

Original Article

Relevance of metal based Ayurvedic formulations in the management of recurrent acute/ chronic pancreatitis

Vaidya Balendu Prakash*, Vaidya Shikha Prakash, Shakshi Sharma, Sneha Tiwari

Padaav Speciality Ayurvedic Treatment Centre, Turner Road, Clement Town, Dehradun, India

ABSTRACT

Recurrent Acute Pancreatitis/ Chronic Pancreatitis (RAP/ CP) is generally marked by sudden onset of symptoms like severe abdominal pain, vomiting and weight loss that needs emergency hospitalization. Owing to irreversible and progressive nature of the disease and limitations of conventional treatment, many patients look for an alternative solution. Here, we report data of 250 well diagnosed cases of acute recurring/ chronic pancreatitis, enrolled in between January 1997 to August 2016, in our Ayurvedic clinical practice in Northern part of India. Ayurveda is well recognized as an independent medical system parallel to conventional medicines in India and a subject is free to opt for any system of medicine for the prevention and treatment of any ailment. The subjects were treated with a complex herbo-mineral formulation based on the principles of Rasa Shastra in Ayurveda that deals with the therapeutics of processed metals in the prevention and treatment of diseases. They were also prescribed a regulated balanced diet and lifestyle. Significant improvement has been noted in subjects who have completed the treatment.

Keywords Rasa Shastra, Ayurveda, pancreatitis, chronic, recurrent acute

INTRODUCTION

Chronic pancreatitis (CP) is a progressive inflammatory disease of the pancreas characterized by irreversible morphological changes typically causing pain and/or permanent loss of function (Sarner and Cotton, 1984; Taber, 1997). The global incidence of Pancreatitis ranges from 2-14/100,000 population but Southern India reports highest incidences ranging from 114-200/100,000 population. The report indicates that India has highest incidences of Tropical Chronic Pancreatitis (TCP), where alcohol is not the major cause (Geeverghese et al., 1969; Garg and Tandon, 2004). Rather it is attributed to protein malnutrition, mineral deficiency, dietary toxins and environmental agents. There are emerging evidences about the role of genetics as well (Balakrishnan et al., 2005).

RAP/CP has no known cure. The acute attacks are largely managed by emergency hospitalisation and treated with analgesics, antibiotics and IV fluids. Enzyme replacement therapy and vitamin supplements are widely used for long terms as prophylactic therapy. Progressive nature of the disease coupled with rising medical cost and limitations of conventional treatment compel many patients to look for alternatives to bring some relief to their lives. India is the only country where different systems like *Ayurveda*, *Unani*, *Siddha*, *Homeopathy* and *Yoga* are officially recognised as independent medical systems, along with conventional medicine termed as allopath. The prevailing laws permit a registered medical practitioner of Ayurveda and Unani to prepare his own

medicines and to use those directly in respective clinical practice for any indication with the consent of the patient (Government of India ministry of health and family welfare, 2003).

In mid 70s, a traditional Ayurvedic physician incidentally observed miraculous effect of a Metal Based Ayurvedic Formulation (MBAF; Herbo mineral formulation used for the treatment of pancreatitis (Patent filed *vide* PCT application no.3373/DEL/2014), in a terminally ill patient of pancreatic cancer (Pal, 2014). Subsequently, MBAF showed empirical success in patients suffering from recurring pancreatitis. The practice was passed on to the next generation and patients continue to get the benefit of this treatment. The ongoing clinical practice was subjected to documentation from January 1997. In this study, we report the effect of Ayurvedic Treatment Protocol, comprised of herbo mineral formulations, customized diet and lifestyle in 250 patients of RAP/ CP who were enrolled till August 2016.

