client was advised to refrain from unprotected penile–vaginal sex until vaginal health improved, with the aim of reducing conception-based stress. Condom use was encouraged if the client was engaged in sexual activity. The client was referred to a sexologist to support her psychosexually, addressing her perceptions of cleanliness and “the chore” of sex.

Dietary advice that included food preparation in a busy lifestyle, guidelines for a low glycaemic and nutrient-rich diet were provided.

Follow-up and outcomes

March 2017: On return five weeks later, the client reported initial BV symptoms resolved with the ascorbic acid pessaries, vaginal and oral probiotic treatment and abstinence from unprotected sexual intercourse. She reported one flare of symptoms post menses, which responded to the intravaginal treatment. She had initiated an agreement with her partner to “take a break from conception”. She reported feeling relieved that the pressure was off for a while and noticed an improved quality of life, her relationship felt less strained and she felt they were able to relax around each other more. They had had sex once, used a condom and the recommended lubricant type. She reported feeling sexual contact was more pleasurable. She had not initiated contact with the sexologist, but had been compliant with all other therapies.

April 2017: The client reported no symptoms experienced, and had been compliant with the treatment plan.

May 2017: No symptoms experienced. The client reported feeling emotionally positive and had engaged in unprotected sex without post-coital symptoms. Vaginal pH assessed at 4.5.

June 2017: Five months after the first consultation, the client had experienced no BV symptoms, even with increased sexual activity. She was more confident and felt in control of her health. Support was then directed towards preconception care and fertility.

Discussion

Naturopathic care is theoretically based on holistic and vitalistic philosophies. In this case, temporarily abstaining from unprotected sexual intercourse, and improving vaginal tissue integrity and resistance to pathogenic organisms improved the vitality of the individual. The treatment incorporated the whole person and supported behavioural changes that reduced conception-based stressors and improved the emotional experience of the client wanting to conceive. Naturopathic care encompasses a framework that can address factors that maintain dysbiosis and recurrent infection. In the case

study, the factors influencing recurrence were identified as frequent introduction of semen into the vagina, the type of lubricant, vaginal dysbiosis and apparent antimicrobial resistance, along with other factors outside the scope of this paper.

Medications, microbe resistance and biofilm

The pharmaceutical treatment of the BV in this case did not effectively prevent BV recurrence. Although metronidazole can temporarily suppress adherent *G. vaginalis* biofilm, it does not prevent recurrent activity post pharmaceutical cessation⁷. In this client’s case, the pattern of recurrence after pharmaceutical treatments illustrated the need for a therapeutic strategy that may concurrently reduce biofilm occurrence in the vagina and additionally improve overall microbial resistance and balance.

Evidence for improving microbial resistance and reducing biofilm formation within the vaginal environment is still largely theoretical. An *in vitro* study demonstrated that *Lactobacilli* colonies may effect biofilm formation by production of acid, bacteriocins or biosurfactant-like substances¹⁰. A systematic review of four clinical trials investigating *Lactobacilli* bacteria effects in comparison with, and to augment metronidazole and oestriol demonstrated a potentially positive role for the probiotic; however, the heterogeneity of the study methods prevented meta-analyses and the authors found that further research was needed to draw positive conclusions¹¹. The BV-associated biofilms of *G. vaginalis* and *A. vaginae* showed increased cell death when *L. reuteri* RC-14 and *L. rhamnosus* GR-1 probiotic strains were introduced post metronidazole treatment⁹. Prescription in this case included the use of these *Lactobacilli* strains vaginally and orally.

Sexual practices

The management of this case included sexual behavioural changes to the frequency and type (using a barrier method) of sexual interaction. The frequency of ejaculative sex associated with attempts to conceive may have predisposed the client to a dysbiotic vagina⁸. Some research proposes that BV is a sexually enhanced disease (SED) with ejaculative sex frequency coinciding with a transition to BV type microflora¹². The microbiomes of females engaged in ejaculative sex are more likely to be dominated by *G. vaginalis* and *L. iners*¹³. Not all females who engage regularly in this type of sexual intercourse experience recurrent symptoms, suggesting that the vaginal defence system and client vitality may have impacted the presentation in this particular case. The prescribed period of abstinence from sexual activities may have improved microbiome stability and pH, and both of these conditions support tissue repair and healing¹³.

The change in lubricant choice to one that did not have a pH and osmolality above the recommended range may have been another positive influence on microenvironment homestasis¹⁴.

Menstruation and vaginal pH

Ascorbic acid pessaries as slow-release, silicon-coated ascorbic acid tablets may prevent recurrence of BV in susceptible women when utilised post menstruation^{15,16}. Krasnopolksy *et al.* showed ascorbic acid pessaries compared to placebo for six days post menses halved the risk of recurrence from 32.4% to 16.2% at six months¹⁵. The localised acidification is believed to make up for the lack of acid resultant from low *Lactobacilli* count¹⁵. Additionally, ascorbic acid vaginal pessaries were identified as effective as metronidazole vaginal gel for the treatment of BV when used for six days in active infection¹⁶. In this case, the client used ascorbic acid pessaries as both a prophylactic and active treatment with apparent success.

Reduction of vaginal dysbiosis risk will support the client in their conception pursuits and reduce the complications of BV in pregnancy and childbirth. Clinical naturopathic approaches that support overall vaginal health have a role as both independent and complementary provision of health care. Effective treatment for recurrent BV provides improved physical health and function and other benefits that extend to social and emotional wellbeing. Strategies that prevent recurrence and reduce the need for pharmaceutical antimicrobial intervention illustrate effective holistic client care.

A strength of this case was that a range of parameters were addressed by only two key prescriptive interventions and sexual behaviour modification. This prescriptive advice was informed by a thorough naturopathic investigation and integrated systems approach. Simplistic treatment prescription contributed to client adherence and possibly treatment outcomes.

Within this case study there were several limitations associated with care and testing. Firstly, despite a variety of indicators that supported the conclusion of effective treatment, there was a lack of pathology-based evidence. The client was satisfied with the resolution of symptoms, specifically no fishy odour, decreased discharge, no symptoms post menses, pH in normal range and reported increase of quality of life and chose not to retest for the presence of BV via the government sexual health clinic. Additionally, there is no commercial way to assess the vaginal microbiome at a species level that would support identification of the impact treatment had on the client's vaginal environment. Given the case treatment was focussed on the role of *Lactobacilli* species and their influence on the microenvironment, including biofilm resistance, a measure of vaginal microbe diversity would have been advantageous. Secondly, in the initial stages of treatment, the male partner as a possible vector of opportunistic and pathogenic microbes was not addressed. The fertility and preconception care that followed the assumed resolution of the BV did incorporate assessment and care of the male partner. Lastly, the application of ascorbic acid pessaries differed to those seen in the studies demonstrating effective treatment of BV. The

ascorbic acid capsules were compounded in clinic as 250 mg of ascorbic acid powder in a gelatin capsule as no commercially available ascorbic acid slow-release tablets are available within Australia.

Conclusion

This case study outlined the naturopathic management of a woman wanting to conceive with recurrent BV and prior use of antimicrobial therapy. A multifactorial approach based on vitalistic philosophies, which addressed tissue integrity, pathogen resistance and overall emotional stressors, and wellbeing resulted in a noteworthy interval of symptom free presentation where previously monthly symptoms would appear.

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Improved progesterone levels and pregnancy following *Vitex agnus-castus* (chaste tree) supplementation in a case of recurrent pregnancy loss: A case report

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Abstract

Recurrent pregnancy loss (RPL) occurs in 1% of couples and is defined as three consecutive failed pregnancies. While controversial, evidence exists that adequate levels of progesterone may be an important factor in pregnancy maintenance and that increasing levels of progesterone may increase the likelihood of success. *Vitex agnus-castus* (chaste tree) is a herbal medicine with evidence to support its use in a variety of hormonal conditions, including premenstrual disorder and cyclic mastalgia through modulation of reproductive hormones. This report details a case of RPL in which low progesterone levels were observed. One month of supplementation with Vitex was followed by successful pregnancy with normal levels of serum progesterone and a live birth at full term. A second successful pregnancy followed, also with Vitex supplementation. Although the exact role of Vitex in this case cannot be confirmed, it adds evidence to the hypothesis that this herb may be an effective intervention in cases of RPL, particularly those involving low progesterone, and that more research is warranted.

Keywords: *Vitex agnus-castus*, herbal medicine, progesterone, spontaneous abortion, recurrent pregnancy loss, luteal phase defect.

