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COST-EFFECTIVENESS ANALYSIS OF LAPAROSCOPIC VERSUS MINILAPAROTOMY CHOLECYSTECTOMY FOR GALLSTONE DISEASE

A Randomized Trial

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Abstract

Objective: To evaluate the total cost of minilaparotomy cholecystectomy (MC) and laparoscopic cholecystectomy (LC) and perform a cost-effectiveness (CE) analysis.
Methods: One hundred adult subjects with painful gallstone disease were randomized: 59 cases for LC and 41 cases for MC. Patients with gallstones shown on ultrasound with normal common bile duct and no history of icterus were included after an informed consent. Cases with acute cholecystitis and raised alkaline phosphatase were excluded. LC was performed using CO_2 insufflation and a Storz 2D video camera. MC was done by transverse rectus cutting incision. Outcome was coded as success or failure. Success was defined as operation without injury to bile duct, viscera or vessels, minimal pain and discomfort at 4 weeks, no wound infection up to 4 weeks, and resumption of work within 2 weeks of operation. The total cost of each case included cost of investigations, cost of disposable articles for operation, cost of drugs, cost of hospital stay, and cost of operation including anesthesia. LC and MC were done with reusable instruments. A "societal viewpoint" has been taken in the cost calculations.
Results: There were 50/59 successful outcomes in LC and 15/40 outcomes in MC group. Total cost for LC was 386,769 rupees (Rs) and for MC was Rs 205,041. CE in LC was Rs 7,735 and in MC was Rs 13,669. Incremental CE ratio comparing LC with MC was 3,028.33.
Conclusion: LC is a more cost-effective method for treatment of gallstone disease.

Keywords: Laparoscopic cholecystectomy, Minilaparotomy cholecystectomy, CE ratio, Incremental cost, Randomized trial

Cholecystectomy is one of the most common general surgical procedures done in most North Indian hospitals. With the introduction of laparoscopic surgery, laparoscopic

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cholecystectomy (LC) has caught the fancy of surgeons as well as the lay public. The benefits of LC are widely publicized in the media. However, the technique requires expensive equipment and the expertise of highly skilled surgeons. In a country with scarce resources, both the availability of funds to buy expensive equipment and highly trained personnel are limited; therefore, it is necessary to evaluate the usefulness of the new technology using cost-effectiveness analysis.

Minilaparotomy cholecystectomy (MC) is a modification of the open cholecystectomy technique in which a smaller incision is given for a length varying from 5 to 10 cm, which is reported to have many of the benefits of LC but at a lesser cost. There are only a few trials comparing LC with MC. These trials have shown that LC is associated with less postoperative pain and discomfort, shorter hospital stay, and earlier resumption of work with comparable complications in the two groups (5;6;7). We conducted a randomized trial to evaluate the cost-effectiveness of LC and compared it with MC.

METHODS

One hundred adult patients with right upper abdominal pain without any history suggestive of obstructive jaundice and ultrasonic demonstration of gallstones with normal common bile duct, pancreas, and liver were included in the study between July 1995 and April 1997. The patients were recruited after giving informed consent and randomized using numbered, sealed envelopes in a ratio of 3:2 (3LC:2MC) ratio. This 3:2 allocation ratio was used to recruit sufficient cases since more patients were willing to undergo LC than MC. Zelen's method of obtaining consent after randomization was used.

Exclusions

Patients with a history of obstructive jaundice and with stones in the common bile duct were excluded. The educational background, economic status, employment status, duration of symptoms, associated medical illness, and history of previous abdominal surgery were recorded on a pro forma. All the LC and MC were performed by consultant surgeons experienced in the two procedures and who were well over the learning curve.

MC was performed by a right upper abdominal transverse rectus cutting incision of 5 to 10 cm in length. LC was done by four trocars using carbon dioxide insufflation. Tube drains were placed in all patients. The time taken for each operation was recorded as the time from the first skin incision to the last suture placement in both techniques. Patients were followed weekly for 4 weeks after discharge from the hospital. On follow-up visits, the wound was assessed for evidence of infection. The wound infection was defined as any discharge from the wound requiring dressing or surgical drainage. The wound pain was recorded on a Visual Analogue Scale (VAS) of 0 to 10. The day of resumption of household and/or office work was recorded.

Assessment of Cost

The total cost of each procedure was calculated as the sum of the direct and indirect costs. The direct costs included the cost of disposable materials for the operation, the hospital stay charges, cost of drugs and investigations, and operation charges, including anesthesia. The operation charges were calculated as the sum total of equipment cost and the operation theater cost (includes personnel cost, anesthesia). The cost of special laparoscopic equipment (camera, monitor, gas insufflator, and laparoscopic instruments) as included in the direct costs.

