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COMPARATIVE CLINICAL STUDY FOR THE MANAGEMENT OF YAKRITDALYUDAR W.S.R. TO ALCOHOLIC STEATOSIS

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ABSTRACT

In today's life, there is great change in the socio-economical conditions, life style, ethical values in the society but this has leads to many health hazards. Addictions to alcohol have also increases in the present population. Chronic alcoholic addiction causes serious effect on the organ liver leading to Alcoholic Steatosis which may turn into alcoholic cirrhosis related Ascites. In *ayurveda, Yakritdalyudar* is one among the eight types of *udara roga* where there is direct involvement of the organ has been mentioned. *When Yakritdalyudar* not treated properly it culminates into *Jalodara* (Ascites). A pilot study was conducted for 30 days to kow the effect of *Rohitakadya churna, Punarnavasava,* Sylimarin in the management of Yakritdalyudar W.S.R. to Alcoholic Steatosis. Comparative effects of therapies reveal that Control drug Sylimarin is more effective than Trial Drug *Rohitakadya churna* and Trial Drug *Punarnavasava with Rohitakadya churna*, whereas Trial Drug *Punarnavasava with Rohitakadya churna* is more effective than Trial Drug *Rohitakadya churna.*

KEYWORDS: *Yakritdalyudar, Punarnavasava, Rohitakadya churna, Sylimarin*

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INTRODUCTION

In today's life, there is great change in the socio-economical conditions, life style, ethical values in the society but this has leads to many health hazards. Addictions to alcohol have also increases in the present population. Chronic alcoholic addiction causes serious effect on liver leading to Alcoholic Liver Disorder (ALD). It is very common global problem and is one of the major medical complications of alcohol abuse related to morbidity and mortality.

ALD has three stages. Alcohol-related fatty liver disease (Alcoholic Steatosis / fatty infiltration) usually comes first, most common response of the liver to moderate or large doses (i.e. binge drinking) of alcohol as well as to chronic ethanol consumption. It can then get worse and become alcoholic hepatitis. Over time, it may turn into alcoholic cirrhosis which is a leading cause of death. Thus the range of clinical features of alcoholic liver disease varies, from asymptomatic to end-stage liver disease with portal hypertension, jaundice and encephalopathy. Hospitalized patients usually have jaundice and hepatomegaly and may exhibit ascites, encephalopathy and fever depending on the severity of their disease[1].

In Ayurvedic classics the effect of excessive intake of alcohol have described under the chapter *Madatyaya*. Depending on the use of alcohol its toxic effects occurs. The clinical features like yellow colouration of the eyes *(pitta nayana),* pain in right hypochondric region (*Parshvashula)* indicates the involvement of liver. These symptoms also found in aggravated stages of Alcoholic Steatosis. In *Samhita* we can also see the description of *Kamala, Udara* which can be the sequele of Alcoholic Steatosis. *Madya* (alcohol) is a leading cause of Pandu *(Pandu Nidana[2],[3]).* When *Pandu* is not treated properly it can lead to *Kamala[4].* According to clinical features like Liver enlargement *(Yakritbhivridhi),* Pain abdomen *(Sidati),* Decreased appetite (*Manda agni*), Fever (*Manda Jwara*), Jaundice (*kapha-pittalingairupadruta*), General weakness (*Ksheenabala*), Anaemia (Atipandu), etc found in Alcoholic Steatosis, we can correlate it with *Yakritdalyudar*[5,6].

As per *Ayurveda*, distension of abdomen *(Udara vriddhi)* by the functional derangement of liver *(Yakrita-Pradusti)* is known as *Yakritdalyudara.* It is one among the eight types of *Udara* where there is direct involvement of the organ has been mentioned, etiopathogenesis of *yakritodara* and *plihodara* are similar except the anatomical location[7].

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When Yakritdalyudar not treated properly it culminates into *Jalodara as all Udara rogas* converts to *Jalodara if* not treated properly where symptoms of *Jatodakavastha* found.

The prevailing situation calls for revalidation of Ayurvedic formulations. As per *ayurveda Nidana Parivarjana* is the first line of treatment for all type of diseases. So in *Yakritdalyudara* caused by *Madyapana,* complete abstinence from the alcohol is the first line of treatment. Several drugs have been described in *Samhita*s as single / compound Drugs. In *Bhaisajya Ratnavali* there is elaboration of *Rohitakadya churna*[8] and *Punarnavasava*[9] for disorders of Yakritdalyudar which is considered here for trial. *Rohitakadya churna* having therapeutic Usages of *Yakrit Roga* whereas *Punarnavasava* having therapeutic Usages of *Amlapitta, Gulma, Udara, Sotha, Pliha, Yakritroga, Sarva Krichhrasadhya Roga*.

Composition of *Rohitakadya Churna*[10] *is Rohitaka* (1 part), *Yavakshara* (1 part), *Bhunimba* (1 part), *Kutaki* (1 part), *Nagaramotha* (1 part), *Navasadara* (1 part), *Atisa* (1 part), *Sunthi* (1 part). Composition of *Punarnavasava*[11] is *Sunthi* (48gm), *Maricha* (48gm), *Pippali* (48gm), *Haritaki* (48gm), *Bibhitaki* (48gm), *Amalaki* (48gm), *Daruharidra* (48gm), *Gokshura* (48gm), *Brihati* (48gm), *Kantakari* (48gm), *Vasamula* (48gm), *Erandamula* (48gm), *Katuki* (48gm), *Gajapippali* (48gm), *Punarnava* (48gm), *Nimbi* (48gm), *Guduchi* (48gm), *Mulaka* (48gm), *Duralabha* (48gm), *Patola* (48gm), *Dhataki* (768gm), *Draksha* (960gm), *Sita/Misri* (4.800 kg), *Madhu* (2.400 kg).

