Original Article

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Comparison of Outcome between Conventional Laparoscopic Cholecystectomy vs Augmented Single Hole Cholecystectomy (ASHCHOLE)

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ABSTRACT

Introduction: Laparoscopic cholecystectomy is the mainstay treatment for symptomatic gallstones. In conventional or standard laparoscopic cholecystectomy four ports (two of 10-mm diameter and two of 5-mm diameter) are usually used. An innovative assisted single whole laparoscopic cholecystectomy procedure using low profile cannulas is designed to contemplate this procedure to reduce cost and have better cosmetic results especially in young females. **Objective:** To compare the outcome between conventional laparoscopic Cholecystectomy vs Augmented Single Hole Laparoscopic Cholecystectomy (ASCHOLE). **Study Design:** Randomized controlled trial. **Setting:** Surgical unit-III Allama Iqbal medical college Lahore, Department of Surgery, Khawaja Muhammad Safdar Medical College Sialkot. **Duration:** 3 years from January 2016 to December 2018. **Sample Size:** 100 cases (50 in each group). **Sampling Technique:** Non-probability Purposive Sampling Technique. **Results:** A total of 100 cases (50 in each group) were enrolled for this study. Group-A patients who underwent ASHCHOLE and Group-B conventional laparoscopic cholecystectomy. Regarding age distribution of the patients majority of the patients in both groups were recorded between 31-40 years of age i.e. 38%(n = 19) in Group-A and 34%(n = 17) in Group-B, 28%(n = 14) in Group-A and 22%(n = ll) in Group-B were between 20-30 years, 22%(n = ll) in Group-A and 28%(n = 14) in Group-B were between 41-50 years while 12%(n = 6) in Group-A and 16%(n=8) in Group-B were between 51-60 years, mean and SD was calculated as 38.43±4.21 years in Group-A and 39.65±511 in Group-B. Gender distribution of the patients show 42 %(n = 21) in Group-A and 36 %(n = 18) in Group-B were male while 58 %(n = 29) in Group-A and 64 %(n = 32) in Group-B were females. Comparison of mean operative time in both groups reveals 50.89±13.42 minutes in Group-A and 34.55±6.17 in Group-B, p value was < 0.005. Comparison of mean pain score in both groups revealed 3.14±0.76 in Group-A and 6.13±1.21 in Group-B, p value was < 0.005. **Conclusion:** The results of the study revealed that ASCHOLE is safe technique having less postoperative pain and single fine scar hidden in umbilicus than conventional laparoscopic cholecystectomy.

Keywords: ASHCHOLE, Conventional cholecystectomy, Postoperative pain, Better outcome.

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INTRODUCTION

About 10% to 15% of the adult Western population have gallstones.[1]1%-4% become symptomatic each year. Laparoscopic cholecystectomy is the main stay treatment for symptomatic gallstones.[2]This procedure results in less postoperative pain, better cosmesis, and shorter hospital stays and disability from work than open cholecystectomy [2-8]. However, the overall serious complication rate in laparoscopic cholecystectomy remains higher than that seen in open cholecystectomy. In conventional or standard laparoscopic cholecystectomy four ports (two of 10-mm diameter and two of 5-mm diameter) are usually used.[3]

The use of four ports has four different scars and postoperative pain. The use of three ports and even single port laparoscopic cholecystectomy has been described in literature.[4,7,8] The gadgets used in single port laparoscopic cholecystectomy are very costly.

An innovative assisted single hole laparoscopic cholecystectomy procedure using low profile cannulas is designed to contemplate this procedure to reduce cost and have better cosmetic result especially in young females. Optical 5mm port and working port for clip applicator and other instruments is introduced through umbilicus using two separate incisions, one 1 cm incision and other 0.5cm incision with a skin bridge of 1mm in between.

A 2mm size liposuction cannula is introduced through a 2 mm stab incision in the in epigastrium to dissect Callot's triangle. This cannula performs functions of retractor, dissector & suction to dissect cystic duct and cystic artery. This modified cannula has been named as Zach's probe dissector named after the principal author.

All grasping, diathermy and clipping are done through 10mm umbilical port. The gall bladder after dividing of cystic duct and cystic artery is dissected out of liver bed. The specimen is brought out through umbilicus after the cutting 1mm skin bridge and joining the two rents in the Linea Alba used for optical and working instruments.

Following removal of specimen 1.5-2 cm rent in Linea Alba is stitched by Prolene No. 1 under direct vision so as to prevent any future port site herniation. The rationale of this study was to introduce a new technique with less postoperative pain and obviously better scar aiming at scarless surgery.

