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Original Article



Comparison of Biliary Leakage between Laparoscopic Versus Open Surgery of Liver Hydatid Cyst: A Randomized Controlled Trial

Muhammad Farrukh Aftab^{1,2*}, Khurram Niaz³, Hassan Abbas⁴, Muhammad Hafeez Ullah¹, Khalid Javed¹ and Laiba Anwar¹

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*Corresponding Author:

Muhammad Farrukh Aftab Torbay and South Devon Trust Foundation Hospital, Torquay, United Kingdom farrukhaf 2001@yahoo.com

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ABSTRACT

Hydatid cyst disease is challenging to treat, and surgery remains curative in the majority of cases. There has been more working done recently on laparoscopic Hydatid cyst disease surgery and comparing the outcomes with the open method. Objectives: To compare the frequency of post-operative outcomes vis. Biliary leakage, post-operative pain, wound infection rate, recurrence of Hydatid cyst disease, and length of hospital stay between open versus laparoscopic surgery in patients with liver Hydatid cyst disease. Methods: This randomized controlled trial was conducted in the Surgical Department of Nishtar Hospital, Multan. 84 patients were enrolled and underwent either laparoscopic or open conservative surgery with external drainage. Outcomes between the two groups in terms of biliary leakage, length of stay, pain, wound infection, and recurrence were compared. Statistical analysis was done using SPSS-25.0. Results: There was no significant difference present between groups in terms of biliary leakage (p=0.33), biliary leak output (p=0.21), and days till leak resolution (p=0.32). Biliary leaks occurred in 16.7% of cases in the open group. Pain scores were significantly lower in the laparoscopic group as compared to the open group (p=0.001). Wound infections occurred in 19% of cases in the open group and 4.8% cases in the laparoscopic group, and were significantly different (p=0.04). 2.4% cases had recurrences in both groups. Conclusions: Biliary leak rates between open and laparoscopic surgery for Hydatid cyst disease are comparable. Open surgery may have greater high-output biliary leaks. Advantages conferred by laparoscopic surgery are shorter length of hospital stay, fewer wound infections, and better pain control.

INTRODUCTION

Hydatid disease (HD) is a zoonotic disease caused by the Echinococcus species of tapeworm worldwide [1]. It is endemic in different countries such as Central Asia, South America, North Africa, the Mediterranean, Turkey, Australia, and New Zealand. The incidence of Hydatid disease in endemic areas ranges from 1 to 220 per 100,000 populations annually. Because of human migration, surgeons in developed countries are encountering patients with hepatic Hydatid disease more frequently, but may be unfamiliar with the treatment options for this

condition [2]. It can affect any part of the body, although the most common 50% to 70% site of occurrence is the right lobe of the liver, and finally cause a hydatid cyst, lower in the Lungs, 10%-15% and 5%-10% respectively in other organs of the human body [3]. Hydatid liver disease affects all age groups and both sexes equally. Most commonly involved age group is the third and fourth decade of life in endemic areas [4]. Without treatment, the cysts grow in size and eventually cause complications, leading to disability or even death. Only in exceptional circumstances

