

Original article**Efficacy of Ayarij Faiqura in Qarah-e-Hazmiya - Randomized controlled Clinical study**Siddiqui MA¹, Quavi A², Quamri MA³**Abstract**

Background and Objective: *Qarahe Hazmiya* (Peptic ulcer disease) is one of the commonest ailment of Gastro intestinal tract, reported to affect around 4% of the population and 10% of people developed it at some point in their life. Etiopathology of the disease is considered as multi factorial mostly treated with medications and rarely with surgery. Several Unani formulation have been indicated effective in *Qarahe Hazmiya*, one of such formulation has been selected to evaluate its efficacy and to validate the same on scientific parameters **Methods:** This study was conducted as a single blind, randomized standard control clinical trial on 28 patients (n=20) in test and (n=8) control groups. Test group received *Ayarij Faiqura* 5gm and control group received Pantoprazole 40 mg, orally in empty stomach for 45 days. The study outcome was assessed as the difference in pre and post treatment through subjective and objective parameters. **Result:** The test drugs revealed statistically significant improvement in burning sensation in abdomen (p<0.0001), pain abdomen (p<0.0001) as subjective parameters in comparison to control group where as objectively endoscopic report showed significantly improvement (p<0.0196) in comparison to control group with respect to the healing of ulcer / erosions. **Interpretation and conclusion:** The study revealed that the test drug had good response in controlling burning sensation and pain abdomen, along with healing of ulcer / erosions in comparison to control drug. No side effect or toxicity was observed during and or after the study. Thus, it could be concluded that the test drug was found to be safe and effective without any adverse effect.

Keywords: Qarah-e-Hazmiya; PUD; *Ayarij Faiqura*; Pantoprazole; Unani Medicine

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Introduction:

Qaraha-e-Hazmiya (Peptic ulcer disease), also known as a gastric ulcer or duodenal ulcer, it is a break in the lining of the stomach, first part of the small intestine, or occasionally the lower esophagus.¹ It affects 4 million people worldwide annually, the incidence of PUD has been estimated at around 1.5% to 3%.² About 10% of people develop peptic ulcer at some point in their life.³ Etiopathology of the disease is considered as multi factorial such as H.pylori, spicy food, smoking, alcoholism, NSAIDs, stress, genetic factors etc.^{4,5} Symptoms of PUD include abdominal pain, upper abdominal discomfort, bloatedness, feeling of fullness, vomiting, weight

loss.¹ Medical management as offered by western system of medicine contains various antibiotics, PPIs (Pantoprazole, Lansoprazole, and Omeprazole etc), H₂ receptor blockers (Ranitidine, Famotidine, Cimetidine etc) and antacids, ⁶ which can provide time being relief only. Unani scholars have used the term as *Qarahe Medah* for ulcer of stomach, later on term *Qarahe Asna ashri* was a coined term for duodenal ulcer which is caused by Khilt laze or safra-e-had.⁷ In Unani System of Medicine ulcer of the gastric mucosa (*Qarahe Hazmiya*) was treated with several Unani formulations which possess activities like Mundammil-e-Qurooh (drugs that heal ulcer, Maniye ufoonat (antiseptic), Dafe

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Humuzat (antacids), Muqawwi-e-Meda (tonic for stomach), Maniye Insebaabe Mavaad hadda (drugs that stop accumulation of pus) indicted for PUD like symptoms which is used by Zakaria Rhazi.^{7,8,9} *Ayarij Faiqura* is a poly herbal Unani pharmacopeal preparation has been selected and hypothesised to evaluate its efficacy and to validate Unani the same on scientific parameters this study is conducted

Material and methods:

A randomized single blind standard controlled clinical trial was conducted at the O.P.D of N.I.U.M, Bengaluru after the approval of the protocol by the Institutional Ethical Committee of National Institute of Unani Medicine, Karnataka.

Inclusion Criteria: Diagnosed cases of *Qarahe Hazmiya* confirmed by endoscopy, patients of either sex, age between 20 to 70 years. **Exclusion criteria:** patients below 20 and above 70 years of age, pregnancy and lactation, gastrinoma (Zollinger Ellison Syndrome), Carcinoma of the gastrointestinal tract, haemetemesis and maelena, gastric or duodenal perforation, cirrhosis of liver, diabetes mellitus, hypertension, severe respiratory diseases, cardiovascular diseases, renal diseases, reflux oesophagitis, hiatus hernia with the investigation of esophageogastro duodenoscopy (EGD) and withdrawal criteria failure to follow the protocol any side effect or reaction or drop out.

