



ORIGINAL ARTICLE

An Open Label Pilot Study of Kalyanaka Ghrita in the Management of Obsessive Compulsive Disorder

Purvi Rajput¹, Prasad Mamidi¹

¹Department of Kayachikitsa Parul Institute of Ayurveda Parul University Vadodara, Gujarat, India

ABSTRACT

Objective: Obsessive-compulsive disorder (OCD) is the fourth most common psychiatric disorder and it interferes with interpersonal relationships, academic achievements, and work. OCD is characterized by obsessions and compulsions. Obsessions are thoughts which are unwanted, intrusive and unavoidable whereas compulsions are repetitive behaviors or mental acts such as washing, cleaning, checking, touching, counting etc. Till date there is no proven drug or therapy in *Ayurveda* to manage OCD effectively. OCD is considered as '*Bhutonmada*' according to *Ayurveda*. The present study was conducted to assess the efficacy of '*Kalyanaka ghrita*' in the management of OCD.

Methods: In present study, 10 subjects with OCD, satisfying the DSM-IV Diagnostic criteria for OCD were selected by simple random sampling method. *Kalyanaka ghrita* was selected as a trial drug and it is administered with a dose of 10 ml, twice a day on empty stomach for the period of two months. One month after completion of treatment, follow-up was done. Before treatment (1st day), after treatment (60th day) and after follow-up (90th day), total three assessments were done. Criteria of assessment were based on the scoring of Yale Brown Obsessive Compulsive Scale (Y-BOCS). Paired t-test was used for statistical analysis.

Results: Effect of therapy based on total score of Y-BOCS has shown 20.4% relief ($p < 0.001$) after completion of treatment period and 44.21% ($p < 0.001$) after follow-up. Mild improvement is found in 90% subjects while 10% had moderate improvement. Conclusions: *Kalyanaka ghrita* has provided clinically significant improvement in OCD.

Keywords: Obsessive-compulsive disorder, OCD, *Ayurveda*, *Kalyanaka ghrita*, Yale-Brown obsessive compulsive scale

INTRODUCTION

Obsessive Compulsive Disorder (OCD) is the fourth most common psychiatric disorder and it interferes with interpersonal relationships, academic achievements, and work. OCD is characterized by obsessions and compulsions. Obsessions are thoughts which are unwanted, intrusive and unavoidable whereas compulsions are repetitive behaviors / mental acts such as washing, cleaning, checking, touching, counting etc (1).

OCD is considered as '*Bhootonmada*' or '*Grahonmada*'

(psychosis of unknown cause) in *Ayurvedic* parlance and *Pragnaaparadha* (intellectual blasphemy) was considered as a contributory factor in the etiopathology of OCD (1). Most of the psychiatric conditions are explained under the domain of '*Unmada*' (psychosis) in *Ayurveda*. The obsessions of OCD can be considered as '*Mano vibhrama*' (disturbance of mental functions) and '*Buddhi vibhrama*' (cognitive disturbances) while compulsions can be considered as '*Cheshta vibhrama*' (disturbances in psychomotor activity) (2).

Few studies have been conducted in the field of *Ayurveda* to manage patients with OCD. Unfortunately till date there is no proven or promising drug or procedure available to manage OCD in *Ayurveda*. In present study, '*Kalyanaka ghrita*' was selected to manage OCD. This formulation has been mentioned in '*Ashtanga*

Corresponding author: Dr Prasad Mamidi, Associate Professor, Faculty of Ayurveda, Abhilashi University, Mandi, Himachal Pradesh, India
E-mail: drprasadmamidi@gmail.com
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hridaya. Kalyanaka ghrita contains 28 ingredients (herbs), and it is indicated in *grahonmada* or *bhootonmada* (3).

METHODS

Aim & Objective

To evaluate the efficacy of '*Kalyanaka ghrita*' in the management of OCD

Study design

An open label pilot study

Selection of subjects

Ten subjects were recruited by following simple random sampling from the OPD (out-patient department) of 'Parul Ayurveda Hospital'.

Inclusion criteria

Subjects who have fulfilled the diagnostic criteria for OCD (300.3) according to 'DSM – IV TR' (Diagnostic and statistical manual of mental disorders, 4th edition, text revision) diagnostic criteria (4) were included in the present study. Subjects belongs to the age group 16–60 years were only included.

Exclusion criteria

Subjects who had other comorbid psychosis or major psychiatric or systemic illness along with OCD were excluded in the present study. Subjects who have been taking allopathic medicines or any other treatments were also excluded from the present study. Hematological and biochemical lab and radiological examinations have been carried out according to the necessity to exclude any major systemic disorders in suspected cases only. In present study no patient was excluded in such a manner.

Ethical clearance

Ethical clearance was obtained from 'Institutional Ethics Committee (IEC)' of Parul Institute of Ayurveda, Parul University (vide ref-PIA/IECHR/2016-17/KC/04 dated 22/10/2016).