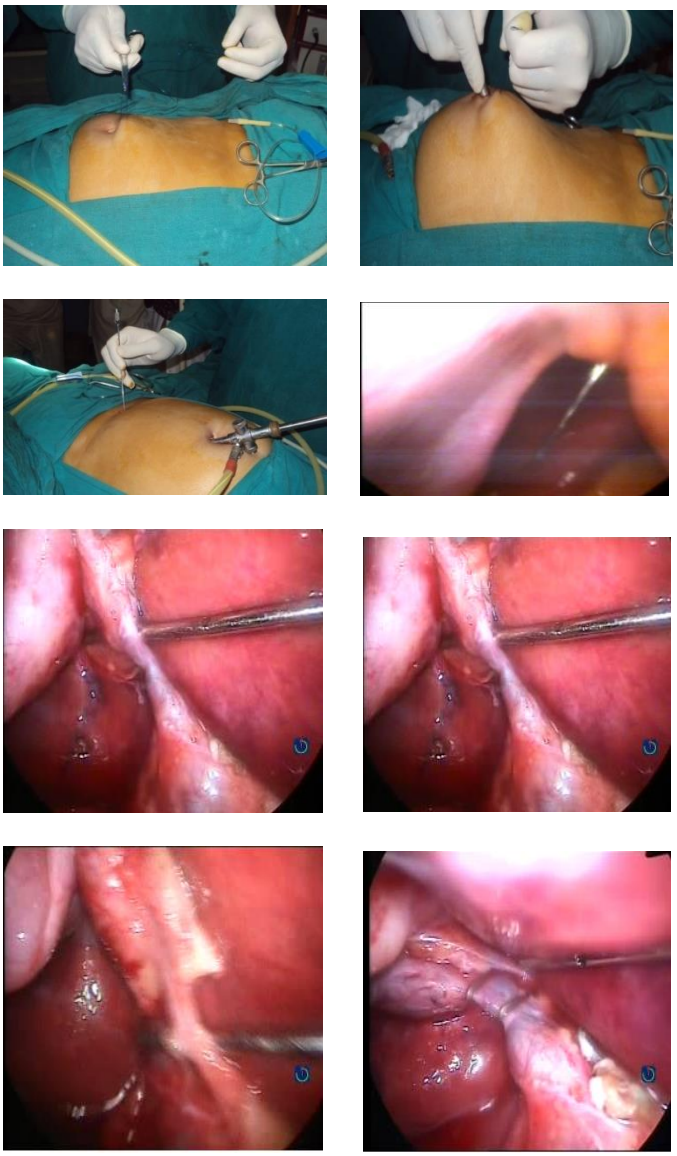


Figure 1: Steps of ASCHOLE

Figure 2: First Postoperative Day

Figure 3: Postoperative scar

OPERATIONAL DEFINITIONS

1-Assessment of patient: It is carried out through visual analog score & patient satisfaction proforma.

- **Patient Satisfaction Proforma**

1. Are you less satisfied with your body since the operation?
range: 1 = no, not at all
2 = a little bit
3 = quite a bit
4 = yes, extremely
2. Do you think the operation has damaged your body?
range: 1 = no, not at all
2 = a little bit
3 = quite a bit
4 = yes, extremely
3. Do you feel less attractive as a result of your disease or treatment?
range: 1 = no, not at all
2 = a little bit
3 = quite a bit
4 = yes, extremely
4. Do you feel less feminine/masculine as a result of your disease or treatment?
range: 1 = no, not at all
2 = a little bit
3 = quite a bit
4 = yes, extremely
5. Is it difficult to look at yourself naked?
range: 1 = no, not at all
2 = a little bit
3 = quite a bit
4 = yes, extremely
6. on a scale from 1 to 7, how satisfied are you with your (incision) scar?

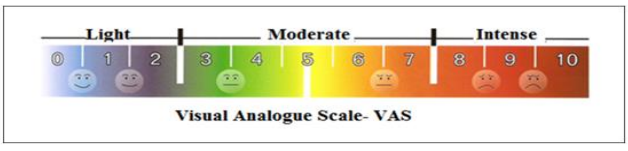
1 = very unsatisfied	2	3	4 = not unsatisfied / not satisfied	5	6	7 = very satisfied

7. On a scale from 1 to 7, how would you describe your (incision) scar?

1 = Revolting	2	3	4 = not revolting/ not beautiful	5	6	7 = beautiful

8. Could you score your own incision scar on a scale from 1 to 10?
9. How confident were you before your operation?
Range: 1 = not very confident
10 = very confident
10. How confident were you after your operation?
Range: 1 = not very confident
10 = very confident

- **Visual Analog Score**



METHODOLOGY

Study Design: Randomized controlled trial.

