

EFFECT OF RASAMRUTAM ON AMLAPITTA (SINGLE BLIND CLINICAL STUDY)

Dr. Viveka Kamble^{1*} and Dr. Sheela Pargunde²

¹MD. Scholar and ²Professor and H.O.D

Department of Rasashastra and Bhaishajya Kalpana, Y.M.T Ayurvedic Medical College,
Kharghar, Navi Mumbai, Maharashtra, India.

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*Corresponding Author

Dr. Viveka Kamble

MD. Scholar Department of
Rasashastra and Bhaishajya
Kalpana, Y.M.T Ayurvedic
Medical College, Kharghar,
Navi Mumbai, Maharashtra,
India.

ABSTRACT

Rasagranthas mentioned materials of mineral, herbal and animal origin for preparing herbomineral drugs i.e *Khalviya rasayan*, *Parpati rasayan*, *Pottali rasayan* and *Kuppipakwa rasayan* from *shodhan*, *jaran*, *maran* and other procedures. *Rasa kalpas* have more potency, high shelf life, require minimum dose. *Kajjali kalpas* are found effective in diseases of almost all *strotasas*. According to modern science hyperacidity is due to imbalance between gastric acid and intestinal secretion and also due to hyper activation of vagus nerve. This may result of anatomical dysfunction of gastroesophageal sphincter causes gastroesophageal reflux diseases. The negligence and chronicity of this condition may lead peptic ulcer and its fatal complications such as internal bleeding, haematemesis, melena,

gastric- outlet obstruction and perforation. The various treatment modalities are available in other medical streams but they have their own limits. According to *ayurved* science, the main cause of *amlapitta* is *viruddha ahar* causes *Agnimandya*, which results into *aam utpatti* and vitiates *pitta*. Contents of *Rasamrutam* mainly act on *agni*, normalize its functions and improve digestion.

KEYWORDS: *Amlapitta* – *Rasamrutam* - clinical trial – single blind interventional study.

INTRODUCTION

Amlapitta is one of the most common diseases and becomes chronic if left untreated. According to ayurvedic classics improper *Ahar* and *Vihar* are the main causes of *amlapitta*. In current era spicy, junk and fast foods, addiction habits^[1,2,3] (smoking, alcohol drinking,

frequent use of NSAID) come under *viruddha ahar*. *Viruddha vihar* include irregular sleeping time, stress^[4], anxiety, anger. *Acharya kashyapa* has first described *amlapitta* as individual disease. *Acharya Madhav nidan*, *acharya Bhavpraksh* and *acharya Chakradutta* also described the *amlapitta* with its detailed management. *Rasamrutam* a herbomineral formulation mentioned in “*yogratnakar*” and clinical research work on this formulation on *amlapitta* has not been done, so it is an opportunity to work on this formulation and may serve as one of the effective substitute drug to treat *amlapitta*.

AIM AND OBJECTIVE

Evaluate the efficacy of *Rasamrutam* in management of *Amlapitta*.

MATERIALS AND METHODS

Study design

The present study is interventional, single blind clinical trial. Patient treated at OPD level (Y.M.T Ayurvedic Medical College, Kharghar) with clinical symptoms of *Amlapitta* were included in the study. Total 10 patients of age between 25 – 60 years, satisfying inclusion criteria were selected. All patients were administered with *Rasamrutam* in *apaan kala* (before meal). The treatment was given for 1 month with follow ups of every seven days. Relief of symptoms of *amlapitta* was assessed by before and after treatment with gradation of clinical features on the basis of scoring pattern.

Inclusion criteria

1. Patients aged above 18 years
2. Patients having clinical symptoms of *Amlapitta* like *Amlotklesh*, *Avipaka*, *Kanthadaha* etc.

Exclusive criteria

1. Patients aged below 18 years.
2. Patient having any serious medical illness like Heart-Pulmonary-Kidney-Liver diseases, Diabetes mellitus, Hypertension, Hyperthyroidism or Hypothyroidism.
3. Patient suffering from gastric ulcer, duodenal ulcer, gastric carcinoma
4. Pregnant and lactating mother.

