

## AN OPEN LABEL CLINICAL STUDY TO EVALUATE THE EFFECT OF *TRUTYADI CHURNA* IN CHOLELITHIASIS

Dileep P.\*<sup>1</sup>, Shailesh Y.<sup>2</sup> and Shrilatha Kamath T.<sup>3</sup>

<sup>1</sup>PG Scholar, Department of Kayachikista, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.

<sup>2</sup>Guide- Assistant Professor, Department of Kayachikista and Manasaroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.

<sup>3</sup>HOD-Professor, Department of Kayachikista and Manasaroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda, Kuthpady, Udupi.

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### \*Corresponding Author

Dileep P.

PG Scholar, Department of  
Kayachikista, Sri  
Dharmasthala  
Manjunatheshwara College  
of Ayurveda, Kuthpady,  
Udupi.

### ABSTRACT

Cholelithiasis is commonly known as Gallstones, formed of abnormal bile composition of cholesterol stones and pigment stones. Biliary sludge is an important precursor to the formation of Cholelithiasis in major cases. As per Ayurveda classics, features and management of Cholelithiasis can be outlined among various disorders like *Gulma*, *Pittaja udarashoola*, *Shakashritha kamala* and *Yakruthdalyodara*.

**Objective:** To evaluate the efficacy of *Trutyadi churna* in the management of Cholelithiasis. **Methodology:** An open label clinical study with pre and post-test design. The 20 patients with diagnostic criteria of Cholelithiasis in gallbladder, were selected from Shri Dharmasthala Manjunatheshwara Hospital of Ayurveda, Udupi, were subjected with 12 gram of *Trutyadi Churna* with Luke warm of 150ml twice after food for 60 days. And follow-up was taken every 15days up

to 90 days. All the parameters in subjective parameters were statistically analyzed with Wilcoxon signed rank test. And all the parameters in objective parameters were analyzed using Paired 't' test. **Results:** *Trutyadi churna* intervention has made a significant improvement with  $p < 0.001$  in subjective parameters like pain in below right shoulder and Objective parameters like size of stone showed a result of 34.45 % in relief with a p value of  $p = 0.068$ , and number of stone showed a 33.4% relief with p value of  $p = 0.014$  which showed a statistically significant result. **Conclusion:** 12gram of *Trutyadi Churna* have shown

significant improvement in the management of Cholelithiasis in total 20 patients. The efficacy of the medication has been proved with the statistical analysis of the parameters.

**KEYWORDS:** Cholelithiasis, *Trutyadi Churna*.

## INTRODUCTION

Cholelithiasis is commonly known as Gallstones, which is considered as a silent biliary tract disorder, in which stones are formed in gall bladder due to various extrinsic and intrinsic factors. The obstruction is caused due to cholesterol and pigmented stones. In developed countries, an overall prevalence of Cholelithiasis is 7.9% men and 16.6% in women aged 18-65 years. In India it is found to be 6.12% in adults. The prevalence rate in 30-69 years of age group is 10%. Between 70-80 years age group is 30-40% and as compared to male 19-20% more in female of all age groups. It is more often seen in women than men with the ratio of 4:1. It is said that gall stones are more common in Fat, Fertile, Forty and Females i.e., four F's.<sup>[1]</sup>

Gallstones usually produce symptoms by causing inflammation or obstruction following their migration into cystic duct or common biliary duct. The most specific and characteristic symptom of gallstone is biliary colic i.e. constant and long-lasting pain. The resultant visceral pain is characteristically a severe, steady ache or fullness in epigastrium or right upper quadrant of abdomen with frequent radiation to the inter-scapular area, right scapula or shoulder. Nausea and vomiting frequently accompany episodes of biliary pain. Complications requiring cholecystectomy are much more common in gallstones who have developed symptoms of biliary pain.<sup>[2]</sup>

Medical Treatment of Cholesterol gallstones can sometimes be dissolved by oral Ursodeoxycholic acid. Common minimal invasive treatments used for Gallstones are endoscopic retrograde sphincterotomy (ERS), endoscopic retrograde cholangiopancreatography (ERCP), extracorporeal shock wave lithotripsy (ESWL). But this form of treatment is suitable only when there is a small number of gallstones. Invasive treatment Procedures like Cholecystectomy has a 99% chance of eliminating the recurrence of Cholelithiasis. But it is only indicated in symptomatic patients and there is a chance of developing a condition called post cholecystectomy syndrome.<sup>[3]</sup>