Various researches[12],[13], carried out on individual drugs have shown that most of the constituent have Hepatoprotective[14],[15], Antihepatotoxic[16],[17], Antioxidant[18], Hypolipidaemic[19], Free Radical Scavenging activity, Hypoglycemic, Hypotensive[20], Choleretic, Diuretic and Hepato Curative effects[21], reduce fatty liver[22],[23] etc. The ingredients of trial drugs show most of ingredients having *Katu, Tikta, Kashaya-Rasa, Laghu, Rooksha-Guna and Katu Vipaka, Ushna-Virya*. These are said to be *Kaphagna, Raktashodhak, Shothahar, Mutral, Anuloman.*

The control drug Sylimarin (140 mg), a well known medicine for liver disorder, considered here for comparison.

Aim and Objectives

This study aims to evaluate the therapeutic efficacy of ***Rohitakadya churna* alone *and with Punarnavasava*** in the management of ***Yakritdalyudar* W.S.R. to Alcoholic Steatosis** and compare this effect with the control drug Sylimarin. The Clinical trial carried out in the P.G. Dept. Of Kayachikitsa, VYDSAM, Khurja (UP).

Material & Methods:-

→ **Study Type -** Randomized open clinical study.

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→ **Sample size** - 45

→ **Plan of study** - The study was carried out for a period of 30 days. Out of the resembling cases of *Yakritdalyudar* W.S.R. to Alcoholic Steatosis, 45 cases were selected according to the selection criteria. They were divided into three groups, In Trial group I (TGI) 15 cases were administered with the trial drug *Rohitakadya churna* (3 Gms with water) twice a day after food. In Trial group II (TGII) 15 cases were administered with the trial drug *Rohitakadya churna* (3 Gms) *with Punarnavasava* (20ml with equal water) twice a day after food. In Control group (CG) 15 cases were administered Tab Sylimarin 140 mg thrice daily after food as a control drug.

→ **Study design**

- ✓ TGI (BT) vs. TGI (AT) - Effectiveness of treatment group - I will be assessed
- ✓ TGII (BT) vs. TGII (AT) - Effectiveness of treatment group - II will be assessed
- ✓ CG (BT) vs. CG (AT) - Effectiveness of Control group will be assessed
- ✓ Comparison of effectiveness among of TGI, TGII and CG done through ANOVA.

→ **Inclusion criteria** - Both male and female patients aged 20 yrs to 70 yrs having classical features of *Yakritdalyudar* W.S.R. to Alcoholic Steatosis were selected for study. The statistical data obtained based on the following subjective and objective parameters.

- ✓ *Sidati* (Pain abdomen)
- ✓ *Agnimandya* (Decreased appetite)
- ✓ *Ksheena bala* (General weakness)
- ✓ *Yakrit vridhi* (Liver enlargement)
- ✓ Elevated SGPT, SGOT
- ✓ USG findings shows Fatty changes in the liver

→ **Exclusion criteria**

- ✓ Patients age below 20 or above 70 years
- ✓ Elevated SGPT or SGOT above 200 units/lit
- ✓ Severe abdominal pain
- ✓ Other possibility of hepatomegaly like viral hepatitis, surgical jaundice etc.
- ✓ Patients with complications like hepatic encephalopathy, coma, variceal bleeding, cirrhosis
- ✓ Patients of diabetes mellitus, hypertension, Ischemic heart disease, chronic renal failure, lung diseases, myxodema, nephritic syndrome, Hepatocelluler or

any other carcinoma, Tuberculosis, STD, sickle cell disease, portal vein obstruction, biliary obstruction, Ascites or any other condition which the Principal Investigator thinks may jeopardize the study.

- ✓ Yakritdalyudara / Alcoholic Steatosis disease in pregnancy.
- ✓ Drug addicts rapid deterioration, who lapsed into coma and bleeding tendencies.

Observations

→ Various demographic parameters viz Age, Sex etc. were analysed in the present trial.

→ **Assessment –** The assessment was done on subjective and objective parameters. The obtained results were analyzed with the use of Wilcoxon signed rank method to check the significance of subjective parameters and Paired 't' test for objective parameters. ANOVA for comparison also implemented.

❖ **Scoring adopted for assessment**

✓ **Sidati (Pain abdomen)**

- Grade 0 - Absence of pain abdomen (No pain)
- Grade 1 – Mild pain present but doesn't disturbs
- Grade 2 - Moderate pain present that disturbs occasionally
- Grade 3 - Moderate pain present that disturbs whole day

✓ **Agnimandya (Decreased appetite)**

- Grade 0 – Normal Digestion
- Grade 1 – Occasionally digestion delays for Guru Aahara but not for Laghu ahara
- Grade 2 – Continuously digestion delays for Guru Aahara but not for Laghu ahara
- Grade 3 - Continuously digestion delays for Laghu ahara also.

✓ **Ksheena bala (General weakness)**

- Grade 0 - No weakness.
- Grade 1 - Weakness but performs day to day activities.
- Grade 2 - Weakness and difficulty in performing day-to-day activities.
- Grade 3 - Cannot able to get up from the bed.

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- ✓ **Yakrit vridhi (Liver enlargement by palpation method)**
  - Grade 0 - Not palpable
  - Grade 1 – Upto 1cm below the right costal margin
  - Grade 2 - 1-2cm. below the right costal margin
  - Grade 3 - >2cm. below the right costal margin
- ✓ **S.G.O.T.**
  - Grade 0 - 5-40 units/lit (Normal)
  - Grade 1 – 41-75 units/lit
  - Grade 2 - 76 -150 units/lit
  - Grade 3 - 150 – 200 units/lit
- ✓ **S.G.P.T.**
  - Grade 0 - 7-56 units/lit (Normal)
  - Grade 1 – 57-100 units/lit
  - Grade 2 - 100 -150 units/lit
  - Grade 3 - 150 – 200 units/lit
- ✓ **USG findings on Fatty changes in the liver**
  - Grade 0 - Normal
  - Grade 1 - When the echogenicity is just increased
  - Grade 2 - When the echogenic liver obscures the echogenic walls of portal vein branches
  - Grade 3 - When the echogenic liver obscures the diaphragmatic outline

❖ **Assessment on results -** The clinical assessment of results will be noted after treatment upon the cardinal Clinical features of subjective and objective parameters. The result in view of percentage of improvement will classify as follows.

