Clinical efficacy of Baladi Manduram in the management of Amlapitta

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Abstract

Background: Amlapitta is a commonly encountered disease of Annavaha Srotasa (gastrointestinal system) described in various classical Ayurvedic texts. The cardinal features of Amlapitta are Avipaka (indigestion), Hritkantha Daha (heart and throat burn) and Tikta-Amlodgara (sour and bitter belching). This disease can be correlated with gastroesophageal reflux disease based on the clinical features. Baladi Manduram is one of the unique formulations mentioned in Rasa Kamadhenu indicated for the management of Amlapitta. Aims: This study is aimed to evaluate the efficacy of Baladi Manduram in the management of Amlapitta. Materials and Methods: A non-randomized, single-armed, open-labeled clinical trial was conducted in thirty patients having classical symptoms of Amlapitta, administered with 500 mg of Baladi Manduram twice a day after meals for 30 days. The assessment was done based on subjective parameters, i.e., Amlodgara (sour belching), Daha (heart burn), Gaurava (heaviness), Utklesha (nausea), Avipaka (indigestion) and Kshudha Alpata (loss of appetite). The results were statistically analyzed using the paired t-test. Results: Statistically highly significant relief (P < 0.001) was noted in Amlodgara, Hritkantha Daha, Utklesha and Agrimandaya and statistically highly significant relief (P < 0.01) was seen in Gaurava and Avipaka. Conclusion: Baladi Manduram can be considered as an effective formulation in the management of Amlapitta.

Keywords: Amlapitta, Baladi Manduram, gastroesophageal reflux disease

Introduction

Gastroesophageal reflux is a disease occurring due to improper functioning of esophageal sphincter. It is a very common disease, affecting up to 8%-20% of adult men and women in the Indian population.1) It also occurs in children. Patients with gastroesophageal reflux disease (GERD) have the signs and symptoms such as heartburn, chest pain, gastric discomfort, abdominal distension, sour belching, food regurgitation, nausea and reduced appetite. These signs and symptoms can be seen in the disease Amlapitta mentioned in Ayurveda.

Amlapitta has been mentioned in various Ayurvedic texts since Samhita period. This disease has been described in detail in classical texts such as Kashyapa Samhita, Yoga Ratnakara, and Bhaishajya Ratnavali. Amlapitta is considered as a Pitta Pradhana Vyadhi (pre-dominant disease) and possess symptoms such as Amlodgara (sour and bitter belching), Hritkantha Daha (heart and throat burn), Gaurava (heaviness), Avipaka (indigestion), Klama (fatigue), Aruchi (tastelessness), Utklesha (nausea), (2) Antra Kujana (gurgling sounds in intestines), Hritshula (heart pain) and Vidbheda (diarrhea). Over indulgence of etiological factors such as faulty life style causes vitiation of Vata Pitta Dosha. Pitta along with Vata or Kapha slackens the Jatharagni factor responsible for digestion, i.e., Jatharagninandya (dimunition of digestion). During this state, consumed food becomes Vidagdha (undigested). Later on, it turns into Shukta (acidified) and it remains in the abdomen for long. At this stage, Vidagdhajirna (indigestion caused due to acidified chyle) manifests which is the premonitory symptom of the disease Amlapitta. Further, vitiated Pitta gets mixed with Shukta and causes Pitta Amavisha Sammurchhana (combination of unmetabolised Rasa and undigested food with Rasa). This condition is called as Amlapitta. (3)

Baladi Manduram is one of the important formulations mentioned in Rasa Kamadhenu for Amlapitta. (3) and Rasa Yoga

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Sagara Vol II Pakaradi Varga. It contains Mandura Bhasma, Bala roots (Sida cordifolia Linn.), Shatavari roots (Asparagus racemosus Willd.), Eranda roots (Ricinus communis Linn.), Yava (Hordeum vulgare Linn.), Guda (jaggery), Jiraka (Cuminum cyminum Linn.), Pippali (Piper longum Linn.), Twak (Cinnamomum zeylanicum Blume), Ela (Elleteria Cardamomum Maton), Patra (Cinnamomum tamala Nees) and Nagakeshara (Mesua ferrua Linn.). All the ingredients present in Baladi Manduram have Kashaya (pungent), Madhura Rasa (sweet), Sheeta Virya, Madhura Vipaka, Deepana (digestion stimulator), Krimighna (anthelmintic), Pitta–Kaphahara (pacifies Pitta and Kapha) and Shopahara (reduces oedema) properties. When combined, these drugs are expected to show their synergistic action against Amlapitta. Hence, with an intention to find the efficacy of Baladi Manduram on Amlapitta with respect to GERD, this drug has been selected.

