

# EFFECT OF GASTRO-HEPATIC PACK AS AN ADJUVANT TO NATUROPATHY AND YOGA INTERVENTIONS IN PATIENTS WITH ALCOHOL DEPENDENCE

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**Abstract:** Gastro-hepatic (GH) pack is one of the naturopathic treatment modality where hot fermentation bag is kept on abdomen and cold ice bag at lower back and then cotton and woollen sheets are wrapped. This study aims to evaluate the effect of Naturopathy and yoga with GH pack on liver profile, withdrawal symptoms and quality of life in alcohol dependence patients. 66 male volunteers were recruited for the study. 33 out of 66 subjects were given GH pack and naturopathy and yoga intervention daily and other 33 subjects had only naturopathy and yoga treatment for 10days. Assessments were done on first day and 10<sup>th</sup> day of treatment. Data were checked for normal distribution and analysed by using Wilcoxon signed rank test and Mann Whitney 'u' test with SPSS (Version 23.0) package. The results of study showed significant improvement in liver profile, quality of life in case group comparatively. Hence the application of GH pack along with naturopathy treatment can be used for alcohol dependence.

**Index Terms:** Gastro hepatic pack, Alcohol dependence, Naturopathy, Quality of life

## INTRODUCTION

Alcohol related liver disease is oldest known liver disease to mankind which varies from fatty liver to cirrhosis of liver.[1] Small or moderate intake of alcohol had shown no clinical evidence, but excessive intake can lead to development of physical tolerance and withdrawal symptoms because of this reason it is difficult to diagnosis alcohol dependence early. One can have burden on physical, mental and social well-being of person due to alcohol abuse. [2] Person may involve in social misbehaviour, domestic violence such as fight, loss of assets, unemployment, arrests, injuries due to traffic accidents, and lost productivity. On physical level there could be cirrhosis of liver, chronic pancreatitis.[3-8] and psychological impairment like stress, delirium, hallucination and emotional imbalance and suicidal idea. [9] It can also alters the neurochemical process of the brain. [10] Excessive drinking for prolonged period of time can lead to serious problems with memory and cognition. [11]

Worldwide health outcome such as life expectancy, patient satisfaction and quality of life had steadily improved over recent decades which is mainly attributed to the use of conventional medicine(CM), but there are still unfulfilled health expectation and most of them with regards to maintaining wellness.[12] Many of the patients supplement their health with complementary and alternative medicine (CAM) because of many reasons like cure illness [13], counteract adverse effects of CM [14], cost-effective and even to promote wellness and holistic care. [15, 16]

Naturopathy is one of the unique systems of the health care system in which it is not limited to a single modality of healing and it cannot be identified with only one therapeutic approach. It is incorporated with many complementary medical approaches to treatment. It has all drugless and non- invasive treatment modalities like clinical nutrition, hydrotherapy, naturopathic manipulation, traditional Chinese medicine/ acupuncture and preventive and lifestyle counselling. [17] Here practitioners combine the art as well as science of medicine, using traditional forms of healing with modern scientific knowledge to treat and prevent the illness. [18] Gastro-hepatic (GH) pack is one of the treatment modalities in hydrotherapy which uses a combination of both hot and cold treatment modalities which have opposite effects on tissue metabolism, blood flow, inflammation, and edema. [19]

## METHODOLOGY

**Participants:** The study population was recruited from Shantivana Yoga and Nature Cure hospital Dharmasthala, Dakshina Kannada, Karnataka. 150 subjects screened through medical consultation and those satisfying the inclusion criteria had been recruited for the study. Recruitment of the subjects were done in a prospective manner and selected subjects were randomly allocated into two groups using computer generated randomizer. A signed informed consent in English/kannada language was obtained from each individual. Institutional Ethical Committee approved the study.

**Inclusion criteria:** Age: 23-65 years,[20] Intake of alcohol from minimum 1 year [20], Intake of spirits and beer, only males, [21] Intake of alcohol should be >60 gram/day, [22] Subjects diagnosed based on Alcohol Use Disorders Identification Test (AUDIT) developed by the World Health Organization (WHO).

