Uttarakhand; Emerging Hub for the Treatment of Pancreatitis

Presented by:

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Pancreatitis

- **Pancreatitis, a miserable inflammation of pancreas, having invariable characteristics; progressive in nature with significant morbidity and mortality.**
- **Many theories towards cause but nothing established; TIGAR-O is widely used (Toxin-metabolic, Idiopathic, Genetic, Autoimmune, Recurrent and Severe Acute Pancreatitis and Obstructive)**
- **Global disease, affecting population**
- **First reported in 1579 by Dutch anatomist JA Vindone**
- **First incidence of Pancreatitis in India was reported by Kini in 1937**
- **Now it is estimated that India has the highest incidences of Pancreatitis**

Types, Symptoms and Diagnosis

- **Broadly classified into Acute and Chronic Pancreatitis**
- **Acute: sudden inflammation of pancreas; Chronic: confirmed sign of structural changes**
- **Symptoms of Pancreatitis include moderate to severe abdominal pain, nausea/ vomiting, backache, weight loss, steatorrhea and uncontrolled blood sugar.**
- **Diagnosis should be made by a competent gastroenterologist using methods like MRCP, ERCP, EUS, CT Scan and Blood tests (*Serum Amylase and Lipase*).**

Conventional Treatment & Prognosis

- **Emergency hospitalization for 3-5 days in acute condition, intravenous fluids, painkillers, enzymes and antibiotics**
- **Lifelong enzymes, fat and protein restricted diet**
- **Pancreatitis is irreversible, progressive and fatal in nature**
- **Up to 90% develop uncontrolled diabetes**
- **17% die in 5 years, 30% in 10 years and 55% succumb to death in 20 years**

Limitations

- **Significant burden on body, mind and financial state of patients and their families**
- **Fear of attacks, progression, cancer and death**
- **Largely incurable disease**

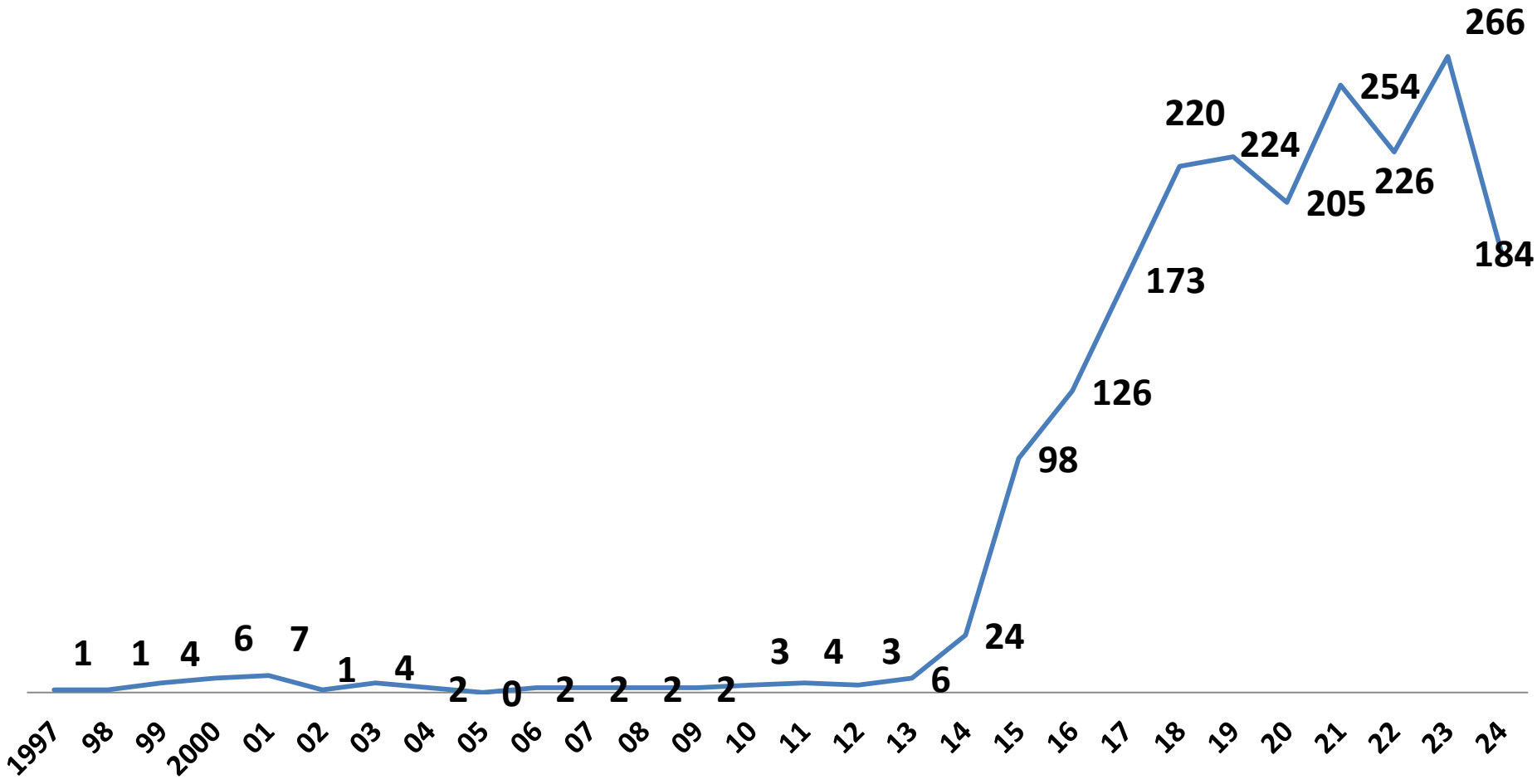
Ayurvedic Intervention

- **Incidental discovery in mid seventies by Late Vaidya Chandra Prakash ji of Meerut**
- **A mineral complex, named *AMAR*, prepared using Mercury, Copper, Sulphur and processed with *Luffa echinata*, *Clitoria ternatea* and lemon juice, was found to be effective**
- **The formulation was refined and subjected to data-based practice from January 1997 following GCP guidelines**