Introduction

Recurrent pregnancy loss (RPL) has various definitions, making clinical research and diagnosis challenging. For the purposes of this case study, we define recurrent pregnancy loss as at least 3 consecutive failed pregnancies at any time prior to 20 weeks post-menstruation. Pregnancy loss is relatively common and estimated at 15–20% of pregnancies, with the majority occurring prior to 10 weeks¹, while RPL, as defined above, occurs in approximately 1% of couples².

Possible causes and contributing factors of RPL include chromosomal abnormalities, thrombophilic disorders such as antiphospholipid syndrome, uterine malformations, infections, hormonal and metabolic dysfunctions such as diabetes mellitus, and sperm DNA fragmentation^{1,2}. Low progesterone and luteal phase defect may also play a role³. Possible lifestyle factors may include, smoking, obesity and use of alcohol, caffeine or social drugs including cocaine¹. Other case characteristics associated with RPL may include psychological factors, unmanaged hypothyroidism and diabetes¹. At least half of RPL cases have no identifiable cause, and it is thought that these cases, as well as most cases of RPL, have

multiple contributing factors¹.

Conventional treatment of RPL aims to investigate the cause and initiate appropriate treatment. This may include surgical considerations, anticoagulants or progesterone administration. In couples without an identifiable cause, psychological support pre-conception and in early pregnancy has shown significant benefit^{4,5}.

Progesterone

Progesterone is a hormone secreted by the corpus luteum post-ovulation and develops the secretory endometrium in preparation for embryo implantation. If implantation occurs, the corpus luteum continues to produce progesterone until weeks 8–10 gestation when the placenta takes over⁶. Progesterone is essential for pregnancy initiation and maintenance. It promotes maternal immune tolerance to the foetus and mitigates uterine contractility⁷. It also triggers the production of progesterone induced blocking factor (PIBF) which possesses anti-abortive effects *in vivo*⁷. Several studies show an association between lower levels of serum progesterone and PIBF and higher risk of spontaneous abortion (SA)⁷. Insufficient progesterone secreted by the corpus luteum may be associated with what is

referred to as a luteal phase defect. Luteal phase defect or deficiency is defined as “insufficient progesterone exposure to maintain a normal secretory endometrium and allow for normal embryo implantation and growth”⁸. Clinically, this may present as a shortened luteal phase and an overall shortened menstrual cycle⁹, and primary infertility or recurrent pregnancy loss in first trimester¹⁰. Assessment of risk for RPL has been based on combined progesterone levels, luteal phase length, and histological features of the endometrium⁹. Luteal phase defect has been controversial due to inconsistencies in the evidence base for diagnosis and treatment. Findings from research have shown that women with RPL are at significant risk for lower progesterone levels in the luteal phase, with 40% of women having luteal phase defect^{10,11}.

Causes of low progesterone are unclear; however, it has been suggested that latent hyperprolactinaemia (pre-menstrual or stress-induced elevated levels of prolactin) may inhibit corpus luteum development and therefore subsequent progesterone release¹². Other possible associations include psychological perceived stress¹³, excessive exercise¹⁴ and exposure to endocrine-disrupting chemicals¹⁵.

Pharmacological preparations of progesterone such as progestogen have not been shown to benefit pregnancy in the general population; however, a statistically significant decrease in SA in women with RPL has been documented¹⁶. Additionally, progestogen has been shown to reduce the rate of SA when used in women with threatened miscarriage¹⁷. While use of exogenous progesterone is common, especially in assisted reproductive technology, concerns exist that intrauterine exposure to exogenous progesterone may increase risk of genital abnormalities in the fetus, such as hypospadias¹⁶.

Vitex agnus-castus

Introduction and biochemistry

Vitex agnus-castus, commonly known as chaste tree, is a deciduous plant with purple-black berries native to Europe and Central Asian countries that is used in botanical medicine¹⁸. Active constituents of Vitex include flavonoids, diterpenes and glycosides, all of which may exert a hormonal action. *In vitro* studies show dopaminergic activity, resulting in prolactin inhibition. As previously discussed, elevated prolactin in humans may inhibit ovulation, development of the corpus luteum and sufficient progesterone secretion and, therefore, inhibition of excessive prolactin inhibition may subsequently increase progesterone¹². Additionally, Vitex’s action of lowering prolactin levels by way of dopaminergic activity also affects follicle stimulating hormone (FSH), and oestrogen and testosterone in women and men, respectively¹⁹. Oestrogenic activity is also exerted by linoleic acid found in the fruit of Vitex¹⁹. Animal studies have shown increased progesterone levels with Vitex supplementation²⁰.

Uses

Vitex is often used for female reproductive disorders, with the majority of the research focusing on premenstrual syndrome (PMS) and premenstrual dysmorphic disorder (PMDD). Numerous studies have shown significant benefit in PMS and PMDD, despite lack of consistency in preparations of Vitex^{19,21-24}. Hyperprolactinaemia may be an important factor in these conditions. As previously discussed, elevated prolactin may inhibit progesterone secretion¹². Vitex’s documented actions of lowering prolactin levels may, in turn, remove its inhibitory effect on progesterone, ultimately normalising progesterone and contributing to positive benefits in PMS and PMDD^{19,25}. Additionally, due to prolactin inhibition, Vitex has been shown to improve latent hyperprolactinaemia and cyclic mastalgia¹². Other research has shown benefits in menopause and fracture healing, and Vitex possessing antimicrobial and antioxidant activity²⁶.

Positive results on menstrual cycle defects have also been shown for use of *Vitex agnus-castus*. One study involving women with luteal phase defects due to latent hyperprolactinaemia found progesterone levels normalised and luteal phase lengthened after 3 months of supplementation with Vitex²⁷. FertilityBlend, a proprietary blend of herbs and vitamins, with Vitex as a key component, found a significant increase in luteal progesterone levels as well as pregnancy rates in a group taking the supplement for three months²⁸. However, due to the proprietary blend of multiple ingredients, outcomes cannot be attributed to Vitex alone. While Vitex has well-documented hormonal activity, which may theoretically influence fertility, we have found no research directly testing the use of *Vitex agnus-castus* for low progesterone in RPL, with primary outcome of maintained pregnancy to second trimester.

Case presentation

Presenting concern

AB, a Caucasian woman presented at age 29 with concerns of recurrent pregnancy loss (RPL). She reported a history of four chemical pregnancies detected by urine or serum bHCG, three of which were in the preceding eight months. These pregnancies resulted in complete spontaneous abortion (SA) at five weeks’ gestation without intervention.

Laboratory assessment was completed immediately prior to and during the fourth SA. At 5 weeks plus 2 days’ gestation, bHCG was 459 IU/ml (normal range: 18–7340 IU/ml) and progesterone was 22.1 nm/L (1st trimester normal range: 18–150 nm/L). At 5 weeks plus 4 days, bHCG was 374 IU/ml and SA occurred two days later.

Past medical history

AB reported a history of moderate facial acne vulgaris and moderate primary dysmenorrhea since menarche. Bilateral dermoid ovarian cysts approximately 1 cm by 2 cm in size were an incidental finding on ultrasound

four years prior. They were monitored annually by ultrasound with no significant change. She had no history of abnormal Papanicolaou tests. AB reported no family history of infertility or genetic conditions. The patient's partner reported no past or current medical concerns and no family history of infertility or genetic conditions.

Psychosocial history

The patient lives with her husband and reports moderate work stress, which she manages with mindfulness meditation.

Medication

AB was not taking any prescription or over-the-counter medication. She used topical benzole peroxide for management of acne vulgaris. She was supplementing folic acid (methylfolate 1000 mcg per day).

Diagnostic focus and assessment

Other laboratory assessment included TSH 0.87 mIU/L (0.3–5.0 mIU/L). Physical examination was within normal limits.

Therapeutic approach

A prescription was made for *Vitex agnus-castus* herbal supplement at a dose of 166.6 mg of 6:1 fruit extract from 1000 mg of fruit per day (Brand: Mediherb, 2 capsules per day). AB reported a high level of compliance and no adverse reactions.

Follow-up and outcomes

After one month of supplementation, the patient completed a home pregnancy test, which was positive. Laboratory assessment completed at 5 weeks plus 2 days' gestation revealed bHCG of 1200 IU/ml and progesterone of 85 nm/L (Table 1). Ultrasound examination two days later revealed a singleton uterine pregnancy.

