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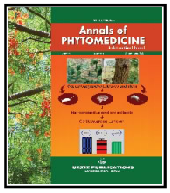

Clinical Trial : Open Access

Clinical study to evaluate the efficacy of *Pippalyadi basti* and *Lekhan basti* in the management of obesity

Ritu Wadhwa◆, Shraddha Umesh Nayak*, Nimisha Patel and Hina Alim*****

Panchakarma Department, D. Y. Patil Deemed to be University, School of Ayurveda, Nerul, Navi Mumbai-400614, India

**Dravyaguna Department, D. Y. Patil Deemed to be University, School of Ayurveda, Nerul, Navi Mumbai-400614, India*

***J.C. Bose University of Science and Technology, YMCA, Faridabad-121006, Haryana, India*

****Department of Life Sciences, University of Mumbai, Vidyanagari, Mumbai-400098, Maharashtra, India*

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Abstract

The prevalence of obesity has increased threefold in the last two decades and continues to rise. Management of obesity with modern drugs remains unsatisfactory. As per research, it is a precursor to coronary heart disease, hypertension, diabetes mellitus, and hyperlipidemia, which have been recognized as the leading killer diseases of the millennium. The present clinical study was conducted to evaluate and compare the clinical efficacy of two herbal therapeutic approaches for obesity on 62 patients at D.Y. Patil Ayurved Hospital, Nerul, Navi Mumbai. A two-month course was designed, in which patients were divided into two groups, each receiving *Pippalyadi basti* and *Lekhan basti* which was given as niruha basti. During this trial, two sittings of nine consecutive basti, with six niruha basti and three anuvasan basti with triphaladi tail, were administered with a gap of 18 days. Assessment of objective criteria involved measurement of body weight and BMI, whereas subjective parameter comprised Alasya (Utsahahani), Atikshudha, Atipipasa, Atisweda, Dourbalya, and Dourgandhya. It was found that *Pippalyadi basti* was as effective as *Lekhan basti* in the management of Medoroga (obesity). Internal purification procedures such as *Lekhan basti* and *Pippalyadi basti* perform strotas shodhan and s*amprapti vighatan* that hold immense potential and effectiveness in reducing body weight and other obesity-related symptoms.

1. Introduction

In the 21st century, with its continuous changing lifestyles, the environment and dietary habits, have made man the victim of many diseases. Obesity is one of them and serves as a multi-factorial, rapidly escalating global public health concern (Fruh, 2017; Lin and Li, 2021). Since 1980, the prevalence of excessive weight gain has doubled globally, and over a third of the world's population has been classified as obese or overweight (Ataey *et al*., 2020). Obese individuals are susceptible to a higher risk of developing a wide range of co-morbidities, such as diabetes, cardiovascular disease (CVD), gastrointestinal disorders, hypertension, obstructive sleep apnea (OSA), muscular and joint disorders, respiratory obstructions, and psychological issues (Sangeeta *et al*., 2021). These conditions can have a significant impact on patients' daily lives and raise mortality rates considerably (Cefalu *et al*., 2015; Fruh, 2017). Even minor weight loss may help patients reduce their risk of this array of comorbid conditions (Cefalu *et al*., 2015).

According to Ayurveda, *Medoroga* or *Sthoulya* is considered as excess fat deposition and, in modern parlance, it is co-related to being overweight or obese (Sharma and Adiga, 2021). *Acharya Charak* described the *Atisthula* person as having the most undesirable constitution in the *Sutra Sthan*. Factors such as diet, environmental factors (socioeconomic status and chemical exposures), sedentary lifestyle, genetics, epigenetic, and development variables all contribute to *Medoroga* risk (Schwartz *et al*., 2017). In order to get the optimum outcomes, Ayurvedic internal medications and *Shodhana* techniques are employed in tandem, which leads to vitiation of the Dosha (Asim, 2020). Obesity management relies heavily on *Pathya Apathya* (diet control) and other lifestyle changes (Sharma and Adiga, 2021).