A total of 70 subjects of PUD were screened and 30 patients fulfilling the inclusion criteria were assigned to the test and standard controlled group by simple randomization method after taking voluntary informed consent. 20 subjects were allocated to test and 8 subjects to the standard control group. Subjective parameters (pain in upper abdomen, burning sensation after meal, vomiting, bloating) were assessed with VAS at baseline and follow up visits (0th, 15th, 30th and 45th days) and objective parameters (Oesophageo gastro duodenoscopy) were carried out on pre and post (i.e. 0th and 45th days) study period. The assessment of safety of treatment was done by the clinical assessment at every visit of follow up and biochemical assessment before and after treatment like Biochemical parameters Complete Blood Picture Blood urea, Serum creatinine, SGOT, SGPT, S. Bilirubin, Blood sugar, Stool for routine, microscopic and occult blood.

Test Drug Composition:

S. NO	Unani Name	Scientific Name	Quantity
1	Sibr	<i>Aloe barbadensis</i>	3334 mg
2	Mastagee	<i>Pistascia lentiscus</i>	238 mg
3	Ood-e-Balsan	<i>Commiphora opobalsamum</i>	238 mg
4	Habb-e-Balsan	<i>Commiphora opobalsamum</i>	238 mg
5	Darchini	<i>Cinnamomum zeylanicum</i>	238 mg
6	Sumbul-Ut-Tib	<i>Nardostachys jatamansi</i>	238 mg
7	Asaroon	<i>Veliriana welchi</i>	238 mg
8	Saleekha	<i>Cinnamomum cassnablume</i>	238 mg

Test group was given *Ayarij Faiqura*^{7,8,9,10} in a dose of 5 g once a day in powder form and the control group was given Pantocid 40 mg, once orally a day before meal for 45 days.

Result:

A total of seventy patients were recruited and screened over a period of 16 months, out of which 28 eligible patients (23 males, 5 females) with a mean age of (40.57±6.85) years were enrolled into the study. Patients were divided into two groups of 20 in test and 8 in control group.

The median VAS Score of burning sensation in abdomen in control group was 8[8,8] on base line (0 day) and 3[2,5] on 45th day, whereas in test group the median score was 8[7,8] on baseline (0 day) and 0[0,3] on 45th day. When the median VAS Score of two groups were compared statistically using Friedman test with Dunn pair comparison test for intra-group comparison and Krushkall Wallis for inter group comparison, it was found that the median VAS Score at 30th and 45th day in control group was reduced significantly (P<0.01) when compared with median VAS Score 0th day of control group. Median VAS Score of test group at 15th day, 30th day and 45th day were reduced significantly (P<0.01) when compared with median VAS Score 0th day of test group. When median Visual Analogue Scale Scores of two groups were compared with each other, it was found that the test group significantly (P<0.01) reduced the scores when compared with median VAS Score at 45th day.

Discussion:

Ayarij Faiqura is one of the compound Unani formulation prescribed since the period of Hippocrates.^{7,8,9,10} The name contains two parts *Ayarij* and *Faiqura* which means *Shareef* (noble) and bitter respectively. *Ayarij Faiqura* is also known as *Dawae Elahi* for various reasons of its effects are

innumerous in the management of various ailments.

¹¹ It has been in use for long time for various therapeutic effects *Mundammile Qurooh*, *Maniye ufoonat*, *Maniye Insebaabe Mavaad hadda*, *Dafe Humuzat*, and *Muqavie Medah wa Am'ma*.^{7,11} This result consistent with the effect of *Ayarij Faiqura* that possesses a good number of herbs which are *Musakkin alam* like *Asaarun*, *Saleekha* as stated by *Najmul Ghani Hkm and. Mohd Abdul Hakeem*¹², and *Muhallile Auram* like *Sibr*, *Darcheeni* as claimed by and cooling¹⁴ effect of *Sibr*, *Asaarun*, *Saleekha*. The result indicates that both, control and test drugs, are effective in reducing the burning sensation in abdomen, while the test formulation is more effective than control drug. This result also revealed with the finding of Panahi Y et al (2015) and Umar WRS (2016).^{15,16}