Enrolments

(n = 2050)

Year wise Enrolments (January 1997 to October 2024)



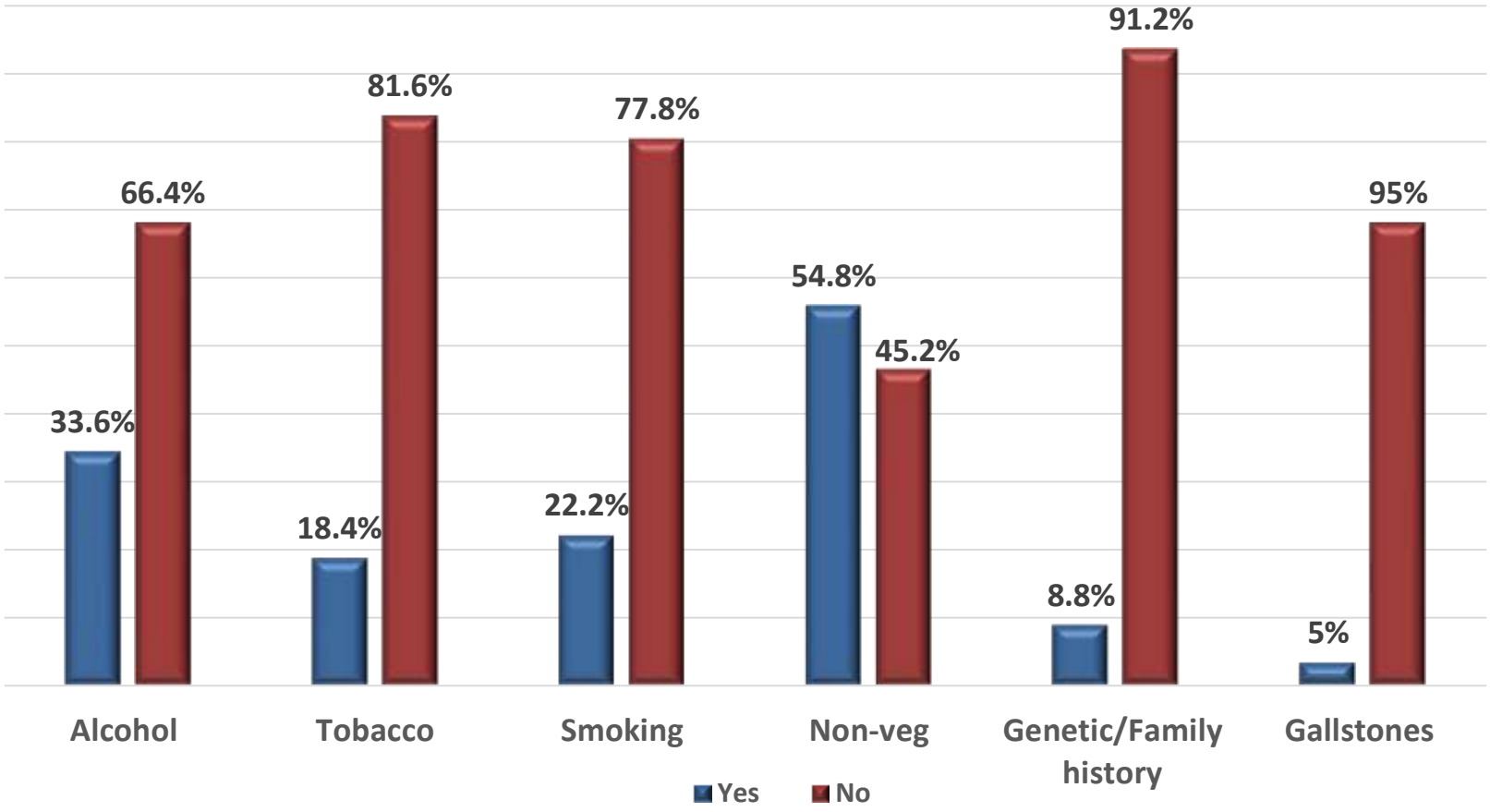
Source: Padaav - Speciality Ayurvedic Treatment Centre, Dehradun & Rudrapur

Some Interesting Findings

Geographical Distribution of Patients (n = 2050)