Setting: Allama Iqbal medical college Lahore & Department of Surgery. Khawaja Muhammad Safdar Medical College Sialkot

Duration: 3 years from January 2016 to December 2018.

Sample size: Sample size of 100 cases (50 in each group)

- 95% confidence interval
- 80% power of test
- Expected mean±S.D of mean pain score in both groups i.e. 2.93±0.98 in Conventional versus 5.23±1.52 in ASHCHOLE.

Sampling Technique: Non-probability purposive sampling technique.

Inclusion Criteria: Patient with diagnosis of symptomatic gallstone disease between ages 20-60 years of either gender scheduled for laparoscopic cholecystectorny.

Exclusion Criteria: Patients not fit for anesthesia. Patients with repeated attacks of cholecystitis, cholangitis or pancreatitis; or radiological finding of complicated gallbladder disease or suspected gallbladder carcinoma (on history, physical and radiographic examination and medical record)

Data Collection: All patients fulfilling the inclusion/exclusion criteria selected for laparoscopic cholecystectomy from Surgical Surgical Unit of Khawaja Muhammad Safdar Medical College Sialkot were included in the study. Approval from ethical committee was obtained. An informed consent was also taken from the patients to include their data in research work with the assurance of confidentiality. Two equal groups (A&B) were made, group A was allotted to the ASCHOLE and Group-B to the patients undergoing conventional cholecystectomy, simple randomization using a random number table was done by the researcher. Procedure was done by the researcher under the supervision of senior registrar having more than
5 years' experience of surgery, the operative time of the procedures and pain score on 8th post-operative hour on VAS was recorded, all this information was recorded on a pre-designed proforma (annexure). At the 6-week follow-up almost all of the patients were satisfied in term of cosmesis and resultant scar, reporting a mean satisfaction score of 9.5 (range: 7–10). The mean time required before returning to work or normal activities was 3 days (range: 2-4 days).

Data Analysis: The collected data was entered in computer software SPSS software (version 11.0). Mean ± standard deviation was calculated for quantitative variables like age, operative time and pain score in both groups. The frequency and percentages were calculated for gender and presented in tabulated form, t-test was applied on mean operative time and mean post-operative pain score in both groups to determine the significance. P value <0.05 was considered as significant.

RESULTS

A total of 100 cases (50 in each group) were enrolled after fulfilling the inclusion/exclusion criteria for comparison of outcome of four port versus single hole laparoscopic cholecystectomy.

Age distribution: shows that the patients in both groups were recorded between 31-40 years of age i.e. 38%(n = 19) in Group-A and 34%(n = 17) in Group-B, 28%(n = 14) in Group-A and 22%(n = ll) in Group-B were between 20-30 years, 22%(n = ll) in Group-A and 28%(n = 14) in Group-B were between 41-50 years while 12%(n = 6) in Group-A and 16%(n=8) in Group-B were between 51-60 years, mean and SD was calculated as 38.43±4.21 years
in Group-A and 39.65±511 in Group-B.

Table 1: Age Distribution of the patients (n=100)

Age (in years)	Group-A (n=50)		Group-B (n = 50)	
	No. of patients	%	No. of patients	%
20-30	14	28	11	22
31-40	19	38	17	34
41-50	11	22	14	28
51-60	6	12	8	16
Total	50	100	50	100
Mean & SD	38.43±4.21		39.65±511	

Gender distribution: showed 42% (n = 21) in Group-A and 36% (n = 18) in Group-B were male while 58% (n = 29) in Group-A and 64% (n = 32) in Group-B were females.

Table 2: Gender distribution (n=100)

Gender	Group-A (n = 50)		Group-B (n = 50)	
	No. of patients	%	No. of patients	%
Male	21	42	18	36
Female	29	58	32	64
Total	50	100	50	100

Operative time: comparison of mean operative time in both groups reveals 71.89±13.42 minutes in Group-A and34.55 ± 6.17 in Group-B, p value was calculated as 0.001.

Table 3: Comparison of mean operative time (n=100)

Operative time (mins)	Group-A (n=50)		Group-B (n = 50)	
	Mean	SD	Mean	SD
	71.89	13.42	34.55	6.17

Mean pain score: Comparison of mean pain score in both groups revealed 3.14±0.76 in Group-A and 6.13±1.21 in Group-B, p value was calculated as 0.00.