**Exclusion criteria:** Open wound or scar on abdomen, recent abdominal surgery, Psychiatric or neurologic illness

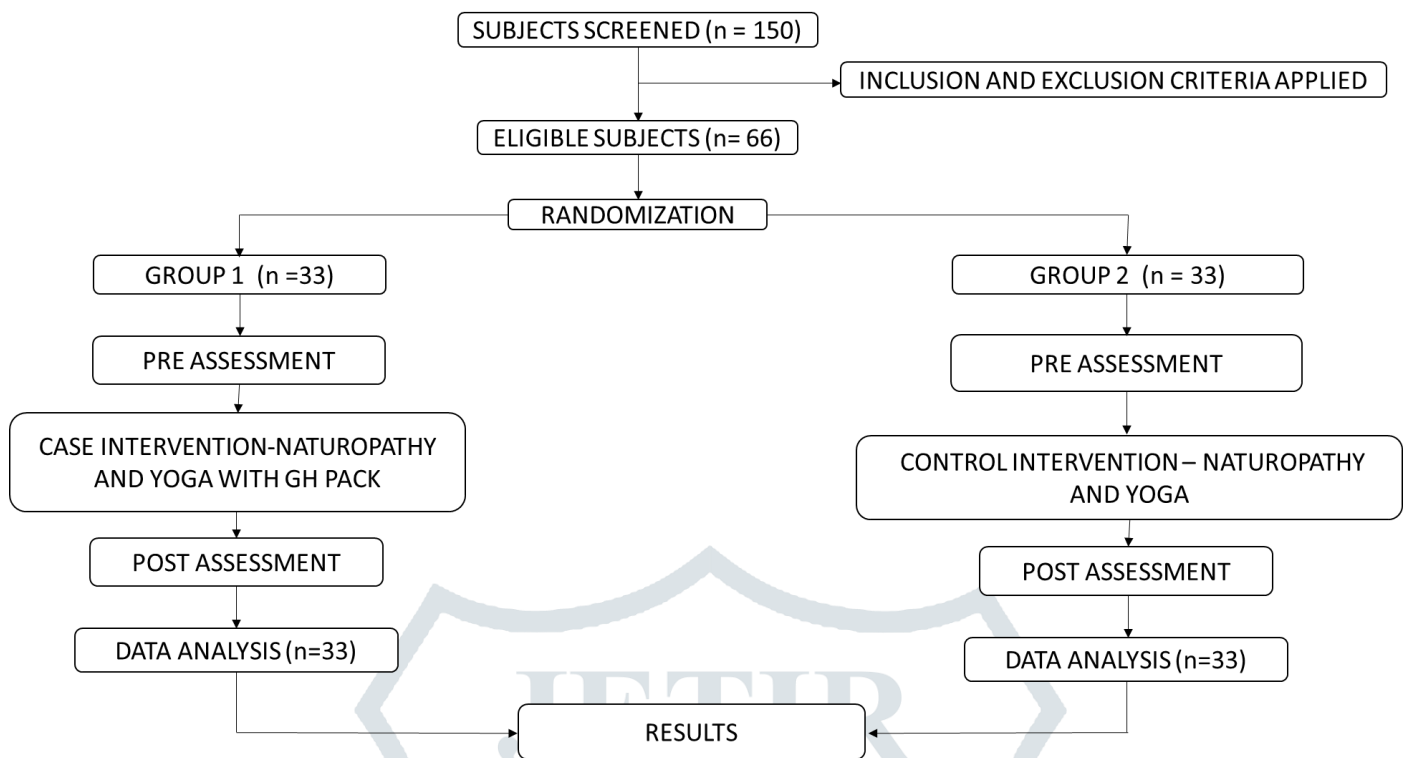
## Study Design:

Recruited subjects who fulfilled the inclusion criteria were divided equally into two groups.

Study design: A prospective randomized controlled trial.

