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"To Comparative Study of Management of Duodenal Ulcer Perforation by Open and Laparoscopic Approach in Tertiary Care Hospital"

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Abstract:-Aims and objectives:-*This randomised observational study was undertaken to evaluate the efficacy , safety and outcome of laparoscopic surgery for perforated duodenal ulcer in comparison with conventional laparotomy and to determine the risk factors which influence the outcome.* ***Material and method:*** *100 patients of all age attending outdoor (OPD) or emergency with duodenal ulcer suggestive for laparoscopic surgery & open surgery admitted to the hospital were studied. All patients diagnosed clinically with perforated peptic ulcers were prospectively nonrandomized to undergo either conventional open or laparoscopic suture omental patch repair.* ***Results-****As regards complications like Fever and Wound infection the frequency of occurrence was more in Open surgery cases as compared to laparoscopy. Thecomparison of surgical procedures in duodenal perforation in terms ofmorbidity 62.9% in open and 26.7% in laparoscopic procedures and mortality 8.6% in open and 6.7% in laparoscopic procedures. The risk factors for Laparoscopic procedure like older age that is greater than 40 years (46.0%), obesity greater than 28 kg/m^2 (23.0%) and size of ulcer >15mm (24.0%), Symptoms surgery interval > 24 hours (82.0%), while diabetes mellitus, cardiovascular disease and Diabetes Mellitus & Cardiovascular disease were 3.0%, 6.0% & 5.0% respectively.*

Conclusion*- Laparoscopic repair of duodenal ulcer perforation is as safe and effective as open repair, has the advantages of less wound related complications, early recovery and return to normal activity. We can say that laparoscopic simple closure of perforated peptic ulcer disease is safe and may suitable method of treatment with adequate preventive care.*

Keywords:- *Peptic ulcer disease , Open surgery , laparoscopy*

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I. Introduction

Duodenal ulcer perforation is one of the common complications of peptic ulcer, a disease despite the use of various antiulcer agents and eradication therapy. It is one of the most common causes of admission in casualty worldwide and more in developing nations.**Error! Bookmark not defined.**

The laparoscopic approach became a widespread procedure. Laparoscopic repair of duodenal perforation is a useful method for reducing hospital stay and complications, and hastening return to normal activity. Treatment for perforated ulcer can be performed laparoscopically in 85% of cases, making it possible to avoid a median laparotomy which can lead to wound infection and late incisional hernia.

Laparoscopic repair of perforated peptic ulcer is a safe and reliable procedure and is proven to be efficient. The advantages of laparoscopic repair have led to a trend that laparoscopic simple closure (LSC) has gradually replaced open repair for patients with PPU with an improvement in medical treatment and universalization of laparoscopic surgery. However, not all patients are suitable for laparoscopic repair. Some studies have reported a significantly higher reoperation rate after laparoscopic repair than after open repair. This study was conducted to compare the efficacy and safety of laparoscopic and conventional methods of closure of duodenal ulcer perforation.

II. Aims And Objectives

To evaluate the efficacy and safety of outcome of laparoscopic surgery for perforated duodenal ulcer in comparison with conventional laparotomy and to determine the risk factors which influence the outcome

III. Materials And Methods

This randomised observational study was carried out on 100 patientsDepartment of General Surgery at ChattrapatiShivajiSubharti Hospital, Subharti Medical College (U.P), 100 patients of all age attending outdoor (OPD) or emergency with duodenal ulcer suggestive for laparoscopic surgery & open surgery admitted to the hospital were studied during the study period one year from October 2016 to November 2017 in this study. Institutional ethics committee permission was taken

All patients with diagnosis of duodenal ulcer perforation undergoing surgery during the study period were included. Patient age < 15 years and > 70 yearspresenting with chief complaints of pain in abdomen for more than 2 days, Shock with systolic blood pressure < 90 mm Hg which did not improve after hydration with 2000 ml of Ringer lactate solution were excluded. We managed 30 patients with laparoscopic surgery and 70 patients had to undergo an open surgery for treatment.A written consent was taken from all potentially eligible subjects and excluded from the study if they were not matched with inclusion criteria of the study. Detailed history and physical examination was performed and recorded on predesigned proforma (annexure 1) from each patient. Patient's personal history, physical examination findings like name, age, demographic profile and clinical examination, type of surgery duration of surgery, time to mobilise the patients, post operative complication & radiological assessments if any were recorded. All patients had an x-ray erect abdomen, USG abdomen and routine surgical examination to confirm the diagnosis. Data was analyzed using Statistical Package for Social Sciences, version 23 (SPSS Inc., Chicago, IL). Results for continuous variables are presented as mean ± standard deviation, whereas results for categorical variables are presented as number (percentage). Chi-square/Fisher exact test has been used to find the significance of study parameters on categorical scale between two or more groups. For comparison of mean, independent sample t-test is performed. The level $P <$ 0.05 was considered as the cutof value or significance