This laboratory and imaging assessment took place with an obstetrician/gynaecologist, who completed a fellowship in reproductive endocrinology and infertility, and to whom AB was referred by her primary health care provider. The positive home pregnancy test preceded the initial visit with this clinician and, thus, no other investigations related to causes of infertility were completed. The specialist advised the patient to discontinue the herbal supplement at 5 weeks plus 4 days and prescribed vaginal pessaries of progesterone (200mg twice per day) until 10 weeks' gestation.

Subsequent ultrasounds and screening testing were normal and the patient had a healthy pregnancy, resulting

in spontaneous vaginal delivery of a healthy infant at full term.

When the patient was 15 months' postpartum, she restarted the Vitex formula. One month later she conceived naturally. The Vitex formula was continued until 8 weeks' gestation and then discontinued. Discontinuation at 8 weeks was based on the placenta assuming the role of progesterone production from the corpus luteum at this point in pregnancy and the patient's desire to discontinue intervention at the earliest opportunity. At the time of writing, the patient is 38 weeks' pregnant. Ultrasound assessment at 12, 20 and 28 weeks gestation revealed a healthy, singleton, uterine pregnancy.

Discussion

The precise role that supplementation with Vitex played in this case is unclear; however, repeated blood work and a proposed biological mechanism lend support to the hypothesis that the intervention may raise progesterone levels or normalise another physiologic parameter, resulting in maintenance of the pregnancy.

Proposed mechanism

In this case, progesterone levels improved between subsequent pregnancies following Vitex supplementation, and pregnancy was subsequently maintained. Adequate progesterone production by the corpus luteum is known to play an important role in the maintenance of pregnancy through the first eight weeks of gestation through a variety of mechanisms. As discussed, Vitex may increase progesterone levels by way of inhibiting prolactin. Prolactin levels were not measured in this case; therefore the role of prolactin is unclear. Documented uses of Vitex supports the proposed mechanism of action of increasing progesterone levels leading to maintained pregnancy.

Strengths and limitations

A strength of this case report is that the laboratory testing was completed at the same gestational age for two consecutive pregnancies, allowing for comparison prior to and after Vitex supplementation.

This report has limitations. Progesterone levels were not assessed in the earlier pregnancies, so it is unclear if low progesterone was associated with previous SAs. Although it may be suspected, this cannot be confirmed. Unfortunately, prolactin levels were not assessed in this case, which also limits the ability to draw inferences about the therapeutic mechanisms.

Table 1: Laboratory values for AB at 5 weeks plus 2 days gestation

	Reference range	4th pregnancy with no intervention	5th pregnancy with Vitex supplementation
bHCG	18–7340 IU/ml	459 IU/ml	1200 IU/ml
Progesterone	18–150 nm/L	22.1 nm/L	85.0 nm/L
Outcome		Spontaneous abortion at 5 weeks +6 days	Pregnancy maintained with full-term live birth

Safety

The safety profile of Vitex is well established and adverse events have been shown to be infrequent, mild and reversible. Despite acknowledgement that Vitex may have a therapeutic role²⁹, use in pregnancy and lactation is currently not recommended based on lack of safety evidence³⁰.

Further research

Few therapeutic options are available for women experiencing RPL in the absence of an identifiable cause. While therapeutic progesterone is a valuable tool, some concerns about side effects to the developing foetus have been cited or hypothesised¹⁶. The potential for Vitex to play a role in the maintenance of hormonal balance in early pregnancy and prevention of SA would be a valuable therapeutic tool. This case report highlights a need for further research on this topic in order to elucidate the effect of Vitex on hormonal balance, progesterone and prolactin in particular, and the role that the herb may play as an intervention in cases of RPL. Randomised controlled trials investigating Vitex supplementation in women with RPL are needed to further explain its clinical effectiveness for progesterone augmentation, prevention of SA and safety in pregnancy.

Conclusion

This report details a case of two successful pregnancies following RPL with *Vitex agnus-castus* supplementation. Vitex may be useful in the prevention of recurrent SA related to sub-optimal progesterone. More research, including intervention studies, is needed to fully investigate the potential for efficacy and safety.

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Permission

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Conflict of interest

The authors declare no conflicts of interest.

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Reviews of medical journal articles

Jodie Tester

These abstracts are brief summaries of articles in recent issues of medical journals. Articles selected are of a general nature for the information of practitioners of naturopathy and herbal medicine. A dominant theme is often present throughout the journals, which will be reflected in the reviews.

Probiotics for prevention of *Clostridium difficile* infection — Cochrane Review

Goldenberg JZ, Yap C, Lytvyn L et al. Probiotics for the prevention of *Clostridium difficile*-associated diarrhoea in adults and children. *Cochrane Database Syst Rev* 2017;12:CD006095.

Antibiotics are one of the most commonly prescribed medications worldwide. While an important medication, antibiotics are associated with *Clostridium difficile* infection (CDI), with complications including toxic megacolon and death. A recent Cochrane review sought to evaluate evidence to answer the clinical question as to whether co-administration of a probiotic is associated with a lower risk of symptomatic *C. difficile* infection in adults and children prescribed antibiotics, without an increase in adverse events.

In total 39 randomised clinical trials were identified, with 31 providing data on CDI. The total number of participants was 9955 (male 52%), with a mean age of 51 years (range 0–84 years). Trials varied from outpatient, inpatient, and combined inpatient and outpatient settings. Study designs had adults (33 studies) or children (6 studies) receiving antibiotics to be randomised to single or multi-strain probiotics versus placebo or no treatment. Probiotics varied between studies with species including *Saccharomyces*, *Lactobacilli*, *Bifidobacteria*, and *Streptococci*. The primary outcome was CDI (diarrhoea with positive stool toxin or culture) and adverse events. The secondary outcome was *C. difficile* detection (or toxin in stool without diarrhoea), and antibiotic-associated diarrhoea.

Co-administration of probiotics and antibiotics was associated with a lower risk for CDI compared to placebo or no treatment (1.5% vs 4.0%, respectively). The efficacy evidence was evaluated to be of moderate quality. The number needed to treat was calculated at 40. Results did not differ significantly when looking at type of probiotic strain or species, higher doses or lower doses, clinical setting and patient group (adult or child).

Probiotics plus antibiotics were associated with a lower risk of adverse events such as abdominal cramping and nausea when compared to placebo or no treatment. Probiotics plus antibiotics were associated with a lower risk of antibiotic-associated diarrhoea compared to placebo or no treatment. The quality of the safety and tolerability evidence was evaluated to be of low quality.

There are a number of limitations to the review including the pooling of trials and results across clinical

settings, ages, and probiotic strains and doses. The trials were conducted in an immunocompetent population group, so its generalisability to immunosuppressed or immunocompromised patients is uncertain. Design of some trials involved open-label intervention which further limits the interpretation.

The Cochrane review provides a high-level summary and overview and concludes that the addition of probiotics to antibiotic treatment is associated with a lower risk of *C. difficile* infection. Further research to identify populations that may benefit most are required, as well as investigating the benefit in an immunocompromised population.

Reproductive life in women with coeliac disease — before and after diagnosis

Grode L, Bech BH, Plana-Ripoli O et al. Reproductive life in women with celiac disease; a nationwide, population-based matched cohort study. *Hum Reprod* 2018;33(8):1538–1547.

Coeliac disease (CD), is an immune-mediated disease following ingestion of gluten proteins which induce inflammation in the small-bowel and an autoimmune response to self-proteins, mainly transglutaminase. Classically, symptoms include diarrhoea, vitamin and mineral deficiencies, and failure to thrive; however, many people with CD have mild and/or non-classical symptoms leading to later in life diagnosis. CD has been associated with several conditions influencing female reproduction and pregnancy outcomes, with previous research reporting higher rates of infertility. The current study aimed to address the influence of CD on a women's reproductive life, both prior to and after the CD diagnosis.

The study was a nationwide matched cohort study using several Danish national health registers. All women diagnosed with CD between 1977 and 2016 were identified, with reproductive events between the ages of 15 and 50 years identified. Data collected included births (live and stillbirths), induced and spontaneous abortions, and molar and ectopic pregnancies. Reproductive outcomes were assessed before and after diagnosis of CD.

Of the 7625 women with a diagnosis of CD identified through the Danish National Patient Register, only women with appropriate follow-up time during their reproductive years were included. This resulted in a cohort of 6319 women diagnosed with CD and 63166 matched women without CD. The majority of women

with CD were diagnosed during their reproductive age (60.3%) and 15% during childhood (<15 years). At index date (of CD diagnosis), the average number of pregnancies was similar between the two cohorts (1.1 pregnancies per woman) and mean age of first pregnancy was approximately the same.

