Cholelithiasis and Ayurveda

1Dr. Avinash Shankar, 2Dr Amresh Shankar, 3Dr Anuradha Shankar

1MD (Internal Medicine); DNB (E&M); PhD, Chairman, National Institute of Health & Research, Warisaliganj (Mawada) Bihar, 805130
2BAMS (BRABU); MBA (Hospital Administration), Bihar State Health Services, Patna
3BAMS (BRABU), Director, Centre for Research in Indigenous Medicine, Warisaliganj (Nawada) Bihar 805130

Abstract: Cholelithiasis in female is increasing rampantly among obese1,2, hyperlipidemic and hypo functioning thyroid women who undergone tube ligation or hysterectomy may be synergized by increasing toxic non nutrie in diet and changed life style, Common surgical preference Cholecystectomy and Choledochotomy though relieve the agonizing pain but alter digestion permanently which predisposes for the continuance of the presentation like heaviness in the abdomen, heart burn, eructation, lethargy, bowel irregularity in spite of dietary restriction.

Placebo based control study to evaluate a herbomineral composit in 216 cases affirm its worth in relieving clinical presentation and USG confirmation in majority cases with grade I clinical response while control group shows only transient symptomatic relief. 3 years post therapy follow up and dietary restriction with maintenance dose of 1 pill daily, non had any bowel irregularity or any evident cholelithiasis or hyperlipidemia.

Keywords: Cholelithiasis, hyperlipidemia, Cholecystectomy, Choledochotomy, herbomineral

1. INTRODUCTION

To curb the rising population female sterilization in early age and a trend of hystrectomy for monetary lust, poses an increased problem of hormonal imbalance resulting in thyroid hypo function and altered calcium metabolism. Thyroid hypo function not only alter the Calcium metabolism but also cause bile concentration leading to Cholelithiasis, as a dictum female, fatty and fourty most commonly prone for cholelithiasis 3,4,5 and present with eructation, heart burn, indigestion, heaviness and pain in the abdomen. In addition changed diatetary and life style also alter the normal digestion and metabolic process due to non nutrient toxic constituent of the food and drinks. 6,7,8,9

The bile super saturation with cholesterol is a key factor of cholelithiasis. The gold standard treatment for symptomatic gall bladder stone is laproscopic cholecystectomy or Oral litholysis remain restricted for few basophilic bile acids i.e- Oral litholytic Urso deoxycholic acid faces a problem of recurrence of gall stone in 5 yrs and risk of surface calcification cholestrol gall stones in about 10 % cases. Statin posses competitive inhibition of 3 –Hydroxy-3-methyl glutaryl Co A reductase 10,11 which reduces biliary cholesterol ability to suppress hepatic cholesterol gall stone formation.

This agonizing condition usually compel the patients to under go surgical intervention i.e. Cholecystectomy which alter vthe digestion of protein and fat permanently due to deficient bile in the duodenum required for activation of protein and fat digesting enzymes secreted from the pancreas. 12,13,14,15,16,17,18,19,20,21

Thus to save the patients from agonizing and costly surgical procedure and their consequent life long presentation due to altered protein and fat digestion 22,23, a herbo mineral therapeutic modality was evolved with an intent to liquefy the bile, check ability to formation of gall stone and lysis of cholelith with cholekinesis to ensure natural transport of bile to duodenum and bio regulation and maintenance of normal digestive process.

2. MATERIAL AND METHODS

Design of study: Placebo based controlled comparative evaluation
2.1. Material

Patients presenting with the features suggestive of Cholelithiasis attending at Medical OPD of RA Hospital & Research Centre during January 2012-2013 been selected and duly confirmed by clinical examination, ultrasonography and cholecystography. Patients of acute onset not responding to conservative line of therapy been not included in the study.

Clinical presentation:

- Sporadic and unpredictable episodes
- Localized pain in epigastrium, right upper quadrant, occasionally radiate to the right scapular tip.
- Pain that start after taking food intense and dull, typically last for 1-5 hours, increases steadily over 10-20 minutes and gradually wanes.
- Constant pain unrelied by emesis, antacid and passing stool usually associated with perspiration, nausea and vomiting.
- Indigestion, dyspepsia, belching and bloating.

 Patients were thoroughly interrogated and investigated to establish the diagnosis and record the base line status of hematologic, hepatic and renal status to adjudge therapeutic efficacy and safety profile.