As the direct references, chapters and exact correlations of gall stones are not available in *Ayurveda* classics, While explaining the *Samprapti* of *Moothrashmari*, *Acharya* says that *Ashmari* is formed in the *Basti* similar to the formation of *Rochana* in the *Pittashaya* of a cow. Hence, the *Ashmari* (stones) formed in *Pittashaya* of humans resembling the (*Go*)*rochana* can be considered as *Pittashaya ashmari*.

On comparing the *lakshana* mentioned in classics to modern symptoms of Cholelithiasis such as- if it is a silent stone- *Gulma*, pain with stones- *Pittaja udarashoola*, stone obstruction- *Shakashritha kamala*, Cholelithiasis causing further liver disorder- *Yakruthdalyodara* and all these features can be considered as prognosis of Cholelithiasis from *Gulma* to *Yakruthdalyodara*. *Sanchari* (movable) or *Achala*(fixed), *Granti*(lump) in epigastrium(in between *hrudaya* and *basti*) are the symptoms of *pittaja gulma* or the silent stones. *Daha-Arathi Nabhi* – burning sensation and pain around the navel region. *Madyandina Kupyanthi Cha Ardha Rathri*- aggravates during afternoon and mid night are the symptoms of *pittja udarashoola* or stone causing pain.<sup>[4]</sup> *Tila pishta nibham varchaha / Sweta varchaha*- change in the colour of fecal matter to greyish is a typical symptom of *Shakhashrita Kamala* or gall stone obstructing neck of gall bladder causing obstructive jaundice. *Aruchi, Daurbalya, Avipaka, Vibanda, Chardi, Murcha* – anorexia, weakness, indigestion, vomiting, fainting are some of the complications of *Yakruttodara* and complications of gall stones respectively.<sup>[5]</sup>

## MATERIALS AND METHODS

**Source of data:** The patients suffering from Cholelithiasis were selected from OPD and IPD of Sri Dharmasthala Manjunatheshara Ayurveda Hospital, Kuthpady, Udupi. *Trutyadi Churna* was obtained from SDM Ayurveda Pharmacy, kuthpady, Udupi.

**Method of collection of data:** The subjects suffering from Cholelithiasis were screened under strict diagnostic, inclusion and exclusion criteria and were selected for the study. Eligible subjects were invited to participate in the study after signing a detailed informed consent and registered for this clinical trial. Thus registered participants were treated with the medication as per the plan of intervention. The outcome measures were assessed at baseline, on Day 15<sup>th</sup>, 30<sup>th</sup>, 45<sup>th</sup>, 60<sup>th</sup> and Day 90<sup>th</sup>.

**Design of the study:** An open label single arm clinical study.

Table no. 1.

Intervention	
Drug name	<i>Trutyadi churna</i> <sup>[6]</sup>
Dose	6grm BD (~ = 1karsa per day) <sup>[7]</sup>
Dosage form	60grm packet for each 5 days
Route of administration	Oral
Time of administration	Morning and Evening after food
<i>Anupana</i>	<i>Ushnodaka</i> (150ml of water)
Duration	60 days
Duration of clinical study:	
Intervention	60 days
Follow up	30 days
Total Duration	90 days

### Diagnostic Criteria

- Patients diagnosed to have Cholelithiasis by U.S.G. Abdomen with or without presence of symptoms of Rome III guidelines for functional gall bladder disorder like- Episodes of pain located in the epigastrium and/or right upper quadrant, Episodes last 30 minutes or longer, recurrent symptoms occur at different intervals, The pain builds up to a steady level, The pain is moderate to severe enough to interrupt the patients daily activities, Pain is not relieved by bowel movements, pain that relived by postural change, pain and nausea with vomiting, pain radiates to intra scapular region and back, Pain awakes the patient from sleep in the middle of the night.<sup>[8]</sup>