1. Maximum improvement - > 75% improvement
2. Moderate improvement - > 50% to 75% improvement
3. Mild improvement - > 25% to 50% improvement
4. Unsatisfactory - Negligible (≤ 25%) improvement

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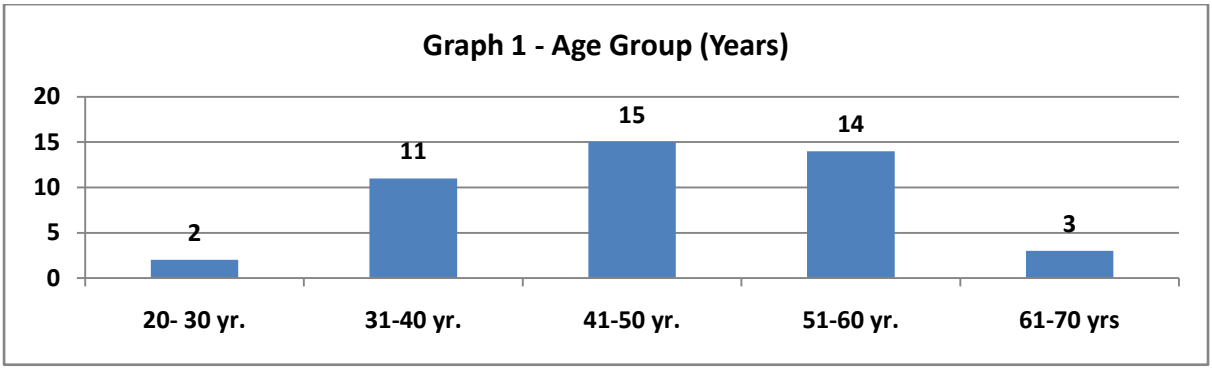
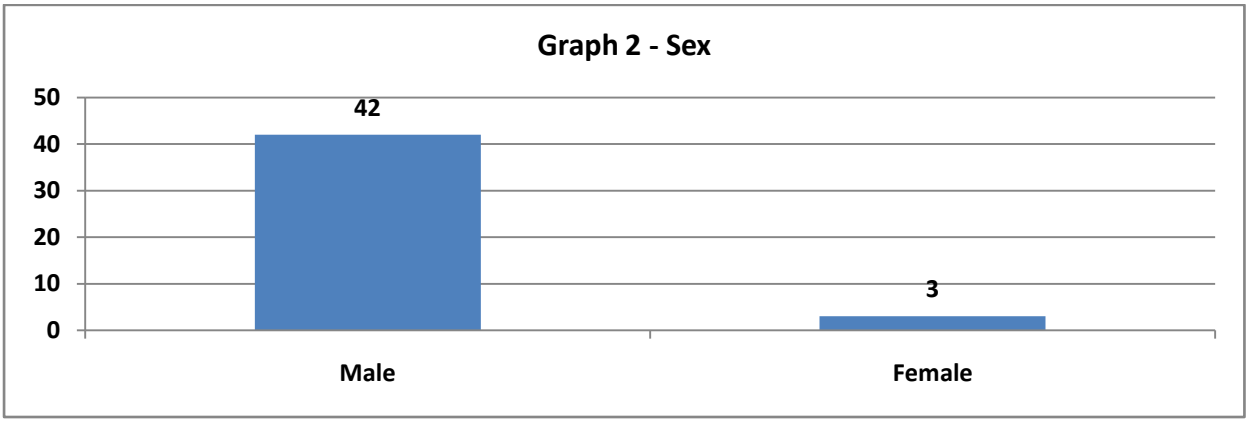
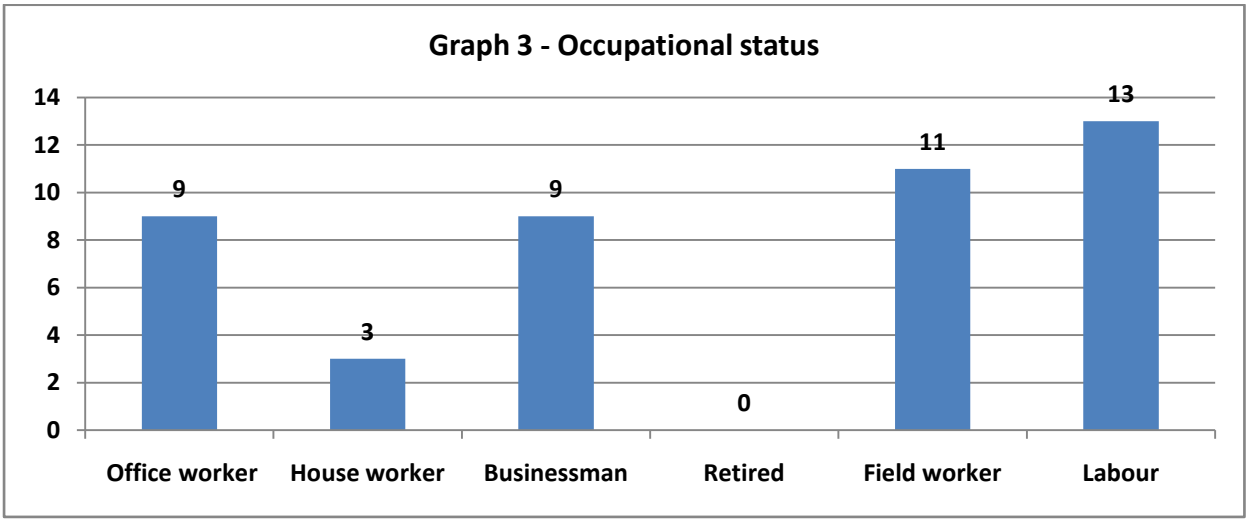
→ **Observations on Demographic data**