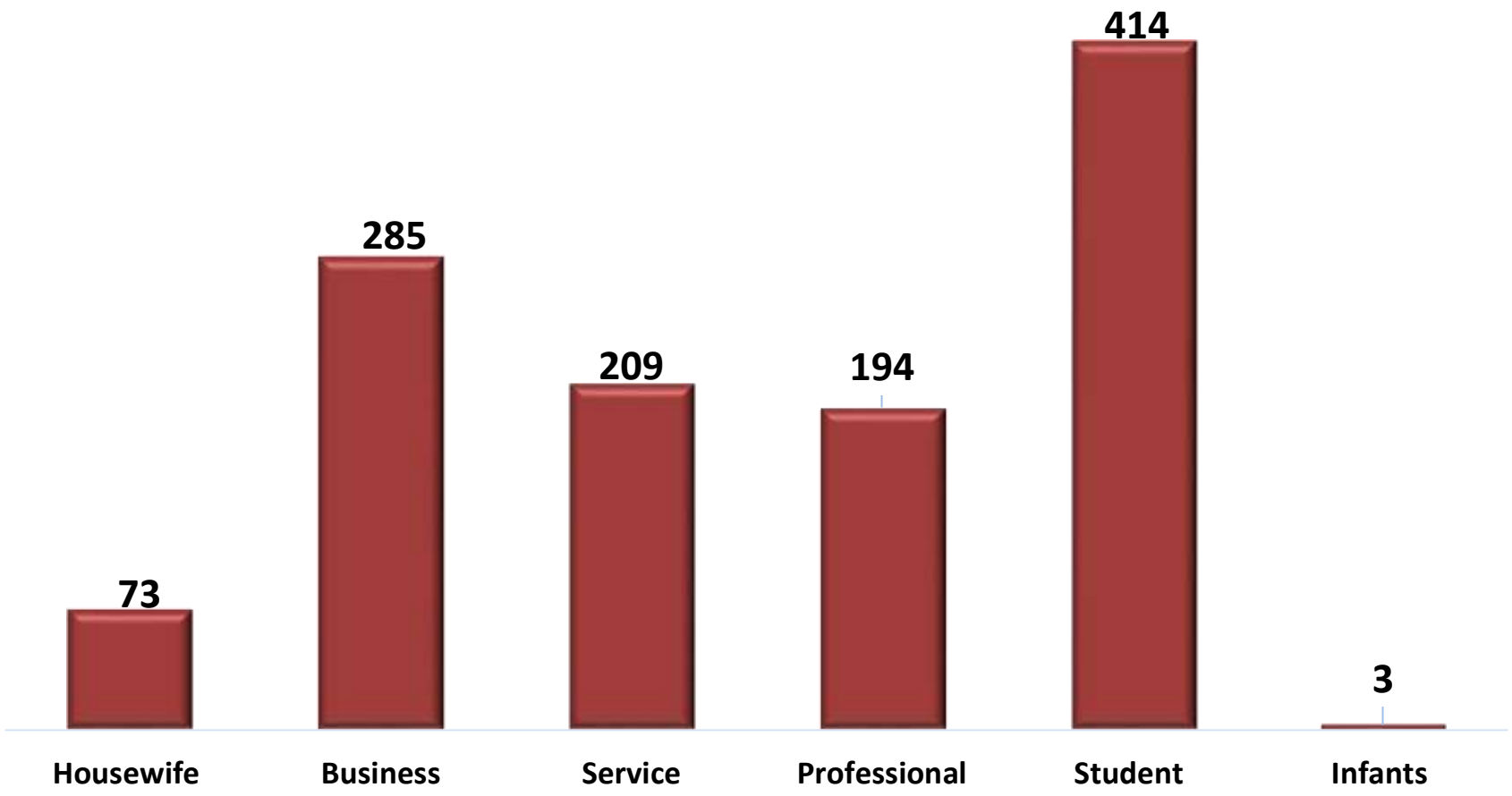
State	No. of Patients	State	No. of Patients
Uttar Pradesh	391	Andhra Pradesh	31
Maharashtra	213	Tamil Nadu	31
Gujarat	136	Odisha	29
Delhi	132	Kerala	28
Karnataka	127	Jharkhand	20
Haryana	126	Jammu & Kashmir	19
Uttarakhand	114	Himachal Pradesh	14
Rajasthan	108	Tripura	5
Madhya Pradesh	107	Goa	4
West Bengal	69	Chandigarh	3
Punjab	68	Pondicherry	2
Telangana	65	Lakshadweep	1
Chhattisgarh	61	Sikkim	1
Bihar	53	Meghalaya	1
Assam	44	Overseas	47

Dietary Pattern and Family History (n = 2050)



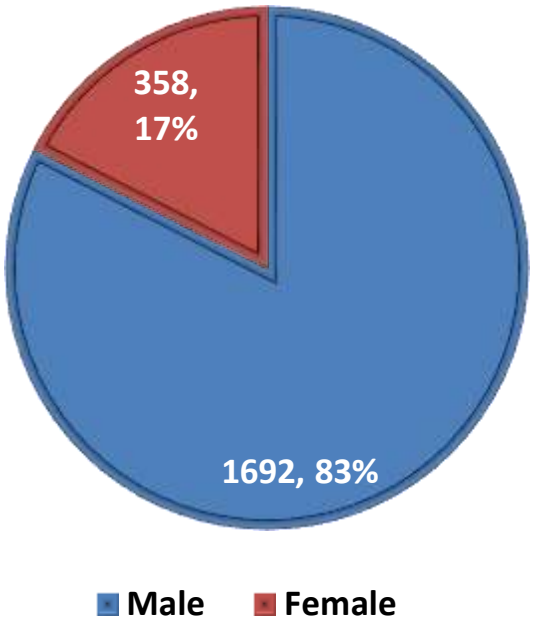
Profession wise Distribution

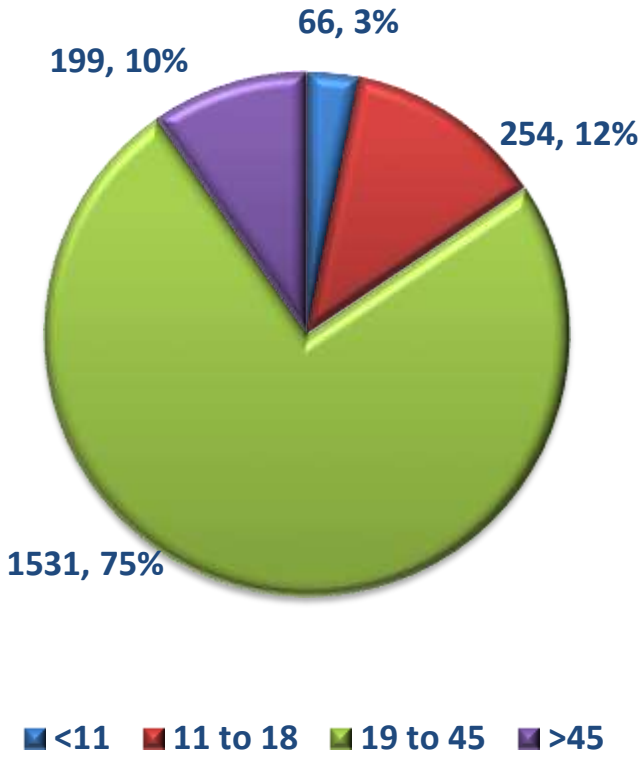
(n = 1178)



Age & Gender

(n = 2050)