Table no. 2.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>Diagnosed case of Cholelithiasis as per diagnostic criteria.</li> </ul>	<ul style="list-style-type: none"> <li>During the phase of biliary colic.</li> </ul>
<ul style="list-style-type: none"> <li>Men and women between the age group of 18 to 65years.</li> </ul>	<ul style="list-style-type: none"> <li>Stone size more than 3cm.<sup>[9]</sup></li> </ul>
<ul style="list-style-type: none"> <li>Participants are willing and able to provide informed consent.</li> </ul>	<ul style="list-style-type: none"> <li>Persons in whom <i>Kshara</i> is contraindicated.</li> </ul>
	<ul style="list-style-type: none"> <li>Patients with gallstones associated with complications, such as acute obstructive Cholecystitis, Acute pancreatitis, Liver failure, Congenital anomalies of gallbladder, Calcified gall bladder, carcinoma of gall bladder<sup>[10]</sup></li> </ul>
	<ul style="list-style-type: none"> <li>Other pathological conditions presenting signs of jaundice</li> </ul>
	<ul style="list-style-type: none"> <li>Immune compromised patients</li> </ul>
	<ul style="list-style-type: none"> <li>Patients suffering from other systemic disorder.</li> </ul>

### Assessment criteria

Signs and symptoms of Cholelithiasis are evaluated before and after treatment. Analysis of the subjective and objective parameters will be done.

**Subjective Parameters****A. PRIMARY OUTCOME****Table no. 3.**

<b>SUBJECTIVE from baseline [time frame day 1 and day 90]</b>						
<b>Grades</b>	<b>Pain in the right upper abdomen</b>	<b>Pain below the right shoulder</b>	<b>Nausea</b>	<b>Vomiting</b>	<b>Flatulence dyspepsia</b>	<b>Recurrent indigestion</b>
<b>0</b>	Absence of pain,	Absent	Absent	Absent	Absent	Absent
<b>1</b>	Pain present, but does not disturb routine and sleep (mild pain),	Present	Present	Present	Present	Present
<b>2</b>	Pain prevent which disturb routine and sleep (moderate),	-	-	-	-	-
<b>3</b>	Severe pain which does not allow to have recumbent position (severe),	-	-	-	-	-

**B. SECONDARY OUTCOME****Table no. 4.**

<b>OBEJCTIVE from baseline [time frame day 1 and day 90]</b>	
<b>Grades</b>	<b>Size of the stone, assessed by Transabdomenal USG findings</b>
<b>4</b>	No change in the size (no response),
<b>3</b>	Reduction of stone size up to 25% (poor response),
<b>2</b>	Reduction of stone size up to 50% (mild response),
<b>1</b>	Reduction of stone size up to 75% (moderate response),
<b>0</b>	Reduction of stone size up to 100% (marked response).

<b>Grades</b>	<b>Number of stone reduction assessed percentage wise by Transabdomenal USG findings</b>
<b>4</b>	Number of stones remains same (no response),
<b>3</b>	Number of stones reduced approximately 25% (poor response),
<b>2</b>	Number of stones reduced approximately 50 % ( mild response),
<b>1</b>	Number of stones reduced approximately 75 % ( moderate response),
<b>0</b>	Number of stones reduced approximately 100% (marked response).

**RESULTS**

In the current study, 20 patients of Cholelithiasis were registered and administered 12 gram of *Trutyadi churna* twice in a day as divided dose of 6 gram once in the morning after food and evening after food with 150ml of warm water for total 60 days with every 15 days follow up taken. The effect of the treatment following medication was assessed periodically in regards to subjective parameters like Pain in the right upper abdomen, Pain below the right shoulder, Nausea, Vomiting, Flatulence dyspepsia and recurrent indigestion. Objective parameters like number of stone and size of stone by using USG abdomen study. The

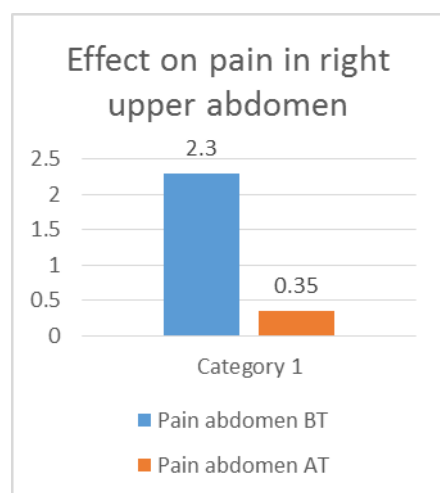
parameters were analysed statistically using Paired 't' test and Wilcoxon sign rank test. The details of the same are elaborated in this section on results.