Preparation of formulation

त्रिकटु त्रिफला मुस्ता विडङ्गचित्रकं तथा । एषां संचूर्णितानां तु प्रत्येकं तु पलं भवेत् ॥ १ ॥

कर्षव्दयं गन्धकस्य तदर्धं पारदस्यच । विडालपदमात्रं तु लिह्यात्तन्मधुसर्पिषा ॥ २ ॥

शीतोदकं चानुपिबेत्क्रमादगव्यं पयस्तथा । अम्लपित्तमग्निमान्दयं परिणामरुजं तथा ॥

कामलां पाण्डुरोगं च हन्यादेतद्रसामृतम् ॥ ३ ॥

(योगरत्नाकर अम्लपित्तचिकित्सा)⁵

Table no. 1: Material of *Rasamrutam*.

Sr. No	Ingredients	Latin name	Part used	Quantity
1	<i>Shunthi</i>	<i>Zingiber officinale</i>	Rhizomes	4 Part
2	<i>Marich</i>	<i>Piper nigrum</i>	Fruit	4 Part
3	<i>Pipali</i>	<i>Piper longum</i>	Fruit	4 Part
4	<i>Haritaki</i>	<i>Terminalia chebula</i>	Fr.pericarp	4 Part
5	<i>Bibhitaki</i>	<i>Terminalia bellerica</i>	Fr.pericarp	4 Part
6	<i>Amalaki</i>	<i>Emblia officinalis</i>	Fr.pericarp	4 Part
7	<i>Musta</i>	<i>Cyperus rotundus</i>	Rhizomes	4 Part
8	<i>Vidang</i>	<i>Embelia ribes</i>	Fruit	4 Part
9	<i>Chitrak</i>	<i>Plumbago zeylanica</i>	Root	4 Part
10	<i>Shuddha Gandhak</i>	<i>Sulphurium</i>		2 Part
11	<i>Shuddha Parad</i>	<i>Hydrargyrum</i>		1Part

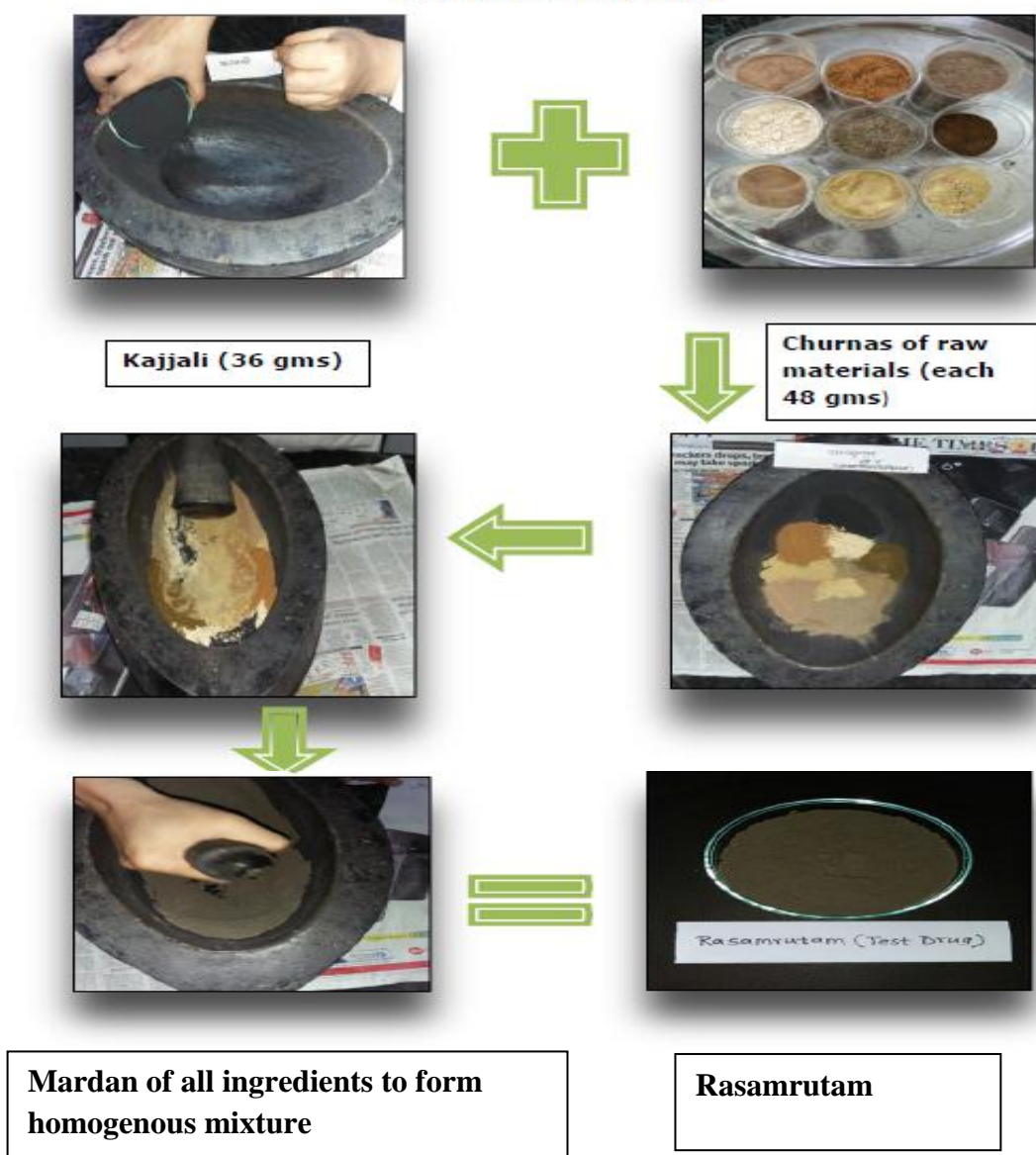
Table no. 2: Properties of ingredients.