¹Department of Surgery, Nishtar Medical University, Multan, Pakistan

²Torbay and South Devon Trust Foundation hospital Torquay, United Kingdom

³Department of Surgery, Quaid e Azam Medical College, Bahawalpur, Pakistan

⁴Department of Surgery, Sheikh Zayed Medical College, Rahim Yar Khan, Pakistan

can spontaneous healing occur through the parasite's death and calcification [5]. First, in the 1600s, surgical procedure was tried for the treatment of hydatid cyst, and still now it is followed as the gold standard treatment and performed by conventional method [3, 6]. Therefore, the primary treatment option for hydatid cyst was only surgery, such as liver resection, cystectomy, pericystectomy, and deroofing with omentoplasty were practiced throughout the years [7], despite the increased interest in nonsurgical techniques. Because open procedures were reported as significant morbidity, especially in terms of wound infection and other complications [8]. The laparoscopic approach has become increasingly popular, although controversies regarding the role of laparoscopy in the management of hydatid disease have not been resolved to date. Laparoscopic approach has the advantages of smaller incision with better cosmetic results, and recent studies reveal the safety and effectiveness of the laparoscopic approach in hepatic Hydatid cyst. Laparoscopic techniques for drainage and unroofing of Hydatid cyst have been reported in a number of series with encouraging results [9]. Local literature on the optimum management of Hydatid disease is lacking, and no consensus guidelines are available. The result of the current study will help to compare the frequency of biliary leakage, pain, wound infection, recurrence, and hospital stay with open versus laparoscopic surgery in patients with liver Hydatid cyst. This will decrease disease-related morbidity in these patients and improve their quality of life. This study aims to compare the frequency of postoperative outcomes vis. Biliary leakage, post-operative pain, wound infection rate, recurrence of hydatid cyst disease, and length of hospital stay between open versus laparoscopic surgery in patients with liver hydatid cyst disease.

METHODS

This Randomized Controlled Trial (IRCT20240503061640 N3) was conducted at Surgical Unit-I, Nishtar Medical University/Hospital, Multan, from 17th June 2022 to 15th January 2023. Sampling was done using the Random Allocation Software 2.0. Patients were allocated to either group using a computer-generated set of random allocation to group A or B. The group allocation was done in advance and sealed in consecutively numbered opaque envelopes. A sample size of 42 patients in each group was calculated by 5% level of significance with 80% power of the study and by taking the expected percentage of complications = 32% with open surgery (group A) and 08% with the laparoscopic method (group B) [10]. The statistician was blinded in the study analysis, i.e. single single-blinded RCT. Both male and female patients of 18-60 years of age with a Hydatid cyst with a size >3cm were

included in this study. Patients with recurrent disease, cysts in liver segment 1 and 7, concomitant cyst in other organs, cysto-biliary communication and patients with ruptured cyst (confirmed from patient record file and any suspected communication was confirmed on CT), Severely anemic patients (Hb levels less than 8 g/dl), pregnant ladies and patients with chronic liver disease (confirmed from patient record file). And Alcoholic abuse (patient's history, alcohol consumption for > 1 year was excluded. The eightyfour patients (84) were enrolled from the Surgical Department of Nishtar Medical University, Multan, after ethical approval (Ref no: 9652) and informed consent of the patients. Baseline demographic data, and comorbid like, hypertension, diabetes, and disease duration, were recorded. Senior Surgeon with five years' post-fellowship experience conducted the laparoscopic or open surgical intervention, with the researcher assisting. The procedures involved cyst aspiration, instillation of scolicidal agent, respiration, cyst content removal, deroofing, and omentoplasty with a drain placement. Standard post-operative care, including analgesics, antibiotics, and albendazole administration, was provided. Diagnosis of hydatid cysts was based on patients' history, physical examination, and confirmed on ultrasound (US) and CT reports. Biliary Leakage was labelled if it was present grossly (brownish yellow) or bilirubin concentration (on lab report) in the drain fluid at least 3 times the serum bilirubin (on lab report) concentration, and detection of biliary leak on abdominal ultrasound after 72 hours of surgery. It was classified as high output or low output based on the fluid in the drain greater than or less than 100ml every 24 hours. Wound infection was assessed clinically, such as redness, swelling, and discharge of pus from the surgical area. It was confirmed on a positive culture report of the wound swab. Pain score zero on the visual pain analogue scale means no pain, and a pain score of 10 means severe pain. After 3 days of procedure, each patient has their pain level based on the visual analog scale (VAS). Early recurrence was assessed based on the presence of signs on sonography within one month of surgery, of residual cyst size increasing, or the presence of new cysts in previous or new locations. Patients were categorized into group A (open surgery) and group B (laparoscopic surgery) and followed up for 72 hours' post-surgery for Biliary leakage, hospital stay, wound infection, pain, and early recurrence, and on follow-up visits at 1, 2, and 4 weeks post-surgery. All the information was recorded on a proforma (attached). If any complication occurred, such as biliary leakage, wound infection, or recurrence, patients were promptly treated by the department, and no cost was borne by the patient. Patients were facilitated if the need for an ERCP arose for post-operative biliary leaks. All the data were entered and

analyzed using SPSS-25. Mean and standard deviation for the age, duration of disease, and hospital stay were calculated. Frequency and percentages were calculated for categorical variables like gender, biliary leak, pain, wound infection, and recurrence. The frequency of biliary leak, pain, wound infection, and recurrence was compared by the chi-square test. Confounding variables like age, gender, hypertension, diabetes, and duration of disease were controlled by making stratified tables. Chi-square was applied for qualitative variables, and a poststratification independent sample t-test will be applied for quantitative results. A p-value ≤0.05 was taken as significant.

