J. Pharm. Pharmacol. 1996, 48: 768–770
Received October 24, 1995
Accepted March 22, 1996

The Podiatric Treatment of Hallux Abducto Valgus and Its Associated Condition, Bunion, with *Tagetes patula*

M. TAUFIQ KHAN*

Department of Pharmacognosy, University of London, 29–39 Brunswick Square, London WC1N 1AX, Department of Homoeopathic Podiatry, The Royal London Homoeopathic Hospital NHS Trust, and the University of East London, UK

Abstract

To assess the effectiveness of marigold therapy using *Tagetes patula* preparations, a double-blind placebo-controlled trial was designed to be carried out over a period of eight weeks. Sixty patients were entered in the trial. Twenty patients with bilateral hallux abducto valgus and its associated condition, bunion, were randomly selected from 37 subjects for group A. For group B, 40 patients with unilateral hallux abducto valgus and bunion were randomly selected from 69 subjects and subdivided into groups Ba and Bb. Patients with ulcerated conditions, those on medication and those who had undergone surgery for the condition were excluded.

The results obtained were highly significant ($P < 0.001$), suggesting that *T. patula* preparations, plus protective pad, were effective in reducing the width of the lesion and level of pain of hallux abducto valgus.

Hallux abducto valgus and its associated condition bunion is a complex progressive deformity affecting the forefoot, where lateral deviation of the big toe is the most obvious feature. Bunion is a swelling of the joint between the big toe and the first metatarsal bone. This is a common condition more frequently found in the female, as a result of wearing inappropriate footwear, and also due to abnormal anatomy when one foot is bigger than the other foot (Khan 1985). Traditional treatment of hallux abducto valgus and bunion is surgery, but surgery has limitations. Many patients suffer with post-operative complications such as painful scar and shortening of the big toe. Surgery is also contraindicated for the elderly and for diabetic patients. There is a need for a painless, non-invasive treatment.

Calendula officinalis is widely used in homoeopathic medicine for the healing of ulcers. During clinical studies at St. Pancras Hospital using *C. officinalis* for the treatment of diabetic ulcer, it was decided to use another species of marigold *Tagetes patula* and compare the result with that obtained with *C. officinalis*.

The object of this study was to investigate the effect of *T. patula* preparations in the treatment of hallux abducto valgus and bunion in terms of pain, swelling and deformity of the first metatarsophalangeal joint.

T. patula preparations have been used in conjunction with podiatric treatment of the condition (Khan 1993). *T. patula* contains patuletin, patulitrin, quercetagetin, tagetone and Ó-terthienyl, the active principles thought to be responsible for the relief of pain, inflammation and reduction of the swollen soft tissues. Further laboratory and clinical evaluation is needed to establish the mode of action. The use of the chiropody pad is widely acknowledged by the profession to redistribute the pressure and friction.

*Present address: The Marigold Clinic, Department of Homoeopathic Podiatry, The Royal London Homoeopathic Hospital NHS Trust, Great Ormond Street, London WC1N 3HR, UK

Materials and Methods

The seeds of *T. patula* were obtained from Sutton Seeds Ltd and the plants cultivated in St. Pancras Hospital Gardens, Camden, London. The plants were authenticated by a botanist at The Royal Horticultural Society. The active samples consisted of *T. patula* paste, tincture and oil. The paste was a composition of equal amounts of petals and leaves mixed with isopropyl alcohol. The tincture was prepared from equal amounts of stems, roots and flowerheads mixed with 80% isopropyl alcohol, the oil from equal amounts of stems, roots and flowerheads mixed with 80% arachis oil. Placebo paste was prepared from exhausted plant material; placebo tincture was 70% isopropyl alcohol and placebo oil was arachis oil.

Semi-compressed chiropody felt, 5 mm, Mefix strapping, 5 cm, Micropore 5 cm, were used as padding materials. Vernier calipers were used to measure the width of the hallux abducto valgus joint, and a tractograph was used for measurement of the hallux angle and intermetatarsal angle in the X-rays.

Procedure

To obtain the required number of 60 patients for the trial, 20 patients with bilateral hallux abducto valgus and bunion were randomly selected from 37 subjects for group A. For group B, 40 patients with unilateral condition were randomly selected from 69 subjects and sub-divided into groups Ba and Bb.

Each patient received treatment in the clinic once a week for four weeks and afterwards the patient continued with follow-up home treatment.

Patients were X-rayed before the first treatment and at the end of four weeks treatment. A photograph was taken before the first treatment, at the end of four treatments and at the end of eight weeks.

Measurements were taken before and after each treatment and at the end of eight weeks.

Using a 0–10 scale of severity, the level of pain was recorded by the patient in an analogue pain-scale diary which

was collected by an independent assessor at each treatment. The assessor took and recorded all measurements.

In group A (bilateral) one foot was treated with active preparations plus protective pad, the other with placebo plus protective pad.