### Effect on pain in the right upper abdomen

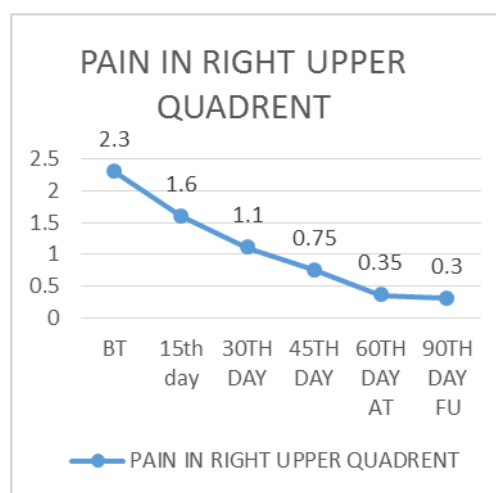
Administration of *Trutyadi churna* was found to be effective in decreasing the pain in right upper abdomen. Among the 20 patients 16 patient had this symptom, the mean score for pain in the right upper abdomen prior to treatment was 2.300 which decreased to 0.350 after the treatment with mean difference of 1.95. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically highly significant with 'P' value of  $P < 0.001$ .

**Table No. 5: Effect on pain in right upper abdomen.**

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	2.300	0.350	1.95	84.782	BT-1.218 AT-0.489	0.272 0.109	3.000 0.000	-3.601	<0.001



**Figure No: 1**



**Figure No: 2**

**Effect on pain below the right shoulder:** Administration of *Trutyadi churna* was found to be effective in decreasing the pain below the right shoulder. Among the 20 patients 18 patient had this symptom, the mean score for pain below the right shoulder prior to treatment was 0.900 which decreased to 0.250 after the treatment with mean difference of 0.650. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically highly significant with 'P' value of  $P < 0.001$ .

Table No: 6 Effect on pain below the right shoulder.

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	0.900	0.250	0.650	72.23	BT-0.308 AT-0.444	0.0688 0.0993	1.000 0.000	-3.606	<0.001

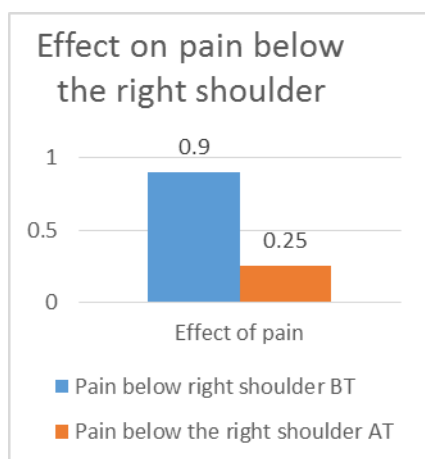


Figure No: 3

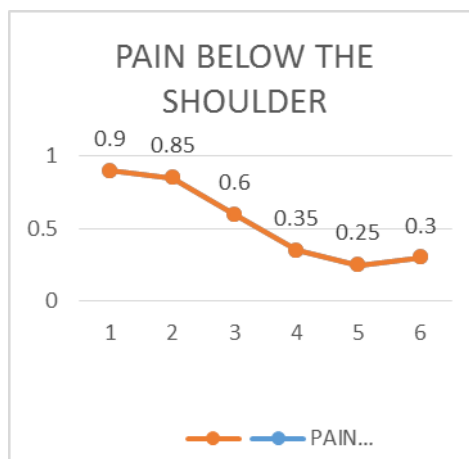


Figure No: 4

**Effect on nausea:** Administration of *Trutyadi churna* was found to be effective in decreasing the Nausea. Among the 20 patients 9 patient had this symptom, the mean score for Nausea prior to treatment was 0.450 which decreased to 0.050 after the treatment with mean difference of 0.400. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of P=0.008.