Dravya	Rasa	Virya	Vipak	Action	Proved activity
Kajjali	metallic	Ushna	Katu	Yogvahi, Krumighna, Rasayan	GI stimulant, Catalytic activity
Shunthi	Katu	Ushna	Madhura	Deepan, Pachan, Krumighna, Grahi	Gastro protective, Anti-ulcerogenic, Anti H. pylori bacteria
Marich	Katu	Ushna	Katu	Deepan, Pachan, Krumighna, Vatanulomaka, Yakrut uttejaka	Gastro protective, Anti-ulcerogenic, Anti H. pylori bacteria
Pipali	Katu	Anushna	Madhura	Deepan, Krumighna, Vatanulomaka, Yakrut uttejaka	Gastro protective, Anti-ulcerogenic, Hepatoprotective
Haritaki	Pancharasatmak	Ushna	Madhura	Deepan, Pachan, Krumighna, Anulomaka, Yakrut uttejaka	Gastro protective, Cytoprotective, Anti-ulcerogenic, Hepatoprotective, Wound healing
Bibhitak	Kashay	Ushna	Madhura	Deepan, Krumighna, Vatanulomaka	Cytoprotective, Anti-ulcerogenic
Amalaki	Pancharasatmak	Shita	Madhura	Deepan, Pachan, Krumighna, Anulomaka, Yakrut uttejaka	Gastro protective, Anti-ulcerogenic, Wound healing

Musta	Tikta, Katu, Kashay	Shita	Katu	Deepan, Pachan, Krumighna, Grahi	Gastro protective, Anti-ulcerogenic, Wound healing, Anti <i>H. pylori</i> bacteria
Vidang	Katu	Ushna	Katu	Deepan, Pachan, Krumighna	Gastroprotective, Anti-ulcerogenic, Wound healing,
Chitrak	Katu	Ushna	Katu	Deepan, Pachan, Krumighna, Pitta saraka	Gastro protective, Anti-ulcerogenic, Anti <i>H. pylori</i> bacteria

Procedure: First of all *Kajjali* (36gm) was taken in *Khalava yantra* and after that fine churnas of *Shunthi*, *Marich*, *Pipali*, *Haritaki*, *Bibhitak*, *Amalaki*, *Musta*, *Vidanga* and *Chitrak* (Each churna 48 gm) were added one by one, the mixture was triturated properly for seven days to get homogenous mixture. The well form *rasamuratam* was observed, collected and weighed, and kept in clean, dried and air tight glass container.

RASAMRUTAM NIRMAN



Dose of Rasamrutam: 1 gm OD before meal

Route of administration: Orally

Anupana: *Madhu* and *Go-ghrít* (3:1)

The trial drug was prepared in pharmacy of Y.M.T Ayurvedic Medical College, Kharghar as required set up was available.