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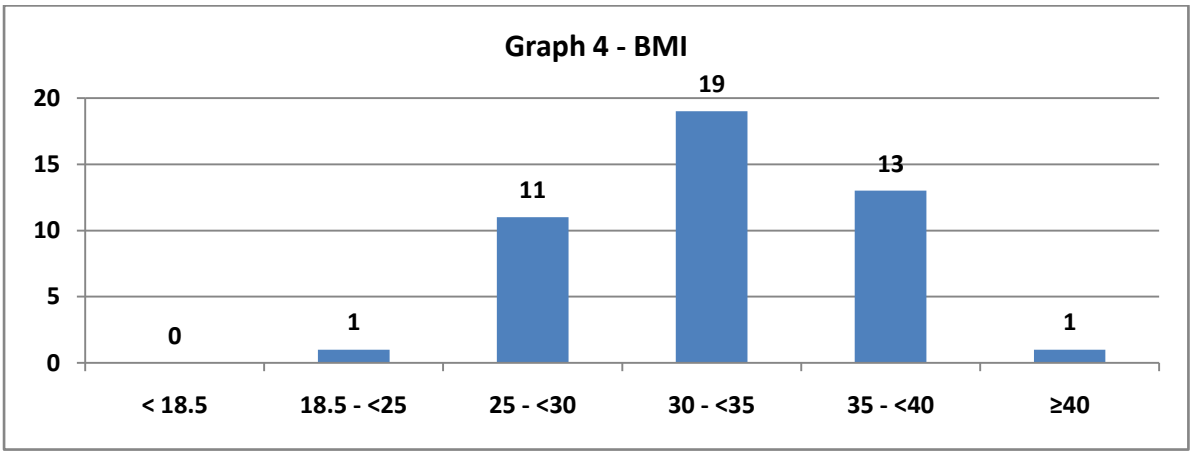