Selected patients were graded as per their clinical presentation as-

| Clinical grades | Presentation |
|-----------------|-------------|
| Mild            | Over weight, eructation, vomiting, heart burn, heaviness in the abdomen Duration <1 year |
| Moderate        | Over weight, eructation, vomiting, heart burn, heaviness in the abdomen, Abdominal pain Duration >1yr |
| Severe          | Agonising abdominal pain, restricted movement, loss of sleep Duration >2 yrs |

2.2. Method

Selected patients were classified in two equal groups comprising 108 cases in each to adjudge the clinical efficacy of the used indigenous composite and its safety profile as compared to conventional therapy.

Study group (Group A): Conventional conservative therapy with indigenous composite pill in dose of 1 pill three times daily

Control group (Group B): Conventional therapy and placebo

Both groups were advised similar dietary restriction. Base line hepato renal and lipid profile been done to adjudge post therapy effect or alteration.

Each selected cases were advised and assured adjuvant pills prepared with required indigenous composite to ensure prompt check on presenting feature

Herbo mineral adjunct is prepared as per follows-

| Constituents:               | Quantity |
|-----------------------------|----------|
| Aloe vera pulp (dried powder)| 100gm    |
| Borax (Sodium borate) fried powder | 50gm     |
| Papaya(Carica papaya root) extract | 25ml     |
| Pathharchoor ( Bergamia ligulata) leaf extract | 25 ml    |

Process:

Fresh pulp of *Aloe vera Indica* leaf is dried in a ghreet painted pan to make dry powder of the pulp. Fried Sodium borate is powdered and a mixed with the Aloe vera pulp powder, to which extract of *Carica papaya* root and *Bergamia ligulata* leaf added and triturated to prepare pills of pea nut size.
Dose: 1 pill three times daily with luke warm water.
Dietary restriction:
No milk, non vegetarian diet,
Restrict oil and fats
Avoid chillies and condiment

Conventional or conservative treatment constitutes:
- Proton pump inhibitor to check hyperacidity
- Improve digestive function and intestinal load by avoiding protein and fat rich diet
- Antacid gel to retain alkalinity of the intestinal content
- Drugs to adjunct hepatic function and promote bile solubility
- Analgesics drugs to promptly check the agonizing abdominal pain.
- In acute cases intravenous fluid to compensate fluid load and provide rest and energy.

Patients were given follow up card to enter clinical response or any adversity during therapy and present at the centre or contact project officer.

| Follow up card |          |          |
|----------------|----------|----------|
| Name of patient: | Age |          |
| Address : | Date of ligation : |          |
| Particulars | Days |          |
| Pain in abdomen | Vomiting |          |
| Heaviness in the abdomen | General debility |          |
| Change in urine color | Change in stool color |          |
| Any other |          |          |

Based on the clinical response and record of the follow up card the therapeutic effect was graded as:

| Response Grade | Characteristics |
|----------------|-----------------|
| Gr I | No recurrence of pain in abdomen and alleviation of all the Presenting complaints without any alteration in hepatorenal and hematological parameters |
| Gr II | Relief of pain but presence of heaviness in the abdomen, appetite non improved |
| Gr III | Transient relief in abdominal pain with recurrence. |

All cases who reported complete relief of presentation under gone for repeat ultra sonography abdomen to assess the status of choleliths and investigated for hematological and hepatorenal parameters to adjudge the safety profile.

3. OBSERVATION

Selected patients were of age group 25-45 and majority (35.6%) were of age group 35-40 yrs (Table 1) and as per duration of illness 12.5% were having complaint <1 yr while 23.4% were from >5 yrs (Table -2)

Patients most common presentations are agonizing abdominal pain, heaviness in the abdomen in majority cases while some also presented with manifestation suggestive of obstetric jaundice (Table-3)
All patients were obese and 45% were with severe obesity having body weight >1.5 times Ideal Body Weight (Table-4). As per clinical severity 65.7% were of moderate and 21.3% were of severe grade of clinical presentation (Table-5).

Hepatic parameter is altered in 26 cases where as lipid profile in 199 cases and all had hypothyroidism (TSH >10) (Table -6).