The indirect cost was calculated as the cost of travel. We have not included the cost of lost wages in either group since most of our patients were housewives. Since it is a

Table 1. Baseline Characteristics

	LC (n = 59)	MC (n = 40)
Mean age	41.13 yrs (95% CI: 37,44)	9.17 yrs (95% CI: 35,42)
Gender	55 females	31 females
	4 males	9 males
Education status	43 literates	29 literates
	16 illiterates	11 illiterates
Mean monthly income	Rs 3,528.8	Rs 3,532.5
	(95% CI: Rs 3,062, 3,995)	(95% CI: Rs 2,537, 4,527)

Table 2. Nature of Work

	LC (n = 59)	MC (n = 40)
Household	36 (61%)	19 (47.5%)
Shares household	14 (23.7%)	6 (15%)
Office	4 (6.8%)	10 (25%)
Household and office	5 (8.5%)	5 (12.5%)

Table 3. Pain Scores on VAS of 0–10 Mean (95% CI)

	LC	MC	
	Mean 95% CI	Mean 95% CI	*p* Value[a]
Pain score at 24 hr after operation	3.2 (2.9, 3.5)	5.5 (5.1, 5.9)	.0000
Pain score at 1st week follow-up	2.2 (1.7, 2.6)	3.6 (3.2, 4.1)	.0000
Pain score at 2nd week follow-up	0.6 (0.3, 0.8)	2.5 (1.8, 3.1)	.0000
Pain score at 4th week follow-up	0.20 (0.06, 0.34)	1.3 (0.8, 1.8)	.0000

[a] *p* Values on Wilcoxon rank-sum test comparing pain scores in LC with MC.

randomized study, the exclusion of loss of wages in both the groups probably will not affect the overall cost-effectiveness.

The existing instruments available in the operation theater were sufficient for performing MC; therefore, no extra equipment cost has been added to this group. However, LC required a special Storz 2D video camera, video monitor, CO_2 gas insufflators, and a set of laparoscopic instruments. The operation theater cost has been estimated by the AIIMS hospital billing section to be 2,000 rupees (Rs) per case for the period of study. The entire set of laparoscopic equipment was bought at the initial cost of Rs 1,329,279. Taking a discount rate of 5% and assuming the life span of the equipment as 7 years, the annual equivalent cost comes to Rs 307,194. We perform an average of 450 LC per year with this set of instruments. Therefore, the average equipment cost per case of LC is Rs 307,194/450 = Rs 682. Thus, operation charges were Rs 2,000 for MC and Rs 2,000 + Rs 682 for LC. Outcome was defined *a priori*, successful removal of gall bladder by either of the techniques, or a failure.

Successful removal was defined as no injury to bile duct, viscera, or vessels, and minimal pain and discomfort at 1 month of follow-up, no wound infection up to 1 month of follow-up, and resumption of daily routine household and/or office work within 14 days of operation.

Failure was defined as failure to remove the gall bladder laparoscopically or by minilaparotomy, necessitating conversion to open cholecystectomy (in MC, extension of incision of more then 10 cm was taken as failure), bile duct or intestinal injury, postoperative wound

infection within 1 month of follow-up, moderate to severe abdominal pain at 1-month follow-up, or failure to resume the household and/or office work up to 14 days after operation.

Cost-effectiveness (CE) in a group was defined as:

$$\text{CE} = \frac{\text{Total cost incurred}}{\text{No. of successful procedures done}}$$

Incremental CE ratio was calculated as (2):

$$\text{CE ratio} = \frac{\text{IC}}{\text{IE}}$$

where
IC = incremental cost = TC1 − TC2; and
IE = incremental health outcome = E1 − E2.

Statistical Analysis

The data were entered on Epi info 6 database (WHO) and analyzed on Stata-6 statistical package (Stata Corp., Texas). Nonparametric statistical tests were used for non-normally distributed data.

RESULTS

A total of 59 patients were entered in the LC group and 41 in the MC group. One patient was excluded from the MC group because she was found to have adenocarcinoma gall bladder postoperatively on histopathology report. One patient was randomized for MC but later decided to undergo LC. Outcome of this case was analyzed in MC in order to adhere to the principle of "intent to treat."

There were 50 successful cases of a total of 59 in the LC group and 15 successful cases of a total of 40 in the MC group.

Mean operative time in the LC group was 54.2 minutes with 95% CI: 48.7, 59.6. In the MC, mean operative time was 57.2 minutes with 95% CI: 51.5, 62.9. The difference in mean operative time between the two groups was not significant (Kruskal-Wallis H = 1.425; $p = .232504$).