Table No: 7 Effect on Nausea.

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	0.450	0.050	0.400	88.89	BT-0.510 AT-0.224	0.114 0.0500	0.000 0.000	-2.828	0.008

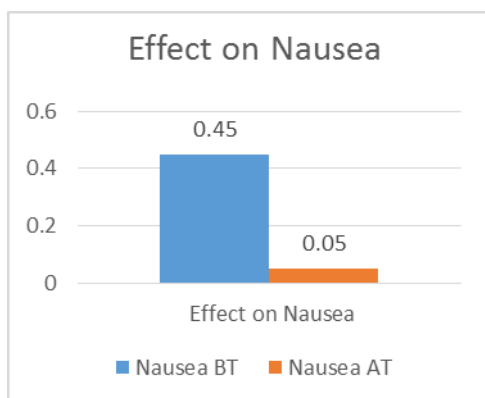


Figure No: 5

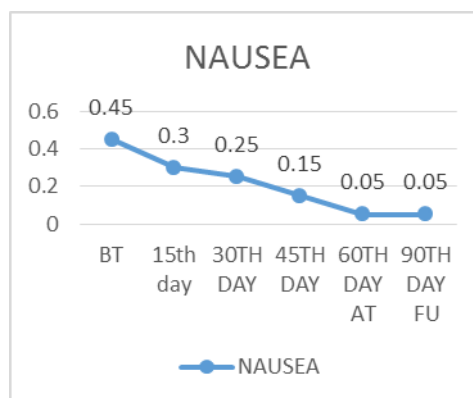


Figure No: 6

**Effect on vomiting:** Administration of *Trutyadi churna* was found to be effective in decreasing the Vomiting. Among the 20 patients 10 patient had this symptom, the mean score for vomiting prior to treatment was 0.500 which decreased to 0.100 after the treatment with mean difference of 0.400. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of  $P=0.008$ .

Table No: 8 Effect on Vomiting.

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	0.500	0.100	0.400	80	BT-0.513 AT-0.308	0.115 0.0688	0.500 0.000	-2.828	0.008

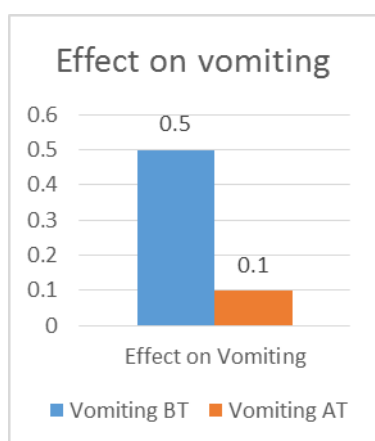


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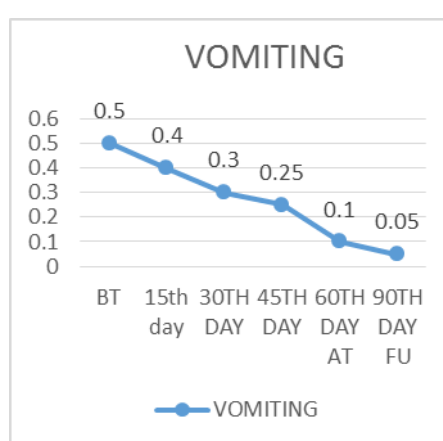


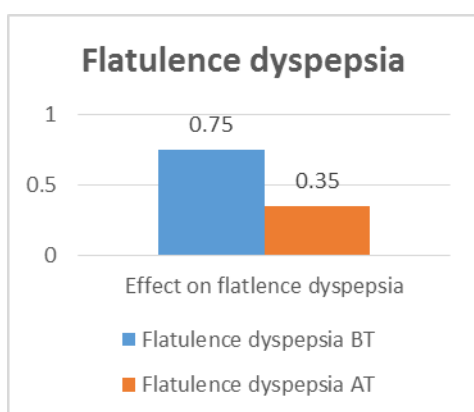
Figure No: 8.