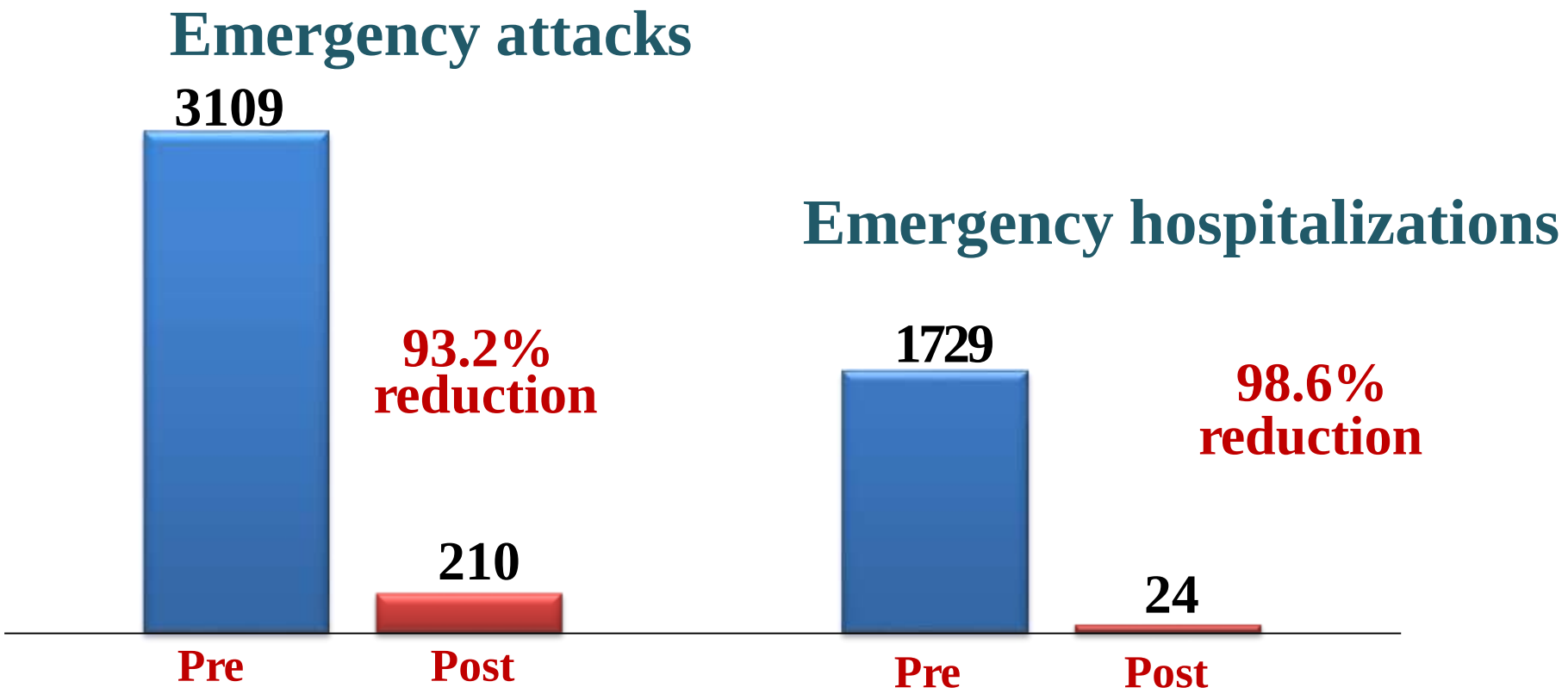


Ayurvedic Treatment Protocol

- **One year-long treatment comprising of customized diet, lifestyle, and medicine**
- **AMAR: 3/4 mg/kg body weight, divided into three doses a day, Prak-20; Hepatoprotective and immunomodulator, Rason vati; Digestive**
- **Complete withdrawal of Pancreatic enzymes**
- **Three meals, three snacks (1600-2200 calories per day)**
- **Vitamin (B12 & D3) supplements if deficient**
- **Management of blood sugar and hypertension through modern medicine**
- **Emergency medicine, if and when required, under the guidance of a Gastroenterologist**

Impact evaluation after one year of AYT

n= 1072/2050



Significant reduction: value>0.0001*

***Statistical analysis done using Wilcoxon signed rank test for paired observations, Mc Nemar's test and paired t-test**

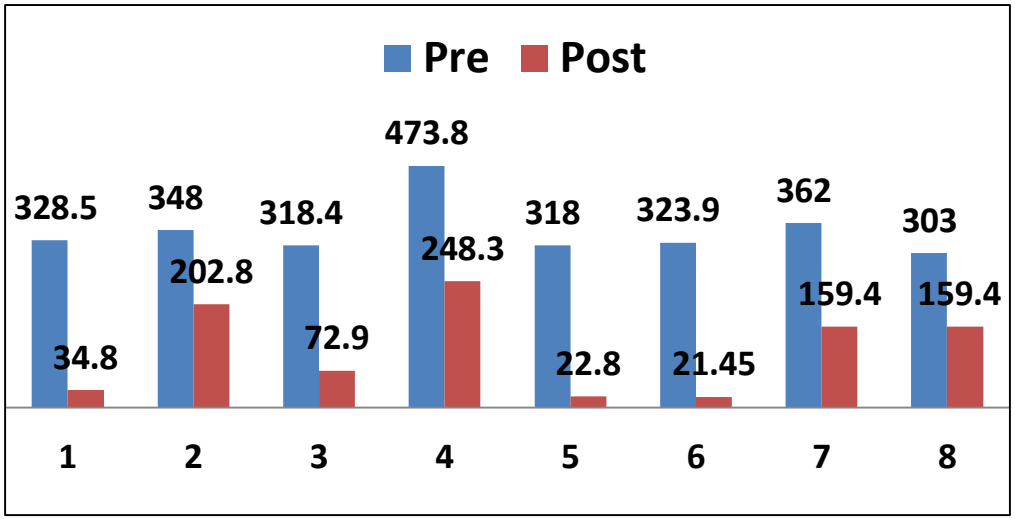
Source: Padaav - Speciality Ayurvedic Treatment Centre, Rudrapur & Dehradun

Arrestation of Progression
(CA19-9 Lowering Effect)

