Western herbal medicine is a useful adjunct to traditional dermatological practice.
Running head: Applications of herbal medicine in dermatology

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<u>Abstract</u>
<u>Background:</u> Herbal medicine is a potential adjunct to conventional pharmaceuticals and may be effective in treating dermatological conditions. Patients have indicated to health care professionals that they consider herbal medicine to be an important complement to traditional dermatological care in the management of skin disease. Herbal medicine practice must be regulated and accountable in order to provide safe and effective care. Our dermatology service has offered a herbal medicine clinic since 2000 and allows patients to benefit from Western herbal medicine in conjunction with conventional dermatology at a University Teaching Hospital.

<u>Objective:</u> To determine patient characteristics, the most common conditions referred and patient-reported outcomes from our service.

<u>Methods:</u> We reviewed the records of patients that used our service during two review periods: between September 2000 and December 2007, and in 2011. We assessed subjectively measured treatment outcomes by asking patients to complete a modified Measure Yourself Medical Outcomes Profile (MYMOP).

<u>Results:</u> 348 patients (253 female, 95 male; aged 10 months–91 years) used our service during the review periods. The median time between the onset of their condition and referral to the clinic was 5 years. 91% of patients were referred for 1 condition: most commonly atopic dermatitis, alopecia and acne vulgaris. 85% of patients reported problems in addition to those for which they were referred. Patients also reported non-dermatological complaints, mainly psychological (18%) or gastro-intestinal (17%). Between their first and last appointments, patients reported a significant improvement in their top 4 problems, dermatological or otherwise, as well as their general wellbeing (p<0.05).

<u>Conclusion:</u> Our dermatology herbal medicine service has a demonstrable impact on patient-reported health outcomes. Dermatologists should consider herbal medicine as an option when conventional treatments have failed or patients express an interest in alternative therapy.

<u>Introduction</u>

Phytotherapy, or herbal medicine, has been common practice for thousands of years, long pre-dating the pharmaceutical industry. Although considered somewhat passé for much of the 20th Century, alternative therapies are becoming increasingly popular, particularly amongst patients with dermatological disease. In the USA, 49% of patients with a skin problem in the past year reported using a herbal supplement within that same period[1]. Patients with chronic illnesses are considered the most likely to seek complimentary therapies and this includes those with psoriasis and atopic dermatitis[2]. The greatest evidence for the use of herbal medicines lies in inflammatory skin disease but herbs are also reported to have beneficial anti-oxidant, anti-bacterial, anti-fungal and anti-histaminergic effects[3, 4]. Regulation of herbal therapies in Europe is recognised to be challenging and the use of herbal remedies is not without risk[5]. Numerous adverse events have been reported in the literature, thus therapies should be administered by an experienced health professional[6]. Patients have in the past reported that they have consulted medical herbalists as an 'alternative' to traditional healthcare and that it has satisfied their expectations primarily due to the collaborative nature of this approach in addition to the therapeutic effect[7].

A herbal medicine clinic has been running within the dermatology outpatients department at our institution since September 2000. The aim of the clinic is to provide an opportunity for patients to safely benefit from Western herbal medicine within a hospital dermatology setting. Western herbal medicine combines orthodox medical knowledge and skills with scientific understanding of plant medicines. Medical herbalists assess the patient as a whole, including health and drug history, lifestyle, emotional state, diet and any other underlying factors, as well as the pathophysiology of the skin or other disease. Herbal treatment aims to alleviate symptoms

and restore the body's normal functions. Lifestyle and nutrition advice encourages patients to maintain healthy lives in addition to reducing the physiological and emotional stresses that may be contributing to their problem.

Herbal medicines are given in various forms, including alcohol-based tinctures, tablets capsules, powders, teas, decoctions, and topical preparations such as lotions, creams and ointments. Safety and known interactions with all pharmaceutical medications are taken into account when prescribing. Dermatologists prescribe no new therapies whilst medical herbalists are treating patients.

Medical herbalists have undergone years of rigorous scientific training and use the same diagnostic and examination skills as doctors. Medical herbalists must meet all terms of clinical governance as well as fulfilling continuing professional development requirements. The National Institute of Medical Herbalists and the College of Practitioners of Phytotherapy are the professional bodies that regulate their practice and both have their own stringent codes of ethics and conduct. Medical herbalists must obtain independent insurance and patients are also covered by hospital indemnity.

