Randomised Trial of Standard Cholecystectomy Versus Mini Cholecystectomy

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Gall bladder disease continues to be one of the most common digestive disorder seen by physicians. Removal of the gall bladder is the standard procedure when the gall bladder is diseased or contains calculi. Standard open cholecystectomy has significant morbidity in the form of post operative pain, pulmonary complications, intra abdominal adhesions, infection, incisional hernia and delayed return to work. Improvements in technique enables operation to be performed safely through a smaller incision (5 cm), During the 15 month study informed consent to randomisation was sought from 60 consecutive patients eligible for the trial.30 patients had standard and 30 had minicholecystectomy. Our results show less operating time ,less postoperative pain and earlier return to work with minicholestectomy than standard cholecystectomy There were 3 complications in standard cholecystectomy (wound infections-2, biliary leak-1) and1 in minicholecystectomy(bile collection- which settled after percutaneous aspiration under ultra sound control)Our results compare favourably with other similar series. In conclusion , cholecystectomy can be safely performed through a 5-7 muscle retracting incision
Key words : Cholecystectomy,, Minicholecystectomy

Gall bladder disease continues to be one of the most common digestive disorder seen by physicians. Removal of the gall bladder is the standard procedure when the gall bladder is diseased or contains calculi. In 1879 the first successful removal of stone from gall bladder in human was performed by Lawson Tariff[1,2].

Cholecystectomy through Laparotomy has been the standard operation for gall stone disease for the past 100 years. It is the most commonly performed elective operation in the West. It is one of the simplest and fastest of all abdominal procedures, provided there is adequate access[3,4,5,6].

Standard cholecystectomy has significant morbidity in the form of post operative pain, pulmonary complications intra abdominal adhesions, infection, incisional hernia and delayed return to work[7].
Improvements in technique enable operation to be performed safely through a smaller incision (5 cm), although laparoscopic cholecystectomy is generally preferred over other modalities, it has still got some disadvantages like more time consumption, a higher of bile duct injury, two dimensional view , need of trained man power and need of expensive instruments[8,9].

Minicholecystectomy has the advantage that neither it requires expensive instruments nor the acquiring of new skills by the surgeon. This operation rather than conventional cholecystectomy is the standard by which alternative methods for treating should be compared[10,11].

Material and Methods:
During the 15 month study informed consent to randomization was sought from 60 consecutive patients eligible for the trial. Mean duration of symptoms before surgery was noted. Pain right hypochondrium, flatulent dyspepsia, nausea and vomiting, heart burn, feeling of heaviness were the main symptoms for which the patients were offered cholecystectomy as the treatment.

Following were the laboratory investigations which were performed haemoglobin, serum bilirubin, alkaline phosphatase, SGPT and SGOT. Ultrasonography was the investigation of choice for the diagnosis of cholelithiasis.

In open cholecystectomy, we made Kocher's incision of about 12-15cm. The rectus abdominis muscle was divided in all cases. A transverse incision was made of 5-7cm in cases where minicholecystectomy was performed. Rectus abdominis muscle was retracted to approach the abdominal cavity.

The data included age, sex, weight of the patient, duration of operation, reasons of conversion from mini to standard cholecystectomy, pain score, post operative nausea and vomiting, post operative complications, length of hospital stay and time to return to normal work.

Results:
During the 15 month study an informed consent of randomization produced two groups of 30 patients each with similar pre operative characteristics.

Table 1. Characteristics of patients

Sex	Standard Cholecystectomy	Mini Cholecystectomy
Male	2 (6.6%)	01 (3.3%)
Female	28 (93%)	29 (96.6%)
Age	55 years	52.2 years
	(35-75 years)	35-70 years
Body	65Kg	66.5Kg
weight	(52-78Kg)	(50-88Kg)
Parity	04	04

Values in prarentheses show the ranges.

The age sex and weight characteristics in both groups are shown in Table no 1. Distribution of patients regarding symptomatology is shown in Table 2.

Table 2. Distribution of patients according to symptoms

Symptomatology	n=	%age
Pain	60	100
Flatulent dyspepsia	48	80
Nausea/vomiting	40	66.6
Heart burn	13	21.6
Intolerance to fat	5	8.3

In this study there was a significant difference between duration of operation in minicholecystectomy with a mean time of 45 minutes compared with 55 minutes mean time in case of standard cholecystectomy as presented in Table 3.

Table 3. Operating time

	n=	Time in minutes	Mean minutes
Standard cholecystectomy	30	50-60	55
Mini cholecystectomy	29	35-45	45
Conversion cholecystectomy	1	75	

Post operative pain was experienced in patients of both the groups with variable intensity. All patients received inj. Pentazocin 30 mg iv during anaesthesia. Additional doses of analgesia were repeated on patient demand. There was definitely more post operative pain in standard cholecystectomy needing increasing requirement of analgesia as mentioned below in Table 4.