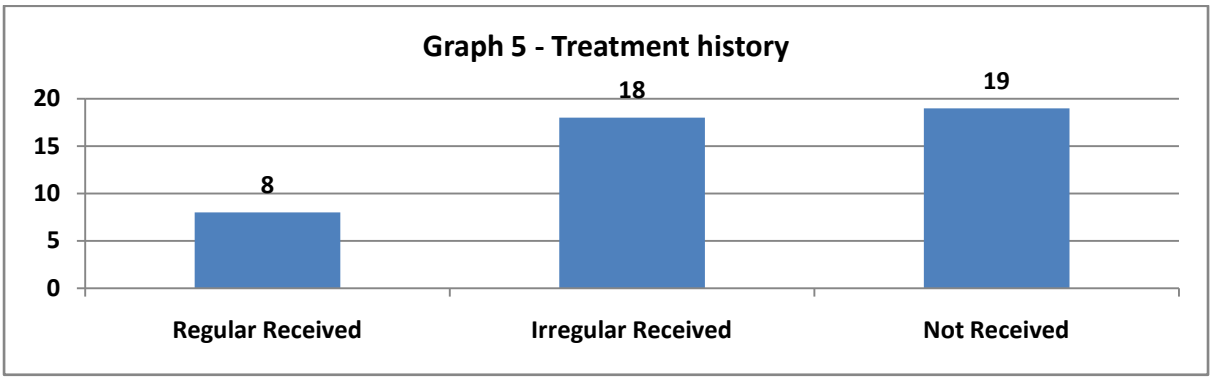

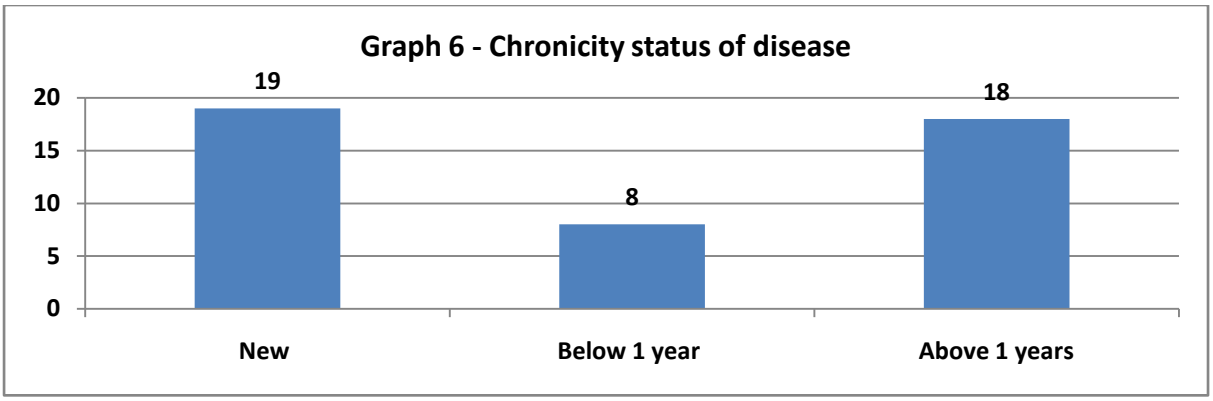

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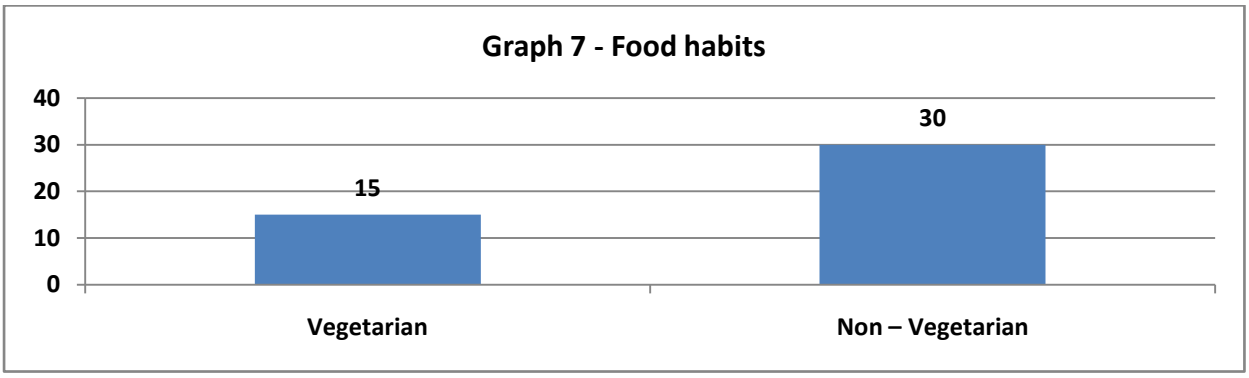
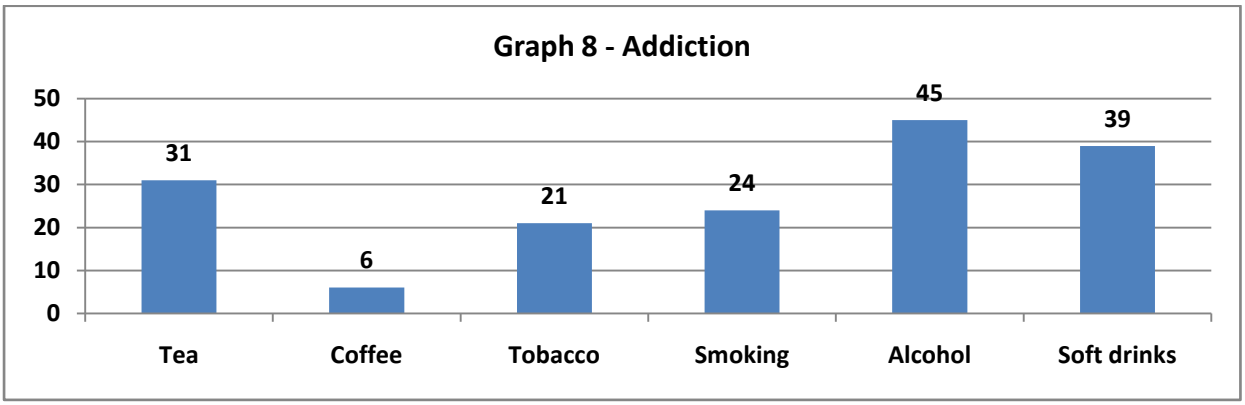
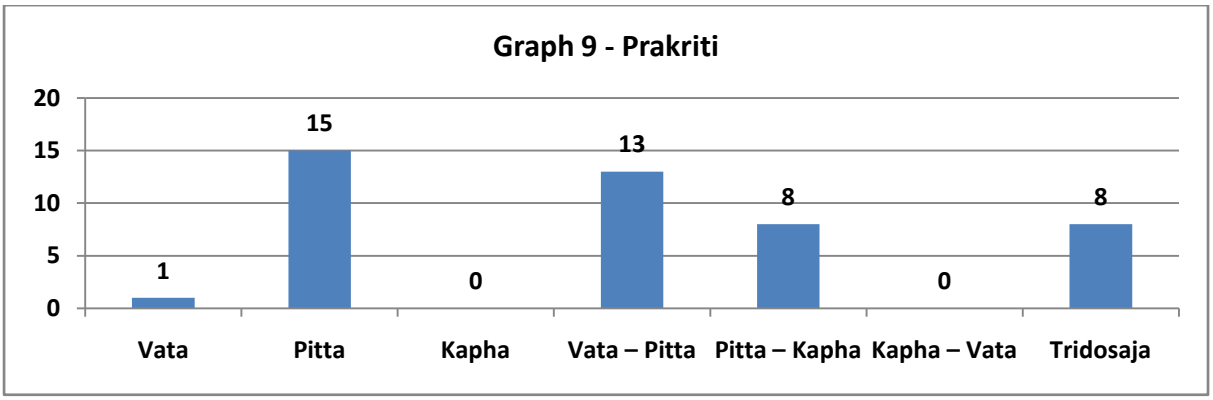
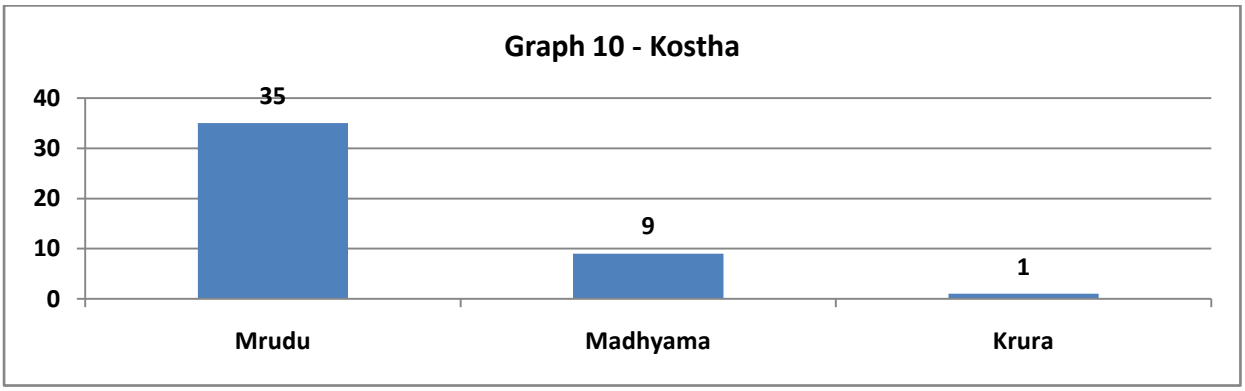
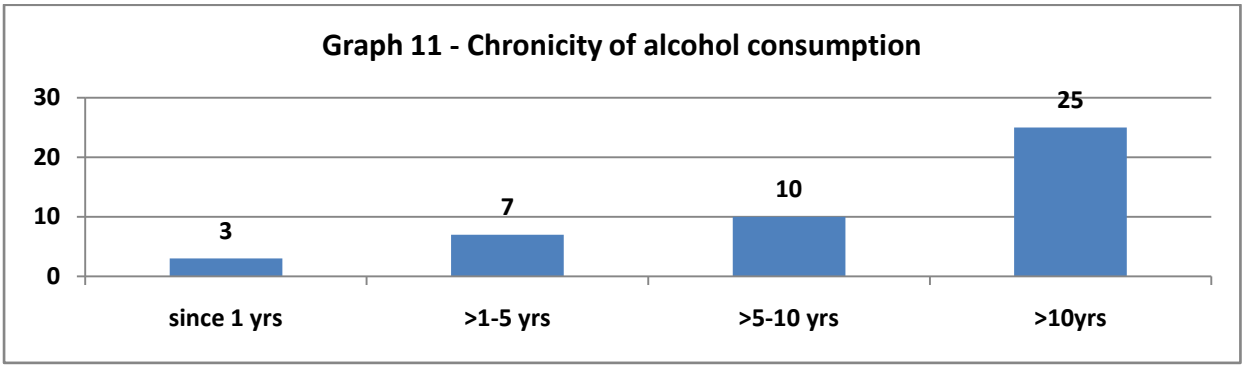
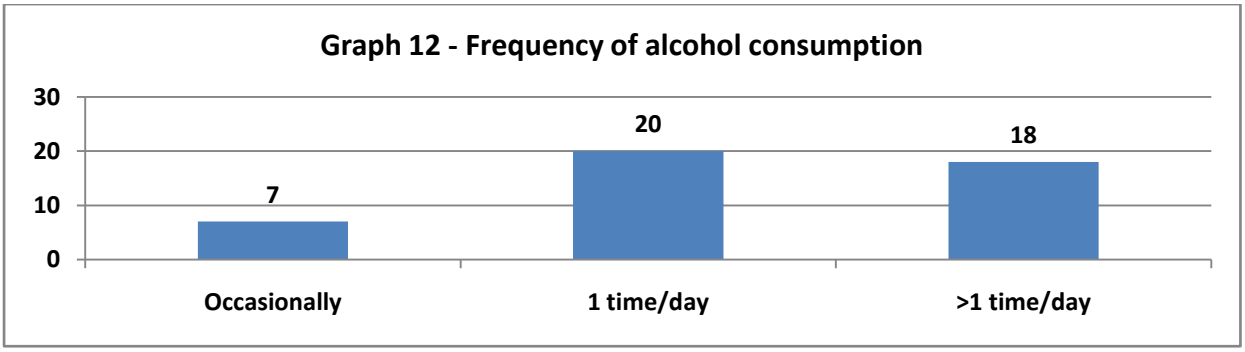