Informed consent

An informed written consent was obtained from all subjects recruited in the present study. The consent form was prepared in accordance with the guidelines of WHO (world health organization) 'Research Ethics Review Committee' (ERC). This informed consent form has two parts: Patient information sheet (included subjects received a copy) and certificate of consent (signed by the subject, attached with the research proforma).

Assessment Criteria

Total three assessments have been carried out, before treatment (1st day), after treatment (60th day) and after follow-up (90th day) by using the 'Yale Brown Obsessive Compulsive Scale' (Y-BOCS). The scale has been in use extensively in research and clinical practice to determine severity of OCD and to monitor improvement during treatment. Y-BOCS measures obsessions separately from compulsions; it specifically measures the severity of symptoms of OCD without being biased towards the type of content of obsessions or compulsions present. The clinical scoring for OCD is composed of 10 questions categorized in to two domains (five questions in obsession rating scale and five questions in compulsion rating scale). Each question is rated on a five point (0-4) scale. The questions are based on time, handicap, frequency, control, and discomfort due to obsession as well compulsions. Total score of this scale ranges from 0-40 (5).

Intervention

Kalyanaka ghrita was prescribed with the dose of 10 ml twice a day, orally before food for the period of 60 days. After completion of 60 days of treatment follow-up period was kept for 30 days. No medicine or any other treatment has been given during follow-up period (60th to 90th day). Final (third) assessment has been taken on 90th day (after completion of follow-up period).

Statistical Analysis

Statistical analysis was done by using student's paired t-test. The data generated in the clinical study was

analyzed by using statistical software, Sigmasat 3.5. Level of significance was kept at $p < 0.05$.

RESULTS

In present study total 10 subjects ($n=10$) were recruited and all of them successfully completed the protocol. Among 10 subjects, 60% subjects were female, 60% subjects belongs to 41-60 yrs of age group, all subjects belongs to 'Hindu' religion, 80% were married and 80% belongs to middle class. There was no positive family history found in all the subjects. In present study, all the subjects (100%) have shown contamination obsessions and miscellaneous obsessions followed by obsessions of symmetry (50%), somatic (40%) and religious obsessions (30%). Most common compulsions found in the present study are, cleaning / washing (70%), miscellaneous (70%) followed by ordering / arranging compulsions (40%). In present study 60% of the subjects belong to the category of 'Severe', 30% were 'extreme' and 10% subjects had 'moderate' severity of illness.

Maximum relief (19.23%) found in items like, 'interference from obsessions' and 'distress from obsessions' followed by 'control over obsessions' (12.5%) and 'time spent on obsessions' (11.11%) after treatment period (Table 1). Maximum relief was observed in domains like, 'distress from obsessions' (62.96%) followed by 'interference from obsessions' (50%) and 'resistance to obsessions' (33.33%) after follow-up period (Table 2).

Maximum relief found in items like, 'distress from compulsions' (38.46%) and 'interference from compulsions' (32%) followed by 'control over compulsions' (21.42%) after treatment period (Table 1). Maximum relief was observed in domains like, 'distress from compulsions' (65.38%) followed by 'interference from compulsions' (56%) and 'resistance to compulsions' and 'control over compulsions' (42.85%) after follow-up period (Table 2).

Effect of therapy based on total score of Y-BOCS scoring, after treatment period has shown 20.4% relief ($p < 0.001$) and 44.21% ($P < 0.001$) after follow-up (Table 3). According to overall effect of therapy, none of them

Table 1: Effect of therapy on individual questions of Y-BOCS (after treatment)

BT [§]	AT [¶]	MD*	% of change ^{§§}	SD ^{¶¶}	SE ^{**}	t value	p value
3.6	3.2	0.4	11.11	0.52	0.16	2.45	0.030
2.6	2.1	0.5	19.23	0.53	0.17	3.00	0.010
2.7	1.7	1.0	19.23	0.00	0.00	~	0.001
3.3	3.0	0.3	9.09	0.48	0.15	1.96	0.080
3.2	2.8	0.4	12.5	0.52	0.16	2.45	0.037
3.3	2.7	0.6	18.18	0.52	0.16	3.67	0.005
2.5	1.7	0.8	32.00	0.22	0.13	6.00	0.001
2.6	1.6	1.0	38.46	0.00	0.00	~	0.001
2.8	2.4	0.4	14.28	0.52	0.16	2.45	0.037
2.8	2.2	0.6	21.42	0.42	0.16	3.67	0.005

[§]Before treatment, [¶]After treatment, *Mean difference, ^{§§}Percentage of change, ^{¶¶}Standard deviation, ^{**}Standard error, [|]Infinite

Table 2: Effect of therapy on individual questions of Y-BOCS (after follow up)