**Group 1 (n = 33):- CASE GROUP** (Naturopathy and yoga with GH pack for 10 days)

**Group 2 (n = 33):- CONTROL GROUP** (Naturopathy and yoga for 10 days)



**Fig: - 1 Illustration of study plan**

#### INTERVENTION:

**Gastro-hepatic pack:** - It was administrated in supine lying position and a hot fomentation applied anteriorly from the 4th rib to the umbilicus which extends to axillary line on each side and then cold bag is applied to the dorsal and lumbar spine on lower back region covering the region of lumbar vertebra. Then the bags was wrapped with cotton cloth and woollen blanket. The treatment was given for 20 minutes. [23]

#### ASSESEMENT

**Liver profile:** - Only SGOT and SGPT was assessed for present study. Kits and chemical reagents were purchased from Spin React, SA. Ctra. Santa Coloma, 7E-17176 SANT ESTEVE DEBAS (GI), SPAIN. Spectrophotometrically, Serum glutamic-oxaloacetic transaminase (SGOT) and Serum glutamic pyruvic transaminase (SGPT) were estimated by using NADH Kinetic UV.IFCC rec. [24] It was done by using versatile biochemistry analyzer CKK24 from ARK diagnostics, Bangalore.

**Withdrawal questionnaire:** - Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised questionnaire was given for withdrawal symptom. [25]

**Quality of life:-**SF-36 is the questionnaire was used to assess quality of life in alcohol-dependent patients. [26] Which was filled by patients and were further scored by using respective scoring keys.

This questionnaire has 36 question which is grouped into 9 health domains. This are as followed [27]:- Physical functioning (PF), Role limitation due to physical health (RLDUPH), Role limitation due to emotional problem (RLDUEH), Energy/fatigue (E/F), Emotional well-being (EWB), Social functioning (SF), Pain (P), General health (GH), Health changes (HC).

#### DATA EXTRACTION

**Liver profile:** - 5 ml of pre-prandial venous blood were drawn from cubital fossa with the help of sterile syringe from each Patient during morning time on first day and 10<sup>th</sup> day of the intervention. All the reports were arranged in excel sheet for further analysis.

**Withdrawal and Quality of life questionnaire:** - Questionnaire were given on the first day, before intervention started and 10<sup>th</sup> day after the completion of intervention. All the questions were explained in their local language or in English, after which patient had selected the appropriate answer for each questions. Later, appropriate scoring keys were applied and all the results were arranged in excel sheets for further analysis.

#### DATA ANALYSIS

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) (Version 23.0). Data was checked for normal distribution using Kolmogorov-Smirnov test and analysed by using t tests. P value less than 0.05 was accepted as an indicator for significance.

#### RESULTS

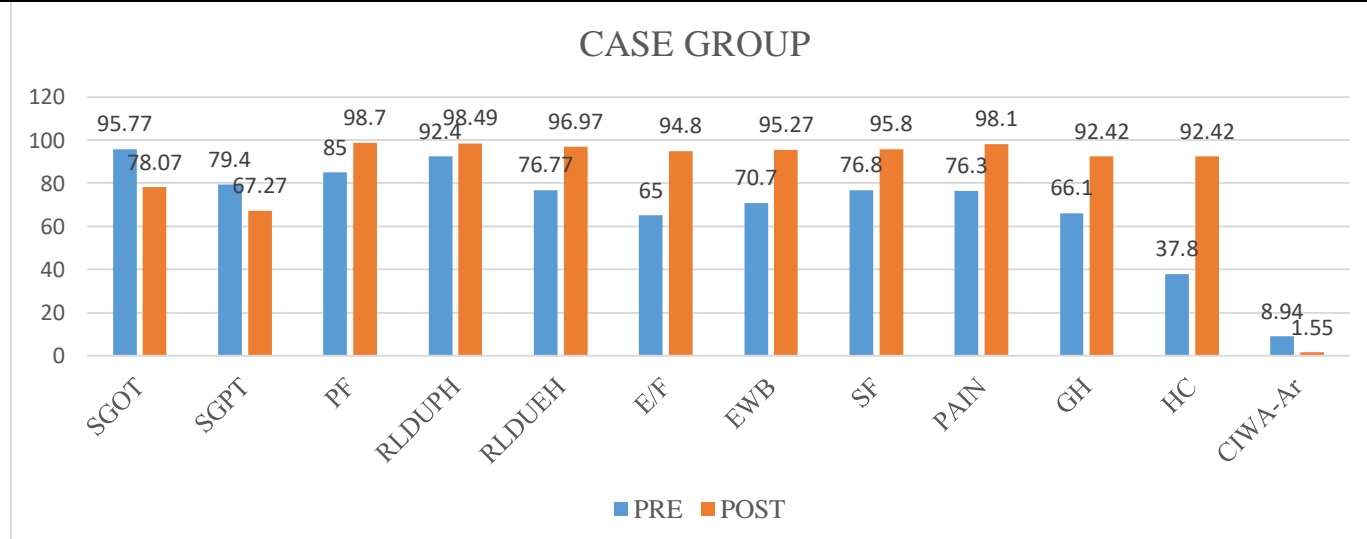
The data were analysed for normality distribution by Kolmogorov Smirnov test, which shown that results were not following normal distribution, therefore further analyse were assessed by using nonparametric tests to see the changes within and between the case (Naturopathy and yoga with GH pack) and control groups (Naturopathy and yoga).

