



Research Article

A RANDOMIZED STUDY TO COMPARE THE CLINICAL OUTCOMES OF MODIFIED GRAHAM'S OMENTOPEXY VS GRAHAM'S OMENTOPEXY IN PERFORATED DUODENAL ULCERS

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ABSTRACT

Introduction: The most accepted method of surgical closure of the peptic ulcer perforation till now has been the Graham's patch repair. Described by Roscoe Graham of Toronto in 1937, where a patch of omentum was used to seal the perforation with no attempt at closing the perforation primarily. Modification of the same is the Modified Graham's Omentopexy wherein the perforation is primarily closed with sutures followed by placement of omental patch and re-knotting of sutures. Recent data suggests that both the procedures have comparable outcomes, however the modified technique could have a significant advantage over the conventional technique in terms of postoperative outcomes like re-leaks, surgical site infection and length of hospital stay.

Material & Methods: Our study was aimed to study the clinical outcomes of Modified Graham's Omentopexy versus Graham's Omentopexy in patients of duodenal ulcer perforation. A total of sixty patients were included in our study, 30 patients each in case group A Modified Graham's Omentopexy (MGO) and control group B Graham's Omentopexy (GO). The cases for the study were randomized using sealed envelope technique. In the case group (group A), all the patients underwent Modified Graham's Omentopexy and in the control group (group B), all the patients underwent Graham's Omentopexy. The patients were followed up for a period of 30 days to see the clinical outcomes.

Results: The day of Ryle's tube, abdominal drain output, day of abdominal drain removal, incidence of surgical site infection, biliary leak, mortality and length of hospital stay were assessed and were found to be similar in both the groups (A & B). Only the difference in Length of hospital stay between the two groups was found to be statistically significant with shorter duration of hospital stay in patients who underwent Modified Graham's Omentopexy (Group A) as compared to those who underwent Graham's Omentopexy (Group B). Though the incidence of surgical site infection and post-operative biliary leak were found to be higher in Graham's Omentopexy group (Group B) it was not statistically significant enough to state that Modified Graham's Omentopexy is better than Graham's Omentopexy.

Conclusion: As both the procedures of duodenal perforation repair were almost comparable in terms of day of Ryle's tube removal, abdominal drain output, day of abdominal drain removal, incidence of surgical site infection, biliary leak and mortality, except with the advantage of shorter hospital stay in patients undergoing Modified Graham's Omentopexy. Hence it is concluded from our study that Modified Graham's Omentopexy can be considered as a safe and effective alternative to the standard Graham's Omentopexy in patients with perforated duodenal ulcers.

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INTRODUCTION

Perforation occurs in 2–10% of patients with PUD and accounts for more than 70% of deaths associated with PUD. Perforation is often the first clinical presentation of PUD.¹The incidence of duodenal perforation is 7–10 cases/100,000 adults per year.^{2,3,4,5,6,7,8} The perforation site usually involves the anterior wall of the duodenum (60%), although it might occur in antral (20%) and lesser-curvature gastric ulcers (20%).⁵

Peptic ulcer perforation presents with an overall mortality of 10% although various authors have reported incidence between 1.3% and 20%.^{9,10,11,12,13,14}. Perforation occurs when ulcer erodes through full thickness of stomach or duodenum. Perforation is most common complication of peptic ulcer. Bleeding ulcer and use of nonsteroidal anti-inflammatory drugs (NSAID) and/or aspirin have been inextricably linked with perforated peptic ulcer disease (PUD) especially in the elderly. More than 20% of patients over the age of 60 years presenting with a perforated ulcer are taking NSAIDs at the time of perforation.¹⁵

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Peptic ulcer perforation is a common life-threatening emergency and requires urgent surgical intervention.¹⁶ Many modalities of treatment are available ranging from nonoperative option to laparoscopic repair. However best treatment is still to be decided. For last many decades, there is no consensus on treatment of perforated pyloroduodenal ulcer which can be treated with conservative treatment, simple closure of ulcer, closure of ulcer with free omentum, closure of perforation with use of pedicled omentum, definitive treatment with truncal vagotomy and drainage procedures or parietal cell vagotomy.¹⁷ The medical therapy for peptic ulcer has proved to be very effective treatment but complication of perforation does occur. Conservative treatment has a limited role.¹⁸ Studies have suggested that if signs of peritonitis are present then exploratory laparotomy should be done.¹⁹ This should be done within 12 hours to avoid poor outcome.¹⁹

In spite of improved understanding of the multifactorial aetiology of peptic ulcer disease (PUD),^{20,21,22} life-threatening complications including acute haemorrhage or perforation occur in a considerable proportion of patients. The mortality rate ranges from 10–40% among patients with perforation,^{23,24,25} and immediate surgery is the treatment of choice in most patients with suspected perforated peptic ulcer (PPU).

The most accepted method of surgical closure of the peptic ulcer perforation is called Graham's patch repair. In 1937, Roscoe Graham of Toronto described this method. The perforated ulcer is identified through the open incision. After laparotomy, packs are placed around the perforation to contain any further spill while the sutures are being placed and then the omental tongue is brought into position. Before sutures are tied, the adjacent omentum is brought up to the perforation with the sutures untied and laid out on the anterior surface of the duodenum, and are then successively tied from the superior to inferior side, to tampon the perforation with the vascularised omental pedicle graft. Care should be exercised to be sure that the sutures are tied sufficiently snugly to hold the omentum in place, but the tension exerted by the tied suture on the omentum should be such that the blood supply to the omentum is not impaired. The patch must be a living omental patch, and the omentum should not be strangulated.