Compared with the non-CD women, women diagnosed with CD had similar rates overall of pregnancy and live birth, and similar risk of stillbirth, molar and ectopic pregnancy, spontaneous abortion and abortion due to foetal disease. However, prior to being diagnosed, CD women had an excess risk of spontaneous abortions and stillbirth, equating to an extra 11 and 1.62 events per 1000 pregnancies, respectively, compared with non-CD women. While there was no difference in number of pregnancies overall prior to index-date in the undiagnosed CD compared to non-CD group, significantly fewer pregnancies occurred in the 0–2 years prior to diagnosis.

The authors suggested that undiagnosed CD, and presumably untreated CD, might increase the risk of adverse pregnancy outcomes. Following diagnosis, and presumably adherence to a gluten-free treatment, the increased risks resolved and normalised to a non-CD population. The research produces interesting findings on several levels; firstly, the results may provide reassurance that women with CD had no ongoing impact on reproduction. Additionally, the results suggest that consideration and early investigation of CD may be appropriate for women experiencing spontaneous abortions and stillbirths.

Maternal sleep patterns in the first 48 hours postpartum

Hughes O, Mohamad MM, Doyle P, Burke G. The significance of breastfeeding on sleep patterns during the first 48 hours postpartum for first time mothers. *J Obstet Gynaecol* 2018;38(3):316–320.

Childbearing affects women's health and sleep in numerous ways: hormonal changes that occur during pregnancy and the postpartum period, the adaptation to new parental responsibilities, in addition to physiological and anatomical alterations contribute to changes in sleep architecture. Most research on postpartum maternal sleep quality and quantity has been undertaken between weeks one and six postpartum. Research looking at maternal sleep in the first six months postpartum identifies relationships between poor maternal sleep and postpartum depression as well as other mental health outcomes. The aim of the current study was to explore sleep patterns and reasons for wakefulness of first-time mothers immediately following delivery.

The study was conducted in University Maternity Hospital, in Ireland. Thirty first-time mothers, who were identified prior in antenatal clinics, completed a postnatal sleep questionnaire detailing their total sleep time (TST), the reasons for being awake, and their level of fatigue. Women with hypertension, thyroid disease, depression, anxiety and known sleep disorders were excluded from

the study. Only women with a singleton pregnancy delivering after 37 weeks were included. Participants completed the sleep logs in real time during the first 48 hours postpartum, while they remained in the hospital environment.

Of the 30 first-time mothers, one-third of patients had spontaneous vaginal delivery, one-third had instrumental delivery, and one-third had caesarean delivery. Of the women, 60% intended to breastfeed their infants and all were successful on day 2. Remained mothers planned to bottle-feed from delivery and did not have any assistance with feeding from nurses or relatives for the first two nights. The most common reasons for being awake was feeding (90%), settling the baby (33.3%), emotions (33.3%), and background noise (27%). Only one patient reported pain as a reason for being awake. The mean TST for the first 48 hours was 9.7 hours (range 5–22). Mothers slept significantly longer in the second 24 hours period postpartum. The mean TST for different delivery methods were 9.3h, 9.2h and 10.6h for spontaneous vaginal, instrumental, and caesarean deliveries, respectively. The authors reported social and demographic factors did not influence sleep duration. No difference in TST was observed with difference in post-delivery analgesia, infant location in same room or neonatal unit, or private or public rooms. Breastfeeding women reported significantly more sleep of 2.59 hours compared to the bottle-feeding women.

The research provides some interesting findings in its exploratory study reporting on sleep patterns in the 48 hours immediately postpartum. While finding that feeding method was the only factor identified that significantly altered sleep duration, this should be interpreted with caution due to the small size of the study and its self-reporting nature. Furthermore, the long-term implications of this difference of sleep duration means remains unclear. Ongoing research in the area may help to better understand factors that influence sleep patterns in the postpartum period and their impact on health outcomes such as depression and mental health are required.

Vitamin D and omega-3 co-supplementation in PCOS

Jamilian M, Samimi M, Mirhosseini N et al. The influences of vitamin D and omega-3 co-supplementation on clinical, metabolic and genetic parameters in women with polycystic ovary syndrome. *J Affect Disord* 2018;238:32–38.

Polycystic ovary syndrome (PCOS) is a common endocrine disorder affecting up to 10% of women of reproductive age. The condition is characterised by impaired menstrual function and fertility, hyperandrogenism, and/or polycystic ovaries, and has also associated with insulin resistance, dyslipidaemia and cardiometabolic risk factors. Previous research has suggested PCOS might be associated with vitamin D; however, trials have produced conflicting results. The purpose of the current study was to investigate the

combined effects of vitamin D and omega-3 treatment on clinical, metabolic and genetic parameters in women with PCOS.

The study was a randomised, double-blinded, placebo-controlled trial conducted in Iran between February and October 2017. Women were aged 18–40 years with PCOS diagnosed based on Rotterdam criteria. Exclusion factors included pregnancy, adrenal hyperplasia, androgen-secreting tumours, hyperprolactinaemia, thyroid dysfunction, diabetes or impaired glucose tolerance at enrolment. Subjects were randomised to take either vitamin D (50,000 IU biweekly) plus 2g/day omega-3 fatty acids from fish oil (Vit D+ ω 3 n=30) or placebo (Vit D+placebo n=30) for 12 weeks. Anthropometric, clinical and biochemical measurements were assessed at baseline at week 12 intervention. All subjects completed food and physical activity records to allow for evaluation of confounding effects of diet and exercise.

Of the 60 participants allocated to treatment, 52 completed the trial (Vit D+ ω 3=26, Vit D+placebo=26). Analysis included all 60 participants based on intention-to-treat principles. Anthropometric measures including mean height, weight, and BMI were not statistically different between groups at baseline or end-of-trial. There was no significant difference in mean macro- and micro-nutrient intake between groups at baseline or end-of-trial. Vit D+ ω 3 co-supplementation significantly decreased serum total testosterone levels compared with Vit+placebo. Additionally, co-supplementation with Vit D+ ω 3 resulted in a significant improvement in beck depression inventory, general health questionnaire scores, and depression anxiety and stress scale scores compared with placebo. Co-administration was found to significantly decrease inflammatory markers, C-reactive protein and malondialdehyde levels, whilst increasing plasma total antioxidant capacity levels compared to Vit D+placebo. No significant effect was observed with co-administration of Vit D+ ω 3 on other hormonal profiles, plasma nitric oxide or total glutathione levels. Real-time PCR demonstrated significant downregulation of intereukin-1 gene expression and upregulated vascular endothelial growth factor with Vit D+ ω 3 co-supplementation.

The findings support anti-inflammatory and immunomodulatory roles of combined vitamin D and omega-3 supplementation in women with PCOS with beneficial effects observed over 12 weeks. Limitations of the trial include its small sample size and short duration of intervention. Future research with well-designed studies in larger populations over a longer duration will provide further understanding.

Low-carbohydrate, high-protein diet with omega-3 supplementation in type 2 diabetes

Liu K, Wang B, Zhou R *et al.* Effect of combined used of a low-carbohydrate, high-protein diet with omega-3 polyunsaturated fatty

acid supplementation on glycemic control in newly diagnosed type 2 diabetes: a randomized, double-blind, parallel-controlled trial. *Am J Clin Nutr* 2018;108:256–265.

Type 2 diabetes mellitus (T2DM) is the most common form of diabetes, characterised by hyperglycaemia and insulin resistance, which contribute to the pathogenesis of diabetic complications. High carbohydrate consumption is a risk factor for high blood glucose resulting in a greater postprandial glucose response than protein or fat. Accordingly, low-carbohydrate diets have gained attention over recent years, with a 2015 review suggesting that a low-carbohydrate diet (<45% total energy) provides favourable effect on glycaemic control, insulin sensitivity, and body-weight control. Increasing the protein content may add further favourable effects on glycaemic control. Recent research also suggests that fat quality rather than quantity is seemingly more important, and of the unsaturated fatty acids, omega-3 (ω -3) has demonstrated beneficial effect on glycaemic control, insulin sensitivity, and chronic inflammation. The aim of the current study was to evaluate the effect of a low-carbohydrate, high-protein (LCHP) diet combined with ω -3 on glycaemic control in patients with T2DM.