When both the groups were compared (case and control group) with each other, there was significant changes in liver profile, and all the domains of Quality of life except RLDUPH, RLDUEH in GH pack group.

In case group there were significant improvement in SGOT, SGPT, Withdrawal symptoms, and all the domain of SF-36 questionnaire for quality of life with p-value less than 0.001. In control group there were significant improvement only in SGOT, SGPT and Withdrawal symptoms.

**Table 1:- Comparison of pre and post data in Case group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36).**

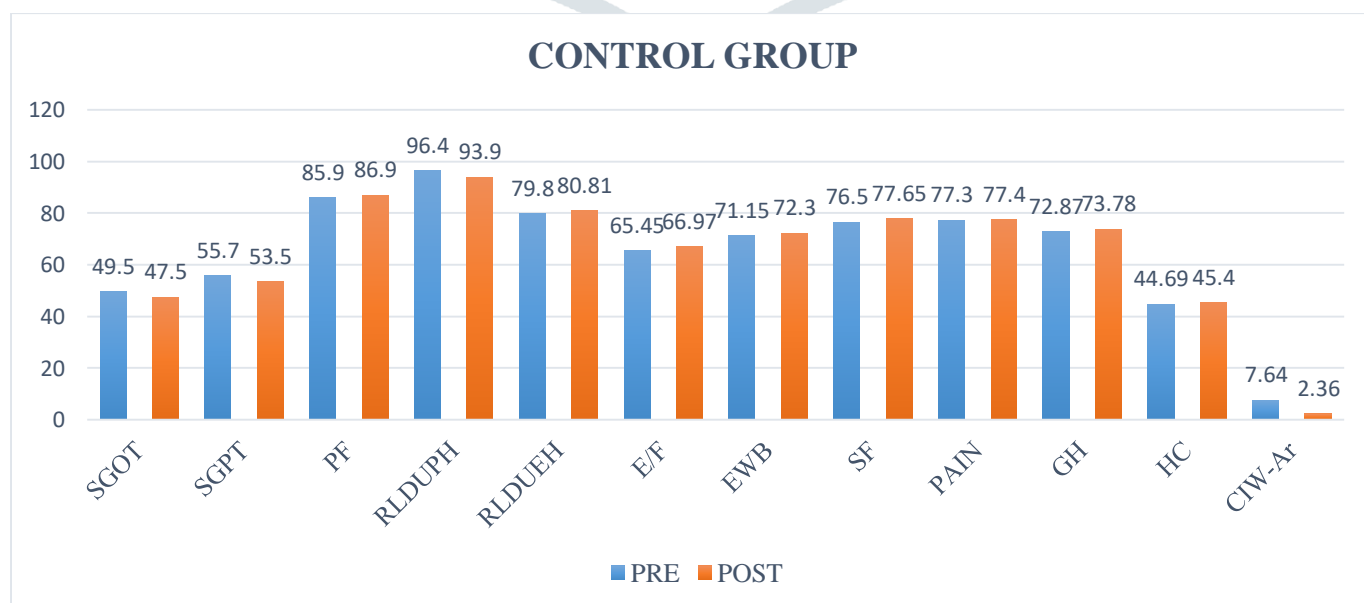
| Variable | MEAN (SD) AND MEDIAN (IQR) |                  |                |                  | Z-VALUE | P-VALUE    | DIFFERENCE                |                       |
|----------|----------------------------|------------------|----------------|------------------|---------|------------|---------------------------|-----------------------|
|          | PRE MEAN (SD)              | MEDIAN (IQR)     | POST MEAN (SD) | MEDIAN (IQR)     |         |            | Wilcoxon signed rank test | Mann Whitney 'u' Test |
| SGOT     | 95.77 ± 126.1              | 73 (88.4-48)     | 78.07 ± 124.84 | 46.7 (74-38)     | 5.012   | P< 0.001** | 17.6 ± 14.4               | 13.2 (19.9-8.4)       |
| SGPT     | 79.4 ± 69.1                | 63.1 (81.4-55.8) | 67.27 ± 70.14  | 52.4 (69.4-34.1) | 3.351   | P< 0.001** | 12.18 ± 9.6               | 9.6 (16.8-6.75)       |
| CIWA-AR  | 8.94 ± 6.16                | 7 (10-5.5)       | 1.55 ± 1.325   | 1 (2-1)          | 5.025   | P< 0.001** | 7.39 ± 5.11               | 6 (9-5)               |