Patients initially consult a trained dermatologist who will diagnose all patients prior to referring them to medical herbalist colleagues, with whom they remain in close communication. Many patients are aware of the existence of a herbal dermatology clinic and will request a referral. Alternatively, dermatologists may present the possibility of a herbal medicine consultation when discussing treatment options with our patients, particularly in those with conditions refractory to conventional therapies.

Aim
The aim of this report is to evaluate the herbal medicine dermatology service that we offer at our institution and help contribute to best practice in the delivery of herbal medicine. We will ascertain the demographics of patients using the service and the conditions for which they were referred, as well as reasons for referral. We aim to establish whether patients' conditions improved after referral to the herbal medicine clinic and for which conditions it was the most beneficial.

This report will provide an understanding of what has been achieved and hopefully demonstrate the potential benefits of other institutions offering their patients a holistic herbal medicine dermatology service.

Materials & Methods
Data was collected from the clinic notes of all patients (new and follow-up) who attended the herbal medicine dermatology clinic during 2 review periods: September 2000 to December 2007 and January to December 2011. Information was gathered on patient demographics, number of patients seen, conditions referred, complexity of problems, length of treatment and the impact of treatment on the patient. Data was analysed from patients' self-assessment of progress by the use of MYMOP from 2002 onwards.

Ethical approval was not required for this report as it was deemed to represent a service evaluation.

MYMOP
With the patients' consent, self-assessment was by completion of a symptom or problem-specific profile prior to treatment and at each visit thereafter by the use of MYMOP forms (provided with permission by the University of Westminster). MYMOP is a validated outcome questionnaire[8], which is individualised to each patient.

At their first appointment, each patient recorded up to five 'problems' (coded as P1 to P5) that they would like help with. The problems may be expressed either as medical diagnoses or described as symptoms in the patient's own words. This information is important to the medical herbalist, as they often treat the patient to address a number of symptoms simultaneously. Patients are also given the opportunity to record four 'activities' that they have difficulty with (A1 to A4). Finally, patients record a 'wellbeing' score (W). For a timescale of during the past week, each question is self-rated on a seven-point scale with 0 being the least severe and 6 being the most severe.

MYMOP has recognised strengths and weaknesses[9]. Although initially patients may require some guidance, its brevity, simplicity and the speed of administration lead to high response and completion rates. It is highly responsive to change and therefore useful in both research and clinical settings. Additionally, because it is patient-centred it can measure the symptoms, whether physical or emotional, most important to the patient. A drawback of this, however, is that some patients may not be able to identify which is an important symptom.

Published work on seven point scales suggests that the minimum clinically important score change lies between 0.5 and 1.0 [8, 10, 11]. For the purposes of this review, the only scores considered are those for the first and the last appointments, as treatment duration may vary. MYMOP responses were analysed using a bivariate analysis (the Wilcoxon signed-ranks test) in order to determine statistical significance.

Results
Patients referred to the service
The herbal medicine service treated 348 patients at a total of 1213 appointments in two review periods, namely between September 2000 and June 2007 and between January 2011 and December 2011. Except where stated, all statistics are based on this population of 348 patients.

Patient Demographics
Seventy-three % of all patients seen were female and 27% were male. The age of patients (at the time of their first appointment) ranged from 10 months to 91 years. The mean (SD) age of all patients was 36 (14) years.

Conditions referred
The vast majority of people (91%) were referred for a single condition. Thirty-one patients were referred for more than one condition.

The most common conditions referred were atopic dermatitis, alopecia and acne vulgaris- accounting for 41% of all referrals (Table 1). Seventy-eight % of referrals were composed of the aforementioned conditions plus psoriasis, acne rosacea, seborrhoeic dermatitis and vitiligo.

Non-skin conditions referred included fatigue, anxiety, depression, gastro-oesophageal reflux disease (GORD), irritable bowel syndrome (IBS) and dysmenorrhoea. All patients referred had at least one skin condition.

Reasons for referral
The 5 consultant dermatologists working in the department were surveyed as to their reasons for referring patients to the herbal dermatology service. All 5 dermatologists stated that they referred patients when conventional treatment had failed or was not suitable. Four stated that they referred patients on the basis of patient preference and 3 made referrals due to their experience of improvements in other patients that had been treated by the herbal dermatology service.