Literature Review

Inflammation is the stereotyped non specific immune response that occurs in reaction to any harmful stimuli, pathogenic organism, foreign body, physical trauma, ionizing radiation, electrical energy, or extremes of temperature (Taber, 1997). Inflammations can be broadly classified into Acute and Chronic. While acute inflammations are attributed to infection, injury or trauma, chronic ones are known to be caused due to long lasting injury, infection or might be idiopathic. Chronic inflammations become a constant low-level physiological response, which the body is no longer able to turn off and it starts damaging healthy tissues. Most of the times, these inflammations are irreversible and progressive in nature and might be fatal.

In recent years, there has been an upsurge in incidences of idiopathic, non communicable and non specific Chronic

*Correspondence: Vaidya Balendu Prakash

E-mail: balenduprakash@gmail.com

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Inflammatory Disorders (CIDs). These cover a number of conditions from several autoimmune and metabolic disorders to even transplant rejection. The number of people suffering from CIDs has been increasing over the last three decades. A study documented that CIDs are the largest cause of death in the world and caused about 29 million deaths in 2002. About 171 million people in the United States are estimated to be affected by CIDs by 2030 (Cicchitti et al., 2015). However, not much data on this effect is available from India.

Inflammations can be treated by addressing the underlying aetiology. Currently available treatments for CIDs involve prolonged use of anti-inflammatory drugs, including non steroidal anti-inflammatory drugs, corticosteroids and immune selective anti-inflammatory derivatives, which have considerable side effects (Bosma-den Boer et al., 2012). A recent review highlighted that current medications used to treat CIDs suppress the symptoms but prevent the complete resolution of the disease, leading to a persistent low grade inflammation. Long lasting use of anti-inflammatory medications is also known to delay full recovery (Bosma-den Boer et al., 2012).

Pancreatitis is one among such inflammatory disorders, which refers to inflammation of the pancreas and is primarily characterised by abdominal pain, nausea, vomiting and indigestion (Kedia et al., 2013). Repeated episodes of abdominal pain, other symptoms and elevated serum Amylase/ Lipase levels without morphological changes in the pancreas is termed as RAP while, signs and symptoms associated with morphological changes in the pancreas is called Chronic Pancreatitis (Kedia et al., 2013; Sawant and Mishra, 2005). The average onset of the disease is 24 years and the disease affects more male population than female population (Sawant and Mishra, 2005). RAP/CP brings gradual fibrotic changes in the pancreas resulting in loss of exocrine and endocrine functions, leading to diabetes mellitus, steatorrhea and unexplained weight loss (Bharathi, 2015). More than 70% of the patients develop diabetes mellitus (up to 90% in cases of chronic calcific pancreatitis) and up to 40% patients develop pancreatic cancer in their lifetimes (Malka et al., 2000; Howes and Neoptolemos, 2002). RAP/CP is progressive and fatal in nature and the prognosis remains uncertain with a 10 year survival of about 70% and a 20 year survival of 45% (Sawant and Mishra, 2005). A recent study showed that even a single attack of acute pancreatitis may harbour underlying chronic pancreatitis (Turner, 2013).

The underlying cause for RAP/CP has not yet been established although it is considered to be a disease of alcoholics, smokers, people with high fat intake and high stress factor. The most accepted etiology for chronic pancreatitis includes Toxic, Idiopathic, Genetic factors, Auto-immune

response, Recurrent acute pancreatitis and Obstructive factors (TIGAR-O) (Etemad and Whitcomb, 2001).

RAP/CP is a global disease and in recent years, there has been an upsurge in its incidences. It is estimated that the annual global market of pancreatic enzymes will touch INR 11,000 Cr by 2023 (US\$ 1,588.8 million) as compared to INR 5000 Cr in 2014 (US\$ 707.0 million) (Transparency Market Research, 2016). It seems that India, especially its Southern states, has the highest incidences of pancreatitis in the world and is termed as Tropical Chronic Pancreatitis (TCP). Most of the patients suffering from TCP are non alcoholic. Protein malabsorption and mineral deficiency are considered to be its major cause (Geeverghese et al., 1969; Rajesh and Balakrishnan, 2012). Another prevalent form of pancreatitis in India is idiopathic pancreatitis (ICP) that accounts for 40% - 60% CP in India and 10% - 30% in the western countries (Rajesh and Balakrishnan, 2012).