RESULTS

Eighty-four patients were enrolled in the study with a mean age of 31.1 ± 7.32 years. There were 33(39.3%) female and 51(60.7%) male enrolled. 8 (9.5%) were hypertensive and 5 (6.0%) were diabetic. The mean duration since symptoms were present or diagnosis was established for Hydatid cyst disease was 30.8 ± 16.6 days (Table 1).

Table 1: Comparison of the Patients' Demographics Between the Two Groups

Variables	Open, Mean ± SD / n (%)	Lap, Mean ± SD / n (%)	p- value	
Age	30.8 ± 6.84	31.33 ± 7.85	0.77	
Duration				
Till Treatment	31.7 ± 16.9	29.8 ± 16.5	0.60	
Gender				
Male	28 (66.6%)	23 (54.7%)	0.26	
Female	14 (33.3%)	19 (45.2%)		
Diabetes				
Yes	2(4.76%)	3 (7.14%)	0.67	
No	40 (95.2%)	39 (92.8%)	0.64	
Hypertension				
Yes	3 (7.14%)(3)	5 (11.9%)	0.45	
No	39 (92.9%)	37(88.1%)	0.40	

The mean length of hospital stay was 5.11 ± 4.57 days. 11 (13.1%) cases presented with a biliary leak. The mean biliary drainage in 24 hours was 138.1 ± 114.5 . The mean number of days till biliary leak resolved was 9.27 ± 4.92. The mean VAS score 72 hours post-operatively was 5.62 ± 1.64 . This decreased to 3.21 ± 1.04 at 1-week follow-up and 1.40 ± 0.69 at 2-week follow-up. 10 (11.9%) patients experienced a wound infection within 72 hours, and 1 (1.2%) presented with a wound infection after 1 week. 2 (2.4%) recurrences were identified at the 4-week follow up and none were identified at the 1 and 2-week follow-up. Differences in both groups were analyzed using a Student's t-test for length of stay, and a significant difference was found (p=0.001). The mean length of stay in the open group was 7.21 ± 5.76 days, while in the laparoscopic group it was 3.43 ± 1.59 days. In the open group, biliary leak was present in 7 (16.7%) patients,

and 35 (83.3%) did not leak. In the laparoscopic group, biliary leak was present in 4(9.5%) patients, and 38(90.5%)were spared. Chi-square analysis showed no difference with a p-value of 0.33. The group had 80.0 ± 21.6 ml per 24 hours. An independent Student's test showed no significant difference in biliary leak output among open and laparoscopic groups, with a p-value of 0.21. It was noted that all the leaks in the laparoscopic group had an output of less than 100ml/24 hours. In the open surgery group, 1 out of 7 leaks was in the range of 100-250ml/24hours, and 2 leaks had an output of greater than 250ml/24hours. Four leaks had an output of less than 100ml/24 hours. The mean VAS score was significantly lower for the laparoscopic group at each follow-up as reflected by the p-value (p=0.001) of the laparoscopic and open group (p=0.02), respectively. Mean VAS pain scores decreased from 5.62 ± 1.64 at 72 hours' post-op to 3.21 ± 1.04 at one week, and $1.40\pm$ 0.69 at two weeks (Table 2).