IV. Observations And Results

In our study average age of patients was 42.72 years, male and female sex ratio was 77:23, vegetarian and non-vegetarian patient ratio was 39:61, 61% patients were consuming tobacco. 56 patients (56.0%) were alcohol addicts, 88 (88.0%) patients were with NSAID intake as part of their lifestyle. 38 (38.0%) patients were with H Pylori infection while 27 (27.0%) patients were with history of ulcer.

The common site of pain in both gastric as well as duodenal ulcer patients was reported in the Generalized abdominal pain (62.0%) followed by Epigastrium (38.0%).

The common nature of pain in duodenal ulcer perforation patients was burning with hunger pangs (37.0%), followed by Burning (31.0%), Severe pain (25.0%) while Hunger pain (5.0%) and Discomfort (2.0%).

Table no. 1: details of various parameters in respect of treatment of patients.

	Mean ± SD		**P value**
	laparoscopic surgery (N=30)	**Open surgery (N=70)**	
Age (year)	35.17±7.83	41.56±11.83	0.0079
Symptoms surgery interval (hours)	24.67±3.10	37.8±9.4	<0.001
Operating time(min)	97.1±7.55	58.03±5.09	<0.001
Antibiotic used (days)	5.3±1.44	9.64±2.06	<0.001
Use of Opiods (days)	5.53±2.13	10.17±1.79	<0.001
Day 2 VAS score	3.13±1.48	6.47±1.35	<0.001

The post-operative complications in both the groups. As regards complications like Fever and Wound infection the frequency of occurrence was more in Open surgery cases as compared to laparoscopy.

Table no 2: show distribution of Post-operative complications in studied patients.

	laparoscopic surgery(n=30)	**Open surgery (n=70)**	**P value**
Fever	10 (10.0%)	25 (25.0%)	0.819
Leak	0 (0.0%)	0 (0.0%)	-
Wound infection	0 (0.0%)	14 (14%)	0.008
Wound pain	2 (2.0%)	19 (19.0%)	0.021
Prolonged ileus	5 (5.0%)	14 (14.0%)	0.696
Respiratory infection	10 (10.0%)	20 (20.0%)	0.633
Wound dehiscence	0 (0.0%)	2 (2.0%)	0.349

Thecomparison of surgical procedures in duodenal perforation in terms ofmorbidity 62.9% in open and 26.7% in laparoscopic procedures and mortality 8.6% in open and 6.7% in laparoscopic procedures.

Table no 3: Showing factors determining the mortality

Factors	Mortality (n=8)	Significance	laparoscopic surgery(n=30)	Open surgery (n=70)
Age				
≤ 40 YRS (n=54)	3	OR=0.6029	1	2
>40 YEARS (n=46)	5	P value = 0.523	1	4
Sex				
Male (n=77)	5	OR=0.4630	1	4
Female (n=23)	3	P value = 0.319	1	2
Symptoms surgery interval (hours)				
≤ 36 hours (n=67)	4	OR=0.46.3	1	3
> 36 hours (n=33)	4	P value = 0.296	1	3
Diameter of ulcer (mm)				
≤1 cm (n=33)	2	OR=0.6559	1	1
>1 cm (n=67)	6	P value =0.618	1	5
Comorbidity				
Present (n=18)	8	OR=5.5714	2	6
Absent (n=82)	0	P value =0.024	0	0

The conversion to open surgery was required in 10 patients, representing 10.0%. Reasons for conversion are 10 patients with severe purulent peritonitis, making identification of perforation difficult and hazardous, and 10 patient owing to the large size of perforation, which was more than 10 mm, and the 4 patients due to hemodynamic (Cardiovascular disease) instability.

The risk factors for Laparoscopic procedure like older age that is greater than 40 years (46.0%), obesity greater than 28 kg/m^2 (23.0%) and size of ulcer >15mm (24.0%), Symptoms surgery interval > 24 hours (82.0%), while diabetes mellitus, cardiovascular disease and Diabetes Mellitus & Cardiovascular disease were 3.0%, 6.0% & 5.0% respectively. These risk factors were present in multiple forms in multiple cases and these risk factors affect the rate of Laparoscopic procedure.