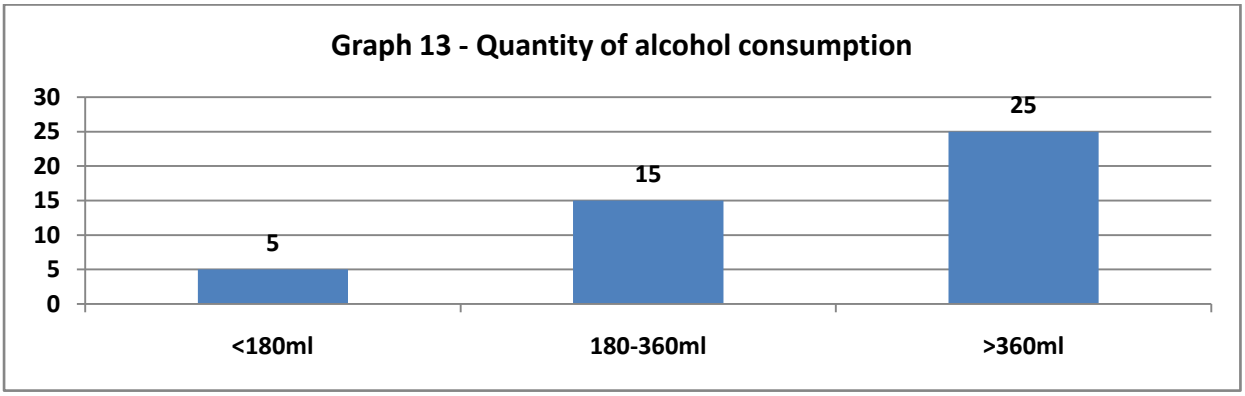





Graph 10 - Kostha
40
30
20
10
0
35
9
1
Mrudu
Madhyama
Krura


Graph 11 - Chronicity of alcohol consumption
30
20
10
0
3
7
10
25
since 1 yrs
>1-5 yrs
>5-10 yrs
>10yrs


Graph 12 - Frequency of alcohol consumption
30
20
10
0
7
20
18
Occasionally
1 time/day
>1 time/day


Graph 13 - Quantity of alcohol consumption
30
25
20
15
10
5
0
5
15
25
<180ml
180-360ml
>360ml

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→ **Observation on statistical data**

Table 1 - Statistical analysis showing the effectiveness of medicine in TG I, TG II and C.G.