There is no direct or indirect reference of Pancreatitis in classical Ayurvedic literature except a term called 'UdarShool' (abdominal pain).

Methodology

The subjects with confirm diagnosis of RAP/CP were selected for Ayurvedic treatment. Such subjects were diagnosed by leading gastroenterologists at various hospitals of repute across India. Diagnosis of RAP/CP was established using clinical, pathological and radiological investigations including USG (Ultra Sonography), EUS (Endoscopic Ultrasound), CT (Computer Tomography), MRI (Magnetic Resonance Imaging), MRCP and ERCP (Endoscopic retrograde cholangiopancreatography) (Figure 1).

The patients and their families were briefed about unknown chemistry and pharmacology of MBAF, duration and cost of treatment prior to commencement of Ayurvedic treatment. Each subject was interviewed for detailed medical history, including number of emergency hospitalisations, follow up visits and expenditure occurred so far. Their demography, dietary habits, lifestyle and family history were also recorded. Copies of relevant medical records including diagnostics and previous medical treatment were collected from each subject. The subjects were evaluated for hemogram, liver function, kidney function, Vitamin D3 and B12. The Ultrasound/ MRCP was also repeated if the last report of the subject was more than three months old.

Patients reported with anorexia, mild to moderate abdominal pain, weight loss, weakness and phobia of the disease. All patients were given Albendazole (deworming medication) on the first day of AYT. They were asked to stop tea, coffee,

Table 1. Financial burden of Pancreatitis on patients

Emergency expenses (INR)	Direct expenses (INR)	Indirect expenses (INR)
Cost of hospitalization	Follow ups, investigations, medicines, consultation	Loss of manpower, cost of travelling, boarding and lodging during treatment for families
3,97,61,000	2,86,44,750	3,04,35,500
Total		9,88,41,250

n = 132.

Table 2. Various parameters before and after treatment

Parameters	Before AYT	After AYT	P value
Number of Attacks*	2 (0 to 25)	0 (0 to 5)	< 0.0001
Number of Hospitalizations*	1 (0 to 20)	0 (0 to 0)	< 0.0001
Intake of enzymes, % [#]	54 (50.9)	0 (0.0)	< 0.0001
Mean Body weight [¥]	57.59 ± 12.65	59.66 ± 12.32	< 0.0001

(n = 106); *indicates median (range) and compared using Wilcoxon signed rank test for paired observations; [#]indicates n (%) and compared using Mc Nemar's test; [¥] indicates mean ± SD and compared using paired t test.

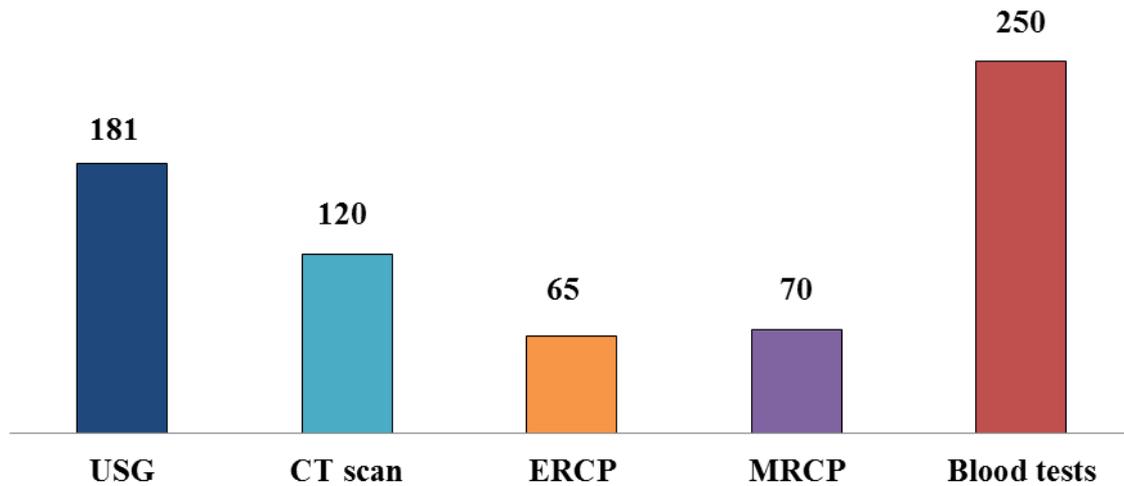


Fig. 1. Methods of diagnosis of the subjects.