Table no 4: Showing the Risk factors for Laparoscopic procedure

Risk factors for Laparoscopic		No of cases	Percentage
Age ≥50 years		34	34.0%
Obesity ≥28 kg/m^2		23	23.0%
Diabetes Mellitus		5	5.0%
Cardiovascular disease		13	13.0%
Diabetes Mellitus + Cardiovascular disease		6	6.0%
Symptoms surgery interval > 24 hours		82	82.0%
Patients with Shock		11	11.0%
Patients with ASA grade III & IV		7	7.0%
Boey Score	**0**	70	70.0%
	1	30	30.%
Patient with intra-abdominal abscess		12	12.0%
Patient with Sepsis		11	11.0%

After the surgery mean days of patient return to normal activity was found lesser in laparoscopic surgery than Open surgery patients. The correlation between return to normal activity in both surgeries was found to be highly significant ($p<0.01$).

V. Discussion

Most cases of peptic ulcer are caused by Helicobacter pylori (HP) discovered by Marshall and Warren in 1984.Neverthelsess the mechanism of HP infection is perforated peptic ulcer (PPU) is not clear.

In present study, there was predominance of male patients. Out of 100 patients included in the study, 77% were male while the rest 23% were female with the male to female ratio of 3.34. On specific categorization 25 male and 5 female patients participated in laparoscopic surgery while 52 male and 18 female were operated through open surgery. In a similar study in Istanbul by **Bas G et al** on evaluation of risk factors of morbidity and mortality in patients with perforated peptic ulcer, noted the preponderance of male in study population with a ratio of 8 to 1.[2] Varying demography, eatery habits and different lifestyle (Alcohol consumption, smoking) were the possible reason for such contrasting appearance of patients in studies gender wise. Similarly Kumar P et al in their study mentioned that majority of patients were male.[3] Similar male dominance in such patients was reported also by **Bertleff et al**. [4]

Further corroborating our observation, a similar study by **Byakodi KG et al** reported male predominance with a ratio of 7.6:1.[5]In same way conforming to our case **Kocer et al** [6]with a ratio of 8:1 and **Boey et al**[7] with a ratio of 6.6:1 observed male predominance on management of duodenal perforation .Overall, the male predominance may be attributed to use of alcohol and smoking.

Individual's personal habits like tobacco consumption, alcohol consumption, smoking etc. have great influence on duodenal functioning. In present study, 61% of the patients were in habit of tobacco consumption, while 56% were used to alcohol consumption. 15% were smokers and 21 % were using pan masala. In addition to that, we found 88% patients with NSAID intake, 38% patients with H Pylori infection and 27% patients with history of ulcer. **Kumar P et alError! Bookmark not defined.** in their study on duodenal perforation mentioned that 75.3% patients included were smokers while 37% were in habit of taking NSAID. In an another Indian study evaluating morbidity and mortality in duodenal perforation by**Byakodi KG et alError! Bookmark not defined.** noted the rate of smoking, alcohol consumption, tobacco chewing and NSAID consumption as 32.6%, 34.9% , 20.9% and 39.5% respectively.[5]

In current study, several comorbidities were encountered in the studied patients. Cardiovascular disease (CVD) was found prevalent among 6% of patients followed by diabetes mellitus (DM) accompanied with cardiovascular disease in 5% of population. However, only DM was seen in 3% of subjects. A study by **Bas G et alError! Bookmark not defined.**in Turkish set up was in concurrence with our findings. **Bas G et alError! Bookmark not defined.** noted cardiovascular disease to be most evident comorbidity in patients associated with others i.e. respiratory illness, renal disease, DM and Rheumatoid Arthritis.

Other parameters like antibiotics used (in days), use of opiods(days) and VAS score on day 2 for postoperative pain were closely examined and significant difference (P value <0.01) was discerned between two groups with remarkably lower values in laparoscopic group. A study by **Kumar P et al**[3] was in close agreement with our findings. Findings by **Kumar P et alError! Bookmark not defined.** are comparable to our results concerning significant difference in operating time and day 2 VAS score. **Lau et al** reported similar difference in the operative times. The longer time taken in laparoscopic repair is off-set by the significantly improved post-operative recovery and patient satisfaction.[8] Studies in literature by **Palanivelu C et al**[9] and **Siu WT et al**[10] concluded that laparoscopic technique gives better postoperative course compared to open repair.

Patients operated with laparoscopic procedure had less number of hospital stay days (10.4 days) while in open surgery restricted patients for longer hospital stay (11.8 days) observing high significant difference (p value<0.001).Orally intake of foods allowed after 8.3 days in laparoscopic group while it was significantly longer (<0.001) in open group i.e. 10.4 days. A study corroborating our findings by **Kumar P et al**[3]noted that the difference of mean days of hospital stay was highly significant (p value<0.001) between the open (8.59 days) and laparoscopic group (5.10 days).Similarly time take to resume oral feeding was also longer in open surgery group with significant difference in a close agreement to our findings.