**Effect on flatulence dyspepsia:** Administration of *Trutyadi churna* was found to be effective in decreasing the flatulence dyspepsia. Among the 20 patients 15 patient had this symptom, the mean score for flatulence dyspepsia prior to treatment was 0.750 which decreased to 0.350 after the treatment with mean difference of 0.400. The analysis by applying the

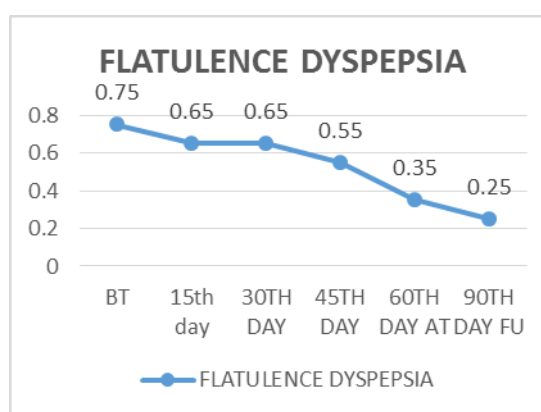
Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of  $P=0.008$ .

**Table No. 9: Effect on Flatulence dyspepsia.**

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	0.750	0.350	0.400	53.34	BT-0.444 AT-0.489	0.099 0.109	0.100 0.000	-2.828	0.008



**Figure No: 9**



**Figure No: 10**

**Effect on recurrent indigestion:** Administration of *Trutyadi churna* was found to be effective in decreasing the recurrent indigestion. Among the 20 patients 13 patient had this symptom, the mean score for flatulence dyspepsia prior to treatment was 0.650 which decreased to 0.200 after the treatment with mean difference of 0.450. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of  $P=0.014$ .

**Table No. 10: Effect on recurrent indigestion.**

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	Z value	P value
	0.650	0.200	0.450	69.23	BT-0.489 AT-0.410	0.109 0.091	0.100 0.000	-2.714	0.014

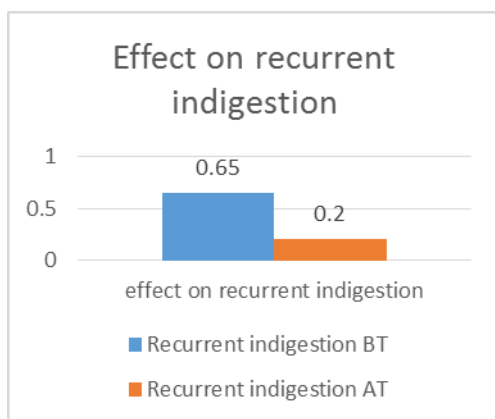


Figure No: 11

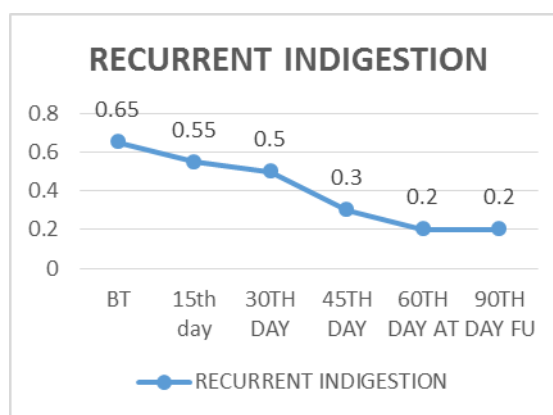


Figure No: 12

**Effect on size of the stones:** Administration of *Trutyadi churna* was found to be effective in decreasing the size of the stones. Among the 20 patients all patient had gallstones, the mean score for size of stone prior to treatment was 16.550 which decreased to 10.850 after the treatment with mean difference of 5.700. The analysis by applying the paired 't' test showed that the improvement was statistically significant with 'P' value of  $P=0.068$

Table No. 11: Effect on size of the stone.