Time to referral
The time from diagnosis of the patient's condition and referral to our service ranged from 1 month to 52 years. The median (IQR) time between condition onset and referral was 5 (7.5) years.

Waiting times
Seventy-two % of patients were seen within 2 months of referral. Delays were often due to a waiting list or finding a suitable time for the patients to attend (clinics are held 2-3 days per month).

Complexity of problems
As patients were permitted to record up to 5 problems, the majority (85%) of patients reported one or more problems other than the condition for which they were referred. Skin and other non-referred problems, for which patients wanted treatment, were classified according to the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) coding system. A number of patients reported more than one problem in a WONCA category and the percentage of patients reporting in each category is summarised in Table 2. Twenty-six % of patients reported additional skin problems and 18% reported psychological problems, with 15% suffering from depression and 11% from sleep disturbance.

Although not all the non-referred problems may be directly attributable to the patients' dermatological disease, the scope of these complaints is highly relevant given the holistic nature of herbal medicine. The identification and management of these co-factors is likely to have a beneficial effect on patient wellbeing, though may result in confounding of our results.

Safety
There were no reported adverse reactions to herbal treatment in the dermatology department. A yellow card system is in place should any adverse reactions occur.

Duration of treatment
Duration of treatment was measured as the time between the first and most recent appointment. Patients attended for between 1 and 30 appointments. The median number of appointments that patients attended was 3 (IQR 2). Five % of patients attended for greater than 10 appointments.

MYMOP analysis
One hundred and eighty-six of 348 patients returned 2 or more MYMOP questionnaires between September 2002 and July 2007 and between January 2011 and December 2011. The MYMOP analysis includes the follow-up scores of these 186 patients. In some cases the data is not available for (or not relevant to) every patient, so the number of patients included in each statistic is specified as N.

Between the first and last appointments, with the exception of wellbeing and P3, the mean change in MYMOP scores showed an improvement of at least 1.0 (Table 3). Problem P5 and Activities A3 and A4 were excluded from statistical analysis due to an inadequate number of responses (21, 9 and 1 respectively).

Overall, the results of the Wilcoxon signed-ranks test indicate that that there is a statistically significant improvement in the MYMOP scores for problems P1 to P4, activities A1 and A2 and wellbeing W (p<0.05).

Analysis of problem P1
A more detailed analysis was carried out on the scores of problem P1. Table 4 shows the mean score changes for different conditions named as problem P1. Although the number of patients in each category is too small to be able to demonstrate significant improvement statistically, the results do show an encouraging trend as a mean score change of 0.5 and over is likely to be clinically significant. This was achieved for the 6 most frequently reported skin problems reported (as well as for non-skin problems).

Atopic dermatitis was most commonly ranked as P1 and a mean score improvement of 1.12 was observed. The next most common problems were alopecia, acne rosacea, acne vulgaris and psoriasis, all of which showed mean score changes of between 0.87 and 2.12. The greatest mean score change of 2.12 was observed in the 16 patients reporting acne rosacea. Other skin problems including granuloma annulare, polymorphous light eruption, erythema nodosum, fungal infection, nail growth problems and xeroderma also showed improvement, by a mean score of 1.17. However, the number of patients reporting each of these conditions was too small to draw conclusions from.

Discussion

Our service is utilized by a diverse range of patients, referred for a number of dermatological conditions. The herbal medicine dermatology clinic allows a thorough holistic assessment of the patient's medical and psychosocial needs in order to help them manage not only their dermatological disease, but also their other self-reported problems.

The results of the overall MYMOP analysis demonstrate that the herbal medicine service is making a measurable impact on self-reported patient health by providing statistically significant improvements. Not only do patients report an improvement in dermatological disease, but also additional conditions and their overall wellbeing. We tentatively conclude that herbal medicine may be particularly effective in the treatment of inflammatory skin diseases such as acne rosacea, acne vulgaris and atopic dermatitis.

Whilst we recognise that this subjective analysis of patient-defined problems may lead to challenges in drawing meaningful conclusions from the data, we feel that our findings remain important given the goals of the herbal medicine service to treat patients holistically.