Basti is one of the *panchakarma* procedures in Ayurveda and is a process in which an anal dose of medical oil, kashayam, fluid is given, and the medications contained in the oil or decoction are absorbed into the gut at the same time. This treatment leads to nourishment of the body and pacification of the associated *Vata* and doshas. *Lekhaniya gana* contains drugs like *Triphala, Shatpushpa (Anethum sowa), Madhu* (honey), *Ushaka* (alkaline soil), *Kasis* (ferrous sulfate), *Tuttha* (copper sulphate), *Shilajatu* (black bitumen), *Saindhav* (sea salt), *Yavakshar* (barly ash, crude potassium carbonate), *Gomutr* (cow urine) (Bhonsle *et al* 2021). Pippalyadi on the other hand has *Chitraka* and *Pippali* in addition to the other components of *Lekahan basti* and can act synergistically to reduce fat from the body. Thus, the aim of the study was to evaluate and compare the clinical efficacy of *Pippalyadi Basti* and *Lekhan Basti* so as to provide a safe, effective, comprehensive, and rational option for the management of *Medoroga*.

Corresponding author: Dr. Ritu Wadhwa

Panchakarma Department, D. Y. Patil Deemed to be University, School of Ayurveda, Nerul, Navi Mumbai-400614, India

E-mail: rituwadhwa21@gmail.com

Tel.: +91-9969689240

2. Materials and Methods

2.1 Study design and eligibility criteria

This randomized, open, comparative clinical trial was conducted at OPD and IPD of D.Y. Patil Deemed to be University, Ayurvedic Hospital, Nerul, Navi Mumbai after obtaining approval from the Institutional Ethics Committee of the Institute (IEC Ref No: DYPUSA/IEC/2019; Dated 18 March 2019). A well-written informed consent was obtained from all the study participants, post explaining them the aims and objective of the study. Further, the participants were enrolled in the study using a convenient sampling method and on the basis of pre-set inclusion and exclusion criteria. The study's inclusion criteria allowed any patient with clinical signs and symptoms of *Sthoulya*, aged more than 18 and less than 50 years, and a BMI of 30-40 kg/m^2 to participate. Also, patients who were eligible for Basti were enrolled. On the other hand, patients with hypothyroidism, hypertension, diabetes mellitus, and cardiac disease, or on long-term steroid/anti-psychotic drugs, or pregnant and lactating women were excluded from the study. This study was conducted from June, 2019 to June, 2021 and duration of the treatment of each patient was 8 weeks.

2.2 Sample size, formulation and intervention

A total of 62 patients (17 males and 45 females) within an age limit of 18-50 years and diagnosed with *Sthoulya*, participated in the study. The participants were randomly allocated to two groups, comprising a total of 31 patients each. Group A received *Pippalyadi Basti* and Group B received *Lekhan Basti*. Table 1 shows the formulations of both the Bastis. Analytical report on the quality of drugs used was obtained from Alarsin Pharmaceuticals, Mumbai. *Triphaladi* tail, which is used for *Anuvasan basti*, was formulated in the Rasashastra Lab, D. Y. Patil School of Ayurveda, Nerul. *Pippalyadi basti* and *Lekhan basti* packets were prepared by the Panchakarma Department of the School of Ayurveda, D. Y. Patil Deemed to be University, Navi Mumbai.

Table 1: Formulation of *Pippalyadi basti* and *Lekhan basti*

Drugs	*Pippalyadi basti*	*Lekhan basti*
Madhu	80 gm	80 gm
Yavakshar	5 gm	5 gm
Saindhva	5 gm	5 gm
Triphalataila	50 ml	50 ml
Kalka	20 gm (*Shatpushpachurna*)	20 gm (*Oshakadigan*)
Gomutra	80 ml	80 ml
Kwath	320 ml (*Pippali, Chitrak*)	320 ml (*Triphala*)

During first sitting of *Basti* treatment, 6 doses of *Pippalyadi/Lekhan basti* (as *Niruha*) 560 ml in the morning empty stomach was administered through anorectal route and *anuvasan* with *triphaladi tail* (100 ml) after meal was given on first day, fifth day and last day. On first day (D1), *anuvasan basti* was given, then three days consecutively (D2, D3, D4) niruha basti was given, following which again on the fifth day (D5) *anuvasan basti* was administered. Thereafter, three days continuous (D6, D7, D8) niruha were given and on the last day (D9), anuvasan basti was conducted. In this manner, a total of 9 *basti* were administered. The same course of *basti* was repeated after a gap of 18 days. Last follow-up was taken after the second *Pariharkaal* (18 days). Follow up with patients was done on the 0, 10th, 28th, 38th and 56th days (8 weeks). The participants followed a regular diet plan as per their interest, but were asked to refrain from consumption of deep-fried food items.