Duration of treatment: 1 month

Diet: Patients were kept on normal diet with special restriction of spicy and oily diet and detailed *pathya- apathy* was explained to each patient.

Follow up: The patients were followed up after seven days for 1 month.

Criteria of assessment

The diagnosis of *Amlapitta* was done according to *lakshanas* described in the *Yogratnakar*.^[5]

Table No. 2: Grading of clinical features of *Amlapitta* according to severity.^[6]

Grades	Lakshan
Avipaak	
G ₀	No digestion
G ₁	Digests normal usual diet in 9 hours
G ₂	Digests normal usual diet in 12 hours
G ₃	Digests normal usual diet in 24 hours or more
Klama	
G ₀	No tiredness
G ₁	Feel tired after exertion work
G ₂	Feel tired after normal work
G ₃	Feel tired even after taking rest
Utklesha	
G ₀	No nausea
G ₁	Feel nausea after eating some peculiar food
G ₂	Feel nausea after eating all kinds of food
G ₃	Full day nausea, not related to eating
Tikta -amla udgaar	
G ₀	No sour and bitter belching
G ₁	Sour and bitter belching after taking spicy food
G ₂	Sour and bitter belching after taking any type of food
G ₃	Sour and bitter belching having no relation with food intake
Guruta	
G ₀	No feeling of heaviness in the body
G ₁	Heaviness after taking more quantity of heavy food
G ₂	Heaviness even after taking light food
G ₃	Heaviness even on empty stomach
Hrit- Kantha Daha	
G ₀	No burning sensation

G ₁	Burning sensation after intake of spicy food
G ₂	Burning sensation even after intake of normal food
G ₃	Burning sensation even on empty stomach
Aruchi	
G ₀	No anorexia
G ₁	Eat food only two times without any snacks in between
G ₂	Eat only once
G ₃	Have no feeling of appetite

5. DISCUSSION AND RESULT

In present study, 10 patients were selected from OPD of college institute, having cardinal features of *Amlapitta*. In age wise distribution, study shows that, 1 patient is from age group 25-30 years, 3 patients is from age group 31-35 years, 2 patients is from age group 36-40 years, 1 patient in 41-45 years, 1 patient is from age group 46-50 years, 1 patient is from age group 51-50 years and 1 patient is from age group 56-60 years. It was observed that out of total patients 8 patients were from working class, 1 patient was business person and 1 patient was house wife. On detailed history taking among patients *ati-lavan*, *kattu ahar*, addition of tea/coffee, *ratri jagaran*, incomplete sleep and stress these *hetus* were found.

On analyzing *lakshanas* of *Amlapitta*, *Avipak* was found to be present in 87.5% patients, *Klama* in 66.66% patients, *Amlotklesh* in 77.77 patients, *Tikta-Amlodgara* in 100% patients, *Gaurav* in 66.66% patients, *Hrit-Kanth daha* in 88.88% and *Aruchi* in 100% patients. *Rasamrutam* is a herbomineral formulation and indicated in *Amlapitta*, *Agnimandya*, *Parinamruja*, *Kamala* and *Panduroga*. All contents of *Rasamrutam* have *Deepana*, *Pachana karma* i.e. increasing appetite effect (*Agni vruddhi*) as per described in classics and counteract the dysfunctions of vitiated *doshas*. *Rasamrutam* acts on *Vyadhi adhisthana* (i.e. *Amashaya*), reduces symptoms of *vyadhi* (*Amlotkesh*, *Hrit-Kantha daha*, *Avipaka*, *Aruchi* etc.) According to modern scientific research following activities of ingredients have been proved, *Kajjali* acts as GI stimulant and catalyst.^[7] *Shunthi* and *Marich* have gastro-protective^[8] activity, anti-ulcerogenic activity^[9,11] and activity against *H.pylori* bacteria^[10,12] *Pippali* has gastro- protective activity, anti-ulcerogenic activity^[13] and hepato-protective activity^[14] *Haritaki* has gastro- protective activity, anti-ulcerogenic activity^[15], hepato-protective activity^[16], cyto-protective^[17] and wound healing activity. *Bibhitak* has cyto-protective and anti-ulcerogenic activity.^[19] *Amalaki* has gastro-protective^[20], anti-ulcerogenic^[21] and wound healing activity^[22], *Musta* has gastro-protective^[23], anti-ulcerogenic activity^[24], wound healing activity and activity against *H.pylori* bacteria, *Vidanga*

has gastro-protective, anti-ulcerogenic activity, and wound healing activity. *Chitrak* has gastro-protective, anti-ulcerogenic activity^[25] and activity against *H.pylori* bacteria.^[26]

Table No. 3: Age wise distribution of patients.