Majority patients of group A show grade I clinical response with complete absence of Cholelith in USG while in group B majority had grade III response with 1 case showing cholelith disintegration in USG. All patients of Group A had improved satus of hematological, lipid, hepatic and renal profile while group B patients show marked alteration (Table-7)

**Table1. Distribution of patients as per age group**

| Age group (in years) | Number of patients |
|----------------------|--------------------|
| 25-30                | 59                 |
| 30-35                | 48                 |
| 35-40                | 77                 |
| 40-45                | 32                 |

**Table2. Distribution of patients as per duration of illness**

| Duration of illness (in years) | Number of patients |
|--------------------------------|--------------------|
| < 1                            | 27                 |
| 1-2                            | 32                 |
| 2-3                            | 44                 |
| 3-4                            | 22                 |
| 4-5                            | 41                 |
| >5                             | 50                 |

**Table3. Distribution of patients as per presentation**

| Common presentation            | Number of patients |
|--------------------------------|--------------------|
| Agonizing abdominal pain       | 178                |
| Eructation                     | 216                |
| Nausea                         | 198                |
| Heart burn                     | 216                |
| Indigestion                    | 216                |
| Frothy stool                   | 192                |

**Table4. Distribution of patient as per their obesity state**

| Age group (in yr) | Number of patients |
|-------------------|--------------------|
|                   | Mild | Moderate | Severe |
| 25-30             | 09   | 19       | 31     |
| 30-35             | 10   | 11       | 27     |
| 35-40             | 19   | 32       | 26     |
| 40-45             | 08   | 11       | 13     |

**Table5. Distribution of patients as per severity of illness**

| Clinical severity | Number of patients |
|-------------------|--------------------|
| Mild              | 28                 |
| Moderate          | 142                |
| Severe            | 46                 |

**Table6. Distribution of patients as per their biochemical status**

| Biochemical parameters | Number of patients |
|------------------------|--------------------|
| Hematological:         |                    |
| Hemoglobin             |                    |
| <10gm%                 | 09                 |
| >10gm%                 | 207                |
| Hepatic profile:       |                    |
| Total Serum bilirubin  |                    |
| < 1mg%                 | 187                |
| >1mg%                  | 019                |
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| Particulars          | Group A | Group B |
|----------------------|---------|---------|
| Clinical response:   |         |         |
| Grade I              | 105     | -       |
| Grade II             | 03      | -       |
| Grade III            | -       | 108     |
| Ultrasonography:     |         |         |
| Presence of cholelith| -       | 107     |
| Absence of Cholelith | 107     | -       |
| Disintegration phase | 01      | 01      |
| Relapse/recurrence in 3 yrs | None | 107 |
| Persistence          | None    | 107     |
| TSH                  |         |         |
| <5.5                 | 108     | 92      |
| >5.5                 | -       | 16      |
| Safety profile:      |         |         |
| Hepatic:             |         |         |
| SGOT                 | 108     | 31      |
| >40                  | -       | 77      |
| SGPT                 |         |         |
| <40                  | 108     | 31      |
| >40                  | -       | 77      |

**Table 7. Shows outcome of the therapy**

4. **DISCUSSION**

Cholelithiasis is increasing among women undergone sterilization or hysterectomy due to obesity and weight gain as a result of increased Thyroid stimulating Hormone concentration and hypo function of thyroid. In addition altered dietary nutrient and changed life style predispose for the hyper biliary concentration with lithogenesis and present with encumbrance like eructation, heaviness in the
abdomen, nausea, vomiting and pain in abdomen, compel the patient to seek urgent care to ensure relief of agonizing pain but cholecystectomy though relieve agonizing pain but make life agonizing permanently due to future altered protein and fat metabolism caused by absence of bile to activate protease and lipase secreted from pancreas.

The present study reveals marked and evident clinical supremacy of the indigenous composit in disintegration of cholelith and its due excretion with bio regulated cholekinesis as compared to surgical cholecystectomy and ensure life time natural bowel bioactivity.

The clinical achievement can be attributed to –

Potent lithotriptic or litholytic effect of active ingradient of Carica papaya root (Caricin), Bergemia ligulata (Bergemin) causes disintegration of choleliths, Sodium borate flower facilitate biliary excretion and improve cholekinesis while active ingradient of Aloe vera indica (Aloin -emodin, aloetic-acid, anthranol, aloin A and B (or collectively known as barbaloin), isobarbaloin, emodin, ester of cinnamic acid), bioregulate lipid profile and serum cholesterol thus check cholelithiasis and dietary restriction and thyroid bioregulation ensure future symptom free life. 

5. CONCLUSION

Women suffering with cholelithiasis had altered thyroid function, lipid profile presenting with various presentation taking indigenous herbomineral composit with dietary restriction had complete symptomatic relief with ultrasonographic evidence of absence of cholelith in majority cases with grade I clinical response whether only 1 patient of control group shows cholelith disintegration in USG and transient relief of presentation with grade III clinical response. Thus Indigenous herbomineral composite prove worth in management of Choleliths.

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