The study was a randomised, double-blind, parallel-controlled trial undertaken in China. Subjects were newly diagnosed with T2DM (within the previous 3 months), aged 40–60 years, BMI 18.5–23.9 kg/m², and not hypertensive. Patients were to be weight stable, to not have recently consumed any medications or supplements that may affect body weight/composition or glucose or lipid parameters, and otherwise generally well with no serious illness. Participants were allocated to either control (CON), LCHP, ω -3, or LCHP+ ω -3 diet group and received individualised diet plans. The ratio of carbohydrate to protein was 42:28 in the LCHP and LCHP+ ω -3 diets, and 54:17 in the CON and ω -3 diets. Participants were given 6g fish oil/day (2.46g eicosapentaenoic acid, 0.69g docosahexaenoic acid, 0.5g docosapentanoic acid) in the ω -3 and LCHP+ ω -3 groups, and 6g corn oil/day (placebo) in the CON and LCHP diet groups. Glycaemic control, anthropometric measures and cardiometabolic risk markers were assessed at baseline, week 4, 8, and 12 (end of study).

In total 122 subjects were randomised for treatment with baseline demographic and clinical characteristics similar between groups. After 12 weeks intervention, LCHP, ω -3, LCHP+ ω -3 had significant improvements on HbA1c and fasting glucose status compared with the CON diet. The significant decrease in fasting glucose in the LCHP+ ω -3 group was observed earlier (week 4) than in both the LCHP and the ω -3 groups. Additionally, HbA1c and fasting glucose decreased significantly more in the LCHP+ ω -3 group compared with both the LCHP and ω -3 groups at end of study. No significant intergroup or within-group differences were found in any cholesterol variables not intergroup differences in anthropometric measures.

The results show some promising results for the combination of LCHP+ ω -3 group in a healthy T2DM

population with improvements observed in HbA1c, and fasting glucose above and beyond other diets investigated. Further research in larger study populations which follows subjects over a longer duration would be valuable.

Intermittent versus continuous energy restriction

Sundfor TM, Svendsen M, Tonstad S. Effect of intermittent versus continuous energy restriction on weight loss, maintenance and cardiometabolic risk: A randomized 1-year trial. *Nutr Metab Cardiovasc Dis* 2018;28:698–706.

Obesity and overweight have reached epidemic levels and contribute to significant global health and economic burden. Weight loss strategies are a mainstay of treatment; however, adherence to long-term diets is limited. In recent years, intermittent fasting has gained interest and popularity. Recent analyses have reported neither intermittent nor continuous energy restriction to be superior to the other. The current study aimed to provide insight over a longer time period with a 1-year, randomised controlled clinical trial undertaken to compare the effects of intermittent energy restriction compared to continuous energy restriction on weight loss, maintenance, and cardiometabolic risk factors.

The study was conducted in men and women with abdominal obesity and at least one additional component of the metabolic syndrome. Participants were aged 21–70 years and had weight stability within ± 3 kg during the previous three months. Exclusion criteria included diabetes if treated with insulin or incretin analogues, bariatric surgery, use of anti-obesity drugs or other drugs affecting body weight, eating disorder, or psychiatric illness, or alcohol or drug abuse that could contribute to difficulties with study procedures. Subjects were randomised to intermittent energy restriction with two non-continuous days fasting/week at 400/600 kcal (female/male) intake or continuous energy restriction to a level that was equivalent to the weekly energy reduction and intake of the intermittent group. The trial lasted for one year, with six-month weight loss phase that included 10 dietitian visits followed by a 6-month maintenance phase with no face-to-face counselling, and a pre-planned weigh-in at 12 months. Both groups received individualised dietary plans and were encouraged to follow the general principles of a Mediterranean-type diet. Additionally, both groups were similarly counselled in cognitive behavioural methods. The primary outcome was change in body weight after one year. Secondary outcomes were changes in weight after six months, and waist circumference, blood pressure, and other cardiometabolic risk factors after six months and 12 months.

In total, 112 participants were randomised to intermittent or continuous energy restriction. Based on dietary records, groups reduced total energy intake by

26% and 28% in the continuous and intermittent energy restriction groups, respectively. Weight loss was similar among groups, with intermittent restriction averaging 8.0 kg compared with 9.0 kg in the continuous energy restriction. Waist circumferences were also comparable with 8.7 cm and 9.6 cm reduction in the intermittent and continuous restriction groups, respectively. Favourable improvements were also observed in blood pressure, triglycerides, and HDL-cholesterol with no difference between groups. Weight regain was minimal and similar between the intermittent and continuous energy restriction groups; however, regained weight was statistically significant in the intermittent energy restriction group. Participants in the intermittent energy restriction reported more hunger compared to continuous restriction.

The study provides interesting findings with similar weight loss reported after six months, and similar maintenance weight in both the intermittent and continuous fasting groups at 12 months. Regardless of diet type, weight maintenance after six months is not achieved by many dieters with the authors noting the potential role of cognitive behavioural counselling, regular follow-up during the weight loss phase, and the pre-planned weigh-in at 12 months. Further studies lasting for an even longer period, or longer term follow-up of the current subjects may provide further insight into the sustainability and weight modifications over the long term.

Air pollution and respiratory disease

Whyand T, Hurst JR, Beckles M, Caplin ME. Pollution and respiratory disease: can diet or supplements help? A review. *Respir Res* 2018;19:79. Available from: <https://doi.org/10.1186/s12931-018-0785-0>

The World Health Organization has identified air pollution as the world's largest environmental health risk factor. The majority of outdoor pollutants include anthropogenic sources such as vehicle emissions, fossil fuel combustion, forest fires and industrial processes. Polluted air contributes to chronic obstructive pulmonary disease (COPD) prevalence and symptom onset, and may be associated with asthma. The current review aimed to assess the role of diet, including vitamin supplementation, in preventing the effects of pollution on asthma and other respiratory diseases.

A search of literature in PubMed was conducted between 2017 to March 2018 for relevant research. In total, 109 papers of mainly original research were identified and used in the review. Key pollutants identified included phthalates, particulate matter, polycyclic aromatic hydrocarbons (PAHs), ozone, nitrogen dioxide, persistent organic pollutants (POPs) and mixed pollutants.

The authors found evidence that several vitamins and nutrients may help protect against air pollution damage that can trigger asthma, COPD, and lung cancer initiation.

In summary, there was evidence to suggest carotenoids, or vitamins D and E may offer some protective benefit. Vitamin C, curcumin, choline, and omega-3 fatty acids may also have some level of protective role. While the Mediterranean diet may be of benefit to the airways, there is no evidence of benefit in protecting against air pollution, with the exception of tobacco smoke. The confounding factors of diet, obesity, co-morbid illness, medication, and environmental exposure make it very difficult for well-designed studies and interpretation of literature.

This review provides an oversight into some of the potential areas of diet that may be worth consideration for predisposed/at-risk individuals. It should be noted that there are limited high-quality studies and some conflicting results, so interpretation of these findings is limited. The review highlights aspects of diet that may be worthy of further robust investigation to better understand their role in protecting against air pollution.



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Reviews of articles on medicinal herbs

Jodie Tester

These abstracts are brief summaries of articles which have appeared in recent issues of herbal medicine journals, some of which may be held in the NHAA library.

Ginkgo biloba as adjuvant therapy in metabolic syndrome — a pilot study

Aziz TA, Hussain SA, Mahwi TO, Ahmed ZH. Efficacy and safety of Ginkgo biloba extract as an “add-on” treatment to metformin for patients with metabolic syndrome: a pilot clinical study. *Ther Clin Risk Manag* 2018;14:1219–1226.

Metabolic syndrome is associated with a multifactorial pathogenesis, and results in the clustering of different metabolic disturbances including glucose intolerance, dyslipidaemia, abdominal obesity, and hypertension. Metformin is an antihyperglycaemic agent used for improving glucose control. Ginkgo biloba (GKB) leaves have traditionally been used for a wide variety of ailments with antioxidant activities. GKB has been used as an adjuvant therapy in treatment of a number of cardiovascular and metabolic diseases. The objective of the present study was to evaluate the effects of GKB extract as an add-on treatment with metformin in subjects with metabolic syndrome.

The study was a prospective, randomised, double-blinded, placebo controlled pilot study conducted between December 2016 and October 2017 in Iraq. Forty patients with metabolic syndrome, as per diagnostic criteria of the International Diabetes Foundation, were enrolled and allocated to receive either GKB extract (120 mg capsule/day) or placebo as an add-on treatment with the currently used dose of metformin (Met + GKB or Met + placebo). Inclusion criteria included aged between 25–65 years, diagnosed as having metabolic syndrome for at least one year, and in whom their glycaemic status was not sufficiently controlled with metformin alone. Outcomes assessed at baseline and after 90 days' treatment included body mass index (BMI), waist circumference (WC), serum leptin, glycated haemoglobin (HbA1c), fasting serum glucose (FSG), insulin, insulin resistance (IR), visceral adiposity index (VAI), lipid profile, and inflammatory markers C-reactive protein (CRP), tumour-necrosis factor- α (TNF- α), and interleukin-6 (IL-6).