Materials and Methods
A total of 33 patients having classical symptoms of Amlapitta attending the OPD of Roga Nidana and Rasa Shastra & Bhaishajya Kalpana department from Institute hospital, were selected irrespective of sex, caste, religion etc., taking due considerations of inclusion and exclusion criteria. The study was started after approval from the Institutional Ethics Committee (IEC/SVAYC/RS/15/49) dated 26-3-2015. Informed written consent was taken from each patient before starting the treatment.

Inclusion criteria
• Patients aged between 20 and 60 years having signs and symptoms of Amlapitta such as Amlodgara, Daha, Gaurava, Utklesha, Avipaka, Agnimandya were selected. Diagnosis of Amlapitta was purely decided only by considering the above-mentioned signs and symptoms present in the patients.

Exclusion criteria
• Patients of age <20 years and >60 years. Patients already diagnosed with or having any history of other systemic diseases such as cardiovascular, nephropathic, neuropathic and any type of malignant disorders were excluded.

Laboratory investigation
• Routine hematological investigations such as hemoglobin percentage, total leukocyte count, differential leukocyte count and erythrocyte sedimentation rate were done.

Posology
• Baladi Manduram was given in the dose of 500 mg twice a day after meals with hot water as Anupana for a duration of 30 days.

Statistical analysis
Statistical test for assessment of the data was performed using the paired t-test using GraphPad Prism software, USA.

Diet and regimen
Pathya (wholesome diet and life style): Patients were asked to follow the meal times and to take light food, coconut water, articles having cooling properties.

Vegetables like white pumpkin, bitter gourd, matured ash gourd, leafy vegetables except methi, wheat, old rice, barley, green gram, sugar candy, cucumber, fruits like gooseberry, dry grapes, black grapes, sweet lime, pomegranate, fig., adequate amount of fluids like pomegranate juice, lemon juice, amla juice, sweetlime juice, warm water, take adequate sleep and rest and to practice Yoga, Pranayama, meditation and exercise regularly.

Apathya (un-wholesome diet and life style): Avoid excessive spicy, sour, salty substances, fried and junk food items. Avoid untimely and irregular food habit, foods containing excess amount of garlic, salt, oil, chillies etc. very often. Avoid lying down immediately after food and in supine position. Avoid smoking, alcohol, tea, coffee and stress.

Method of preparation of Baladi Manduram
Raw materials such as Mandura and Triphala were obtained from the local market of Chennai, Tamil Nadu, India. roots of Bala (Sida cordifolia Linn.), roots of Shatavari (Asparagus racemosus Willd.), roots of Eranda (Ricinus communis Linn.), Yava (Hordeum vulgare Linn.), Jiraka (Cuminum cyminum Linn.), Pippali (Piper longum Linn.), Twak (Cinnamomum zeylanicum Blume), Ela (Elleteria Cardamomum Maton), Patra (Cinnamomum tamala Nees), Nagakeshara (Mesua ferrua Linn.), Guda (jaggery) and Kumari (Aloe barbadensis Mill.) were obtained from the TTD, Sri Srinivasa Ayurvedic Pharmacy, Tirupati, Andhra Pradesh, India. Gomutra (cow urine) was collected from the TTD Goshala, Tirupati, Andhra Pradesh, India.

Mandura was taken and subjected to Shodhana (purification) by Niravapa (quenching) in Gomutra Triphala Kashaya (decotion) for seven times. Then, the Shodhita Mandura (purified Mandura) was triturated with Kumari Svarasa (juice) and subjected to Marana (incineration) by Gaja Puta (furnace) for seven times. Guda (jaggery) was made into Paka (syrup consistency) and fine powders of herbal ingredients and Mandura Bhasma were added one by one and heated on moderate flame. After self-cooling, the mixture was dried under sunlight in a tray. Homogenous mixture of Baladi Manduram was filled in the capsules of 500 mg.