| PF       | 85 ± 13.6                  | 90 (95-75)       | 98.7 ± 2.80    | 100 (100-100)    | 4.472   | P< 0.001** | -13.78 ± 12               | -10(-22.5-(-5))       |
| RLDUPH   | 92.4 ± 14.6                | 100 (100-87.5)   | 98.49 ± 6.05   | 100 (100-100)    | 2.271   | P< 0.001** | -6.06 ± 14.0              | 0(0-0)                |
| RLDUEH   | 76.77 ± 32.7               | 100 (100-66.7)   | 96.97 ± 9.72   | 100 (100-100)    | 3.375   | P< 0.001** | -6.06 ± 14.0              | 0 (0-0)               |
| E/F      | 65 ± 16.4                  | 70 (75-57.5)     | 94.8 ± 5.79    | 95 (100-90)      | 4.947   | P< 0.001** | -29.8 ± 17.5              | -30(-17.5-40)         |
| EWB      | 70.7 ± 20.3                | 76 (84-64)       | 95.27 ± 5.78   | 95 (100-90)      | 4.983   | P< 0.001** | -24.48 ± 19               | -20 (-8-(-34))        |
| SF       | 76.8 ± 19.5                | 87.5 (87.5-62.5) | 95.8 ± 10.67   | 100 (100-100)    | 4.232   | P< 0.001** | -18.9 ± 17.4              | -12.5 (-12.5-(1.5))   |
| P        | 76.3 ± 15.69               | 77.5 (90-67.5)   | 98.1 ± 3.91    | 100 (100-100)    | 4.556   | P< 0.001** | -21.8 ± 16.0              | -22 (-10-(32.5))      |
| GH       | 66.1 ± 19.1                | 70 (80-60)       | 92.42 ± 7.51   | 95 (100-85)      | 4.947   | P< 0.001** | -26.3 ± 17.9              | -25(-10-(-32.5))      |
| HC       | 37.8 ± 15.46               | 50 (50-25)       | 92.42 ± 11.6   | 100 (100-75)     | 5.102   | P< 0.001** | -54.54 ± 18               | -50(-50-(-75))        |