MYMOPs are useful for monitoring patient-assessed changes in health but, as the 'problems' monitored are based on the patient's own language, they do not always correlate with medical diagnoses. Despite this, we endeavoured to classify each problem as defined by WONCA guidelines. Although the numbers for each condition are relatively small, our results show an encouraging trend supporting the use of herbal medicine in the management of dermatological disease. Further data collection and analysis is necessary in order to identify the conditions that would benefit most from herbal medicine input. Going forward, the MYMOP will be modified to contain pre-defined dermatological diagnoses in order for us to demonstrate condition-specific outcomes. Addition of the dermatology life quality index (DLQI) and patient health questionnaire-9 (PHQ-9) will allow us to better evaluate the psychological impact of the service.

Whilst we recognise that pharmacotherapy will remain the primary treatment option in the arsenal of the dermatologist, clinicians should explore patient beliefs regarding alternative therapies and consider referral to a medical herbalist if appropriate. In patients that are willing to engage, herbal medicine is likely to have a demonstrable benefit on both dermatological disease and general wellbeing.

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Tables

Table 1: Conditions referred in order of frequency

Conditions referred	No. patients	% Patients
Atopic dermatitis	59	17
Alopecia	45	13
Acne vulgaris	41	11
Psoriasis	30	9
Acne rosacea	27	8
Seborrhoeic dermatitis	25	7
Vitiligo	24	7
Urticaria	16	5
Dermatalgia	9	3
Warts	6	2
Other skin (<1% each)	70	20
Non-skin	14	4

Table 2: Other problems reported by patients (non-referred)

Conditions referred (most commonly reported)	No. patients	% Patients
Dermatological (pruritus, alopecia)	92	26
Psychological (sleep disturbance, depression, anxiety)	61	18
Gastro-intestinal (IBS, abdominal pain)	60	17
Respiratory (asthma, allergic rhinitis)	38	11
General & unclassified (fatigue)	30	9
Female genital (menorrhagia, dysmenorrhoea)	26	7
Musculoskeletal (arthralgia)	22	6
Endocrine/Metabolic/Nutritional (weight gain, diabetes)	19	5
Neurological (headaches)	15	4
Cardiovascular (hypertension, varicose veins)	14	4

IBS: Inflammatory bowel syndrome

Table 3: Descriptive statistics showing scores for problems (P1-P4), activities (A1 & A2) and wellbeing (W) before and after treatment, and score changes.

	N	Min	Max	Mean	SD	p-value
P1 initial score	202	0	6	4.15	1.45	
P2 initial score	166	0	6	3.94	1.55	
P3 initial score	117	0	6	3.69	1.64	
P4 initial score	71	1	6	3.58	1.56	
A1 initial score	92	0	6	4.57	1.56	
A2 initial score	42	1	6	4.21	4.07	
Wellbeing initial score	191	0	6	2.97	1.55	
P1 final score	186	0	6	2.95	1.65	
P2 final score	151	0	6	2.73	1.74	
P3 final score	106	0	6	2.81	1.83	
P4 final score	64	0	6	2.59	2.01	
A1 final score	82	0	6	3.18	2.12	
A2 final score	36	0	6	2.75	2.19	
Wellbeing final score	179	0	6	2.36	1.44	
P1 change score	186	-5	5	-1.21	1.58	<0.001
P2 change score	150	-6	6	-1.26	1.93	<0.001
P3 change score	105	-5	6	-0.93	1.67	<0.001
P4 change score	59	-4	4	-0.97	1.52	0.003
A1 change score	80	-5	6	-1.46	1.83	<0.001
A2 change score	36	-4	6	-1.50	1.73	<0.001
Wellbeing change score	170	-4	6	-0.61	1.56	<0.001

N = No. patients providing a score; SD = standard deviation

Table 4: Problem P1 score changes

P1 condition	N	Min	Max	Mean	SD
Atopic dermatitis	33	-2	5	-1.12	1.71
Alopecia	23	-5	4	-0.87	1.79
Acne rosacea	16	-3	5	-2.12	1.36
Acne vulgaris	14	-3	2	-1.40	1.14
Psoriasis	13	-3	4	-1.15	1.63
Seborrhoeic dermatitis	6	-1	3	-1.00	1.67
Vitiligo	6	-3	3	-0.50	2.07
Urticaria	4	-4	2	-0.75	1.66
Other skin	38	-4	5	-1.17	1.62
Non-skin	33	-4	4	-1.58	1.33

N = No. patients providing a score; SD = standard deviation