Criteria for assessment
General observation
Various demographic parameters namely, age, marital status, religion and nature of work were analyzed in the present clinical trial.

Subjective assessment
Criteria of assessment was based on relief in the signs and symptoms of Amlapitta before and after the treatment. For this purpose, cardinal signs and symptoms were given scores.
Symptom score

1. Amlodgara
- No belching: Grade 0
- Feeling of belching with no sound: Grade 1
- Feeling of belching with mild sound: Grade 2
- Feeling of belching with severe sound: Grade 3

2. Daha
- No burning sensation (no retrosternal discomfort): Grade 0
- Sensation of warmth on throat occasionally: Grade 1
- Burning sensation on throat and chest after a mild oily/spicy food: Grade 2
- Feeling of burning sensation always irrespective of the diet: Grade 3

3. Gaurava
- Normal: Grade 0
- Feeling of heaviness in morning: Grade 1
- Feeling of heaviness in morning and evening after food: Grade 2
- Feeling of heaviness always: Grade 3

4. Utklesha
- No nausea: Grade 0
- Mild nausea: Grade 1
- Severe Nausea: Grade 2
- Severe nausea with vomiting: Grade 3

5. Avipaka
- No indigestion: Grade 0
- Unable to digest mild fatty food: Grade 1
- Unable to digest 3-course meal (breakfast, lunch and dinner): Grade 2
- Unable to digest any kind of food: Grade 3

6. Agnimandya
- Normal: Grade 0
- Only takes lunch and dinner: Grade 1
- Loss of interest in lunch or dinner: Grade 2
- No desire to take food: Grade 3

Criteria for overall effect of therapy
The total effect of the therapy was assessed considering the following criteria: Complete remission: 76%–100%, Markedly improved: 51%–75%, Mild improvement: 26%–50%, No improvement: <25%.

Statistical evaluation of results
The obtained information was analyzed statistically in terms of mean score (x), standard deviation, standard error. Paired t-test was conducted at the level of 0.05, 0.01 and 0.001 of P levels. The results were interpreted as follows: Insignificant: P > 0.05, Significant: P < 0.05, Highly significant: P < 0.01, Extremely significant: P < 0.001

Observations
A total of 33 patients with signs and symptoms of Amlapitta were registered. Out of them, 30 patients completed the course of treatment. Two patients dropped out due to unknown reasons, whereas one patient dropped due to transfer of job to the other state. In the present study, maximum number of patients, i.e., 10 (33%), were between 20 and 29 years of age group, 8 (27%) patients were between 30 and 39 years of age group 6 (20%) patients were between 40 and 49 years of age group and 50 and 60 years of age group each. Eighteen (60%) patients were male and the rest of the patients, i.e., 12 (40%), were female; maximum number of patients, i.e., 28 (94%), were Hindu and 23 (77%) patients were married. Seventeen (57%) patients were from urban area, while 13 (43%) patients were from rural area. Majority of patients, i.e., 17 (57%), were educated and 19 (63%) patients belonged to middle class. Total 12 (40%) patients were doing moderate work whereas 9 (30%) patients were engaged with sedentary work and labor works. Maximum number of patients, i.e., 24 (80%), consumed mixed diet; 8 (26%) patients had Mandagni (low digestion state) and Tikshnagni (hyper digestion state) each; and 7 (24%) patients had Samagni (balanced digestion state) and Vishamagni (impaired digestion state) each. Fifteen (50%) patients had disturbed sleep while 15 (50%) patients had normal sleep. Maximum number of patients, i.e., 14 (47%), did not have any addiction; 6 (20%) patients were smokers; 7 (23%) patients had habit of drinking alcohol and 3 (10%) patients had habit of chewing tobacco. Fourteen (47%) patients were of Pitta–Kapha Prakriti, 9 (30%) patients were of Vata–Pitta Prakriti and 7 (27%) patients were of Vata–Kapha Prakriti. Majority of the patients, i.e., 18 (60%), had Mridu Koshtha and 19 (63%) patients suffered some kind of emotional stress in their life. Insidious onset was found in 22 (73%) patients, 17 (57%) patients had diet as aggravating factor, 5 (17%) patients had cold climate, 4 (13%) patients had drug, 1 (3%) patient had occupation and 3 (10%) patients had posture (lying) as an aggravating factor. Ten (33%) patients had chronicity of 1 year, 8 (27%) patients had chronicity of 2 years, 7 (23%) patients had chronicity of 3 years and the remaining 5 (17%) patients had chronicity of 4 years of the disease.