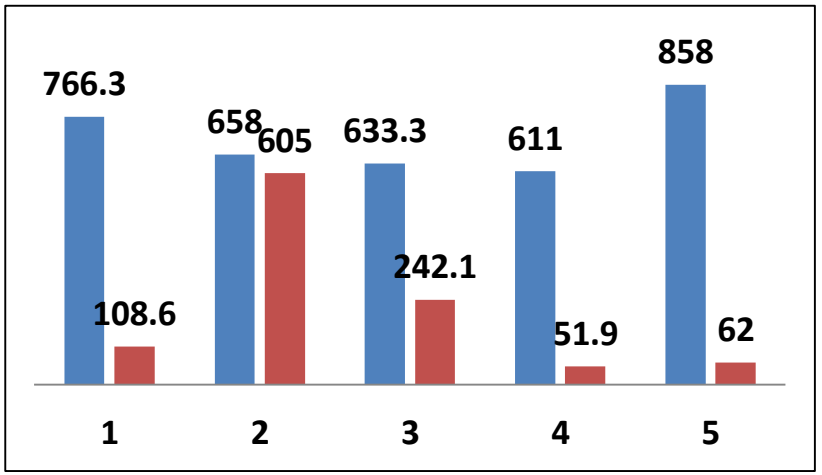
- **AMAR brings normalcy and reduction in CA19-9 levels in majority of the cases**
- **A data on 18 patients with elevated CA19-9 levels, ranging from 300 to about 10000 U/mL, shows reduction in the levels after start of AYT**
- **The downtrend begins within the first 10 days of treatment**
- **Further progression of the disease is seen in only 2.7% cases**