In groups Ba and Bb (unilateral), group Ba was treated with active preparations plus protective pad, group Bb with placebo plus protective pad.

Method of treatment

Week 1. T. patula tincture (active) was applied over the bunion joint, then a cavity pad placed over the bunion. In the placebo group *T. patula* tincture (placebo) was applied over the bunion joint then a cavity pad placed over the bunion.

The cavity pad on one foot was filled with active paste and the other foot with placebo paste. A piece of Micropore was used to cover the cavity pad, and the pad strapped with Mefix plaster.

The treatment was repeated at weeks two, three and four. At the end of the fourth week, the final pad was removed and the patient was asked to continue with follow-up home treatment, active or placebo tincture and oil which were supplied to be used three times a day for the first week, twice a day for the second week, once a day for the third week and none for the fourth week.

During the home treatment, Tubifoam was used for four hours a day to prevent pressure and friction at the bunion joint. The trial had the approval of the ethical committee of The Royal London Homeopathic Hospital.

Results

The data from groups A, Ba and Bb were analysed with paired and unpaired *t*-tests using the Microsoft Excel spreadsheet statistical program.

Evaluation of the results was also by means of photographs and radiographs (group A only) taken before and after treatment and by patient subjective response (questionnaire).

Table 1 shows an example of the data collected, in this case the data is shown for Group Ba, the active preparation with protective pad.

The results from analysis of all groups showed that in Group A, there was a relief of pain, reduction of soft tissues and partial correction of angle for the active treatment, whereas the placebo treatment showed a little reduction in pain and soft tissues from 0–4 weeks only and no reduction in the angle. When the pad was removed after week 4, the condition worsened.

In Group Bb, the active treatment showed relief of pain, reduction of soft tissues and partial correction of angle. The placebo group showed a little reduction in pain and soft tissues from 0–4 weeks only and no reduction in the angle. When the pad was removed after week 4 the condition worsened.

The X-ray results from group A active and placebo were compared using related *t*-test to determine the *P* value. The hallux angle at 0–4 weeks ($n = 10$), showed a significant difference at $P < 0.001$, as did the intermetatarsal angle.

Patients' subjective responses

Subjective responses were recorded on a 4-point questionnaire following the 8-week treatment. In response to question 1 on the effect of the treatment, in the active group 70% felt very much better, 30% better. In the placebo group 100% felt about the same.

In response to question 2 describing the effect of the treatment, in the active group, 100% felt it was good. In the placebo group, 45% felt it was poor, 55% average.

In response to question 3 on reduction of the bunion, in the active group 50% reported very much reduced and 50% much reduced. In the placebo group 100% noticed no change.

In response to question 4 rating the quality of treatment, in

Table 1. Effect of marigold therapy and protective pad on the reduction of width (mm), angle (°) and level of pain (mode) in patients with unilateral Hallux abducto valgus and associated bunion.

Subject	Pretreatment			Week 1			Week 2			Week 3			Week 4			Week 6			Week 8		
	Width	Angle	Pain	Width	Angle	Pain	Width	Angle	Pain	Width	Angle	Pain	Width	Angle	Pain	Width	Angle	Pain	Width	Angle	Pain
1	36	30	10	35	29	5	32	28	0	30	26	0	28	24	0	25	22	0	22	20	0
2	34	35	10	30	33	4	28	32	0	25	30	0	22	28	0	20	25	0	20	23	0
3	40	25	10	38	24	6	35	22	2	33	21	0	30	20	0	28	20	0	25	20	0
4	35	30	10	34	29	5	32	27	1	30	25	0	28	24	0	25	22	0	23	20	0
5	35	30	10	33	28	5	30	27	2	28	24	0	25	22	0	22	23	0	20	20	0
6	35	20	10	34	19	6	33	18	1	32	17	0	30	161	0	25	15	0	20	15	0
7	40	20	10	38	19	5	35	18	0	33	16	0	32	16	0	30	15	0	25	15	0
8	34	60	10	33	58	6	32	56	2	30	54	0	28	50	0	26	45	0	23	42	0
9	34	23	10	33	22	4	32	21	0	30	20	0	26	19	0	24	18	0	23	17	0
10	33	30	10	32	29	5	31	28	1	30	27	0	28	25	0	25	23	0	23	20	0
11	30	24	10	28	23	6	26	22	2	25	20	0	24	19	0	231	18	0	22	15	0
12	30	15	10	29	14	5	28	13	0	27	12	0	26	11	0	25	10	0	20	10	0
13	39	20	10	38	19	6	35	18	2	33	17	0	30	16	0	28	15	0	25	15	0
14	35	20	10	34	19	5	33	18	1	31	17	0	27	16	0	26	16	0	25	15	0
15	29	20	10	28	19	4	26	18	2	25	17	0	23	16	0	22	15	0	20	15	0
16	37	40	10	34	38	6	33	36	1	32	35	0	30	33	0	28	30	01	25	28	0
17	34	20	10	33	19	5	31	18	1	30	17	0	28	16	0	26	15	0	25	15	0
18	33	17	10	32	16	5	30	15	2	29	15	0	27	14	0	26	13	0	24	12	0
19	35	43	10	32	41	5	30	38	2	29	36	0	27	34	0	26	30	0	24	28	0
20	30	20	10	29	19	6	28	18	2	27	1	0	25	16	0	23	15	0	21	15	0
Mean	34·4	27·1	10	32·85	25·85	5·2	31	24·55	1·2	29·45	23·15	0	27·2	21·75	0	25·15	20·25	0	22·7	19	0
s.d.	3·1	10·8	0	3·05	10·48	0·7	3	10·11	0·8	2·61	9·80	0	2·6	9·06	0	2·39	7·94	0	2·1	7	0