Age groups	No. of patients
25-30 years	1
31-35 years	3
36-40 years	2
41-45 years	1
46-50 years	1
51-55 years	1
56-60 years	1
Total	10

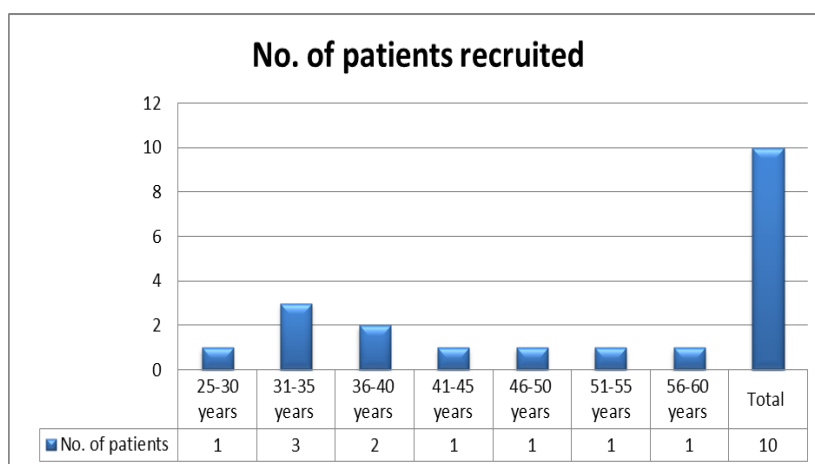
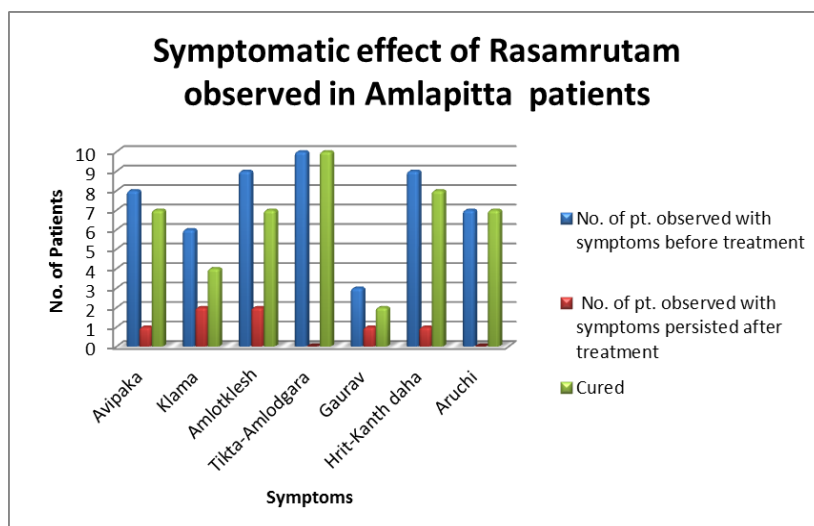


Table No. 4: Effect of *Rasamrutam* observed in *Amlapitta* patients.

Sr.No	Symptoms	No. of pt. observed with symptoms before treatment	No. of pt. observed with symptoms persisted after treatment	Cured	%
1.	<i>Avipaka</i>	8	1	7	87.5%
2.	<i>Klama</i>	6	2	4	66.66%
3.	<i>Amlotklesh</i>	9	2	7	77.77%
4.	<i>Tikta-Amlodgara</i>	10	0	10	100%
5.	<i>Gaurav</i>	3	1	2	66.66%
6.	<i>Hrit-Kanth daha</i>	9	1	8	88.88%
7.	<i>Aruchi</i>	7	0	7	100%



6. CONCLUSION

Amlapitta is an *Agnimadyajanit vyadhi* causing *Annavahastrodushti* which lowers the quality of life. It is mainly caused by improper diet, addiction habits, irregular sleeping pattern and abnormal psychological health. These entire factors imbalance *tridosha*, mainly *pitta* which leads to *Amlapitta*. The continue intake of *hetus* aggravate the disease. The *rasamrutam* with *anupana* is very effective in managing *Amlapitta*, no adverse effects have been noticed.