Table 4: Comparison of Mean pain score (n=100)

Pain score	Group-A (n = 50)		Group-B (n=50)	
	Mean	SD	Mean	SD
	3.14	0.76	6.13	1.21

Return to activity and patient satisfaction score: Other parameters studied in this research are return to activity and patient satisfaction score. Length of hospital stay was short in Group-A (1-2 days) as compared to Group-B (2-3 days). Group-A patients return to normal activities (5-9 days) earlier then Group-B (7-12 days). Cosmesis score, overall satisfaction score and confidence after surgery was good in Group-A patients as compared to Group-B patients.

Table 5: Return to activity and patient satisfaction score

Parameters	Group A	Group B
Length of Hospital Stay	1-2 days	2-3 days
Return to normal activity	5-9 days	7-12 days
Cosmesis Score	8-10	6-7
Overall satisfaction score	9-10	7-8
Confident after surgery	8-10	6-8

DISCUSSION

Approximately 25 million adults in the United States have gallstones. 'Increasing age, obesity, hypernutrition, rapid weight reduction, ileal disease or resection, and certain ethnicity (eg, Pima Indians) are risk factors for developing gallstones.[3] Approximately 80% of patients with gallstones are asymptomatic and 20% have symptomatic biliary colic.[4]

We planned this study considering that the results of this study may be a guide to the surgeons who want to use single port technique for laparoscopic technique while the literature review is variant regarding operative time and post-operative pain score on VAS, an additional benefit of single port incision is "scar mark", in single port incision only one scar mark as compared to four scar marks in four ports laparoscopic cholecystectomy.

The results of the current study reveal operative time as 71.89±13.42 minutes in Group-A and 34.55±6.17 in Group-B, p value was calculated as 0.001, while comparison of mean pain score in both groups revealed 3.14±0.76 in Group-A and 6.13±1.21 in Group-B, p value was calculated as 0.00.

The findings of our study are in agreement with a local study showing that operative time (OT) was significantly lower in the four ports Laparoscopic group (28 versus 67 minutes) while another carried out study[10] in Pakistan shows that the operative time was 38.50±8.92 minutes and 80.17±30.16 minutes in four ports versus single port respectively while pain score measured on VAS scale (0-10 cm scale), it was 2.93±0.98 in four ports and 5.23±1.52 in single hole laparoscopic cholecystectomy.

Our results are in contrast with Prasad A and workers[9] reveals significant difference in the pain score between four ports versus single incision (3.14±0.76 in Group-A & 6.13±1.21 in Group-B). As for primary endpoints, SILC (single incision laparoscopic cholecystectomy) proved to be feasible although operative times compared with four port laproscopic cholecystectomy were significantly longer.

In a nonrandomized trial comparing SILC and standard laparoscopic techniques, Phillip and co-workers[5] proved an increased mean operative times for SILC. This is most likely explained on the basis of an inherent learning curve with any new technology such as SILC.

A recent study regarding SILC showed that the overall success and complication rates were 91% and 6%, respectively, which is in accordance with the results of our study.[6]

Another recent study by Jeff SW and colleagues[6] reviewed the initial results and surgical outcomes of single incision laparoscopic cholecystectomy and found that the initial cases to the subsequent cases, in the latter group the operating time was significantly shorter (86 vs 71 minutes; P=0.02), and the success rate was higher (80% vs 100%; P=0.05). During the median follow-up period of 6.8 months, four patients had complications i.e. postoperative urinary retention, haematoma and an incisional hernia.

However, we agree with the recommendations of the above study that the case of unclear anatomy or difficult dissection, additional working ports should be added without hesitation", and hypothesis of the study that "there is a difference in single and four ports laparoscopic cholecystectomy regarding mean operative time and mean postoperative pain score".[11,12]

Other parameters studied in this research are return to activity and patient satisfaction score. Length of hospital stay was short in Group-A as compared to Group-B which is explained by less number of incisions and less post-operative pain. Group-A patients return to normal activities earlier then Group-B due to above mentioned reasons.

Cosmesis score, overall satisfaction score and confidence after surgery was good in Group-A patients attributed to scarless surgery as compared to Group-B patients.

CONCLUSION

ASHCHOLE represents a new technique and concept in minimally invasive surgery. It was noted that the people started opting this surgical approach after seeing the results of novel surgical technique in the ward. It has far better outcome than conventional laproscopic cholecystectomy.

LIMITATION

This procedure cannot be performed in acute cholecystitis or in patient expected to have difficult anatomy. It should be performed only by experienced surgeons who have good hand eye coordination.

SUGGESTION

We suggest that this procedure should be further practiced and implemented in different surgical units because of it cost effectiveness and good outcome

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