Table 2: Gradation scale of subjective parameters used for the assessments

Grade	*Alasya*	*Atikshudha*	*Atipipasa*	*Atisweda*	*Dourbalya*	*Dourgandhya*
0	Working satisfactorily	Normal appetite 2-3 times daily	Normal thirst	Sweating after heavy work and fast movement	Can do routine exercise	Absence of bad smell
1	Work satisfactorily with late initiation	Excess appetite 2-3 times daily	Up to 1liter excess intake of water	Profuse sweating after moderate work and movement	Can do moderate exercise without difficulty	Occasional bad smell from the body which is removed after bathing
2	Work unsatisfactorily under mental pressure and takes time	Excess appetite 3-4 times daily	1-2 liter excess intake of water	Sweating after little work and movement	Can do only mild exercise	Persistent bad smell limited to close areas, difficult to suppress with deodorants
3	Not starting work on his responsibility and doing slowly less work	Excess appetite 4- 5 times daily	2-3 liter excess intake of water	Profuse sweating after little work and movement	Can do mild exercise very difficulty	Persistent bad smell felt from long distance and is not suppressed by deodorants
4	Does not take any initiation/not want to work even after pressure	Excess appetite more than 5 times daily	More than 3 liter intake of water	Sweating even at rest or in cold season	Cannot do even mild exercise	Persistent bad smell felt from long distance even tolerable to the patient himself

2.3 Method of data collection and assessments

Case record forms (CRF) were filled with details of the patient, their history, physical examination and pathology investigation. Assessment of objective criteria involved measurement of body weight and BMI, whereas subjective parameter comprised *Alasya* (Utsahahani), *Atikshudha*, *Atipipasa*, *Atisweda*, *Dourbalya*, and *Dourgandhya*. The grading of subjective parameters is shown in Table 2.

2.4 Statistical analysis

All continuous variables were summarized using the mean and standard deviation. Graph Pad Version 3.6 software was used for the statistical analysis of the data. A paired t-test was used for the intragroup assessment of objective parameters, whereas an unpaired t-test was applied to assess intergroups. In order to evaluate the comparative efficacy of the *Pippalyadi basti* and *Lekhan basti* in Group A and Group B, respectively, Wilcoxon matched pairs signed ranks test was employed. A *p*-value <0.05 was considered significant.

3. Results

The demographics of the study population are represented in Table 3. The mean age of the subjects in Group A was recorded as 41 ± 7.7 years, which differed slightly from the mean age of the Group B subjects, *i.e*., 38.03 ± 7.7 years. The difference in the mean age of both Groups were found to be statistically non-significant, indicating the non-biased allocation of the subjects to both the each group. In Group A, 77.41% were found to be female participant and 22.58% were males. On similar lines, a slight difference was observed in Group B to encompass 67.74% of females and 32.25% of males. All of the participants in both groups were found to be middle-class, with a preference for mixed diets and a preference for living in urban areas (Table 3). Furthermore, the highest percentage (41.93%) of participants had higher secondary education, whereas 66.51% of people in Group B held graduate degrees in terms of their education. Illiteracy was recorded at 3.22% in both the groups. The distribution of the participants in terms of their religion was also observed to be at par in both groups. In Group A, 38.70% of subjects were involved in professional occupations and the least percentage (6.45%) belonged to the labour class group. This observation varied in Group B, where maximum subjects (41.93%) had sedentary occupations and none of them belonged to the labour class (Table 3).