Of 60 patients randomised to treatment, 40 completed the 90 days, with the results of only the 40 included in the study (Met + GKB n= 22, Met + placebo n=18). At baseline, there were no significant difference between groups. Following 90 days' adjuvant GKB with metformin, significant decreases were observed in FSG, HbA1c, insulin, IR, BMI, WC, VAI, serum leptin, and inflammatory markers compared to baseline levels. Significant improvements from baseline were not

observed in the placebo group. GKB extract did not alter serum triglyceride levels.

A limitation of the study is the small sample size and that the study was not an intention to treat analysis that included all subjects allocated to treatment, which provide more rigorous research findings. However, recognising this study as a pilot with preliminary results, its positive outcomes support further high-quality research to better understand the role of GKB as an adjuvant treatment to metformin in the management of metabolic syndrome.

Rhodiola and saffron combination in mild-moderate depression

Bangratt M, Abdellah SA, Berlin A et al. A preliminary assessment of a combination of rhodiola and saffron in the management of mild-moderate depression. *Neuropsychiatr Dis Treat* 2018;14:1821–1829.

Depression is a leading cause of global health burden, with an estimated one in five adults experiencing at least one episode of depression in their lifetime. Underdiagnosis and undertreatment of depression have been reported, and conventional antidepressant medications are often associated with incomplete response rates, low remission rates, risk of relapse, and side effects. In mild-moderate depression, therapeutic guidelines recommend the use of psychological treatment or an antidepressant medication. Costs and accessibility impact availability of psychological services, and patients with mild-moderate depression may not wish to commence antidepressant medications for concerns with potential side effects. Accordingly, interest remains for therapies that provide efficacy in mild-moderate depression that are well tolerated. Two herbal medicines previously explored for potential antidepressant effects include *Crocus sativus* (saffron) and *Rhodiola rosea* (rhodiola). The aim of the current study was to observe the effect of a fixed combination of these two herbs in mild-moderate depression.

The study was an open-label, observational, longitudinal study conducted within general practices across France. Adult patients aged 18–45 years, diagnosed with mild-moderate major depressive disorder (MDD) according to the ICD10 and with a Hamilton Rating Scale for Depression (HRSD) score of 8–18 were included. Exclusion criteria included use or recent use of antidepressants, severe MDD, suicide attempt or ideation, psychiatric disorders, using chronic treatments, using medications containing piperine or St John's

wort, and pregnant or lactating women. Subjects were supplemented with a combination rhodiola and saffron extract tablet (154 mg rhodiola and 15 mg saffron) (Phytostandard; PiLeJe Laboratoire, Paris, France), with the recommended dose of two tablets per day for six weeks. The primary endpoint was change in HRSD score after six weeks. Secondary endpoints included the Hospital Anxiety and Depression Scale (HADS), Patient Global Impression of Change (PGIC), Clinical Global Impression-improvement (CGI-I) and CGI-severity (CGI-S).

In total, 45 patients were recruited into the study, of which 82% were female. Mean age at inclusion was 47.6 years. The average duration of the ongoing depressive episode was 4.4 ± 4.5 months. After six weeks of supplementation, a significant decrease in HRSD scores of $58\% \pm 28.5\%$ was reported. Score improvement was reported by 85.4% of patients. A significant reduction in HADS score was reported, with the decrease significant from baseline score at two weeks. At the end of study, both GPs and patients reported improvement in depression through significant changes in CGI-I and CGI-S scores. The supplementation was well tolerated with no serious adverse events reported.

Limitations of the study include small numbers, the open-label design and lack of a comparator arm. The results of the preliminary study, however, suggest a potential role for the combination supplement in mild-moderate depression. Further research is required to assess effect compared to placebo and active treatments, to ascertain optimal dose and duration of supplementation, and for longer term follow-up for remission and relapse rates.

Withania somnifera as adjunct to antipsychotics in schizophrenic symptom exacerbation

Chengappa KNR, Brar JS, Gannon JM et al. Adjunctive use of a standardized extract of *Withania somnifera* (ashwagandha) to treat symptom exacerbation in schizophrenia: a randomized, double-blind, placebo-controlled study. *J Clin Psychiatry* 2018;79(5):17m11826.

The immune-inflammatory dysregulation theory in schizophrenia posits that an imbalance of pro- and anti-inflammatory cytokines and elevated inflammatory proteins contribute in a subgroup of patients with schizophrenia to experience symptom exacerbations. Previous research has reported a small treatment effect with adjunctive treatment with COX inhibitors for patients with positive symptom exacerbation. *Withania somnifera*, has demonstrated immunomodulatory and anti-inflammatory actions in animal studies, in addition to anxiolytic benefits and a good safety profile in early human studies. Accordingly, the authors of this study hypothesised that standardised extracts of *Withania somnifera* (WSE) may be beneficial for exacerbated symptom management in patients with schizophrenia. The aim of the study was to assess whether adjunctive

treatment with WSE improves psychopathology and stress in patients with schizophrenia or schizoaffective disorder in a randomised, double-blind, placebo-controlled clinical trial.

The study was conducted at ambulatory clinics associated with the Western Psychiatric Institute and Clinic, in Pittsburgh, Pennsylvania, with subjects recruited from June 2013 to July 2016. Subjects were male or female aged 18–75 years with DSM-IV-TR schizophrenia or schizoaffective disorder with diagnosis affirmed by Mini-International Neuropsychiatric Interview. At study entry, the Positive and Negative Syndrome Scale (PANSS) total score had to be ≥ 60 . With a score of ≥ 5 on any 1 item or a score of ≥ 4 on any 2 items of the positive symptom cluster or unusual thought content. Symptom exacerbation extended for more than two weeks but less than one year, and patients were to have been receiving antipsychotic agents for at least four weeks. Subjects were randomly allocated to receive WSE (1,00mg/day) or identical placebo for 12 weeks, as an adjunct to their regular antipsychotic medications. Primary outcomes were change in PANSS from baseline to end of treatment including PANSS total, positive, negative and general symptoms. Secondary outcomes included stress and inflammatory indices evaluated through the Perceived Stress Scale (PSS), C-reactive protein (CRP) and S100 calcium-binding protein (S100B).

Of 82 subjects screened for consent and eligibility, 66 (33 WSE and 33 placebo) subjects formed the efficacy-defined intention-to-treat population. There was no significant difference between groups regarding completion rates with 28 and 31 subjects in the WSE and placebo groups, respectively, completing the study. Baseline characteristics were comparable between groups. The mean duration of current symptom exacerbation being nearly 16 weeks. At the end of treatment, WSE was associated with significantly greater reduction in PANSS negative, general, and total symptoms when compared to placebo. These effects were significant from 4 weeks and remained significant until end of study. No significant effect on positive PANSS was observed. PSS scores also improved significantly with WSE compared to placebo. CRP and S100B trended towards greater decline in the WSE group; however, there was no significant difference between groups. Treatments were generally well tolerated with no severe adverse events noted.

The authors conclude that whilst an early study only, the results demonstrate adjunctive treatment with a standardised extract of *Withania somnifera* in addition to antipsychotic medications may provide benefit in schizophrenic patients with symptom exacerbation in domains of negative, general, total symptoms, and stress. Future research is required to confirm these findings, to ascertain optimal dosing, and to assess the effect of WSE on functional and cognitive status.

Traditional Chinese medicine for PCOS

Liao WT, Chiang JH, Li CJ, Lee MT, Su CC, Yen HR. Investigation of the use of traditional Chinese medicine for polycystic ovary syndrome in a nationwide prescription database in Taiwan. *J Clin Med* 2018;7:179. Available from: doi:10.3390/jcm/7070179

Polycystic ovary syndrome is estimated to affect 5–10% women worldwide, with reproductive implications including anovulatory infertility, oligomenorrhoea, amenorrhea, and hyperandrogenism. Furthermore, PCOS is associated with metabolic disorders, including insulin resistance, type-2 diabetes and obesity. Treatment for PCOS often differs depending on symptoms being addressed at a point in time. Traditional Chinese medicine (TCM) is commonly used within Chinese society for treatment of gynaecological problems and infertility, with previous research demonstrating potential benefit in PCOS. The authors of the current study aimed to understand the clinical characteristics and behaviours of women with PCOS with regard to TCM, using data from the National Health Insurance Research Database (NHIRD) of Taiwan.