Table 2: Biliary Leak Outcomes for Open Vs Laparoscopic Group

Variables	Open, Mean ± SD / n (%)	Lap, Mean ± SD / n (%)	p- value			
Biliary Output (ml/24hours)	171.4 ± 134.4	80.0 ± 21.6	0.21			
Days						
Till the Resolution of the Leak	10.4 ± 5.94	7.25 ± 1.25	0.32			
Biliary Leak						
Yes	7(16.7%)	4(9.5%) 38(90.5%) 0.33				
No	35 (83.3%)					
Pain						
VAS at 72 Hours	6.90 ± 1.07	4.33 ± 0.95	0.001			
VAS at 1 Week Follow-Up	4.02 ± 0.56	2.40 ± 0.73	0.001			
VAS at 2 Week Follow-Up	1.57 ± 0.85	1.24 ± 0.43	0.02			

The mean age of patients with a biliary leak was 33±9.27 years and without a biliary leak was 31.1±7.81 years in the laparoscopic group, and no difference was observed (p=0.66). In the open group, patients had a mean age of 30.5 ± 3.40 years in the biliary leak group vs 30.9 ± 7.37 years in the no leak group, with no difference between the groups (p=0.89). Age did not affect recurrence in the laparoscopic group (p=0.58) and had no effect in the open group (p=0.37). VAS score was stratified as higher than or equal to 5 or less than 5, and an independent Student's t-test was used to assess whether there was a difference in the mean age for higher pain scores and for lower pain scores. No difference was found with a p-value of 0.84. Age did not affect wound infections in the laparoscopic group (p=0.30) or in the open group (0.19). The mean duration of symptoms was 40.5±33.3 days for those with a biliary leak and 28.7±14.2 days for those without a biliary leak in the laparoscopic group, and no difference between the groups was observed (p=0.18). In the open group mean duration of symptoms was 26 \pm 10.9 days in the biliary leak group, and it was 32.9 \pm 17.7 days in the no leak group, with no difference observed

(p=0.32). Duration of symptoms did not affect recurrence in the laparoscopic group (0.18) and had no effect in the open group (p=0.50). Chi-square test was used to assess the effect of gender on outcomes. For the laparoscopic group, gender did not affect biliary leak (p=0.84), wound infection (p=0.89), recurrence (p=0.35), or pain scores (p=0.61). For the open group, gender did not affect biliary leak (p=0.24), wound infection (p=0.78), recurrence (p=0.47), and pain score (0.82) (Table 3).

Table 3: Outcome of Recurrence and Wound Infection in Both Groups Assessed by Chi-Square Analysis

Variable SSI	Open	Lap	p-value
SSI at 72 Hours	8 (19.0%)	2(4.8%)	0.04
SSI at 1 Week	1(2.4%)	0(0%)	0.31
Recurrence at 4 Weeks	1(2.4%)	1(2.4%)	1.00

Length of stay was assessed in terms of wound infection and pain for each group. For patients with a wound infection length of stay was found to be significantly higher than those without an infection in the laparoscopic group (p=0.01) and in the open group (p=0.05). Pain score had a significant effect on length of stay, where patients with pain scores higher than 5 had lengthier stays (p=0.001). There were no recurrences at the 1 and 2 week follow up with 1 recurrence in each group at the 4 week follow up which was analyzed as statistically insignificant. Wound infection rate was lower in the laparoscopic group at 72 hrs. Follow up, i.e, 4.8% (n=2) and none at one week (Table 4).

Table 4: Effect of Pain and Wound Infection on Length of Stay

Variables		Mean ± SD	p-value
Pain	>/=5	6.65 ± 5.39	0.001
	<5	3.16 ± 1.16	
Wound Infection (Laparoscopic)	Yes	6.00 ± 4.24	0.008
	No	3.30 ± 1.36	
Wound Infection (Open)	Yes	10.75 ± 8.94	0.01
wound infection (open)	No	6.38 ± 4.53	

DISCUSSIONS

The postoperative course of laparoscopic Hydatid disease surgery is not fully evaluated, but still, there is an increased tendency of laparoscopic intervention in Hydatid disease of the liver. The literature has mixed data about this notion [11]. Moreover, even though surgery remains the Gold standard for Hydatid disease of the liver but still optimal choice of conventional versus laparoscopic needs to be addressed. Both approaches include removal of cyst contents, avoidance of spillage of contents, sterilization, and obliteration of the cavity [12]. A meta-analysis performed by Sokouti et al. depicted the advantages of the minimally invasive puncture, aspiration, injection, and respiration technique in simple, uncomplicated cysts that are accessible [13]. It offers a less invasive, cost-effective,