aerated drinks, reheated food, packaged food items and drinks, refined flour, onion, tomato and garlic. They were subjected to an Ayurvedic regime of treatment, diet, lifestyle and medicines (Aahar, Vihar and Aushadh). They were prescribed Narikel lavan 1 gm BD, Prak 20 (A proprietary Ayurvedic medicine prepared by *Bharat Bhaishajyashala Pvt Ltd. Mfg License No. A-1969/91* by Dept. of AYUSH, Ministry of Health and Family Welfare, Govt. Of Uttarakhand.) 1 gm BD, MBAF 125 mg during meals and Rason vati 500 mg with hot water after meals with 1200-1600 calorie diet, divided into three meals and three snacks, along with eight hours sleep and moderate physical and mental rest (Vaidya et al., 2010). The diet also included dairy products, fat and protein. Subjects who were deficient in Vitamin D3 were given a weekly dose of 60,000 IU Cholecalciferol with 100 gm milk cream for sixteen weeks and those deficient in Vitamin B12 were given daily supplement of Mecobalamin 1500 mcg with breakfast. The first three weeks residential treatment was given under close supervision of the Ayurvedic physician in his clinic. The service of a conventional doctor was taken to control high blood sugar among diabetic patients. After the initial residential treatment, subjects were prescribed monthly Ayurvedic formulations and kept under daily follow ups via mails or telephone. The treatment was repeated every month for duration of one year. On completion of one year, patients were called for follow up examination and the treatment was stopped. These patients continue to remain in contact.

RESULTS

A total number of 250 patients of RAP/CP volunteered for Ayurvedic treatment from January 1997 to August 2016. Nearly two third subjects were males and one fourth were females with a mean age of 31 ± 12.2 years. The demography depicts 62% vegetarians, 76.8% non alcoholics, 85.6% non tobacco users and 94.8% subjects with no family history (Figure 2). The subjects had a history of 45.3 ± 49.6 months with 1779 attacks and 1030 hospitalizations and had been treated conservatively under expert advice using analgesics, antibiotics, IV fluids and enzyme replacement therapy. 50.9% patients had been put on lifelong pancreatic enzymes ranging from 20,000 to 75,000 IU per day. Some of the patients had also undergone surgical intervention before starting ayurvedic treatment.

A random survey conducted on 132 patients revealed that

these subjects had spent a total amount of INR Nine crores eighty eight lacs forty one thousand two hundred and fifty (9,88,41,250/-) prior to Ayurvedic treatment on emergency hospitalizations, follow ups and indirect expenditure (Table 1).

Subjects showed improvement in overall appetite, energy, pain, stability in sugar levels and general well being within the first three weeks of commencement of the treatment. There is significant reduction in frequency, intensity of pain and need of hospitalization with significant gain in body weight (Table 2). No grade II toxicity has been reported in the treated patients. They are leading a symptom free life (Figure 4).