BT [§]	AT [¶]	MD*	% of change ^{§§}	SD ^{¶¶}	SE ^{**}	t value	p value
3.6	2.5	1.1	30.55	0.32	0.10	11.00	0.001
2.6	1.3	1.3	50.00	0.48	0.15	8.51	0.001
2.7	1.0	1.7	62.96	0.48	0.15	11.13	0.001
3.3	2.2	1.1	33.33	0.32	0.10	11.00	0.001
3.2	2.3	0.9	28.12	0.32	0.10	9.00	0.001
3.3	1.9	1.4	42.42	0.52	0.16	8.57	0.001
2.5	1.1	1.4	56.00	0.52	0.16	8.57	0.001
2.6	0.9	1.7	65.38	0.48	0.15	11.13	0.001
2.8	1.6	1.2	42.85	0.42	0.13	9.00	0.001
2.8	1.6	1.2	42.85	0.42	0.13	9.00	0.001

[§]Before treatment, [¶]After treatment, *Mean difference, ^{§§}Percentage of change, ^{¶¶}Standard deviation, ^{**}Standard error

Table 3: Effect of therapy on total score of Y-BOCS (after treatment & After follow up)

BT [§]	AT [¶] /AF	MD*	% of change ^{§§}	SD**	SE**	t value	p value
29.4	23.4 (AT)	6	20.40	4.72	1.49	16.43	0.001
29.4	16.4 (AF)	13	44.21	1.70	0.54	24.18	0.001

[§]Before treatment, [¶]After treatment, ^{||}After follow up, *Mean difference, ^{§§}Percentage of change, ^{**}Standard deviation, ^{**}Standard error

Table 4: Overall result of therapy

Category	After treatment (%)	After follow up (%)
Cured	0	0
Marked improvement	0	0
Moderate improvement	0	10
Mild improvement	10	90
Unchanged	90	0

got complete cure and marked improvement. Mild improvement is found in 90% subjects whereas 10% had moderate improvement after follow-up period (Table 4). The improvement was most promising after follow-up period than after treatment period.

DISCUSSION

OCD is a chronic disease which is characterized by obsessions and/ or compulsions. There is evidence that different subtypes of OCD exists and hence it is considered as heterogeneous disorder. OCD is most frequently observed in boys and shown high comorbidity with various other psychiatric disorders especially with depression. Drug therapy for OCD contains mainly selective serotonin reuptake inhibitors (SSRI). In addition to drug therapy, cognitive-behavioral therapy (CBT) has proved to be efficacious (6). According to *Ayurveda*, OCD comes under the domain of 'Unmada', which is characterized by the derangement of mental functions. *Unmada* is characterized by the derangement of *manas* (mind), *buddhi* (cognition), *smriti* (memory), *bhakti* (desire), *sheela* (habit), *cheshtha* (activities) and *achara* (conduct). 'Agantuja unmada' or 'Bhutonmada' or 'Grahonmada' is a sub type of *Unmada* (7). OCD is considered as 'Bhutonmada' by previous scholars (1). Use of old *ghrita* (clarified butter) and *rakshoghna dravya's* (herbs which possess anti-demonic properties) are indicated for the management of *bhutonmada*. '*Kalyanaka ghrita*' is also mentioned for the management of *bhutonmada* (7).

Kalyanaka ghrita contains various herbs and it is an Ayurvedic formulation mentioned in all classical Ayurvedic texts. The word '*Kalyanaka*' means 'the superior one'. *Kalyanaka ghrita* is a medical preparation of herbs with *ghrita* as the basic ingredient. *Kalyanaka ghrita* contains various herbs like *Haritaki* (*Terminalia chebula*), *Vibhitaki* (*Terminalia bellirica*), *Amlaki* (*Phyllanthus emblica*), *Vishala* (*Citrullus colocynthis*), *Bhadraila* (*Amomum subulatum*), *Devadaru* (*Cedrus deodara*), *Haridra* (*Curcuma longa*), *Manjishta* (*Rubia cordifolia*), *Kushtha* (*Saussurea lappa*) etc. *Kalyanaka ghrita* has been mentioned in treating various psychiatric conditions (8). Based on these features in present study *kalyanaka ghrita* has been selected.

Contamination, symmetrical and religious obsessions, cleaning / washing, checking, counting and ordering/ arranging compulsions are the commonest symptoms of clinical presentation of OCD in present study. In present study it has been found that most of the patients have responded positively in short course of treatment (60 days) and the positive effect continued even after stopping the treatment (follow-up period); this may be due to the long term and cumulative effect of the drug. There were no side effects or adverse reactions reported by any subject during the trial. Overall 44.21% of relief on Y-BOCS ($p < 0.001$) has been found. The drug is effective in improving assessment parameters, safe for long term use and cost effective.

CONCLUSION

'*Kalyanaka ghrita*' has shown promising results in the management of OCD. Further studies are required with large sample and also with control group to substantiate the present study findings.

Conflict of Interest: Authors declared no conflict of interest.

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