Subjective parameters									
Parameters		Mean Score		Mean diff.	± S.D.	± S.E.	w– Value	p - Value	Remark
		B.T.	A.T.						
Sidati (Pain abdomen)	TGI	2.33	1.11	1.22	0.44	0.15	45	0.0039	V.S.
	TGII	2.44	1.00	1.44	0.53	0.18	45	0.0039	V.S.
	C.G.	1.75	0.63	1.13	0.35	0.13	36	0.0078	V.S.
Agnimandya (Decreased appetite)	TGI	2.40	1.10	1.30	0.48	0.15	55	0.002	V.S.
	TGII	2.27	0.93	1.33	0.62	0.16	120	< 0.0001	E.S.
	C.G.	2.23	0.85	1.39	0.51	0.14	91	0.0002	E.S.
Ksheena bala (General weakness)	TGI	1.88	1.13	0.75	0.46	0.16	21	0.0313	S
	TGII	1.89	1.00	0.89	1.05	0.35	15	0.0625	N.Q.S.
	C.G.	1.91	0.73	1.18	0.75	0.23	45	0.0039	V.S.
Yakrit vridhi (Liver enlargement)	TGI	2.47	1.27	1.20	0.68	0.17	91	0.0002	E.S.
	TGII	2.40	1.20	1.20	0.41	0.11	120	< 0.0001	E.S.
	C.G.	2.20	1.00	1.20	0.41	0.11	120	< 0.0001	E.S.
Objective parameters									
Parameters		Mean Score		Mean diff.	± S.D.	± S.E.	t– Value	p - Value	Remark
		B.T.	A.T.						
SGOT	TGI	74.53	42.60	31.93	8.34	2.15	14.836	< 0.0001	E.S.
	TGII	73.60	37.27	36.33	11.59	2.99	12.145	< 0.0001	E.S.
	C.G.	84.20	32.87	51.33	11.68	3.02	17.024	< 0.0001	E.S.
SGPT	TGI	72.93	48.93	24.00	11.69	3.02	7.954	< 0.0001	E.S.
	TGII	78.27	45.20	33.07	12.56	3.24	10.2	< 0.0001	E.S.
	C.G.	79.87	43.40	36.47	9.88	2.55	14.289	< 0.0001	E.S.
USG findings on Fatty changes in the liver	TGI	1.67	0.87	0.80	0.77	0.20	4	< 0.0001	E.S.
	TGII	2.20	0.93	1.27	0.46	0.12	120	< 0.0001	E.S.
	C.G.	2.27	0.93	1.33	0.62	0.16	120	< 0.0001	E.S.

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Table 2 - Percentage (%) of improvement in individual parameters of each group

Subjective & Objective parameters	TG I	TG II	C.G.
Sidati (Pain abdomen)	52.38 %	59.08 %	64.29 %
Agnimandya (Decreased appetite)	54.17 %	58.80 %	62.08 %
Ksheena bala (General weakness)	40.00 %	47.06 %	61.92 %
Yakrit vridhi (Liver enlargement)	48.64 %	50.00 %	54.55 %
SGOT	42.84 %	49.37 %	60.97 %
SGPT	32.91 %	42.25 %	45.66 %
USG findings on Fatty changes in the liver	47.99 %	57.59 %	58.80 %

Table 3 - Comparison of effects on different subjective parameters (ANOVA)

Subjective & Objective parameters	Group	Mean Rank Difference	Remark	P Value
Sidati (Pain abdomen)	TG I vs. TG II	-2.889	Ns	P>0.05
	TG I vs. C.G.	1.264	Ns	P>0.05
	T.G. II vs. C.G.	4.153	Ns	P>0.05
Agnimandya (Decreased appetite)	T.G. I vs. T.G. II	0.2167	Ns	P>0.05
	T.G. I vs. C.G.	-1.565	Ns	P>0.05
	T.G. II vs. C.G.	-1.782	Ns	P>0.05
Ksheena bala (General weakness)	T.G. I vs. T.G. II	-0.3056	Ns	P>0.05
	T.G. I vs. C.G.	-4.205	Ns	P>0.05
	T.G. II vs. C.G.	-3.899	Ns	P>0.05
Yakrit vridhi (Liver enlargement)	T.G. I vs. T.G. II	0.6	Ns	P>0.05
	T.G. I vs. C.G.	0.6	Ns	P>0.05
	T.G. II vs. C.G.	0	Ns	P>0.05
SGOT	T.G. I vs. T.G. II	-4.4	Ns	P>0.05
	T.G. I vs. C.G.	-19.4	E.S.	P<0.001
	T.G. II vs. C.G.	-15	V.S.	P<0.01
SGPT	T.G. I vs. T.G. II	-9.067	Ns	P>0.05
	T.G. I vs. C.G.	-12.467	S	P<0.05
	T.G. II vs. C.G.	-3.4	Ns	P>0.05
USG findings on Fatty changes in the liver	T.G. I vs. T.G. II	-0.4667	Ns	P>0.05
	T.G. I vs. C.G.	-0.5333	Ns	P>0.05
	T.G. II vs. C.G.	-0.06667	Ns	P>0.05

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→ **Observation on Clinical result**

Table 4 - Showing the Clinical assessment of Result after treatment

Clinical assessment	T.G. I		T.G. II		C.G.	
	Total no. of patients	Percentage (%)	Total no. of patients	Percentage (%)	Total no. of patients	Percentage (%)
Maximum improvement / Cured	0	0	0	0	0	0
Moderate improvement	0	0	5	33.33%	6	40%
Mild improvement	14	93.33%	10	66.67%	9	60%
Unsatisfactory	1	6.67%	0	0%	0	0