Lowering Trend

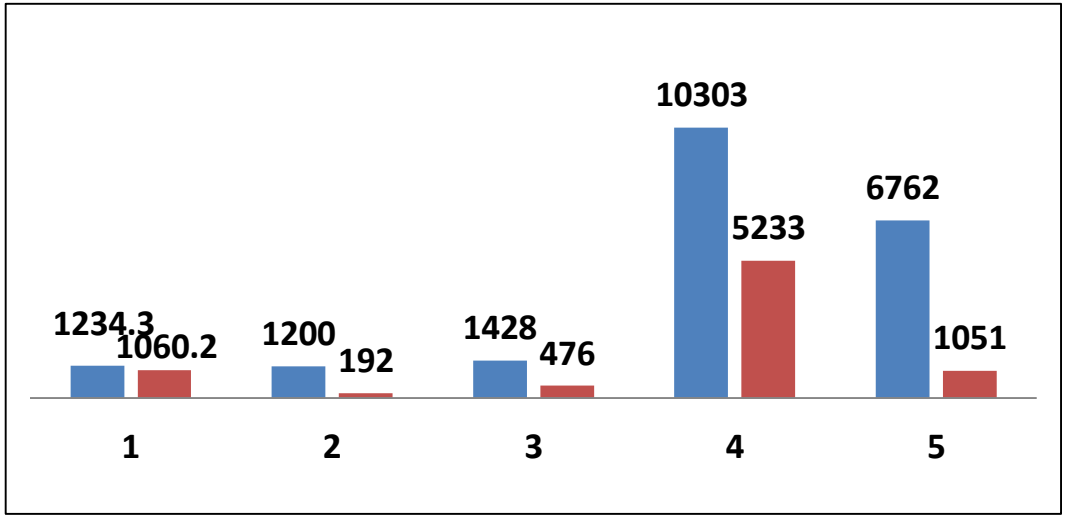
CA19-9: 300 – 600 U/mL



CA19-9: 600 – 900 U/mL



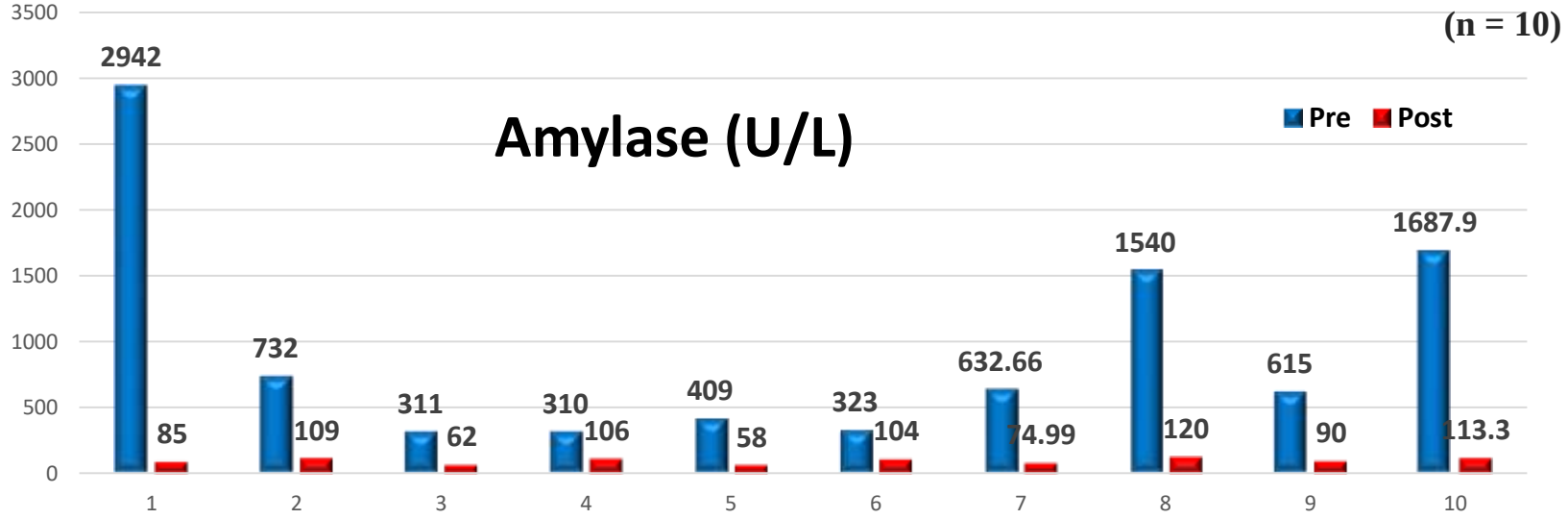
CA19-9: >1200 U/mL

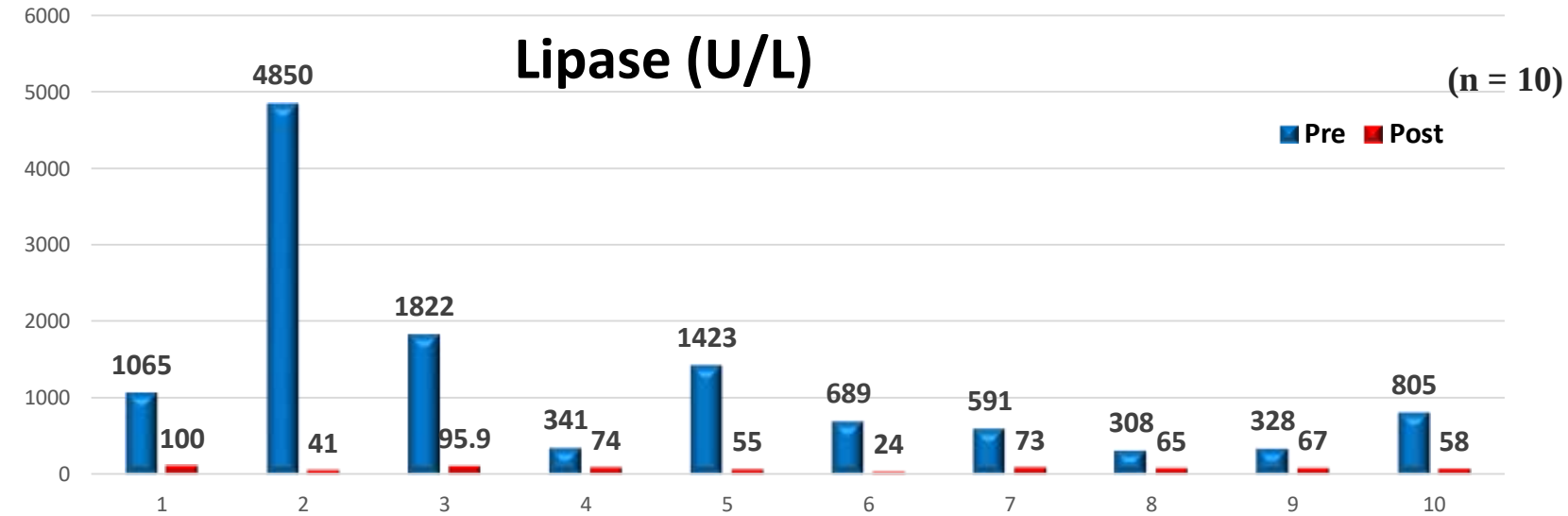


Effect in Acute Phase

(Amylase & Lipase Lowering Effect)