In Taiwan, TCM has been subsidised under their national health insurance (NHI) system since 1996, providing a data collection for research. The NHI covers three modalities of TCM; Chinese herbal products manufactured by GMP (good manufacturing practice)-certified pharmaceutical companies; acupuncture, moxibustion, and cupping therapy; and manipulative therapy including acupressure, chiropractic, and tui na massage. The study used reimbursement claims data deposited in the NHIRD, with patients aged 18 years and older who were diagnosed with PCOS in NHIRD between 1997 and 2010 included. Patients who received TCM between the initial diagnosis of PCOS and study endpoint were included in the TCM group ($n=5962$). Patients with PCOS who had not taken any TCM after the initial PCOS diagnosis date were included in the non-TCM cohort ($n=720$). Potential confounders considered included diabetes mellitus, infertility female, hirsutism, obesity, lipid metabolism disorders, major depression, anxiety, and amenorrhea.

The analysis included a total of 6682 subjects diagnosed with PCOS during between 1997 and 2010. Age was similar between groups, with the highest proportion of subjects aged 18–29 in both groups. TCM users were associated with a higher prevalence of infertility, amenorrhoea, and anxiety, while the prevalence of diabetes mellitus, obesity, lipid metabolism disorders, and major depression were similar between groups. Of the TCM patients, 50.37% PCOS patients were treated with herbal medicine only, with the bulk of the remaining TCM patients undergoing combination treatment. Most patients (60.32%) had visited TCM clinics less than three times, while more than a quarter (25.9%) patients had received TCM more than six times.

The study provides a large-scale report on the utilisation patterns of TCM by patients newly diagnosed

with PCOS, with insight into proportion of users of TCM, frequency of visits, and modalities of therapeutics utilised. Limitations of the study and dataset include the absence of details on disease severity, treatment efficacy, and cost of treatment to the NHI. Research that addresses some of these gaps would provide further insight.

Cumulative ginseng intake and cognition in later life

Lho SK, Jim TH, Kwak KP et al. Effects of lifetime cumulative ginseng intake on cognitive function in later life. *Alzheimers Res Ther* 2018. Available from: <https://doi.org/10.1186/s13195-018-0380-0>

Ginseng is one of the most widely sold medicinal herbs worldwide, popularised for its potential benefit in cognition amongst other actions. Research has demonstrated ginseng constituents to alter brain cholinergic function, decrease inflammation, and reduce production of amyloid beta proteins. Whilst some randomised clinical trials have suggested ginseng may be effective for cognitive improvement in people with Alzheimer's disease (AD), meta-analyses and systematic reviews have determined the effect of ginseng in AD to be inconclusive. In the current study, the authors aimed to investigate the effects of lifetime cumulative ginseng intake on cognitive function in a community-dwelling population-based prospective cohort of Korean elders.

The project was part of a population-based prospective cohort study of Korean elders aged 60 years and older. Within the study cohort, 6818 completed baseline cognitive function. The present study sample was drawn from these subjects with exclusion criteria including participants with partial or no information regarding neuropsychological tests, diagnostic deferral due to comorbid major depressive disorder or intellectual disability, or with no information regarding ginseng intake. Follow-up evaluations were conducted every two years with the current study including the first and second follow-up studies. Ginseng intake was assessed at each visit and cumulative ginseng intake calculated to categorise participants as "no use", "low use" (<5 years), or "high use" (>5 years). Cognitive function was assessed using the Mini-Mental State Examination (MMSE) as well as a variety of neuropsychological tests to determine a baseline score (CERAD total score). An analysis of covariance was conducted to compare the impact of cumulative ginseng intake on MMSE and CERAD scores, with adjustments for potential covariates, at baseline and during the four years of follow-up.

In total, 6422 participants were included, of whom 56.8% were female, with a mean age of 70.2 ± 6.9 years, and 8.0 ± 5.3 education years. Of these, 677 subjects (10.6%) had ever used ginseng. The low use group (below median, <5 years) included 491 subjects, and the high use group (above median, ≥ 5 years) included 186 subjects. The mean age of the no use group was significantly higher than the low use group, but comparable to the high use group. Higher ginseng use was associated with more

years of education and more likelihood of being in a higher socioeconomic status (SES) group. There were no differences in smoking habits, alcohol intake, hypertension rates, stroke history, and presence of APOE e4 allele between groups. The high use group demonstrated higher baseline CERAD total scores compared to the no use group after controlling for covariates, such as age, sex, education years, SES, smoking, alcohol intake, hypertension, stroke history and APOE e4 allele. There was no difference in baseline MMSE scores between groups after adjusting for covariates. Changes in cognitive function over the two- and four-year follow-up as assessed by change to CERAD total score, did not differ according to ginseng use.

The study reports interesting findings in that individuals with a high lifetime cumulative ginseng intake demonstrated higher CERAD total scores in late life compared to non-users; however, changes in cognitive function were not influenced by intake over subsequent years. The authors note that these results indicate long-term use of ginseng may be beneficial to late life cognitive function; at this stage, however, the results do not support a change in cognitive decline. Studies that continue to follow the cohort over further follow-up periods to assess for change in cognitive function between different user levels over a longer time period will be of interest.

Cannabis-based medicines in chronic neuropathic pain conditions in adults

Mücke M, Phillips T, Radbruch L, Petzke F, Häuser W. Cannabis-based medicines for chronic neuropathic pain in adults. *Cochrane Database Syst Rev* 2018; Issue 3. No: CD012182. DOI: 10.1002/14651858.CD012182.pub2

Neuropathic pain is associated with 6–10% of chronic pain conditions and is described as pain caused by a lesion or disease of the somatosensory system. Neuropathic pain results in varying clinical presentations of sensory loss (numbness) and sensory gain (allodynia) with the most common causes including diabetes, shingles, amputation, neuropathic pain after surgery or trauma, stroke or spinal cord injury, trigeminal neuralgia, and HIV infection. Many people with neuropathic pain conditions are significantly disabled with moderate to severe pain for years. Current pharmacological treatment options for neuropathic pain are of limited effectiveness for some people, with adverse effects often outweighing the benefits. Accordingly, there is great interest in other effective therapeutic options. Cannabis has been long used in pain reduction and is often promoted by patients and their advocates to treat chronic pain. The aim of the review was to assess the efficacy, tolerability, and safety of cannabis-based medicines compared to placebo or conventional drugs for conditions with chronic neuropathic pain in adults.

Databases including Central, MEDLINE, Embase, and two trial registries were searched in November 2017 for published and ongoing trials involving cannabis in the treatment of neuropathic pain. The review included studies that were randomised, double-blind, controlled

trials of at least two weeks duration and at least 10 participants per treatment arm. Comparative trials of medical cannabis, plant-derived and synthetic cannabis-based medicines against placebo or any other active treatment of conditions with chronic neuropathic pain in adults were included. Efficacy was calculated as the number needed to treat for an additional benefit for pain relief of 30% and 50% or greater, patient's global impression of improvement, dropout rates due to lack of efficacy, and the standardised mean differences for pain intensity, sleep problems, health-related quality of life, and psychological distress. Tolerability assessment included number needed to treat for an additional harmful outcome, withdrawal due to adverse events and specific adverse events, nervous system disorders and psychiatric disorders. The meta-analysis was completed using a random-effects model.

In total, 16 studies ranging from 2 to 26 weeks' duration were included in the review, encompassing 1750 participants. Cannabis-based medications included an oromucosal spray, a synthetic cannabinoid, inhaled herbal cannabis, and plant-derived tetrahydrocannabinol (THC) and were compared against placebo (15 studies) or analgesic, dihydrocodeine, (one study). Study quality was assessed with quality rated as high in two studies, moderate in 12 studies, and low in two studies. Nine of the studies were at high risk of bias for their study size. Overall, the quality of the evidence was rated as very low to moderate.

When the data was pooled, cannabis-based medicines were associated with small improvement in pain relief of 30% or greater and 50% or greater, when compared to placebo. Patient impression of change was reported to improve with cannabis; however, the quality of evidence was noted to be very low quality. Compared to placebo, cannabis-based medicines were associated with a higher number of study withdrawals due to adverse effects, and a higher incidence of nervous system adverse events. Psychiatric disorders occurred in 17% of participants using cannabis-based medicines and 5% using placebo. Long-term risk analysis was not able to be determined.