DISCUSSION

RAP/CP is an inflammatory state of pancreas. It is irreversible and progressive in nature and leads to gradual morbidity. Besides its invariable characteristics, it also brings substantial physical, emotional and financial burden to its patients and their families. Consumption of alcohol is considered to be the main causative factor of RAP/CP. However, Indian subcontinent has more cases of TCP. In the present observational study, subjects opted for metal based Ayurvedic treatment in desperate state of mind after hearing anecdotal success stories. The incidental effect of MBAFs continue to bring long term relief to RAP/CP patients though, no direct or indirect reference is available about this disease in classical texts. MBAF are prepared using the principles of *Rasa shastra*,

Table 3. Results of random analysis of three batches of MBAF (Source: IISc, Bangalore)

MBAF A	MBAF B	MBAF C
CuFeS2	CuFeS2	CaSO4
CuFe2O4	CuFe2O4	CuS
KCu2(OH)(SO4)2.H2O	Cu2SO4	SiO2
Cu2SO4	KCa2(Si7Al)O17(OH)2	K2Mg(SO4)2.6H2O
KFe3(SO4)2(OH)6	KCu2(OH)(SO4)2.H2O	KFe3(SO4)2(OH)6
KCa2(Si7Al)O17(OH)2	KFe3(SO4)2(OH)6	KFe(SO4)2
SiO2	CuS	HgS
CuS	K2Cu(SO4)2.6H2O	FeSO4(H2O)7
K2(Cu(H2O)6).(SO4)2	SiO2	Ca(Mg.67Fe.33)(CO3)2
K2MgSiO4	Cu4SO4(OH)6	K2Cu(SO4)2.6H2O
Cu4SO4(OH)6	MgFe2O4	
	K2SO4	

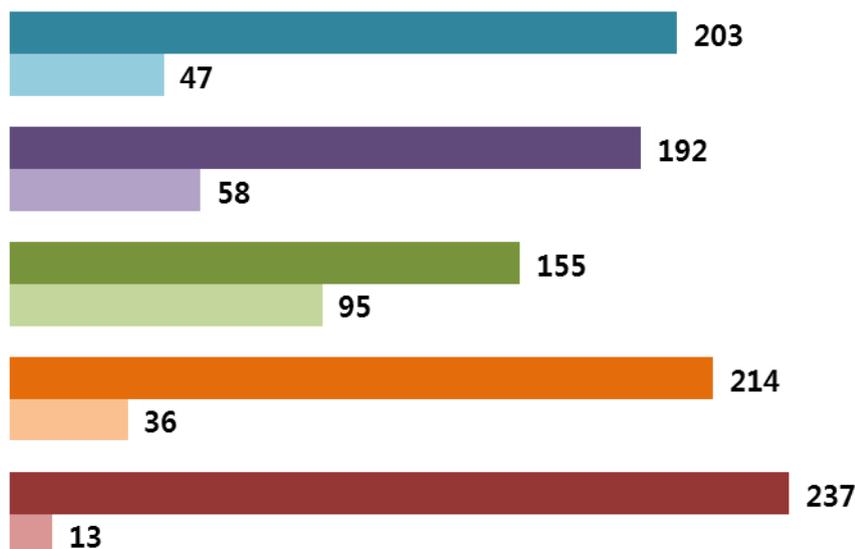


Fig. 2. Demography, dietary habit and family history of the subjects.

a specialty of Ayurveda. In Ayurvedic texts, Mercury has been referred to as *Rasa* due to its ability to imbibe other metals within itself (Virupaksha Gupta et al., 2011). *Rasa Shastra* is the science which deals with the therapeutics of Mercury, Gold, Silver, Iron, Tin, Lead and Zinc etc. termed as *dhatu* (Savrikar and Ravishankar, 2011). These metals undergo tedious processing with herbs on fire and convert into safe and therapeutic form. *Dhatu vigyan* means science of metals. '*Dharanat dhatavah*' means that the thing which bears is known as *dhatu*. The term *dhatuis* used for '*Rasa Rakta Maans Medh Asthi Majja Shukra*' (body tissues) and for Gold, Silver, Copper, Iron, Tin, Lead and Zinc. Masters of *Rsashastra* have ascribed close linkage between both types of *dhatu* (*Vaidya Chandra Prakash* as dictated by *Guru Maharaj. Dhatu Vigyan*: Unpublished handwritten booklet). Dietary, environmental, ecological or lifestyle related factors may bring imbalance among these *dhatuis* in body tissues and cause pathogenesis of disease in the human body.