the active group 55% rated it excellent, 45% very good. In the placebo group 80% rated it average, 20% poor.

Discussion

The objective of this study was to investigate the effect of *T. patula* preparations in the treatment of Hallux abducto valgus and its associated condition, bunion, in terms of pain, swelling and deformity of the lst metatarsophalangeal joint. The active groups showed improvement in width, angle of Hallux abducto valgus and bunion and level of pain which was maintained throughout the 8-week trial period. In group A (active) the percentage of reduction in width was 34·69%, angle 30% and in the level of pain 100%. In group Ba (active) the percentage of reduction in width was 34%, angle 29·88% and in the level of pain 100%.

Group A (placebo) and Group Bb (placebo) showed a little reduction in pain and soft tissues from 0–4 weeks only and no reduction in angle of Hallux abducto valgus. When the protective pad was absent after week 4 the condition worsened. The improvement in these groups from weeks 0 to 4 would seem to be due to the effect of the protective pad.

Photographic observation of the bilateral and unilateral Hallux abducto valgus and bunion showed reduction of swelling and correction of deformity in the active groups. No obvious change was noticed in the placebo groups.

The cavity pad served not only as a container for the *T. patula* paste but also acted as protection against pressure and friction on the lesion. When there is constant pressure or friction as is the case when wearing shoes with narrow toebox and high heels, the bunion joint becomes traumatized and deformed with pain and inflammation being experienced over a longer period.

Treatment with *T. patula* preparations with protective pad would therefore seem to be more effective than without the pad in the treatment. However, in the active groups improvement was obtained even without the pad but at a lower level (Khan 1993). This indicated that *T. patula* preparations without protective pad would be suitable for patients with plaster allergies. The non-invasive nature of the treatment would be helpful to patients at risk for whom traditional treatment such as surgery could be contra-indicated. It would also be an alternative treatment for patients who do not respond to other treatments.

Contraindications

No adverse effects were reported during the clinical trial.

Mechanism of action

In previous single, open and double-blind placebo-controlled clinical studies preparations of various Tagetes species (*T. patula* and *T. erecta*) were used to investigate their therapeutic action in the treatment of bunion and other bone and joint disorders. The clinical evidence showed that *T. erecta* is also effective in relief of pain and inflammation and in reducing the size of Hallux abducto valgus and bunion (Khan 1995).

Conclusion

The results obtained in this study show a high level of significance ($P < 0.001$) suggesting that *T. patula* preparations plus protective pad are effective in the treatment of hallux abducto valgus and its associated condition bunion, in reduction of size of lesion and relief of pain.

Acknowledgements

I wish to express my gratitude to Professor Fred Evans, Dr E. Williamson and Annie Cavanagh, Department of Pharmacognosy, University of London, for their help in the preparation of this paper. I would like to record my sincere thanks to Mrs Sue Neville, Mr P. Ranasinghe and Mrs Jill Mantle, Institute of Health and Rehabilitation, University of East London, for their supervision in this study and to Dr P. Renton, Consultant Radiologist at St. Pancras Hospital, for his help in providing X-ray facilities. My thanks also go to the Chief Executive of the Royal London Homoeopathic Hospital for providing clinical research facilities, to Dr P. Fisher, Consultant Rheumatologist, for his assistance in research and to Margaret Cooper, Hon. Secretary/Trustee of the Marigold Trust for sponsoring my research.

References

Khan, M. T. (1985) Report: Official trial for HV with Marigold Therapy. 40th. Cong. La Ligue Medicale Homeopathetique Internationale, Lyon, France, pp 232–234

Khan, M. T. (1993) Marigold Therapy in the Treatment of Hyperkeratotic Plantar Lesion. BSc Thesis, University of Brighton

Khan, M. T. (1995) Clinical Study to Investigate the Effect of Marigold Therapy in the Treatment of Hallux Abducto Valgus and its Associated Condition Bunion. MSc Thesis, University of East London