The body mass index (BMI) is a straightforward and widely used metric for categorising different degrees of adiposity (Nuttall, 2015; Ofei, 2005). Thus, objective parameters like weight and BMI were measured in both the groups before and after treatment. The mean weight in Group A was found to be 77.75 ± 7.40 kg before treatment and was observed to significantly (p<0.001) decreased to 70.87 ± 6.77 kg after treatment. A similar significant (p<0.001) drop in mean weight was observed in Group B, from 85.87 ± 9.45 kg before treatment to 78.03 ± 9.25 kg after treatment (Table 4). On the other hand, mean BMI was recorded at 32.43 ± 1.70 kg/m^2 which was significantly (p<0.001) reduced to 29.62 ± 1.64 kg/m^2 in group after therapy. Likewise, the mean BMI of Group B also significantly reduced (p<0.001) after treatment, from 33.36 ± 2.20 to 30.32 ± 2.21 kg/m^2, thus indicating the efficacy of both the treatments.

Table 3: Demographics of the study population

Demographics	Group A	Group B
Mean age (years)	41 ± 7.7	38.03 ± 7.7^{NS}
18-20 (%)	0	3.22
21-30 (%)	12.90	12.90
31-40 (%)	38.70	48.38
41-50 (%)	48.38	35.48
Gender		
Female (%)	77.41	67.74
Male (%)	22.58	32.25
Economical status		
Higher class (%)	0	0
Middle class (%)	100	100
Lower class (%)	0	0
Education		
Degree (%)	32.25	64.51
Higher secondary (%)	41.93	22.58
Primary school (%)	19.35	3.22
Illiterate (%)	3.22	3.22
Post Grduate	3.22	6.45
Religion		
Hindu (%)	96.77	96.77
Muslim (%)	3.22	3.22
Occupation		
Active (%)	22.58	25.80
Sedentary (%)	32.25	41.93
Labour (%)	6.45	0
Others (%)	38.70	32.25
Marital status		
Married (%)	93.54	90.32
Unmarried (%)	6.45	9.67
Diet		
Vegetarian (%)	0	3.22
Mixed (%)	100	96.77
Habitat		
Urban (%)	100	100
Rural (%)	0	0

Various subjective parameters like *Alasya* (Utsahahani), *Atikshudha*, *Atipipasa*, *Atisweda*, *Dourbalya* and *Dourgandhya* were also measured at grade scale of 0 to IV. For *Alasya*, the median score of *Alasya* in Groups A and B both was recorded to be 2 and was noted to be improved to score 0 in Group A and to score 1 in Group B with statistically significant (p< 0.001). Albeit the difference between the A and B Groups remained non-significant. A quite similar observation was evident for *Atikshudha* and *Atisweda* scores as well. On intergroup comparison, the difference between the groups was found to be statistically significant, though for *Atisweda*, results were insignificant. Further for *Atipipasa*, the median score of both the

Groups enriched from 1 to 0. Grade scale of *Daurbalya and Daurgandhya* was also found to improve. For *Daurbalya*, Group A showed median score of 2 before treatment that was recovered to score 0 after treatment. On the other hand, median score of 1 persisted even after therapy in Group B for *Daurbalya*. Subjective parameter of *Daurgandhya* was found to have 2 to 0 score improvement in Group A and 1 to 0 in Group B. The intergroup comparison was found to be statistically non-significant (Table 5).

Table 4: Objective parameters of both the groups before and after treatment

Objective parameters	Group A		Group B	
	BT	AT	BT	AT
Mean weight (kg)	77.75 ± 7.40	70.87 ± 6.77	85.87 ± 9.45	78.03 ± 9.25
Range (min-max)	67.00 – 89.00	60.00 – 82.00	69.00 – 108.00	60.00 – 100.00
Intragroup comparison	t = 20.12 (p<0.001)		t =22.21 (p<0.001)	
Intergroup comparison	t = 3.42 (p<0.001)			
Mean BMI (kg/m²)	32.43 ± 1.70	29.62 ± 1.64	33.36 ± 2.20	30.32 ± 2.21
Range (min-max)	30.20 – 36.70	26.70 – 33.30	30.00 – 39.70	26.40 – 36.70
Intragroup comparison	t = 18.9 (p<0.001)		t = 22.35 (p<0.001)	
Intergroup comparison	t = 1.407 (p>0.05)			

The abbreviations used for: BT- Before treatment and AT- After treatment.