Results
Effect of Baladi Manduram on Amlapitta in thirty patients
Statistically extremely significant relief (P < 0.001) was seen in Amlodgara, Hrithkanthadaha, Utklesha and Agnimandya and statistically highly significant relief (P < 0.01) was seen in Gaurava and Avipaka [Table 1].

Overall assessment of therapeutic effect
The therapy had shown marked improvement in 67% of patients, mild improvement in 27% of patients, and complete remission was noticed in 6% of patients [Table 2].

Discussion
Amlapitta is a Pitta dominant disease in association with Kapha and Vata Dosha. Excess formation of vitiated Pitta is the main pathological mechanism behind manifestation of this disease. The Pitta gets vitiated due to improper dietary and lifestyle habits. The drugs that have Tikt–Madhura Rasa (bitter–sweet taste), Madhura Vipaka (post digestive effect...
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Amlodgara

Vidahi

Hrithkantadaha

Madhava

Laghu

Avipaka

Agni Mandya

in sweet taste), Sheeta Virya (cooling energy of substance), Laghu (light), Ruksha Guna (dry) and pacifies to Pitta-Kapha properties are beneficial in the management of Amlapitta. Numerous herbal and herbomineral formulations are mentioned in Ayurvedic classics for the management of Amlapitta. No previous research works have been carried out in this formulation indicated for Amlapitta. Hence, the formulation Baladi Manduram has been selected for the present research work to evaluate its efficacy in the management of Amlapitta.

In the present study, maximum number (60%) of patients belonged to middle age, which is Pitta-predominant period of life. This may be due to the adoption of busy lifestyle, habitualization to unhealthy food habits and irregular daily regimen, stress and addictions in this age group. Most (57%) of the patients belonged to urban habitat. Urbanization leads to increased pollution; fast and modernized lifestyle; irregular food habits; stressful condition; and usage of fast foods, food additives, adulterants and preservatives. Maximum (57%) numbers of patients were educated. It shows that in this fast and competitive era, stress is the predominant causative factor in developing Amlapitta among educated people. Most of the patients in this study were nonvegetarian; Madhava Acharya has mentioned excess consumption of nonvegetarian food and Vidahi Annapana (foods which cause burning sensation inside) as cause of Amlapitta. Maximum (63%) numbers of patients belonged to middle class; the probable explanation for this high incidence may be irregular dietary habits and occupational stress in them. It is evident that the middle class are more prone to stress and strain in their routine life either socially or financially. In the present study, 26% of patients suffered from Mandagni (lowered digestive state) and Tikshnaagni (hyper digestive state) and 24% of patients suffered from Vishamagni (impaired digestive state) and Samagni (balanced digestive state). Classics has mentioned that Mandagni is the main reason for the development of all diseases. Mandagni is the root cause of Ama (toxic residue which is produced after indigestion) formation and it is Ama which is responsible for the development of Vidagdhaajirna (early changes of Amlapitta). Tikshnaagni causes excess secretion of gastric juice, which irritates gastric mucosa. Nearly 50% of patients had disturbed sleep while 50% had normal sleep. This type of sleeping habit may be due to discomfort of the disease or extra hours of sleep during daytime which leads to Ajirna. Diwaswapna (day sleep) vitiates Tridosha as per Sushruta and especially Pitta and Kapha Doshas as per Charaka. Disturbed sleep increases psychological stress which leads to impairment of Agni. This is one of the cause of Amlapitta. Habit of drinking alcohol was noticed in 23% of patients while 20% were smoker and 10% had a habit of chewing tobacco. Intake of alcohol vitiates all qualities of Pitta. Excessive intake of tobacco, gutkha and pan-masala may impair Agni and lead to manifestation of Amlapitta. These factors cause irritation of gastric mucosa and vitiates Doshas mainly Pachaka Pitta and Kledaka Kapha. Majority (47%) of patients belonged to Pitta–Kapha Prakriti, as Doshik predominance of disease is Pitta Kapha, so more number of people were of this Prakriti when compared to others. These patients are prone to Amlapitta due to intake of Tikshna (spicy), Ushna (hot), Lavana (salty), Khara (rough), excessive cold and heavy foods. Nearly 60% of patients had Mrudu Koshtha, excess Pitta in any form will have an effect on Koshtha and in this case, the Sara (mobile), Drava (liquid) Guna of Pitta, leads to Mrudu Koshtha.

