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**Controlled Clinical Trial  
Comparing Early With Interval  
Cholecystectomy For Acute  
Cholecystitis**

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**Abstract**

*The traditional management of acute Cholecystitis is initial conservative treatment with intravenous fluids, nasogastric suction, analgesic/antispasmodics, antibiotics and bed rest followed by elective surgery. Although early cholecystectomy has been advocated but there is a school of thought strongly supporting the initial conservative treatment. This paper reports the results of such a trial in which 104 patients have been studied.*

*Of 44 patients managed conservatively, 4 patients had associated medical disease, 10 required urgent surgical intervention, because of failure of medical treatment, and two patients died.*

*Of 60 patients treated by early cholecystectomy, there were two patients with associated liver abscess: in one case it had burst into the peritoneal cavity. Surgery was difficult in 10 cases. Cholecystectomy was possible in all. Blood loss and time consumed were slightly more than in the interval cholecystectomy.*

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*Post-operative complications were more in failed conservative medical treatment; patients treated conservatively stayed more in the Hospital. Those treated by early cholecystectomy spent less time in the Hospital and avoided the complications of failed conservative treatment.*

## **Introduction**

The traditional management of acute cholecystitis is initial conservative treatment with intravenous fluids, nasogastric suction, analgesic/antispasmodic, antibiotic, bed rest etc. followed by elective surgery. Although early cholecystectomy has been advocated, there is a school of thought strongly supporting the initial conservative treatment. This paper reports the results of such a trial in which 104 patients have been studied.

Forty four patients were managed conservatively, 4 patients had associated medical disease, one with myocardial infarction. Two patients with diabetes mellitus, and one with hypertension, 10 required urgent surgical intervention, because of failure of medical treatment. On exploration the gall bladder was distended, tense, oedematous with gangrenous patches over the fundus and body, one case had perforation at Hartmann's pouch. Cholecystectomy was done in all.

Of the 60 patients treated by early cholecystectomy, there were two patients with associated liver abscess, in one it had burst into the peritoneal cavity along with Cholecystitis, Surgery was difficult in 10 cases with more blood loss than the usual and so blood was transfused. Cholecystectomy was possible in all, Blood loss and time consumption was slightly more than in the interval cholecystectomy.

Two patients died in the first group of conservative management: one patient 50 year old female with cholecystitis and myocardial infarction who died on the third day probably because of another episode of myocardial infarction; another patient 45 years old female had diabetes mellitus with cholecystitis. She was on insulin for the last one year; she died on the sixth day when she developed signs and symptoms of peritonitis all of a sudden. On immediate exploration the whole of the gall bladder was gangrenous with multiple small liver abscesses, leading to peritonitis and she died the same evening.

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Post-operative complications were more in failed conservative medical treatment. Patients treated conservatively stayed more in the Hospital. Those treated by early cholecystectomy spent less time in the Hospital and avoided the complications of failed conservative treatment.

The traditional management of acute cholecystitis is initial conservative treatment followed by elective cholecystectomy after an interval of 8-10 weeks. DU Plessis and Jersky advocated<sup>2</sup> this policy for three reasons:

1. Uncertainty of diagnosis.
2. The risks of operation in the acute condition, particularly on elderly patients with associated medical disease.
3. The mortality from acute cholecystitis is low. Other favour a more aggressive surgical approach with the operation within seven days of the onset of acute cholecystitis. Van Der Linden and Sunzel stated that the operation is not hazardous, its main advantage being the early relief of pain and a shorter stay in Hospital<sup>5</sup>.

Because attitudes have usually been based on retrospective studies, it was decided to set up a controlled trial of the two treatments in the Surgical Unit of Lady Reading Hospital, Postgraduate Medical Institute, Peshawar. This paper reports the early results obtained so far:

#### **Patients and Method**

The trial which is still in progress is a prospective controlled trial of a simple design. All cases with a diagnosis of acute cholecystitis of less than 10 days duration were included in the trial. The criteria for diagnosis were Clinical, Haematological, Radiological and Sonographical. The history included upper abdominal pain, sudden in onset, severe in nature, localising in the right hypochondrium and radiating to the inferior angle of the right scapula. The clinical signs consisted of pyrexia with an associated tachycardia, tenderness, rebound tenderness and rigidity in the upper right quadrant. A neutrophil leukocytosis was considered for the diagnosis. Liver function test, Urine Analysis, Serum Amylase, Blood Urea, Blood Sugar and Electrolyte were also done to exclude other associated pathological conditions. X-ray chest and abdomen (in erect position) were obtained to

exclude perforation of abdominal viscus. The diagnosis was confirmed by Ultrasonography.

The following patients were not included in the trial: Those presenting with obstructive jaundice, ascites or malignancy; those above 90 years of age; those patients with palpable mass in the right hypochondrium.

While the provisional diagnosis was being confirmed, all the patients were treated with nasogastric suction, intravenous infusion, antibiotic and analgesic/antispasmodic. The operation was performed by the consultant surgeon only.

Conservative treatment was considered to have failed if there were signs of spreading peritonitis, increasing attacks and severity of pain, pulse and temperature not settling, and general condition of the patient deteriorating; or the patient returned soon after discharge because of further attack of acute cholecystitis.

So far 104 patients have been admitted to the trial, 44 have been treated by conservative regime and 60 by early cholecystectomy.

## **Results**

The mean age of the two group was similar; the sex ratio was similar, showing a female preponderance; and the duration of symptoms was similar in both groups.