The study provides an overview into the therapeutic use of cannabis-based medicines in adults with chronic neuropathic pain. While the authors recognise that potential benefits may lead to pain improvement compared to placebo, it is noted that any benefit may be outweighed by potential harm and adverse events. Limitations of these studies include the generalised moderate–low quality of trials and the small samples, which the authors note was contributed to by exclusion criteria including participants with a history of substance abuse and other significant comorbidities. At present, the authors conclude that there is currently no high-quality evidence supporting efficacy of cannabis-based medicines in chronic neuropathic pain and suggest that few people with chronic neuropathic pain, at best, will benefit from long-term use of cannabis-based medicines. Considering appropriate stopping rules to avoid unnecessary exposure to harm in the absence of benefits may be indicated.

Herbal medicines in common psychiatric disorders: 10-year updated review

Sarris J. Herbal medicines in the treatment of psychiatric disorders: 10-year updated review. *Phytother Res* 2018;32:1147–1162.

The role of herbal medicine in the treatment of a number of psychiatric conditions is becoming more established, with increasing clinical evidence across a variety of plants. In 2007, a systematic review of herbal medicines across a breadth of psychiatric disorders was performed by the current author. In the previous publication, which reviewed 27 plants, the summary reported while numerous plants demonstrated potential efficacy many, with the exception of Kava and St John's wort, were researched in small sample studies only. The purpose of the current review was to provide a 10-year update of research within the field.

Human studies involving herbal medicines for the treatment of major psychiatric disorders, including depression, anxiety, obsessive-compulsive, seasonal affective, bipolar, psychotic, phobic, somatoform, and attention-deficit hyperactivity disorders were identified using Ovid Medline, PubMed, and the Cochrane Library. The updated search was conducted during September to October 2017. The review included meta-analyses and randomised controlled clinical trials, with non-randomised or non-placebo controlled trial reviewed where there was preclinical data. *In vitro* studies were used for safety and active constituents. Studies focused on whole herbal extracts, with the use of intravenous,

topical or inhalant administration excluded. Traditional Chinese or Kampo formulas were not included in the current review.

In total, 24 individual herbal medicines were identified, being used for 11 psychiatric conditions. *Hypericum perforatum* (St John's wort) and *Crocus sativa* (saffron) have high-level evidence supporting their efficacy in major depressive disorder. For generalised anxiety disorder and non-specific anxiety, high-quality evidence was reported for *Piper methysticum* (Kava), *Passiflora incarnata* (passionflower), and *Galphimia glauca* (galphimia). Other herbal medicines that have been researched with promising preliminary results include *Rhodiola rosea* and *Curcuma longa* for treatment of depression, *Withania somnifera* for anxiety and/or stress, and *Ginkgo biloba* as an adjuvant therapy to antipsychotics in chronic schizophrenia. While herbal medicines have been investigated in other mental disorders, there is currently no strong evidence supporting herbal interventions in dysthymic disorder, seasonal affective disorder, social phobias, obsessive-compulsive disorder, or attention-deficit hyperactivity disorder.

The updated review provides an excellent overview of herbal medicines and research within a number of common psychiatric conditions. The author notes that while the evidence base has increased over the past decade, there remains the need for ongoing high-quality, randomised, controlled, clinical trials to understand the scope of therapeutic effect and to ensure optimal and appropriate use of herbal medicine.

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MedPlant

With reference to the Cochrane review investigating the role of cannabis-based medicines in adults with chronic neuropathic pain, which of the following conclusions is incorrect:

- No high-quality evidence supporting efficacy of cannabis-based medicines in chronic neuropathic pain.
- Few people with chronic neuropathic pain will benefit from long-term use of cannabis-based medicines.
- Long-term safety analysis of cannabis-based medicines was favourable.
- Cannabis-based medicines were associated with a higher number of study withdrawals due to adverse effects, and a higher incidence of nervous system adverse events.

Regarding the study investigating *Withania somnifera* extract (WSE) as an adjunctive treatment to antipsychotics in schizophrenic patients, which of the following statements is incorrect:

- WSE was associated with significantly greater reduction in PANSS negative, general, and total symptoms when compared to placebo.
- WSE was not associated with significant effect on positive PANSS, compared to placebo.
- WSE was associated with significant improvement in PSS scores, compared to placebo.
- WSE was associated with significantly greater reduction in CRP and S100B, when compared to placebo.

With reference to the study investigating the effect of a saffron and rhodiola combination in depression, which if the following statements is incorrect:

- After six weeks of supplementation, a significant decrease in HRSD scores of was reported.
- After one week of supplementation, a significant reduction in HADS score was reported.
- Limitations of the study include the open-label design and lack of a comparator arm.
- The supplementation was well tolerated with no serious adverse events reported.

With reference to the study investigating the effect of ginseng and cognitive function, which of the following statements is correct:

- Lower ginseng use was associated with more years of education and higher socioeconomic status group.
- The high use group demonstrated higher baseline CERAD total scores, compared to the no use group after controlling for covariates.
- There was a significant difference in baseline MMSE scores between groups after adjusting for covariates.
- Changes in cognitive function over the two- and four-year follow-up as assessed by change to CERAD total score were dose-dependant on ginseng use.

With reference to the study reporting the use of ginkgo biloba (GKB) extract in metabolic syndrome, which of the follow statement are correct:

- The study compared metformin and GKB in subjects with metabolic syndrome.
- The study was an intention-to-treat analysis.
- GKB extract was not observed to alter serum triglyceride level.
- Significant increases were observed in HbA1c and inflammatory markers compared to baseline levels in the GKB + met group.

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Sarris J. Herbal medicines in the treatment of psychiatric disorders: 10-year updated review. *Phytother Res* 2018;32:1147–1162.

MedJourn

With reference to the study investigating the intermittent energy restriction (IER) versus continuous energy restriction (CER), which of the following statements is incorrect:

- Total energy intake by 26% and 28% in the CER and IER groups, respectively.
- Weight loss and weight regain was similar between IER and CER groups.
- Improvements in blood pressure, triglycerides, and HDL-cholesterol were observed with no difference between groups.
- Participants in the CER reported more hunger compared to IER.

With reference to the Cochrane review investigating the role of probiotics in preventing *Clostridium difficile* infections (CDI), which of the following statements is incorrect:

- The trials were conducted in an immunocompetent population group so its generalisability to immunocompromised patients is unclear.
- Strengths of the review including the pooling of trials and results across clinical settings, ages, and probiotic strains and doses.
- Co-administration of probiotics and antibiotics was associated with a lower risk for CDI compared to placebo or no treatment with the evidence of moderate quality.
- Co-administration of probiotics and antibiotics were associated with a lower risk of adverse events compared to placebo or no treatment with the evidence of low quality.

With reference to the study investigating the effect of LCHF and ω-3 supplementation in recently diagnosed T2DM, which of the following statements is incorrect:

- LCHP, ω-3, LCHP+ω-3 had significant improvements in HbA1c and fasting glucose levels compared with the control at week 12.
- LCHP+ω-3 group resulted in significant decrease in fasting glucose by week 4.
- LCHP+ω-3 group resulted in significantly greater reductions in HbA1c and fasting glucose compared with the LCHP and ω-3 groups.
- LCHP+ω-3 group resulted in significantly greater reductions in cholesterol measures compared with control.

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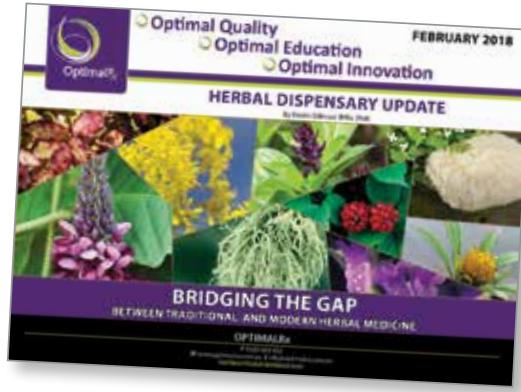


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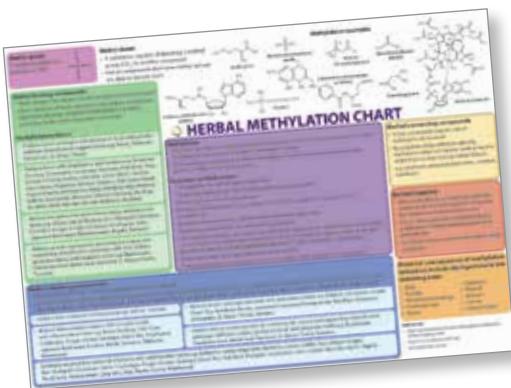
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