Table 4. Pain score (VAS)

Additional doses of analgesic	Standard cholecystectomy n=	Mini cholecystectomy n=
1	4	12
2	4	8
3	7	5
4	6	5
5	3	-
6	2	-
7	3	-
8	1	-

$P < 0.05$ (Mann-Whitney U test)

Regarding post operative course bowel sounds appeared 8 hours (6-24 hours) in mini cholecystectomy and bowel sounds appeared after 20 hours (16-30) in standard.

Minicholecystectomy was successfully completed in 29 patients. In a 45 years old man incision was converted to a standard one because of multiple adhesions resulting in obscure anatomy.

There were 10 complications in standard cholecystectomy like wound infection in 2 cases and biliary leak in one which spontaneously closed after 4 days drainage.

Table no 5 Postoperative complications

Complications	Minicholecystectomy	Standard Cholecystectomy
Prolonged bile leakage	0	1
Biloma	1	0
Wound infection	0	2
Scar pain	3	7

The single early complication seen in minicholecystectomy group was delayed bile collection in a 45 year old male. He was readmitted with the complaints of pain, fever and marked tenderness in the right hypochondrium. Ultrasonography confirmed the collection which was drained by putting a tube drain. There was a significantly shorter stay in minicholecystectomy as compared to standard cholecystectomy as shown in Table 7.

Table 7. Length of hospital stay

No of days	Standard Cholecystectomy	Mini cholecystectomy
2	0	0
3	0	28
4	15	1
5	9	0
6	5	0
7	1	0

$P < 0.01$ (Student 't' test)

Patients returned to normal activity and work significantly faster after successful minicholecystectomy as shown in Table 8

Table no 8: Time to return to normal work

Standards cholecystectomy n=		Mini cholecystectomy	
No. of pts.	No. of weeks	No. of pts.	No. of weeks
0	2	2	3
0	3	19	3
0	4	7	4
7	5	1	5
12	6	0	6
7	7	0	0
4	8	0	0
0	0	0	0

$P < 0.05$ (Student 't' test.

Discussion:

Despite many recent innovations in the treatment of gall stones cholecystectomy remains the treatment of choice.

Table 9 : Comparison of sex incidence in different series in cholecystectomy

Study	No. of Pts. n=	Male (%)	Female (%)
Menqebauer et al (1991)	100	82	18
Peters et al (1991)	100	81	19
Soper et al (1991)	618	75	22
Southern Surqeons (1991)	1518	75	25
Bankun et al (1992)	37	70	30
Fullarton et al (1994)	100	78	22
Fullarton et al (1994)	100	78	22
McMohan et al (1995)	151	88	12
McGinn et al (1995)	150	72	28
Chaudry et al (1995)	80	85	15
Present study (1997)	100	93	7

Current methods of dissolution, disintegration of gall stones have unsatisfactory long term results. The results of

our study also compare favourably with other studies.

Sex incidence was 93% female and 7% male which was not dissimilar to other studies as shown in Table 9. The mean age of our patients was 52.5 years with range of 35-75 years. Its comparison with other studies is shown in Table 10.

Table 10 Age incidence in minicholecystectomy

Study	Mean age in years	Range in years
Barkun et al(1992)	52.3	34-70
O'Dwyerr et al (1993)	46	27-74
Tate et al 91993)	49.9	38-60
McMohan et al (1995)	52	41-63
McGinn et al (1995)	57	26-84
Present study 91997)	52.5	35-75

Our operating time 45 minutes was significantly lower than in other studies as shown in table 11.

Table no 11: Operating time in minicholecystectomy

Study	Operating Time (minutes)	P value
Barkum et al (19920	73.1Ý25	0.08
Barkum et al (19930	73.1Ý25	0.08
Zahid et al (1993)	60(45-88)	-
McGinn et al (19950	50	<0.05
Present study (1997)	44.72Ý11.04	<0.05

In our series mean time to return to normal activity was four weeks which compare well with other studies as shown in table no 12.

Table no 12: Mean time taken by patients to return to normal activity in minicholecystectomy

Authors	Minicholecystectomy (weeks)
Dubois et al (1982)	4.8
Barium et al (1993)	2.8
Zahid et al (1993)	1.7
Tate et al (1993)	2.8
McGinn et al (1995)	6.0
Present study (1997)	4.0

In our study we demonstrated shorter duration of operation, lesser post operative pain and earlier return to work with lesser post operative complications in mini cholecystectomy as compared to standard cholecystectomy.

In conclusion cholecystectomy can be performed safely through a 5-7 cm muscle retracting incision in most patients with symptomatic gall stones. In addition mini cholecystectomy does not need expensive equipment or specially trained surgeons[10,11].

Conclusion:

Parameters of comparison like duration of operation, mean hospital stay, quality of recovery, return to activity. cost effectiveness and lesser post operative pain are in favour of mini cholecystectomy. Conversion to standard should be done in cases of technical difficulty. Minicholecystectomy has definite advantages over standard cholecystectomy in term of operating time, post-operative pain, mean hospital stay, return to activity. With minimal retraining most of the general surgeons can perform most of the cholecystectomies through a small incision Conversion to standard cholecystectomy should be done where technical difficulties are encountered.

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