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8. REFERENCES

1. Su-Lin Lim¹, Claudia Canavaro² et.al, Iregular Meal Timing Is Associated with Helicobacter pylori Infection and Gastritis, Hindawi, 2012 Dec 9,vol 2013, article ID 714970, <http://dx.doi.org/10.504/2013/714970>
2. L.F.Li, R.L.Y. Chan et.al, Cigarette smoking and gastrointestinal diseases: The casual relationship and underlying molecular mechanisms (Review), International Journal of Molecular Medicine, May 22, 2014, 34. <http://dx.doi.org/10.3892/ijmm.2014.1786/>
3. C.Musumba, D.M. Pritchard, Review article: cellular and molecular mechanism of NSAID-induced peptic ulcers, Wiley Online Library, August 18, 2009; 30, <https://doi.org/10.1111/j.1365-2036.2009/>

4. Bradely LA, Richter JE, Pulliam TJ et.al, The relationship between stress and symptoms of gastroesophageal reflux: the influence of psychological factor, pub med, January 1993; 8(1). <https://www.ncbi.nlm.gov>
5. Vd.Shree Laxmipatishastri, Yogratnakar, vidyotini tika, reprint, Chaukhamba prakashan, Varanasi, 2015; 237.
6. Chauhan Gauri, Mahapatra Arun Kumar, Kumar Abhimanyu, Study on clinical efficacy of Avippatikar choorna and sutshekhar rasa in the management of urdhwag amlapitta, Journal of Pharmaceutical and scientific Innovation, 2/2/15; 4(1). DOI; 10.7897/2277-4572.0414
7. [http://drshriraj.blogspot.com//2009/01/pharmacology of kajjali kalpas.](http://drshriraj.blogspot.com//2009/01/pharmacology%20of%20kajjali%20kalpas.)
8. Siddaraju M.Nanjundaiah, Harish Nayak et.al, Gastroprotective effect of Ginger Rhizome (*Zingiber officinale*) Extract: Role of Gallic Acid and Cinnamic Acid in H⁺, K⁺-ATPase/H.pylori Inhibition and Anti-Oxidative Mechanism., Hindawi, May 28, 2009; 2011, <http://dx.doi.org/10.1093/ecam/nep060/>
9. Al-Yahya MA, Rafatullah S, Mossa JS, Ageel AM, Prmar NS, Tariq M., Evaluation of the anti-ulcerogenic effect of zingiber officinale (Ginger) root in rats, International Journal of current Microbiology and Applied Sciences, 2014; 3: 1, ISSN: 2319-7706, <http://www.ijcmas.com>
10. Mahady GB, Pendland SL, Yun GS, Lu ZZ, Stoia A., Ginger (*Zingiber officinale* Roscoe) and the Gingerols Inhibit the Growth of cag A⁺ Strains of *Helicobacter pylori*, NIH Public Access, Anticancer Res., sep-oct, 2003; 23(5A): 3699-702, PMID:PMC3761965 <https://www.ncbi.nlm.nih.gov/>
11. Ramnik Singh, Jyotsana Madan, Harwinder Singh Rao, Antiulcer Activity of Black Pepper against Absolute Ethanol Induced Gastric Mucosal Damage in Mice, Pharmacognosy Magazine, 2005; 4, www.phcog.com
12. Nagendra Thermalingam, Sa-Hyun Kim, and Jong Bae Kim et.al, Inhibitory effect of piperine on *Helicobacter pylori* growth and adhesion to gastric adenocarcinoma cells, BMC, 2014 December 16. <http://doi.org/10.1186/1750-9378-9-43>
13. Agrawal. A K, Rao. Ch V, Sairam. K, Joshi. V K, Goel. R K, Effect of *Piper longum* Linn, *Zingiber officinalis* Linn and *Ferula* species an gastric ulceration and secretion in rats, Indian journal of Experimental Biology, October, 2000; 38. <https://www.semanticscholar.org>