**Fig: -2 Comparison of pre and post data in Case group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36).**

**Table 2:- Comparison of pre and post data in Control group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36).**

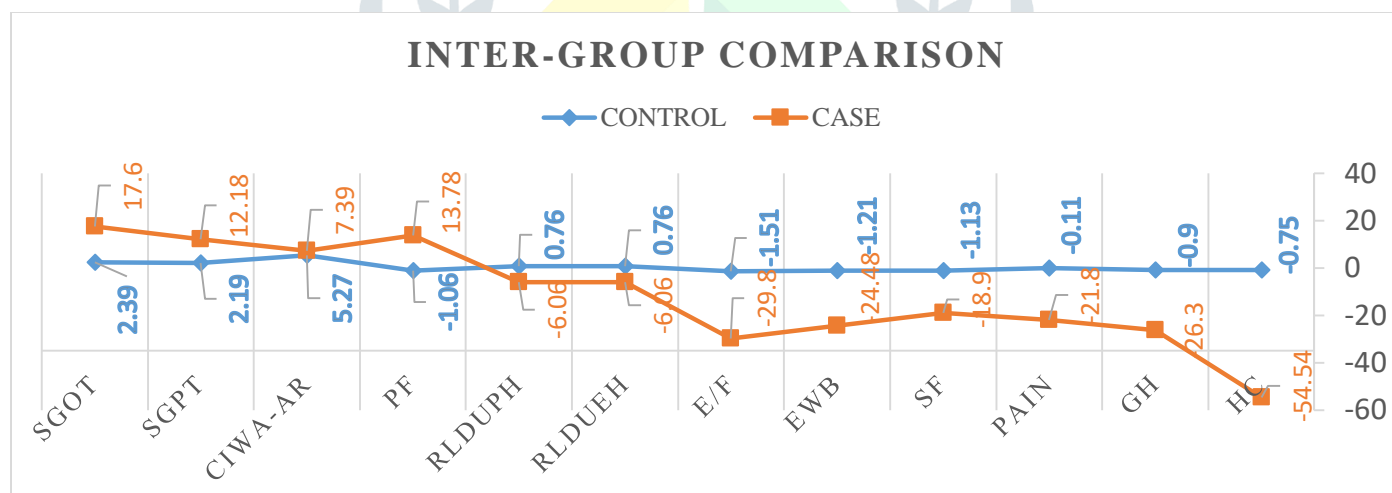
| Variable | MEAN (SD) AND MEDIAN (IQR) |                  |                |                  | Z-VALUE | P-VALUE    | DIFFERENCE  |                 |
|----------|----------------------------|------------------|----------------|------------------|---------|------------|-------------|-----------------|
|          | PRE MEAN (SD)              | MEDIAN (IQR)     | POST MEAN (SD) | MEDIAN (IQR)     |         |            | MEAN (SD)   | MEDIAN (QR)     |
| SGOT     | 49.5 ± 22.3                | 43(62.5-33)      | 47.1± 22.18    | 42.2(60.8-30.35) | 3.851   | P< 0.001** | 2.39± 4.66  | 2.9(4.75-1.2)   |
| SGPT     | 55.7 ± 24.8                | 49.6 (70.5-38.2) | 53.5± 46.3     | 46.3(69.2-33.4)  | 3.351   | P< 0.001** | 2.19± 5.36  | 2.7(4.2-1.05)   |
| CIWA-AR  | 7.64 ± 5.56                | 6(10.5-3)        | 2.36± 1.496    | 2(3-1)           | 4.978   | P< 0.001** | 5.27± 4.42  | 3(8-2)          |
| PF       | 85.9 ± 12.01               | 90(95-82.5)      | 86.9± 11.9     | 90(95-80)        | 1.163   | 0.245      | -1.06± 5.69 | 0(2.5-(-5))     |
| RLDUPH   | 94.6 ± 12.1                | 100(100-100)     | 93.9± 15.3     | 100(100-100)     | 0.378   | 0.705      | 0.76± 11.6  | 0(0-0)          |
| RLDUEH   | 79.8 ± 29.9                | 100(100-100)     | 80.81± 27.6    | 100(100-66.7)    | 0.108   | 0.705      | 0.76± 11.6  | 0(0-0)          |
| E/F      | 65.45 ± 11.5               | 70(75-60)        | 66.97± 12.62   | 70(75-60)        | 1.416   | 0.157      | -1.51± 5.79 | 0(0-(-5))       |
| EWB      | 71.15 ± 18.4               | 76(86-64)        | 72.3± 18.4     | 76(80-71)        | 0.878   | 0.380      | -1.21± 7.1  | 0(0-(-3))       |
| SF       | 76.5 ± 17.0                | 75(87.5-62.5)    | 77.65± 19.7    | 75(100-61.2)     | 1.083   | 0.279      | -1.13± 12.3 | 0(0-(-1.25))    |
| P        | 77.3 ± 17.87               | 80(90-67.25)     | 77.4± 19.70    | 75(100-61.2)     | 0.032   | 0.975      | -0.11± 6.31 | 0(0-(-2.5))     |
| GH       | 72.87 ± 10.83              | 75(82.5-65)      | 73.78± 10.97   | 75(80-67.5)      | 1.267   | 0.205      | -0.90± 5.65 | 0(0-(-5))       |
| HC       | 44.69 ± 13.63              | 50(50-25)        | 45.4± 18.17    | 50(50-25)        | 0.229   | 0.819      | -0.75± 19.2 | 0(12.5-(-12.5)) |