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	't' value	P Value
	16.55	10.85	5.70	34.45	BT-14.148 AT-11.895	3.164 2.660	14.000 7.550	1.934	=0.068

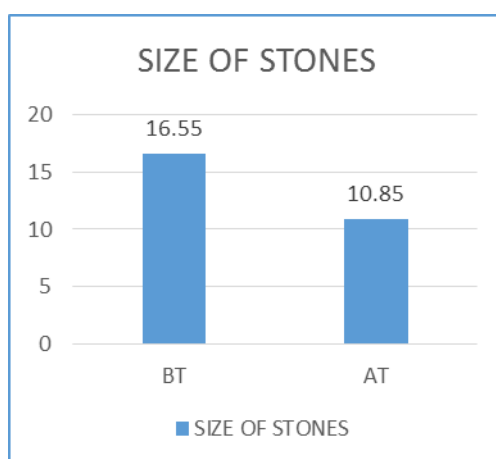


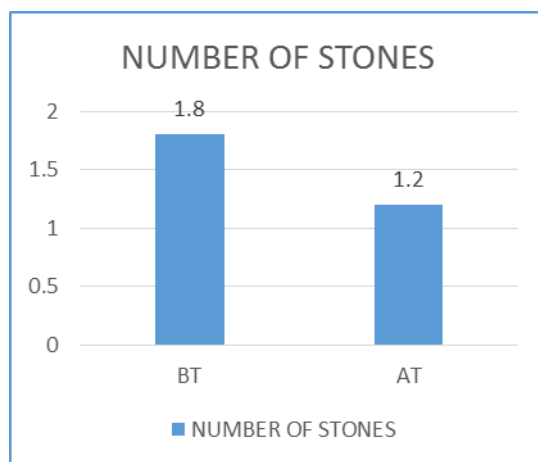
Figure No: 13.

**Effect on number of the stones:** Administration of *Trutyadi churna* was found to be effective in decreasing the number of the stones. Among the 20 patients all patient had gallstones, the mean score for number of stone prior to treatment was 1.800 which decreased

to 1.200 after the treatment with mean difference of 0.600. The analysis by applying the paired 't' test showed that the improvement was statistically significant with 'P' value of  $P=0.014$ .

**Table No: 12 Effect on number of the stone.**

After 60 <sup>th</sup> day	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD	SEM	Median	't' value	P value
	1.800	1.200	0.600	33.34	BT-1.196 AT-1.281	0.268 0.287	1.000 0.000	2.698	=0.014



**Figure No: 14.**

### Overall assessment in response to treatment

In the study 55% had excellent improvement, 25% had moderate improvement, 15% had good improvement, 0% had a fair improvement and 5% had no improvement.

**Table no. 13.**

Sl no.	IMPROVEMENT	SCALE	NO. OF PATIENTS	% OF PATIENTS
1.	EXCELLENT	75-100%	11	55%
2.	MODERATE	50-75%	5	25%
3.	GOOD	25-50%	3	15%
4.	FAIR	0-25%	0	0%
5.	NO RESPONSE	0%	1	5%

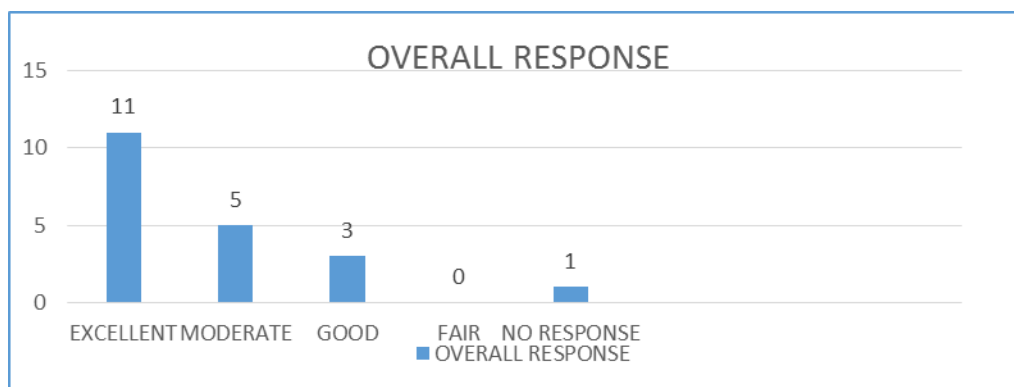


Figure no. 15.

Among the 8 parameters which are taken for the study, in which 3 parameters as Pain in right upper abdomen (84.78%), Nausea (88.89%), Vomiting (80%) shows excellent response having more than 75% results. In 3 parameters like Pain below the right shoulder (72.23%), Flatulence dyspepsia (53.34%), and Recurrent indigestion (69.23%) shows moderate response having results between 50-75%. In 2 parameters like number of gall stone reduction (33.34%) and Size of gall stone reduction (34.45%), there was a good response which comes under 25-50% results.