The median VAS score of abdominal pain in control group was 8[5,8] on base line (0 day) and 3[1,5] on 45th day, whereas in test group the median VAS score was 8[7,8] on baseline (0 day) and 0[0,3] on 45th day. When median VAS Score of two groups were compared statistically, using Friedman test with Dunn pair comparison test for intra group comparison and Kruskal Wallis for inter group comparison, it was found that the median VAS Score at 30th and 45th day in control group was reduced significantly (P<0.01) when compared with median VAS Score 0th day of control group. Median VAS Score of test group at, 30th day and 45th day were reduced significantly (P<0.01) when compared with median VAS Score 0th day of test group. When median Visual Analogue Scores of two groups were compared with each other, it was found that the test group were significantly (P<0.01) reduced the scores when compared with median VAS Score at 45th day. This result coincides with the effect of *Ayarij Faiqura* that possesses *Muhallile Auram* drugs like *Sibr* and *Balchhar* according to *Allama Najmul Ghani* and¹³*Ibn Baitar*.¹⁴ The result shows that both control and test drugs are effective in reducing the abdominal pain, while the test formulation is more successful than control drug. This result accordance with the effect of *Ayarij Faiqura* that possesses a good number of herbs which are *Muqawwi medah*, *Muhallile Varm*, *Mudammile Qurooh* and *Kasirur Riyah* such as *Sibr*, *Darcheeni*, *Mustagee*, *Balsan*.¹²

¹⁴Ulcer healing was assessed by endoscopic report of 14 patients out of 20 in test group showed complete healing after 45 days of drug administration, while in 6 patients no significant response was observed. In control groups report of endoscopy, only one patient

showed complete healing, while no significant change was observe in remaining [Figure 2.]. The two groups were compared using chi-square (χ^2) test with Yate correction and was found that the test group showed significantly (p<0.0196) better cured when compared with the control in respect to the healing of ulcer. This result concurs with the effect of *Ayarij Faiqura* that contains copious herbs with potent medicinal properties like *Mudammile Qurooh*, *Mujafife Qurooh*, *Mohallil*, *Dafe ufoonat*, *Jaali*, *jazib* such as *Sibr*, *Darcheeni*, *Asaarun*, *Balchhar*, *Mustagee* as described by Unani scholars.^{7,8,10, 11} During the course of the trial some patients complained of burning in anus while passing stools and one patient complained of mild per rectal bleeding. The patient who complained of per rectal bleeding was excluded from the trial. About *Ayarij Faiqura* Ibn Sina had stated that some time patients complain of per rectal bleeding and burning in anus due to *sehaj amaa* because of its *mushil* effect. He advocated adding *Izkhar* and *Vard* for preventing this adverse effect of *Ayarij Faiqura*. We have taken formula of *Ayarij Faiqura* from National Formulary of Unani Medicine. The safety parameters assessed for patients were Hb%, TLC, Blood urea, Serum creatinine, SGOT, SGPT, ESR, FBS and S Bilirubin. The data was analyzed using paired t test. There was no significant difference (p>0.05) between pre and post treatment for each safety parameters.

Conclusion:

Qarahe Hazmiya is one of the commonest diseases affecting the Oesophageo- gastrodeudenal tract. This is more common in south India. Patients of *Qarahe Hazmiya* have the complain of discomfort due to pain in abdomen, belching, bloating, burning sensation. Males are more affected than females due to use of beverage, smoking, alcohol and spicy food, and *Helicobacter pylori* and *Khilt lazze*. The overall result of test drug was found quit encouraging in the treatment of *Qarahe Hazmiya*. Significant improvement was observed in burning sensation of abdomen, pain in abdomen and on objective parameter i.e. endoscopy results revealed good effect in healing of ulcer or erosion. The result is $\chi^2=p<0.019$. No adverse effect was observed in the test group and overall observance to the treatment was found admirable.