The main MBA Fused for the treatment of RAP/ CP is prepared using Mercury, Sulphur and Copper as raw material. These undergo numerous processing for years, mostly repeated grinding in iron vessels (till > 88% particles attain size < 5µm) and heating in clay pots (365 - 400 °C for 12 - 80 hours). The random analysis of three batches of MBAF carried using XRD technique demonstrates that the subjected formulation is a complex of minerals and is devoid of any free metal (Table 3). The study of first 250 patients clearly demonstrates that all subjects had RAP/CP. Similarly, observations indicate that MBAF brought significant relief in reducing number of hospitalisations, intensity and frequency of attacks. It also improved physical and psychological state with significant reduction in cost. Subjects also reported weight gain and improvement in quality of life.

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Dairy products and rich protein diet is contradictory in the treatment of pancreatitis. However, patients were given a diet rich in protein and dairy products after starting Ayurvedic treatment. The observed effect of Ayurvedic treatment on pancreatitis patients raises many questions regarding its intrigue chemistry, dose schedule, mode of action and duration.

Heavy metals are known to be toxic but in this study, no grade II toxicity has been reported in any subject (Singh et al., 2011). Ayurveda is an ancient system of medicine of India which is not understood for its therapeutic efficacy. Its principles were laid thousands of years ago using language, parameters and protocols of that era. In recent years, complementary and alternate medicines have gained wide popularity but mostly on wellness part. *Prima facie* evidences do suggest that Ayurveda might have therapeutic effects as well. Therapeutic use of metals is a virgin area of science and not much work has been done on this specialized branch of Ayurveda. We suggest that scientific fraternity take note of these preliminary findings and will develop a pragmatic approach to explore the therapeutics of metal based Ayurvedic treatment for the prevention and treatment of both types of Pancreatitis. This will require a combined programme where traditional wisdom should be incorporated with modern scientific tools to develop a reproducible, safe and effective treatment protocol.

CONCLUSION

The preliminary clinical data indicates that MBAF derived from *Rasa shastra* in *Ayurveda* might be a potential prophylactic treatment for RAP/ CP.

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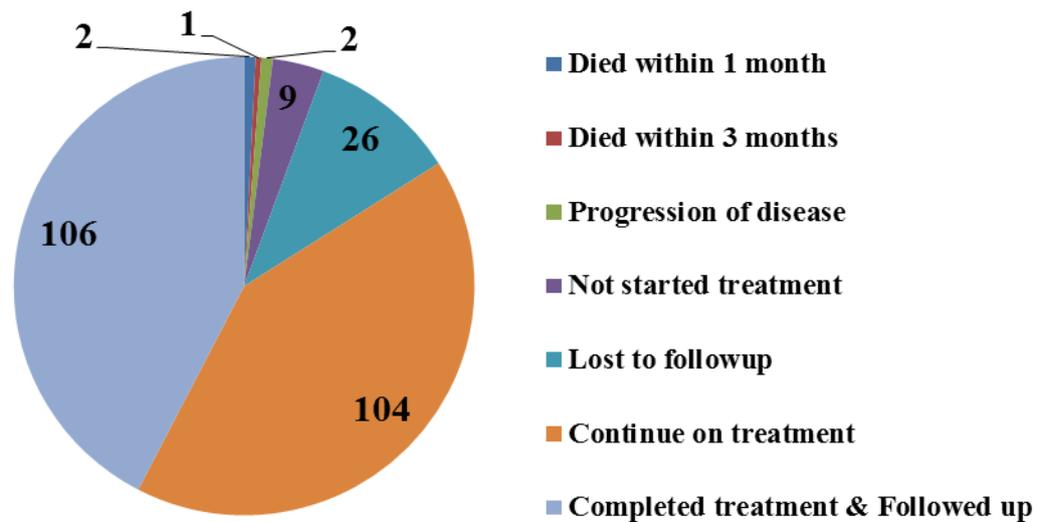


Fig. 3. Results at a glancet.

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CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

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