## DISCUSSION

**Pain:** All the patients in this group showed a significant result in pain on the right upper abdomen by 84.782%. This may be attributed to the *Vatanulomana* and *Vata shamaka* properties of *Trutyadi churna*. As it contains *Yavakshara* leading to relieving the spasm of gall bladder, cystic duct and also reducing the irritation to the *Vidhagdhta* of pitta and relieving the pain. **Referred pain below the right shoulder:** All the patients in this group showed a significant result in the referred pain by 72.23% and this result showed that *Trutyadi churna* is effective in reducing the referred pain below the right shoulder. **Nausea:** All the patients in this group showed a significant result in nausea symptoms by 88.9% and here the drug played a major role in controlling the symptoms of nausea and its management. **Vomiting:** All the patients in this group showed a significant result in vomiting symptom by 80% and this result showed that *Trutyadi churna* is beneficial in treating vomiting. **Flatulent dyspepsia:** All the patients in this group showed a significant result in the referred pain by 53.34% and this result showed that *Trutyadi churna* is effective in controlling the flatulence dyspepsia. **Recurrent indigestion:** All the patients in this group showed a significant result in the referred pain by 69.23% and this result showed that *Trutyadi churna* is effective in reducing the recurrent indigestion. **Size of the stone:** Out of 20 patients 7 patients got full reduction of

stone i.e., complete removal of stone. And 9 patients showed a marked reduction of stone approximately 5-6mm reduction and overall results in reducing the size of the stone by 34.34%. This shows that the drug *Trutyadi churna* is effective in reducing the number of stones. **Number of stones:** Out of 20 patients 7 patients got zero stones after the drug intake up to 60 days and most of the patients showed a marked reduction in number of stones. So total 20 patients had sum of 36 stones in total and after study it was reduced to 24 in total with overall reduction in number of stone by 33.34% this showed that the *Trutyadi churna* is very effective in reducing number of stones.

After 60 days of treatment, over all response of the drug on signs and symptoms were collectively presented here in a nut shell. In the study 55% had excellent improvement, 25% had moderate improvement, 15% had good improvement, 0% had a fair improvement and 5% had no improvement. Among the 8 parameters which are taken for the study, in which 3 parameters as Pain in right upper abdomen (84.78%), Nausea (88.89%), Vomiting (80%) shows excellent response having more than 75% results. In 3 parameters like Pain below the right shoulder (72.23%), Flatulence dyspepsia (53.34%), and Recurrent indigestion (69.23%) shows moderate response having results between 50-75%. In 2 parameters like number of gall stone reduction (33.34%) and Size of gall stone reduction (34.45%), there was a good response which comes under 25-50% results. Overall response based on the signs and symptoms is statistically significant in the present study. All most all the patient showed an improvement in all symptoms.

## CONCLUSION

From the clinical study conducted on 20 patients of Cholelithiasis, through specific observations, following conclusions were drawn. Cholelithiasis is found to be a metabolic hazard as more number of patients seen in present study was having pathology of impaired cholesterol metabolism. The present study, it was observed that Cholelithiasis is common in the age group 40 years and above, females are more prone to get than males, occupation wise employees will get more affected, more in middle class with mixed dietary habits who had a habit of eating junk food. The formulation reduced the size and number of calculi in all the patients. In 7 patients there was a complete removal of all the calculi was observed. During the follow-up period of 30 days, 75% patients didn't had any recurrence of symptoms. The preparation of *Trutyadi churna* and administration was simple, palatable, easy for administration, free from adverse effects and therapeutic efficacy is good and it can be done

as an outpatient procedure. So, it can be adopted as a remedy for treatment of Cholelithiasis. The overall result found was about 55%, having marked improvement. As the references available in the classical texts the disease Cholelithiasis can be correlated as *Pittashaya Ashmari*. Probably by increasing the duration of treatment and dose of *Trutyadi Churna*, and by changing *Anupana* or *Sahapana* better results may be obtained by further studies. Even after 60 days of medication should be continued further.

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