In the present study, 63% patients had emotional stress. Stress is something that stimulates our body to respond in an abnormal way. The mental stress and strain leads to irregular fluctuations in the production of gastric secretions ultimately causing damage to the gastric mucosa. Vagal stimulation along with sympathetic irritation of gastric mucosa can be attributing factor for anxiety and emotional stress. Data showed that aggravating factor in 17 (57%) patients was due to diet, 5 (17%) patients due to cold climate, 4 (13%) patients due to drug intake, while 3 (10%) patients by improper posture and 1 (3%) patient had occupation as aggravating factor. Intake of spicy food, Pitta Kaphavardhaka Ahara (food which aggravated Pitta and Kapha) Vitiates Pitta, which causes Vidagdhaajirna. This in turn leads to Amlapitta.

Table 1: Effect of Baladi Manduram on subjective parameters in thirty patients

| Parameters       | n  | Mean  | Mean difference | Relief (%) | SD  | SE   | t     | P    |
|------------------|----|-------|-----------------|------------|-----|------|-------|------|
|                  | BT (0 day) | AT (30 day) |
| Amlodgara        | 30 | 1.96  | 0.63            | 1.33       | 68  | 0.71 | 0.13  | 10.26| <0.001|
| Hrithkantadaha   | 30 | 1.9   | 0.76            | 1.14       | 60  | 0.6  | 0.11  | 9.87 | <0.001|
| Gaurava          | 25 | 1.64  | 0.88            | 0.76       | 46.30| 0.4  | 0.08  | 8.71 | <0.01 |
| Utklesha         | 20 | 1.7   | 0.75            | 0.95       | 55.80| 0.67 | 0.15  | 6.19 | <0.001|
| Avipaka          | 23 | 1.65  | 0.82            | 0.83       | 50  | 0.76 | 0.16  | 5.09 | <0.01 |
| Agni Mandya      | 25 | 2.08  | 0.96            | 1.12       | 53.80| 0.8  | 0.16  | 6.72 | <0.001|

Table 2: Overall assessment of clinical trial

| Result                    | Number of patients (%) |
|---------------------------|------------------------|
| Complete remission        | 2 (6)                  |
| Marked improvement        | 20 (67)                |
| Improvement               | 8 (27)                 |
| No improvement            | 0 (0)                  |

n: Number of patients suffering from symptom, BT: Arithmetic mean of scoring before treatment, AT: Arithmetic mean of scoring after treatment, SD: Standard deviation, SE: Standard error, P: Significance of treatment on specific symptom
Intake of nonsteroidal anti-inflammatory drug stimulates H$_2$ receptors in stomach which leads to excess gastric secretions. According to Acharya Sushruta, left lateral sleeping posture is considered as ideal posture because it helps in proper digestion and absorption of Ahara.[12] Other postures such as supine, right lateral and prone position may cause improper gastric secretions, which leads to impaired digestion. Awaking late night and untimely food intake in software engineers, watchman etc., due to their occupation leads to Vata Prakopa (vitiates aggravation of Vata) and Kapha Kshaya (decreased Kapha), which ultimately leads to Amlapitta.

**Effect of Baladi Manduram on subjective parameters**

**Effect on Amlodgara**

Amlodgara is mentioned as one of the balanced Pitta symptoms.[13] Normal Pitta has Katu Rasa (pungent), but in Vidagdha state, it is transformed to sour taste. The sour and liquid properties of Pitta are also increased, resulting in impaired digestion, indigestion, and leads to Amla/Tikta Udgar. The significant relief in this symptom may be due to Snigdha (unctuous), Laghu (light) and Picchila Guna (lubricous property) and Katu Vipaka (post digestive effect in pungent flavour) of Bala, Shatavari, Eranda, Pippali and Chaturjataka,[14] Am Pachana (digestion of unmetabolised food) property of Nagakeshara, Twak and Patra.[15]