Table 5: Scoring of different subjective parameters before and after treatment in Group A

Grade	*Alasya*		*Atikshudha*		*Atipipasa*		*Atisweda*		*Daurbalya*		*Daurgandhya*	
Group A	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)
IV	0	0	0	0	0	0	0	0	0	0	0	0
III	20	0	13.3	0	0	0	10	0	13.3	0	3.3	0
II	73.3	0	73.3	0	43.3	0	50	0	40	0	43.3	0
I	6.6	43.3	13.3	30	33.3	26.6	16.6	30	33	43.3	40	20
0	0	56.6	0	70	23.3	73.3	23.3	70	13.3	56.6	13.3	80
Median	2	0	2	0	1	0	2	0	2	0	2	0
Intragroup comparison	p<0.001		p<0.001		p<0.001		p<0.001		p<0.001		p<0.001	
Group B	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)	BT (%)	AT (%)
IV	0	0	3.3	0	3.3	0	0	0	0	0	0	0
III	13.3	0	13.3	3.3	0	0	0	0	0	0	3.3	0
II	70	10	56.6	6.6	13.3	3.3	23.3	0	40	0	6.6	0
I	13.3	50	26.6	60	50	30	50	46.6	50	56.6	50	23.3
0	3.33	40	0	30	33.3	66.6	26.6	53.3	10	43.3	40	76.6
Median	2	1	2	1	1	0	1	0	1	1	1	0
Intragroup comparison	p<0.001		p <0.001		p<0.001		p<0.001		p<0.001		p<0.001	
Inter group comparison A vs B	p>0.05 NS		p<0.01 Significant		p>0.05 NS		p>0.05 NS		p>0.05 NS		p>0.05 NS	

The abbreviations used for: BT-Before treatment, AT-After treatment, NS-Non significant.

Table 6: Overall assessment of the therapy in two groups

Overall assessment of treatment	Group A		Group B	
	No. of participants	Percentage	No. of participants	Percentage
Grade I	00	00%	01	03.33%
Grade II	22	73.33%	10	33.33%
Grade III	08	26.67%	05	16.67%
Grade IV	00	00%	14	46.67%
Grade V	00	00%	00	00%
Total	**30**	**100%**	**30**	**100%**

Table 6 represents overall assessment of the therapy in both the groups. Near about 3.33% subjects in Group B displayed Grade I in overall symptom assessment that is marked as complete remission showing 100% relief in signs and symptoms and >20% reduction in body weight. Marked improvement (Grade II) was observed in 73.33% subjects of Group A and 33.33% of Group B. These subjects showed more than 75% relief in symptoms and 15% reduction in body weight. Further, 26.67% and 16.67% people of Groups A and B, respectively expressed 50 -70% relief in sign and symptoms and 10-15% reduction in body weight that was categorized as moderate improvement (Grade III). 14.47% of Group B patients showed only mild improvement of 25-50% relief in sign and symptoms with 6-10% reduction in body weight (Grade IV). None of the subjects were reported to have Grade V assessments.

4. Discussion

Sthaulya (obesity) is a condition that is characterised by an excess of *Medodhatu* (fat) in the body. An illness known as *Sthaulya* is characterised by an excess of *Medodhatu* in the body (Anon, 2004). In the *Santarpanottha vikar* (a disease caused by over consumption of calories), this is one of the symptoms (Gujarathi *et al*., 2014). *Lekhan basti* and *Pippalyadi basti* execute an important role in hindering the pathogenesis process (*samprapti vighatan)* of *Sthoulya*, which is highly influenced by *Kapha dosha* and *Medadhatu* (fat deposits) (Raina *et al*., 2018). A *Kapha* physique is physically strong, compact, and broad, with expansive thighs, hips, butts, and chest, with a predisposition to be chronically overweight. Together with *Medadhatu*, this might be called the primary *Dosh-Dushyaghatak* in *Sthoulya*. Due to the *avaran* (obstruction) of the *strotas* (internal transport system) by *Medadhatu* (fat deposits), there is *vruddhi* (progression) of *koshtagatvata* (samanvata), which ultimately results in *atibubhuksha* (craving for food). *Bastichikitsa* is used to rectify *tikshna jatharagni* and *mandamedodhatvagni* (Bhonsle *et al*., 2021).