In the LC group there was no conversion, no randomization violation, and per-operative cholangiogram was not done. In the MC group there was conversion to open cholecystectomy in one patient with stones in the common bile duct, where the incision was extended to more than 10 cm in length. In this patient a per-operative cholangiogram was done after clearance of stones in the common bile duct.

The mean day of drain removal in the LC group was 1.2 days (95% CI: 0.94, 1.6). In the MC group, mean day of drain removal was 1.6 days (95% CI: 1.2, 2). The difference between the two groups was not significant on Wilcoxon rank-sum test ($p = .06$).

Mean postoperative hospital stay in the LC group was 1.2 days (95% CI: 0.9, 1.6) and in the MC group was 1.62 days (95% CI: 1.19, 2.0, Wilcoxon rank-sum test ($p = .06$)).

Bile leak was present in one patient (1.7%) in the LC group and five patients (12.5%) in the MC group. It stopped without any intervention in all the cases and there was no bile duct injury. On comparison of bile leak between the LC and MC groups, bile leak was significantly less in the LC group (Fisher exact test, $p = .038$).

Wound infection was present in 11 patients in the MC group; of these, seven had only serous discharge, which stopped with daily dressings and antibiotics. Four patients had pus discharge from the wound. Return to routine household and/or office work was delayed in all patients with wound infection.

Table 4. Cost and Outcome in Each Procedure

	LC (n = 59)	MC (n = 40)
Total cost in rupees	386,769	205,041
Mean of total cost	6,555.407	5,126.025
95% CI of total cost	5,754.5, 7,356.27	4,543, 5,708
Successful outcome	50 (84.7%)	15 (37.5%)
Cost per unit successful outcome (CE ratio)	7,735.38	13,669.40

Cost Analysis

The total costs with their 95% CI for both the groups are given in Table 4. The cost per unit successful outcome is less in the LC group.

Incremental CE Ratio

$IC = TC1 - TC2 = 386769/59 - 205041/40 = 6555.4 - 5126.025 = 1429.375$;
$IE = E1 - E2 = 50/59 - 15/40 = 0.847 - 0.375 = 0.472$; and
Incremental CE ratio $= IC/IE = 1429.375/0.472 = 3028.33$
where
TC1 = total cost per person, in present value terms, for LC program;
TC2 = total cost per person, in present value terms, for MC program;
E1 = total health outcome per person, in present value terms, for LC program; and
E2 = total health outcome per person, in present value terms, for MC program.

DISCUSSION

Laparoscopic cholecystectomy is now regarded as the gold standard treatment for gallstone disease. For a procedure to be called a gold standard, it should be safe and effective with minimal complications and should preferably be cost-effective.

The mean operative time was less in laparoscopic compared with minilaparotomy cholecystectomy. However, some studies have disagreed with this finding (3;7;8). We did not perform preopcholangiogram in all patients, which might lead to increased operative time and cost in the laparoscopic group, since laparoscopic cannulation of the common bile duct requires more expertise and time. Incidence of bile leak was higher in MC; wound infection rates were also high in MC. The LC group had no wound infection. Similar findings are reported in the literature (4). However, Majeed et al., McMahon et al., and Supe et al. (3;7;8) reported no difference in morbidity between the two groups. Postoperative hospital stay was less in the LC group. LC was associated with earlier return to routine household and office work when compared with MC. These findings are supported by others (1;4;5;7); however, Majeed et al. (3) and Supe et al. (8) reported no difference between the two groups. Postoperative pain was also less in the LC group. Similar findings were reported by other authors (7;8), but Majeed et al. (3) found no difference between the two groups. Cost of each procedure was higher in LC than MC, but based on the criteria of success and failure, LC had fewer failures than MC, and therefore the CE ratio was less. The incremental CE ratio was found to be 3,028.33. Majeed et al. (3) and McMahon et al. (7) reported that LC involved greater costs, but none of them actually calculated the cost-effectiveness. LC had nine failures, all of which were due to late resumption of daily routine and/or office work.

The MC group had 25 failures out of 40 cases. The causes for failure were wound infection in 11, delayed return to work in 13, and moderate pain at 4 weeks in 1 case. Of the 11 patients with wound infection, 7 had only serous discharge, which stopped with

daily dressing and antibiotics. Four patients had pus discharge from the wound. Return to routine household and/or office work was delayed in all patients with wound infection. Our study clearly demonstrated greater incremental CE for the LC group at our hospital. We recommend its adoption by most public sector hospitals because it will result in significant savings. This recommendation should be taken with a word of caution that the surgical team should be appropriately trained and adept in laparoscopic techniques such as dissection, clipping, and knot tying and suturing while viewing a 2D television image.

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