**Fig 3:- Comparison of pre and post data in Control group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36).**

| Variable | Case Group- post-test |                    | Control Group- post-test |                 | Z-VALUE                   | P-VALUE               |
|----------|-----------------------|--------------------|--------------------------|-----------------|---------------------------|-----------------------|
|          | MEANS (SD)            | MEDIAN (IQR)       | MEANS (SD)               | MEDIAN (IQR)    | Wilcoxon signed rank test | Mann Whitney 'u' Test |
| SGOT     | 17.6±14.4             | 13.2(19.9-8.4)     | 2.39±4.66                | 2.9(4.75-1.2)   | 6.220                     | p<0.001***            |
| SGPT     | 12.18±9.6             | 9.6(16.8-6.75)     | 2.19±5.36                | 2.7(4.2-1.05)   | 5.099                     | p<0.001***            |
| CIWA-AR  | 7.39±5.11             | 6(9-5)             | 5.27±4.42                | 3(8-2)          | 2.371                     | 0.018                 |
| PF       | -13.78±12             | -10(-22.5-(-5))    | -1.06±5.69               | 0(2.5-(-5))     | 4.620                     | p<0.001***            |
| RLDUPH   | -6.06±14.0            | 0(0-0)             | 0.76±11.6                | 0(0-0)          | 1.955                     | 0.051                 |
| RLDUEH   | -6.06±14.0            | 0(0-0)             | 0.76±11.6                | 0(0-0)          | 1.955                     | 0.051                 |
| E/F      | -29.8±17.5            | -30(-17.5-(-40))   | -1.51±5.79               | 0(0-(-5))       | 6.516                     | p<0.001***            |
| EWB      | -24.48±19             | -20(-8-(-34))      | -1.21±7.1                | 0(0-(-3))       | 6.070                     | p<0.001***            |
| SF       | -18.9±17.4            | -12.5(-12.5-(1.5)) | -1.13±12.2               | 0(0-(-1.25))    | 4.619                     | p<0.001***            |
| P        | -21.8±16.0            | -22(-10-(32.5))    | -0.11±6.31               | 0(0-(-2.5))     | 5.501                     | p<0.001***            |
| GH       | -26.3±17.9            | -25(-10-(-32.5))   | -0.90±5.65               | 0(0-(-5))       | 6.395                     | p<0.001***            |
| HC       | -54.54±18             | -50(-50-(-75))     | -0.75±19.2               | 0(12.5-(-12.5)) | 6.698                     | p<0.001***            |

**Table 3:- Comparison of difference of Case group and Control group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36)**



**Fig 4 :- Comparison of difference of Case group and Control group with respect to liver profile, CIWA-Ar and quality of life questionnaire (SF-36)**

**DISCUSSION**

Present study was conducted on the objective to see the effect of naturopathy and yogic intervention and gastro hepatic pack treatment for 10 days on liver profile, withdrawal symptoms and on quality of life of the individuals. The result of this study shows that there was significant improvement in case groups in terms of liver profile, withdrawal symptoms and quality of life when compared to control group.