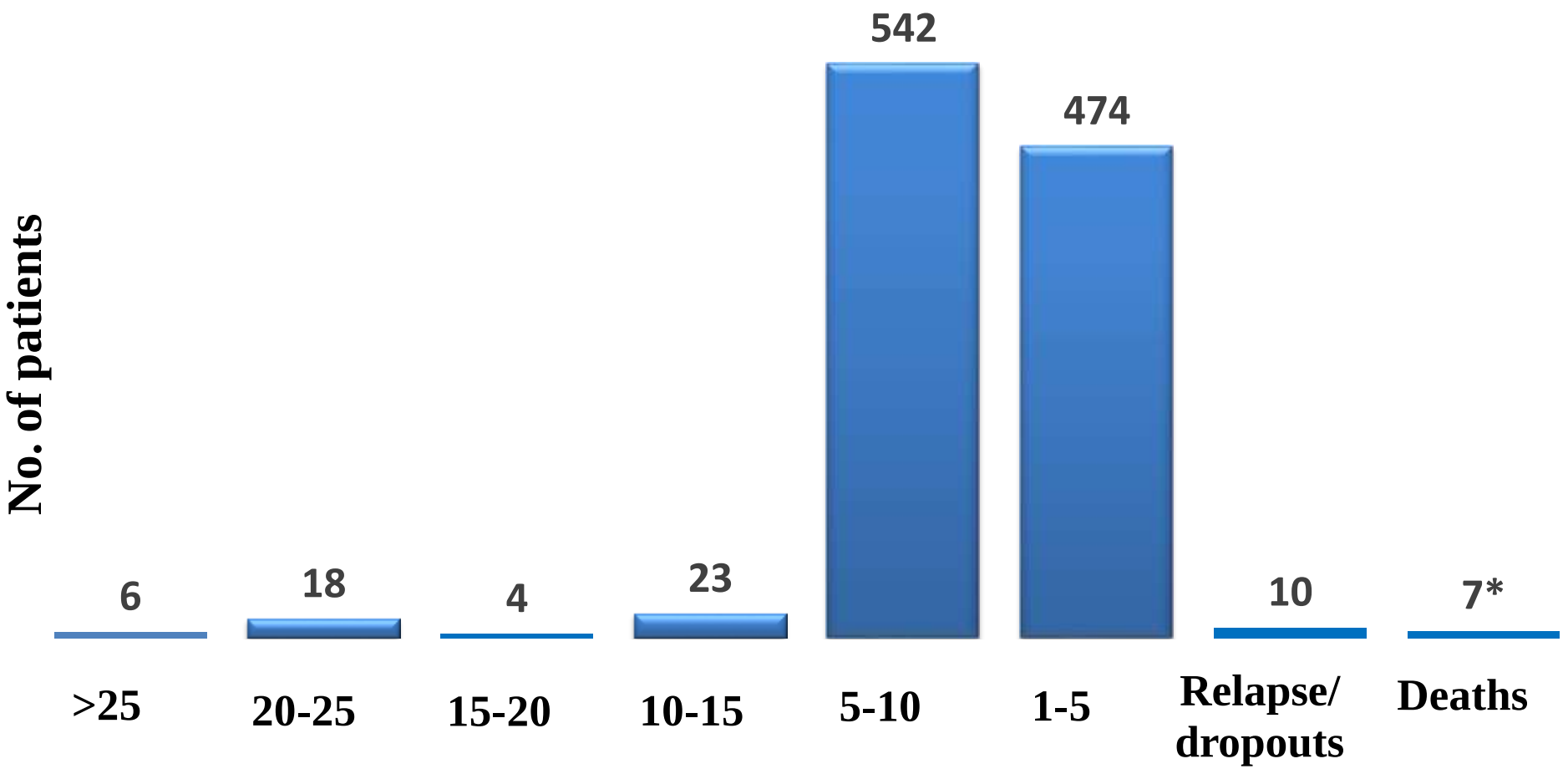
Effect evaluation after ten days of AYT





Sustainable effect of AYT

n= 1084/2050



#First patient completes 27 years long disease-free survival after getting nine recurring attacks in the year prior to AYT

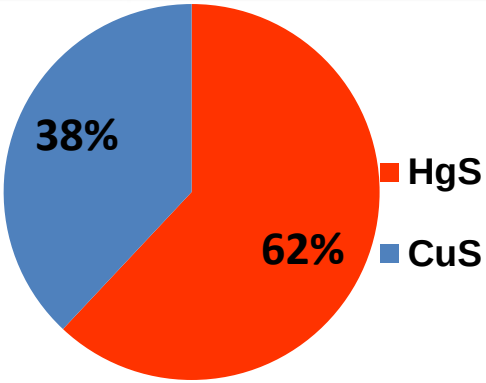
*5 deaths post relapse, 1 due to hepatic failure and 1 due to cardiac arrest

Scientific Development of Amar

- **Started in 2014 with support of Department of Science & Technology, Uttarakhand Government**
- **Nodal agency – Uttarakhand Council of Science & Technology (UCOST)**
- **Partial funding of 47 lacs**

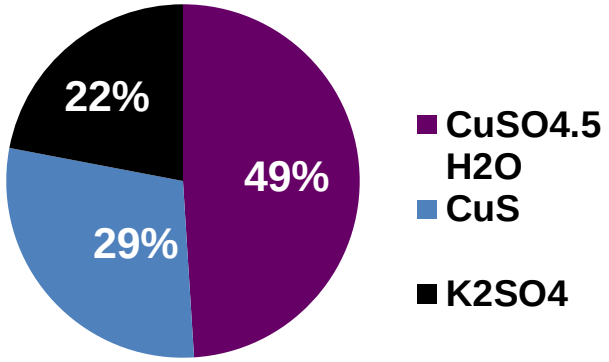



Process Standardization & Characterization

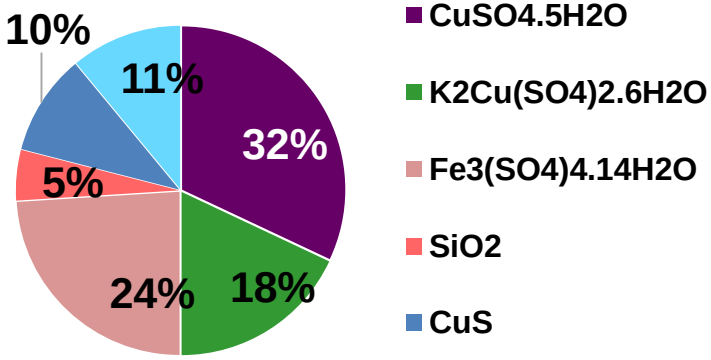


After 1st GJ

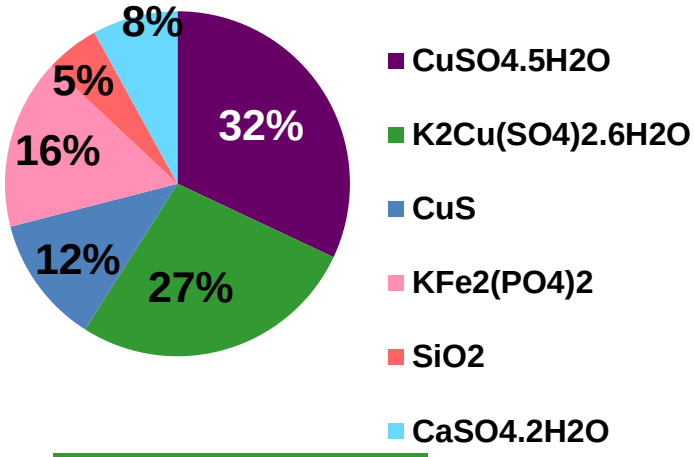
(GJ - Gandhak Jarana)



After 32nd GJ



After 64th GJ



After 100th GJ

Analyzed using XRD, EDAX, TEM and SEM at Department of Inorganic & Physical Chemistry, IISc, Bangalore

Indian Patent No. 529197

Safety Evaluation (OECD Guidelines)