### **Outcome in the Conservative Group**

Of the 44 patients treated by conservative management, elective cholecystectomy has subsequently been performed in 30 patients; 4 patients refused operation and they are still waiting for another attack of cholecystitis. 10 patients required urgent operation because of failure of conservative treatment. 2 patients died: one with acute cholecystitis and myocardial infarction had another infarction episode, and the second one from diabetes mellitus and acute cholecystitis.

### **Outcome in the Early Operation Group**

Sixty patients were treated by early operation. In 3 patients there was technical difficulty and so separation of gall bladder was performed from the fundus towards the neck; however, cholecystectomy was done.

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Generally the blood loss in the early operation group was slightly more than that in the elective group. The common bile duct required exploration in 4 patients due to palpable stone in the common bile duct.

At operation the gall bladder was usually distended, oedematous with some adhesions with the greater momentum, colon and duodenum. Separation is easy with finger if done in a proper plane. Then holding the gall bladder with sponge holding forceps, after aspirating the contents, dissection is not much difficult. 20 patients had dark patches on the body and fundus of the gall bladder due to incipient gangrene but perforation had not occurred. There were 2 cases of liver abscess along with acute cholecystitis, one patient had perforation at Hartmann's Pouch leading to localised peritonitis. Another patient had a stone in the cystic duct which had ulcerated through the wall and peritonitis had only been prevented by the adherent duodenum and momentum. All 20 patients were considered to be at immediate risk of developing generalised peritonitis. All patients had a tube drain inserted in sub-hepatic space, through a separate stab incision.

### **Mortality**

There were 2 mortality in the conservative group, both had acute cholecystitis with associated medical disease: one patient had myocardial infarction and the other patient had uncontrolled diabetes mellitus along with acute cholecystitis.

### **Morbidity**

In the conservative group of 44, ten patients required urgent operation because of failure of conservative treatment; one patient with diabetes mellitus as well had to stay long in the ward due to wound sepsis and delayed healing; and two patients developed chest complication which cleared off with changed antibiotics.

In the early operation group of 60, ten patients had wound infection, ranging from skin redness to abscess formation: two out of these 10 required proper drainage and appropriate antibiotic after culture/sensitivity which showed mixed infection of E-coli and staphylococci. In 4 patients bile drained through the tube for more than 48 hours but the drainage then ceased spontaneously without further complication. One patient needed re-exploration after 8 hours due to bleeding of cystic artery, in which the

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ligature had slipped, required more blood transfusion and securing hemostasis. She recovered and went home on 10th day.

### Discussion

Despite the small number of patients in this trial, the preliminary results permit some broad conclusions. Though there is slightly greater technical difficulty in operating on some of the patients in the acute phase, there is in fact no mortality or serious morbidity in this group, in particular there was no evidence of increased risk of damage to the common bile or hepatic ducts.

Secondly the Ultrasonogram has reduced the mis-diagnosis of acute cholecystitis to almost nil. It is true that operation may turn out to be unnecessary if under taken early in the acute phase. Essenhich estimated that as many as 16 percent have un-necessary operation<sup>3</sup>. The chance of correct diagnosis is increased by the sophisticated technique of ultrasound. In the present series there was no mis-diagnosis.

We found that the operation was more difficult in cases when there was failed conservative treatment. The common belief of dangerous period in acute cholecystitis being 7th to 14th day is not correct, due to early treatment with some antibiotic available every where and so the course of events is changed. On one hand we have performed cholecystectomy on 10th day quite easily, on the other hand we have seen mass formation on third day of acute cholecystitis, preventing surgical intervention in our series.

Secondly considerable technical difficulty can be met when conservative treatment fails. Wright and Holden described a mortality as high as 24% if operation had to be carried out after the fourth day of conservative treatment<sup>6</sup>. In two of our cases technical difficulty was such that we had to remove gall bladder piece-meal. The main benefit of early cholecystectomy is that serious complications of conservative treatment can be avoided. Schrohl et al in a review of 5000 patients found that in 630 the gall bladder had perforated<sup>4</sup>, an incidence of 12.6%. Du Plessis and Jersky considered that perforation had occurred in 15% of 250 patients<sup>2</sup>. In the present series 20 out of 60 patients (33.3%) undergoing early operation and 10 patients in the conservative group of 44 patients (22.6%) were noted to have necrotic changes in the gall bladder and one patient had complete

gangrenous perforated gall bladder. It can, therefore, be concluded that with proper clinical assessment and investigations including Ultrasonography, early operation may be of some benefit to the patients in avoiding some of the complications of medical treatment and allowing a shorter stay in the Hospital. There is no evidence that such an approach is accompanied by a higher morbidity/mortality. Bailey and Love state that because of the frequency of perforation in acute salmonella typhi infection of the gall bladder (common in Asia), early operation must always be advised<sup>1</sup>. These results encourage us to continue this controlled trial of the treatment of acute cholecystitis.

**TABLE-I**  
**STRATIFICATION**

	Early Operation	Conservative Treatment
No. of cases	60	44
Age	20-60 years (mean 40 years)	20-60 years (mean 40 years)
Duration of symptoms	1-10 days	-30 days
Male/Female Ratio	3 - 60 (1 : 20)	2 - 44 (1 : 22)

**TABLE-II**  
**TOTAL DURATION OF HOSPITAL STAY**

Group	No. of Cases	Days in Hospital
Early operation	60	4-10 days (mean 6 days)
Conservative successful	34	7-12 days (mean 8 days)
Conservative failed	8	12-30 days (mean 22 days)

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