Discussion

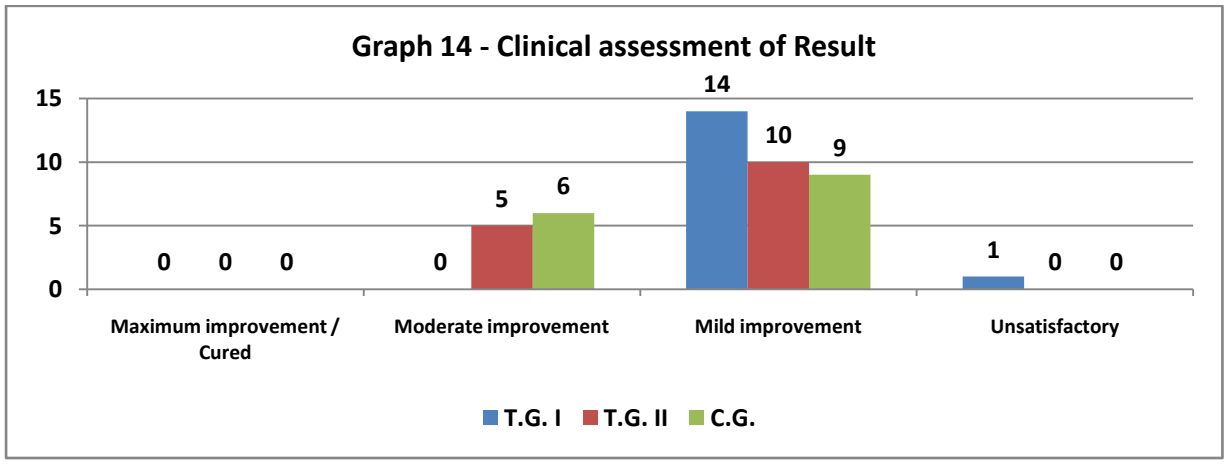
Among various drugs described in *Ayurveda,* the drugs which are mentioned as *Yakrututtejaka, Pitta Saraka, Pleehagna or Yakritaghna* etc are useful in *Yakritdalyudara* disease to bring back the liver to the normal condition. In *Bhaisajya Ratnavali* there is elaboration of *Rohitakadya churna and Punarnavasava* for disorders of *Pleehayakrit Vikara* which was taken for trail. Most of these drugs are having *Katu, Tikta, Kashaya-Rasa, Laghu, Rooksha-Guna* and *Katu Vipaka, Ushna-Virya.* These are said to be *Kaphagna, Raktashodhak, Shothahar, Mutral*, *Anuloman*. On the basis of their pharmacodynamics it can be proposed that all drugs used in the preparation of compound are mostly *Kaphapitta Shamaka* in property. The control drug Sylimarin is also a known medicine for liver disorder, hence chosen for comparison.

In this study the demographic data reveals that Highest number of patients i.e. 33.34% were between age group of 41-50 years, Maximum i.e. 93.33% of patients were male, Highest number of patients i.e. 28.89% were Labour, Maximum i.e. 42.23% of patients were in 30 - <35 BMI, Most of the patients i.e. 42.22% were not received any treatment, Maximum i.e. 42.22 % of the patients were newly diagnosed, Maximum i.e. 66.67% of the patients were Non-Vegetarian, All i.e. 100% were addicted to alcohol, Maximum patients i.e. 33.33% were of *Pittaja Prakriti*, Most of the Patients i.e. 77.78% were of *mrudu kostha*, Maximum of the patients i.e. 55.56% were consuming alcohol since >10yrs, Most of the

patients i.e. 44.44% were consuming alcohol 1 time/day, Most of the patients i.e. 55.56% were consuming alcohol >360 ml per day.

The Clinical data reveals that the Percentage (%) of improvement in TG I in *Sidati* (Pain abdomen) 52.38 %, *Agnimandya* (Decreased appetite) 54.17 %, *Ksheena bala* (General weakness) 40.00 %, *Yakrit vridhi* (Liver enlargement) 48.64 %, SGOT 42.84 %, SGPT 32.91 % and USG findings 47.99 %, whereas the Percentage (%) of improvement in TG II in *Sidati* (Pain abdomen) 59.08 %, *Agnimandya* (Decreased appetite) 58.80 %, *Ksheena bala* (General weakness) 47.06 %, *Yakrit vridhi* (Liver enlargement) 50.00 %, SGOT 49.37 %, SGPT 42.25 % and USG findings 57.59 % and the Percentage (%) of improvement in C.G. in *Sidati* (Pain abdomen) 64.29 %, *Agnimandya* (Decreased appetite) 62.08 %, *Ksheena bala* (General weakness) 61.92 %, *Yakrit vridhi* (Liver enlargement) 54.55 %, SGOT 60.97 %, SGPT 45.66 % and USG findings 58.80 %. Statistical analysis also shows maximum were very/ extremely significant.

The clinical result reveals that all the drugs derived improvement leading to Maximum, Moderate, Mild and Unsatisfactory having 0%, 0%, 93.33%, 6.67% by TGI, 0 %, 33.33%, 66.67%, 0 % by TGII and 0 %, 40%, 60%, 0 % by C.G. respectively. Thus all the therapies proved to be effective in combating the disease *Yakritdalyudar* W.S.R. to Alcoholic Steatosis.



The Comparative effects of therapies reveals that in most of the symptoms C.G. (Sylimarin) is more effective than Trial Drug I (Rohitakadya churna) and Trial Drug II *(Rohitakadya churna* and *Punarnavasava*), whereas Trial Drug II *(Rohitakadya churna and Punarnavasava)* is more effective than Trial Drug I (*Rohitakadya churna)*. Unsatisfactory

benefit itself a guarantee against effectiveness of the drug that has been reflected as zero (0%) with the Trial Drug II and C.G. which highlights the effectiveness of these drug whereas it was present as 6.67% in Trial Drug I.

Conclusion

Results of this study indicate that, the efficacy of all the trial drugs found capable to enforce relief as a statistically significance response was obtained after the therapy in maximum symptoms and at the end of the study none of the case remained unchanged, but it is more in Sylimarin. In this trial none of the cases got 100 % result i.e. Cured among all groups, this may be due to the time boundation and the small sample size. As Yakritdalyudar W.S.R. to Alcoholic Steatosis is a chronic disorder, so it requires further large scale study and more time period to obtain more impressive results.

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