There was a significant improvement in case group in terms of SGOT, SGPT, CIWA-Ar, physical functioning, role limitation due to physical health, role limitation due to emotional problems, energy/fatigue, emotional wellbeing, social functioning, pain, general health and health changes. Whereas in control group there was significant improvement in SGOT, SGPT and CIWA-Ar. This improvement in both the group can be possibly can be due to abstinence of alcohol use which is also one of the primary and effective management for alcoholism. Abstinence is important because it will reduce the load of oxidative stress formed on liver due to intake of alcohol and won't overload the organ further. One of the study showed that withdrawal from alcohol for one month had developed



significantly lesser postoperative complications when compared to patient who continued drinking. The underlying mechanism for this improvement in outcome was due to reversibility of ethanol induced organ dysfunction which resulted with abstinence. [28]

According to naturopathy system the main cause of diseases is violation of nature's law and this can be cured by obeying the law of nature or return to the nature. Body has as its own ability of healing and if provided with support by the means of treating with nature's element in the form of hydrotherapy, diet therapy, mud therapy and also yoga, it can boost the healing process of body and reduce the load on the body. [29]

With Naturopathy intervention, GH pack was given as add-on treatment once daily to case group continually for 10 day. When both the group was compared, case group which received the GH pack has shown better results than control group. The possible mechanism for this could be when hot application is given on abdominal wall there is increased hepatic blood flow. In a study it showed that after application of hot peloid paraffin pack on abdominal wall resulted in increased regional hepatic blood flow. [30]

Generally hepatic blood flow is mainly regulated by autonomic nerve system, but it has been observed that hepatic blood volume decrease by 35% and vasodilation increased by 15% due to adrenergic stimulation by norepinephrine but whether there is any relation between  $\alpha$  and  $\beta$  adrenergic receptors for this effect is not clear. [31] Whereas in a study it showed that in heart the toxicity ischemia occur due to acute ethanol, the possible cause would be increased xanthine oxidase activity or due to beta-adrenergic stimulation. [32]

Therefore increased oxidase activity and decrease blood volume due to adrenergic stimulation due to alcohol can be seen. This same mechanism would have work in hepatic blood flow reduction due to alcohol intake in individual and in GH pack the hot fermentation bag is kept on abdomen which primarily helps in increased the blood flow. This occur because there will be reduction in the sympathetic nervous system activity due to external heat application which result in increased hepatic blood volume. There won't be direct effect of heat on the liver because of convective heat transport. [33]

In another study it is showed that there will be increased blood flow when heat is applied, later there will be progressively declining of blood flow when heat application is continued but the blood flow will be still about 5 times greater than initial value. [34] Wang B et al showed that there is effective clearance of xenobiotics or drug metabolites by kupffer cell which one of the nonparenchymal cell of hepatic lobules because of slow blood flow which allow enough time for phagocytosis and maropinocytosis process. [35]

Cold application on lower back also have physiological changes such as reduction of blood flow to the area. In a study application of local cold pack on quadriceps muscle for 20 min reduces blood flow by 49%. [36] Ice application had also show to produce other physiological changes, such as reduction in edema, nerve conduction velocities, pain. [36] And cellular metabolism and also induce local anaesthesia. It also reduce the effect of ischemic tissue damage and reduce microcirculatory impairment and muscle necrosis. [38]

Therefore possible mechanism of GH pack can be sudden increase in hepatic blood flow which will improve the liver function and later there will be reduction in hepatic flow but it will maintain 5 -6 time more than initial flow, during this reduction of flow the phagocytosis and maropinocytosis process may help in removing unwanted metabolites from liver. And there will be vasoconstriction due to cold application on lower back in GH pack which might help in supplying blood to other part of body as liver where demand of blood supply increase after heat application.

#### Limitations of the study:

Larger sample size would have given more authenticated results.

Limited duration of the study.

There was no follow up maintain to see further improvement.

#### Future prospects emerging through this study:

Since the study was aim to see the effect of GH pack, future studies can be conducted on larger sample and prolonged duration of intervention with proper diet regiment and treatment protocol for better results.

**Abbreviations:** CM=Conventional Medicine, CAM=complementary and alternative medicine, GH PACK= Gastro-Hepatic Pack, AUDIT= Alcohol Use Disorders Identification Test, WHO = World Health Organization, SGOT= Serum glutamic-oxaloacetic transaminase, SGPT= Serum glutamic pyruvic transaminase, CIWA-Ar = Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised, PF = Physical functioning, RLDUPH = Role limitation due to physical health, RLDUEH = Role limitation due to emotional problems, E/F = Energy/Fatigue, EWB = Emotional well-being, SF = Social functioning, P = Pain, GH = General health, HC = Health changes.

**Competing Interests:** The authors declare that they have no competing interests

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