Interestingly, in our study no case of leak was seen either in lap group or in open group. A similar study evaluating risk factors of morbidity and mortality in patients with perforated peptic ulcer by **Bas G et al**[2] in Istanbul published that 21 complications were observed in 15 (15.5%) patients. Primarily wound infection, abdominal abscess, pneumonia, duodenal fistula, cardiovascular insufficiency, generalized peritonitis were seen. 10 patients had one complication, four patients had two, and 1 patient had three.

Manifestations of such a large number of complications owe reference to the several pre-operative comorbidities associated with the patients. Another concurring study by **Mathur PN et alError! Bookmark not defined.** also found surgical site infection in 31.6% of cases as the commonest post-operative complication. It was primarily because of per operative spoilage of wound by intraperitoneal purulent fluid and food particles despite all precautions. Moreover, Wound dehiscence occurred in 17 (4.55%) cases which required secondary pulmonary infection, pneumonia occurred in 16 (4.28%) patients. Interestingly, findings **Kumar P et al**[3] were in close concurrence with our results. **Kumar P et al**[3] noted that significant difference (p value=0.025) in wound infection between lap and open group, no case of leak was seen in their case too. Prolonged ileus (4.54% only in open group) and Pulmonary infection (2.27% in both open and lap group)were among some other presenting complications.

However, the rate mortality was higher (6 cases, 8.6%) in open group than laparoscopic group (2 cases, 6.7%) but the correlation was found to be non-significant (p value=0.747) between the two groups over the incidence of mortality. Post-operative results suggested the laparoscopic procedures being the advantageous and better in comparison to open surgery. In a similar study by **Bas G et al**[2] reported the overall morbidity and mortality rates were 15.5% and 5.2% respectively. Three patients died because of disease-related complications (duodenal fistula and generalized peritonitis). In a Korean study on risk factors associated with conversion of laparoscopic simple closure in duodenal ulcer by **Ji-Hyun Kim et alError! Bookmark not defined.** found that 30-day mortality was found in the conversion group (12.5% vs. 0%, respectively; p value = 0.003).

In current study, 10(10%) patients converted to open route the primary cause and motivation of conversion were severe purulent peritonitis accompanied with bowel adhesion. Moreover, 4 (4%) cases were found to have additional hemodynamic instability during surgery. In a similar study by **Kumar P et al**[3] reported that out of 44 patients undergoing laparoscopic procedure only 1(2.27%) to open routedue to inadequate omental patch mobilization. In another study by **Ji-Hyun Kim et alError! Bookmark not defined.** reported the

rate of conversion to be 10.4% and ulcer perforation size and prolonged duration of symptoms influence the conversion.

In current study, several risk factors were found to be associated with laparoscopic surgery. Symptoms and surgery interval greater than 24 hours,Boey Score (0 or 1), BMI ≥28 kg/$m^{2,}$ older age (≥50 years) and Cardiovascular disease were the prominent. While Patient with Sepsis, Patients with Shock, Patients with ASA grade III & IV, Diabetes Mellitus accompanied with cardiovascular disease and Diabetes Mellitus were also present as minor risk factors. A study evaluating risk factors of laparoscopic procedure by **Ji-Hyun Kim et alError! Bookmark not defined.**noted thatsize of theperforation was the only risk factor for conversion in the multivariate analysis. In another similar study by **Lunevicius R and Morkevicius M**[13] noted that Ulcer perforation size of >8 mm is a significant risk factor influencing the conversion rate., Ulcer perforation size of >8 mm is a significant risk factor influencing the conversion rate. An increase in the suture leakage rate is predicted by delayed presentation of >9 h.

VI. Conclusion

Laparoscopic surgery seems to be more efficient, soothing and reliable in patients of relatively younger age. Highly significant difference concerning antibiotic used, use of opiods ,pain score was clearly observed between the lap and open group, indicating lap as better alternative to open surgery with expert hands. Significant shorter days of hospital stay was observed in case laparoscopic group compared to open group. Notably, there was significant difference regarding wound infection and pain in two groups**.** Overall, 8(8%) cases of mortality was observed in present study. Correlation of Coexisting comorbidities, diameter of ulcer, symptoms surgery interval and age factor was evaluated and only comorbidity was observed to have significant correlation. We can say that laparoscopic simple closure of perforated peptic ulcer disease is safe and may suitable method of treatment with adequate preventive care.

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