and low-morbidity solution to a complex problem. It is mainly reserved for the surgically unfit patients or in case of contraindications to surgery, which includes biliary communication with a subsequent high recurrence rate [14]. Our study confirms that the laparoscopic approach to Hydatid cyst disease (HCD) surgery is safe and effective, consistent with most literature. Laparoscopy offers significant advantages over open surgery, including fewer wound infections, better post-operative pain control, and shorter hospital stays with similar results to open surgery in terms of biliary leak and recurrence [15]. Though statistically not significant, our data did show that biliary leaks were nearly 7% fewer in the laparoscopic group and resolved in fewer days with lesser output and fewer highoutput fistulas than the open surgery group. This may be the first time a study has reported on the difference between biliary outputs between the two groups, keeping in mind high and low output fistulae. Biliary complications, however, were not statistically significant between the two groups and were comparable; thus, both procedures are equally effective and safe in terms of the occurrence of this outcome. Previous studies support our findings, noting that laparoscopic techniques can mitigate biliary leaks. A study used magnification to check for biliary communications in the cystic cavity, and this was hypothesized to decrease the rates of biliary leaks occurring with laparoscopic surgery. The laparoscopic group in our study experienced only minor leaks of ≤100ml/24 hours, unlike the open group, which had some major leaks [16]. Wang et al. have commented that leaks may occur and complicate up to 30% of all HCD surgical procedures, thus our leak rates of less than 20% in both open and laparoscopic surgery are acceptable by the established norms in the literature [17]. Masood et al. conducted a randomized trial comparing the two techniques in HCD surgery in children. Study had a VAS score of 6.3 in the lap group and 7.16 in the open group postoperatively, and this was significant even after 72 hours, where the laparoscopic group had a VAS of 1.3 and the open group had a VAS of 4.26. This was not comparable to our study, where at 72 hours our patients had a pain score of 4.33 in the laparoscopic group and 6.9 in the open group, and this was higher than that experienced in this study cohort but still lower in the laparoscopic group [18]. Biliary complications, though not statistically significant, were fewer and less severe in the laparoscopic group [19]. There is no standard time for biliary leak resolution. Most leaks in our study subsides in one month, with a predilection for early resolution with post-laparoscopic leaks. Abbasi et al. in their study found that biliary leakage occurred in higher percentages in the case of radical surgery, like pericystectomy, as compared to endocystectomy [20]. In

our study, all patients underwent conservative surgery, and this may be the reason for a slightly lower biliary leak percentage in our cohort of patients. Contrarily, some authors hypothesized that conservative surgery is more likely to result in leaks [21]. In their series, they identified that patients with outputs of greater than 250ml were less likely to spontaneously resolve, and the time till resolution ranged from three weeks to three months. Most of our patients' leaks resolved within a month, the longest requiring 21 days. It is clear from the literature that definitions of minor and major leaks are not consistent across the board, and this leaves gray areas, and outcome reporting is affected [22]. Open surgery may have a higher propensity for post-operative biliary leaks than laparoscopic surgery. But this difference was statistically insignificant in our study. This may simply be due to the advantage of magnification that laparoscopy offers in closing larger biliary communications intra-operatively, resulting in a greater percentage of minor biliary leaks post-operatively that are amenable to conservative treatment [23]. Different studies reiterate the fact that wound infections and length of stay are considerably better in the laparoscopic cohort as compared to open intervention [24]. Hospital stay was shorter in the laparoscopic group at a mean of 6 days; in our cohort, the laparoscopic group had a mean stay of 3.41 days. Zaharie et al. did their study a decade earlier than ours, and with enhanced recovery protocols, patients after laparoscopic surgery are discharged in shorter durations than before [5]. On the other hand, Hospital stay was similar between the groups, with only a difference of a mean of 1 day; however, this was not the case in our study, and there were no factors identifiable in their study findings to appreciate why this occurred.

CONCLUSIONS

Biliary leak rates between open and laparoscopic surgery for Hydatid cyst disease are comparable. Open surgery may have greater high-output biliary leaks. Advantages conferred by laparoscopic surgery are shorter length of hospital stay, fewer wound infections, and better pain control.

Authors Contribution

Conceptualization: MFA

Methodology: MFA, KN, HA, MHU, KJ, LA

Formal analysis: MFA

Writing review and editing: MFA, KN

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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