14. S.S. Jalalpure, M.B. Patil, N.S. Prakash, K. Hemalata and F.V. Manvi, Hepatoprotective Activity of the Fruits of *Piper longum* Linn, Indian journal of Pharmaceutical Sciences, July, 2003; 65(4). <http://www.ijpsonline.com>
15. D Raju, K Ilango, V Chitra, K Ashish, Evaluation of Anti-ulcer activity of methanolic extract of *terminalia chebula* fruits in experimentak rats, Journal of Pharmaceutical sciences and Research, 2009; 1(3). www.jpsr.pharmainfo.in
16. Anwesa Bag, Subir Kumar Bhattacharyya, and Rabi Ranjan Chattopadhyay, The development of *Terminalia chebula* Retz (Combretaceae) in clinical Research, Asian Pacific Journal of Tropical Biomedicine, 2013; 3(3). doi:10.1016/S2221-1691(13)60059-3, www.elsevier.com/locate/apjtb
17. Vaibhav Mishra, Manali Agrawal, gaurav Madhur Tadigoppula Narender et.al, Anti-secretory and cyto-protective effects of chebulinic acid isolated from the fruits of *Terminalia chebula* on gastric ulcers, Phytomedicine: international journal of phytotherapy and phytopharmacology, Feb 2013; 20(2013). doi:10.1016/j.phymed.2013.01.002, <http://www.researchgate.net/publication/235796307>
18. Hitesh Jawanjal, Mithun S. Rajput, Purni Agrawal, Vikramsingh Dange, Pharmacological Evaluation of Fruits of *terminalia belerica* Roxb. for Antiulcer Activity, Journal of Complementary and Integrative Medicine, 2018.06.18, 9, <http://doi.org/10.1515/1553-3840.1556>
19. Al-Rehaily AJ, T.S.Al-Howiriny, M.O.Al-Sohaibani, S.Rafatullah, Gastroprotective effects of 'Amla' *Emblica officinalis* on in vivo test models in rats, November 10, 2004; 9. <https://doi.org/10.1078/09447110260573146>
20. N.V. Rajeshkumar, Marie Therese & Ramadasan Kuttan, *Emblica officinalis* Fruits Afford Protection Against Experimental Gastric Ulcers in Rats, Pharmaceutical Biology, 2001; 39(5). <http://doi.org/10.1076/phbi.39.5.375.5902>
21. Miriyala Sumitra, Panchatcharam Manikandan, Vinaya Subramani Gayathri, Panchatcharam Mahendran et.al, *Emblica officinalis* exerts wound healing action through up-regulation of collagen and extracellular signal-regulated kinases (ERK1/2), The international journal of tissue repair and regeneration, 2009 january 16, <http://doi.org/10.1111/j.1524-475X.2008.00446.x>
22. Muhammet E. Guldur, A. Ozgonul, Ibrahim H. Kilic, O. Sogut, M. Ozaslan, M. Bitiren, M. Yalcin and D. Musa, Gastroprotective effect of *Cyperus rotundus* extract against gastric mucosal injury induced by ischemia and reperfusion in rats, International Journal of Pharmacology, 2010; 6. [http:// www.cabdirect.org](http://www.cabdirect.org)

23. Mansoor Ahmad, Mahay Rookh, Asif Bin Rehman, Asma Wazir et.al, Assessment of anti-inflammatory, anti-ulcer and neuropharmacological activities of cyperus rotundus Linn, Pak.j. Pharm. Sci., November 6, 2014, 27. <http://ncbi.nlm.nih.gov>
24. Kakjing Dadul falang, Mary Ogonnaya Uguru, Noel Nenman Wannang, Iliya Hosea Azi, Nwoye Chiamaka, Anti-ulcer activity of plumbago zeylanica linn root extract, Scholars Reserch Library, 2012; 2(5). <http://scholarsresearchlibrary.com/archive.html>
25. Yuan Chuen Wang, Tung lian Huang, Anti-Helicobacter pylori activity of Plumbago zeylanica L., Wiley Online library, January 09, 2006; 43. <https://doi.org/10.1016/j.femsim.2004.10.015>