**Effect on Hridkantha Daha**

Hridkantha Daha mainly occurs due to Pitta Prakopa and Kapha Kshaya. Significant relief in this symptom may be due to Sheeta Guna and Sheeta Virya of Mandura Bhasma[16] and jaggery. Vitiated Pitta might have got normalized due to pacification of Pitta, property of Bala, Shatavari, Eranda, Yava and Guda.[17]

**Effect on Utklesha**

Utklesha mainly occurs because of excess Sama Pitta with involvement of Kapha. The significant relief found in this symptom may be due to sweet, pungent, astringent taste of Mandura Bhasma, Twak, Nagakeshara and Shatavari.[18]

**Effect on Agnimandya**

Statistically highly significant relief was seen in Agnimandya. This improvement may be due to Stomachic, Digestant and faecal astringent properties of Mandura Bhasma, Pippali, Jiraka, Patra, Ela and Twak.[19]

**Effect on Avipaka**

Mandagni leads to Ajirna (Vidagdhajirna) which in turn leads to Amlapitta. The significant relief found in this symptom may be due to digestive property of Pippali, Jiraka, Nagakeshara, Twak and Ela[20] and Am Pachana (digestion of unmetabolised food) property of Twak, Nagakeshara, Jiraka and Ela.

**Effect on Gaurava**

This symptom is due to Kapha Prakopa. The significant relief found in this symptom may be due to pacification of Kapha. Lekhana (scraping) and Laghu (light) property of Mandura Bhasma, Pippali, Jiraka and Eranda.[21]

Probable mode of action of Baladi Manduram

Evaluation of five fundamental parameters of drug (Rasa Panchaka) for Baladi Manduram suggests that it is sweet, astringent in taste, light, rritant in nature, cool property, cooling energy of substance. It has Madhura Vipaka (sweet post digestive effect), vitiated Pitta-Kapha, Stomachic and digestive process of un-metabolised food, analgesic and anti-inflammatory properties. Mandura Bhasma has an astringent taste, dry, light, cool potential, post digestive effect in pungent flavour, Stomachic and pacifies Pitta-Kapha property. By virtue of its taste and properties, it pacifies aggravated pitta and thereby improves the digestion and metabolism. Intake of iron oxide helps in reducing the excess digestive acid secretion from the gastric mucosa.[22] Bala has Balya property (increase strength), pacifies to Vata, scraping effect and pacifies Tridosha. It has anti-inflammatory, analgesic and wound-healing properties.[23] Shatavari roots have Agni Vardhaka (digestive stimulant), Vayah-Sihapani (anti ageing), rejuvenator effect and increases strength. Research studies on Asparagus racemosus have shown that it has antidyspepsia, antiulcerogenic and antioxidant properties.[24] Erana roots has Ama Pachana (digestion of unmetabolized food) and aphrodisiac properties and antulcer, anti-inflammatory, antihistaminic and antioxidant activities.[25] Yava has antioxidant and anti-inflammatory activities.[26] Pippali and Jeeraka have Deepana, Vata–Kaphahara, aphrodisiac and rejuvenator properties and anti-inflammatory, antioxidant, analgesic and antiulcer activities.[27] Chaturjataka (Twak, Ela, Patra and Nagakeshara) pacifies Vata-Kapha, possess Stomachic, Digestant, antihistaminic and anti-hemorrhoidal, gastroprotective, antispasmodic, anti-inflammatory and antioxidant properties.[28]

Due to the presence of above-mentioned properties, Baladi Manduram helps in reducing the aggravated Pitta Dosha, stabilizes the state of Agni, helps in Ama Pachana (digestion of unmetabolised food), pacifies Vidagdhajirna and thereby improves digestion, absorption and assimilation, thus relieving the symptoms of Amlapitta.

**Conclusion**

Baladi Manduram has provided significant results on the parameters of Amlapitta. Based on the present clinical study, it can be concluded that Baladi Manduram is an efficacious formulation for the management of Amlapitta. No adverse effects were reported during the entire study period. The present clinical trial was carried out on a limited number of patients. Hence, an extended study with more clinical parameters and on a large number of patients can be considered to find the effect treatment prevention of recurrence.

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**Conflicts of interest**

There are no conflicts of interest.
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