Owing to the prominence of *Lekhana karma*, *Lekhana basti* has been chosen. In comparison to *vamana* and *virechana*, it is safe and simple to administer for *Sthoulya* therapy. This fact is supported by previous literature (Hiware and Parwe, 2018; Bhende *et al*., 2020). *Taila*, *madhu*, *gomutra*, and *lavana*, which include *ushana* and *tikhna guna*, were combined to create basti. *Anupravana bhava* is *taila's* character trait. *Grahani* is the final point of absorption because of the illioceacal valve. By reaching the *grahani*, basti prevents fat absorption. A combination of the *Saman vayu* being pacified and *Jatharagni* being brought back into the normal range, as well as activating the vyana Vayu, allows *Lekhan* treatment to work at a cellular level (Bhonsle *et al*., 2021).

Pipplyadi basti is nowhere mentioned for the treatment of *Sthoulya*. However, *Acharya Charak* has advocated the use of *basti* with *lekhan*, *rookshan*, and *teekshna* properties. Similar properties are possessed by *Pipplyadi basti Dravya* and were the reason for its use for the first time in the treatment of *Sthoulya*. *Acharya Charak* has described *Ardhashlokokta basti* in *siddhisthan* and has advocated 3 types of *Vata*, *Pitta, and Shaleshmahar basti*, *Pippalyadi basti* is one of them that is indicated as *Shleshma Rogeshu Hiteshu*. *Pippalyadi basti* contains *Pippali* and *Chitrak* that has *Ushna veerya* and *Katu vipaka* (Pandey, 2005), thus these have effective role on *kapha dosha* and by their *Ushna veerya*, they possess *vatahar karma*, in that way prime cause of disease, *i.e*., *kapha* and *vata* are managed. *Pippalyadi basti* comprises mainly *gomutra*, *shatpushpa*, *lavan*, honey, *yavakshar that* possess *ruksha*, *tikshna guna*, *ushna veerya* and *vata kaphashamak* properties, thus providing a significant effect on most of the symptoms of sthoulya.

By virtue of *Deepan*, *Pachan karma* of *chitrak* and *Pippali* (Pandey, 2004), this combination works even at the level of *Agni*, and corrects *medodhatu agnimandyta*. Also, it checks further progression of disease by preventing the formation of *Meda*. Qualities of *triphaladi taila* which are used as Anuvasan basti in this patient is mentioned in *Sthoulya dhikara* by *Chakradatta* (Tripati, 2014). Many researchers have already established the role of *Lekhan basti* in Sthoulya. But, *Pippalyadi basti*, with its role in *kostha and dhatuagni* (metabolism), could have better results in the management of *sthoulya*. The ingredients of *Pippalyadi basti* are simple, easily available and very effective. Kalk drugs (*Oshakaadi Gani Kasis, Tutha, Shilajit, Hingu etc*.,) of *Lekhan basti* sometimes create complications that may be avoided by opting *Pippalyadi basti* for *sthoulya chikitsa*. Our studies support that the therapeutic efficacy of *Pippalyadi basti* is on par as *Lekhan basti*.

The limitation of the study is that a purposive (non-probability) sampling technique was applied and patients were all recruited from a single center.

5. Conclusion

Medoroga (obesity) is a *Dushya* Dominant *Vyadhi*. There is an involvement of all the three *dosha* in *Medoroga* but, the vitiation of *Kapha Dosha* and *Medodhatu* are of prime importance. Etiological factors, *i.e.*, dietary, psychological, and lifestyle-related factors, mainly vitiate *Kapha-Meda*. This vitiated *Meda Dhatu* obstructs the path of *Vata Dosha* and causes its *Avarana*, which results in the provocation of *Vata Dosha*. Genetic factors (*Beejadushti*), sedentary lifestyle and *Kapha* predominant *Prakriti* increase the prevalence of obesity. In order to overcome this issue, *Kapha-Vata-Meda Hara* and *Apatarpanakara* can be a line of treatment. In our study, both *Lekhana basti* and *Pippalyadi basti* exhibited statistically significant effects in objective as well as subjective criteria in reducing signs and symptoms of *Medoroga*. *Thus, Pippalyadi basti* was found equally effective as *Lekhana basti* in the treatment of signs and symptoms, along with the reduction in the total body weight.

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Conflict of interest

The authors declare no conflicts of interest relevant to this article.

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