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Conflict of Interest: NIL

Table No-1: The demographic characteristics of all the two groups are shown in below:

S.No	Content	No. of Patients
1	Age	40.57±6.85
2	Sex-M/F	23/5
3	Dietary Habits-Mixed/ Vegetarian	22/6
4	History of NSAIDs-Present/ Absent	26/2

Table No-2: Effect of test drug on Burning Sensation and Abdominal Pain

Subjective Parameters	Groups	0 day	15 th day	30 th day	45 th day
Burning sensation	Control (Pantoparazole)	8[8,8]	5[5,8]	5[2,5]*	3[2,5]*
	Test (Ayarij Faiqura)	8[7,8]	5[4,5]+	3[0,4]+	0[0,3]+,* Δ
Abdominal pain	Control (Pantoparazole)	8[5,8]	5[5,8]	5[3,5]*	3[1,5]*
	Test (Ayarij Faiqura)	8[7,8]	5[4,5]	3[0,4]*,+	0[0,3]+,* Δ

Comparison and Kurshkall wallis for intergroup

comparison

□ *p < 0.01 with respect to control 0 day

□ +p < 0.01 with respect to test 0 day

□ Δ p < 0.01 with respect to control on 45th day

Test used Friedman test with Dunn'' pair

comparison test for intra group

Comparison and Kurshkall wallis for intergroup

comparison

□ *p < 0.01 with respect to control 0 day

□ +p < 0.01 with respect to test 0 day Δ p < 0.01 with

respect to control on 45th day

Table No-3: Effect on Gastroduodenal ulcer / Erosion by Endoscopic report:

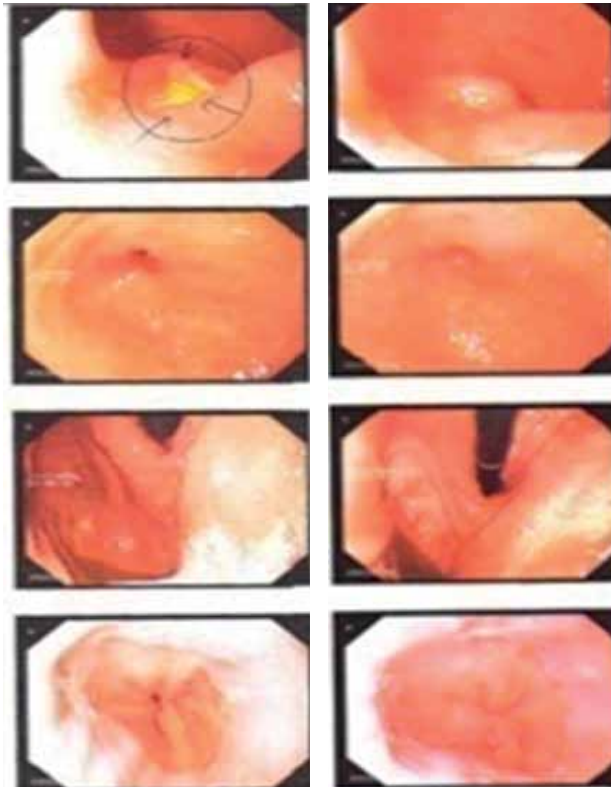
Group	No. of patients with ulcer / Erosion	Cured	Not Cured
Control (Pantoparazole)	8	1	7
Test (Ayarij Faiqura)	20	14	6

Test used χ^2 with Yate Correction with P < 0.0196.

Case -01 (Test Group)

Before Treatment

After treatment



Case -02 (Test Group)