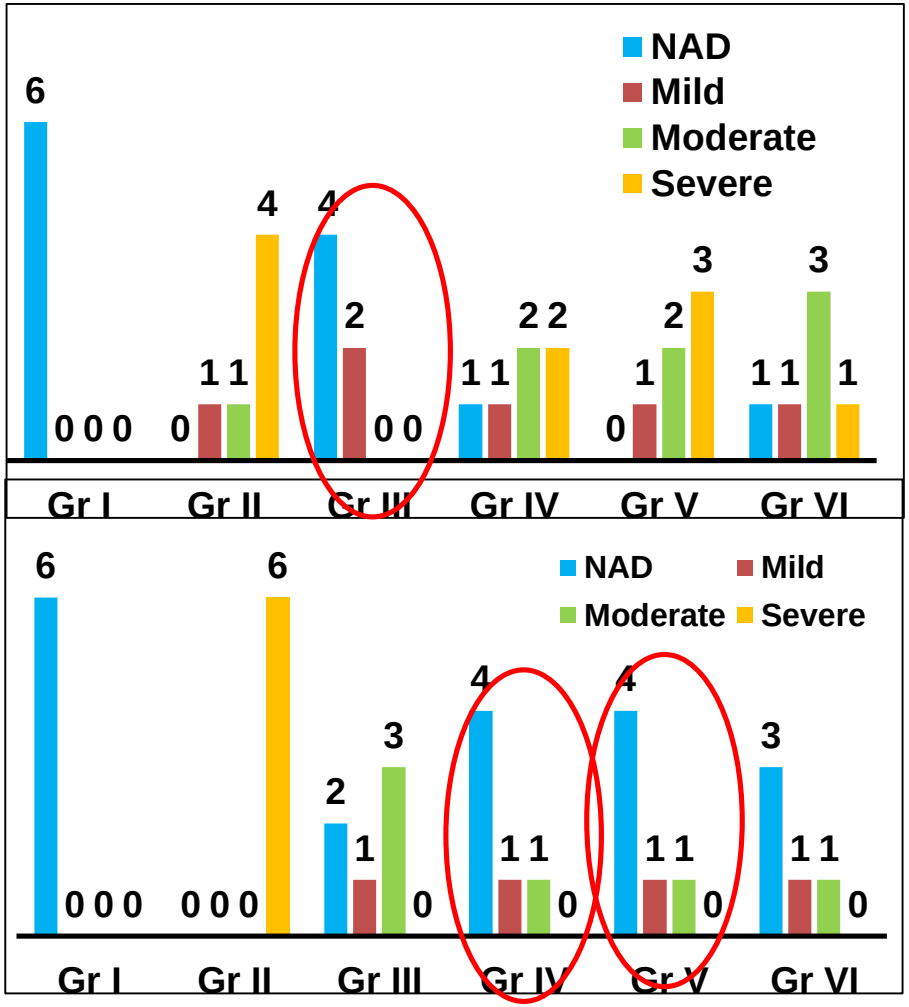
Particulars	Acute Study			Sub-acute Study				Chronic Study					
Species used	Sprague Dawley Rats			Sprague Dawley Rats				Sprague Dawley Rats					
Dose interval	Single dose			24 hours				24 hours					
Route of administration	Oral			Oral				Oral					
Duration of dosing	Single dose			28 days				180 days					
Duration of post-exposure follow-up	14 days			14 days (high dose group)				28 days					
Groups	I	II	III	I	II	III	IV	I	II	III	IV	V*	VI*
Number and sex of animals	3♀	3♀	3♀	6♀ +6♂	6♀ + 6♂	6♀ +6♂	6♀ +6♂	20♀ + 20♂	20♀ + 20♂	20♀ + 20♂	20♀ + 20♂	10♀ + 10♂	10♀ + 10♂
Unit dose (mg/kg)	2000	300	300	0	75	150	300	0	40	80	160	0	160
Results	Mortality in 30 minutes	No toxicity	No toxicity	No observed adverse effect level (NOAEL)– 300 mg/kg/ day				No observed adverse effect level (NOAEL)– 160 mg/kg/ day					

Data on file; Courtesy: Vipragen Biosciences Limited, Mysuru

Pancreatitis Protective Properties – Experimental Model

- **Evaluation of protective activity of AMAR on L-Arginine induced chronic pancreatitis in male albino wistar rats**

Gr	Treatment group	Doses
I	Untreated control	-
II	Disease control (L-Arginine)	2.0/ 2.0 g/kg
III	HMF + L-Arginine	25/ 13 mg/kg
IV	HMF + L-Arginine	50/ 19 mg/kg
V	HMF + L-Arginine	100/ 25 mg/kg
VI	6-α-methylprednisolone + L-Arginine	30/ 15 mg/kg



Conclusion

- **Amar emerged as strong Pancreatitis protective, safe and therapeutically effective in the treatment and prevention of Pancreatitis**

Prakash VB et al. Anti-Inflammatory Properties of a Processed Copper Complex in L-Arginine Induced Pancreatitis - Two Experimental Studies, EC Gastroenterology and Digestive System, 6.7 (2019): 519-524

Current Scenario

- **Continuity of documentation of clinical practice at Village Ratanpura, Tehsil Gadarpur, District Udham Singh Nagar, Uttarakhand, where patients from across the country and abroad**

Major Hospitals Treating Pancreatitis in India

Name of Hospital	Place/ State
Asian Institute of Gastroenterologist (AIG)	Hyderabad, Telangana
Sir Ganga Ram Hospital	Delhi
Medanta Hospital	Gurugram, Haryana
All India Institute of Medical Science (AIIMS)	Delhi
Postgraduate Institute of Medical Education & Research (PGI)	Lucknow & Chandigarh
Fortis Hospital	Delhi
Institute of Liver & Biliary Sciences (ILBS)	Delhi
Global Hospital	Mumbai, Maharashtra
Apollo Hospital	Delhi
Max Hospital	Delhi
Dayanand Medical College (DMC)	Ludhiana, Punjab
Pushpawati Singhania Research Institute	Delhi
Deenanath Mangeshkar Hospital	Pune, Maharashtra
SMS Hospital & Medical College	Jaipur, Rajasthan
GB Pant Hospital	Delhi
CMC Hospital	Vellore, Tamil Nadu

Ayurvedic Treatment for Pancreatitis
(Indian Scenario)

• **Who is the most authentic physician for the treatment of pancreatitis in India?**

- **In India, Vaidya Balendu Prakash is regarded as one of the most authentic pioneering physicians in the treatment of chronic and acute pancreatitis through Ayurveda. His organization, Padaav Specialty Ayurvedic Treatment Centre, offers a year-long treatment program with an intensive 21-day indoor regimen at their Rudrapur facility.**

(extract from ChatGPT)

Task Ahead

- **Ayurvedic treatment works but how – Action?**

- **How long should the treatment be given – Duration of treatment?**

- **There is a dire need to connect experience based evidently effective Ayurvedic into mainstream treatment by combining traditional wisdom of India with tools and technology of modern sciences.**

Thank You!