Before Treatment

After treatment

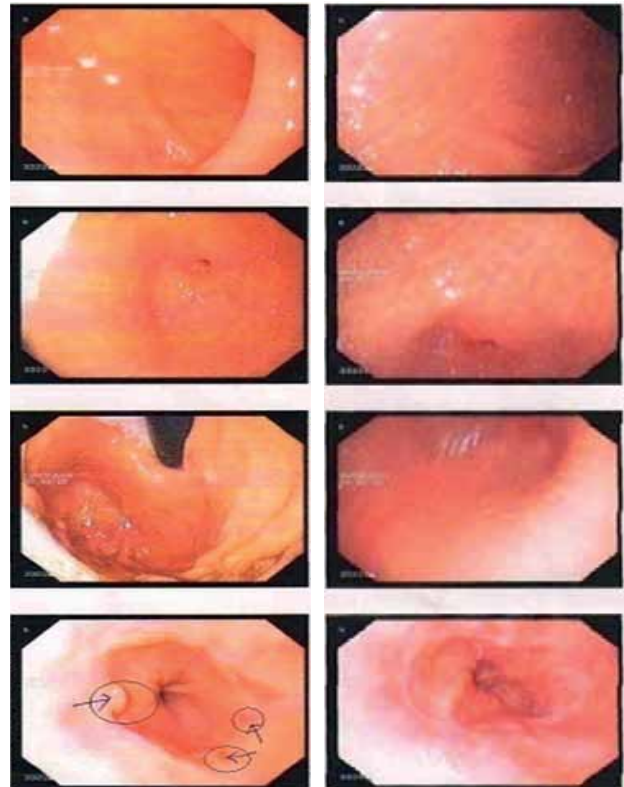
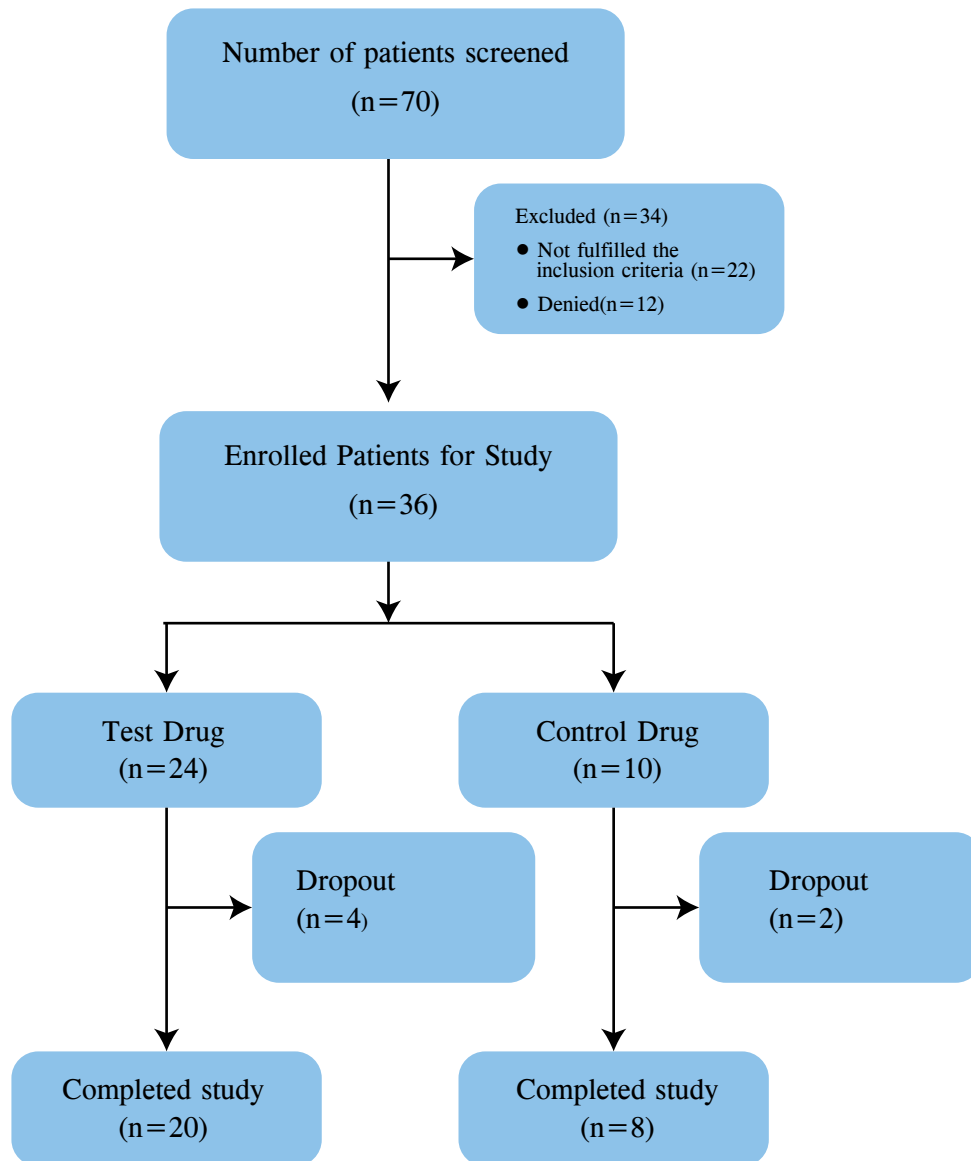


Figure No. 1: Flow diagram of the study



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