The technique was later modified and called as Modified Graham's patch repair (MGPR), in which the three or four sutures are placed as described above and are then tied to close the ulcer. The omental patch placed on the tied suture, and another set of knots are tied to hold the omentum in place over the duodenal perforation closure. There is concern that the omentum will not be as intimately applied to the duodenal perforation and may not represent as good a seal as is the case when the omentum is laid directly on the open ulcer bed.

Nowadays, Modified Graham's patch repair is a frequently selected procedure for perforated peptic ulcer. This has motivated us to conduct a study on this modified technique and compare the outcomes with Graham's Omentopexy.

MATERIAL AND METHODS

The proposed study was conducted in the Department of Surgery, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi. A total of 60 patients with perforated

duodenal ulcer were selected, of which 30 patients in group A underwent Modified Graham's Omentopexy (MGO) and 30 patients in group B underwent Graham's Omentopexy (GO) and were evaluated for the study period of 18 months.

Duration of Study: 18 months (2017-2019)

Study Design: Randomized study.

Inclusion Criteria

All patients above the age of 12 years who presented to surgical emergency department with duodenal perforation.

Exclusion Criteria

1. Patients with multiple perforations.
2. Patients with duodenal perforation of size more than 2 cm.
3. Patients with co-morbid conditions as Chronic Obstructive Pulmonary Disease
4. (COPD), Coagulopathies, Diabetes Mellitus (DM).
5. Patients with unhealthy Omentum or any other associated intra-abdominal pathology.

All matched patients, selected for the study by applying inclusion and exclusion criteria, were grouped into two groups, namely group A and group B by means of closed envelop technique (a method of sealed, numbered envelopes opened in sequence). The envelop was opened once the operating surgeon rules out the last exclusion criteria of intra-operative omental changes or any other intra-abdominal pathology. After Omentopexy, two drains, one in Morrison's pouch (Right subhepatic) and the other in pelvis were placed and fixed. The rectus sheath was then closed with continuous 1-0 prolene and the skin with staples. Patients were observed for the following clinical outcomes during the post-operative period:

1. Surgical Site Infection.
2. Day of Ryle's tube removal.
3. Abdominal drain output.
4. Biliary leak.
5. Day of abdominal drain removal.
6. Duration of post-operative hospital stay.

Post-operatively both groups of patients were prescribed 2 weeks treatment with standard triple drug therapy to eradicate *Helicobacter pylori*. Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. The comparison of normally distributed continuous variables between the groups has been performed using Student's t test. Nominal categorical data between the groups has been compared using Chi square test or Fisher's exact test as appropriate. P<0.05 has been considered statistically significant.

Observation and results

Observation & results

This study was conducted in the Department of General Surgery, Safdarjung Hospital, New Delhi. A total of 60 patients were included in this study, all of whom presented to the surgical emergency and were diagnosed to have duodenal ulcer perforation. The patients after all routine pre-operative workup were randomly divided into two groups A & B via

closed envelope technique. The patients in group A underwent Modified Grahams Omentopexy (MGO) and those in group B underwent Grahams Omentopexy (GO) on a randomized basis. The patients were followed up post-operatively for a period of 30 days. The results noted were as follows:-

Mean Age of Presentation

Table 1 Showing mean age of occurrence of duodenal perforation with standard deviation and its p value. (GO- Graham's Omentopexy, MGO- Modified Graham's Omentopexy)

	Surgery		p value
	GO	MGO	
	Mean ± SD	Mean ± SD	
Age (Years)	43.80 ± 14.70	43.30 ± 15.59	0.899

The mean age in group A(MGO) is 43.30 ±15.59 years and the mean age in group B (GO) is 43.80 ±14.70 years. The p value for age distribution of patients was found to be 0.899, which is statistically insignificant.

Gender Distribution

Table 2 Showing gender distribution among patients of perforated duodenal ulcer. (GO- Graham's Omentopexy, MGO- Modified Graham's Omentopexy)

Sex	Surgery				p value
	GO		MGO		
	Frequency	%	Frequency	%	
F	8	26.7%	4	13.3%	0.333
M	22	73.3%	26	86.7%	
Total	30	100%	30	100%	

Majority of the patients in both the groups were males. In group A (MGO) 86.7% of the patients were males and in group B(GO) 73.3%, the percentages of female patients in both the groups was 13.3% and 26.7% respectively. The p value for sex distribution was found to be 0.333 which is statistically insignificant.

Days of Ryle's Tube Removal

Table 3 Showing the day on which Ryle's tube was removed. (GO- Graham's Omentopexy, MGO- Modified Graham's Omentopexy)

Day of Ryle's tube removal	Surgery				p value
	GO		MGO		
	Frequency	%	Frequency	%	
2	7	23.3%	16	53.3%	0.045
3	12	40.0%	9	30.0%	
4	10	33.3%	3	10.0%	
5	1	3.3%	2	6.7%	
Total	30	100%	30	100%	

It was noted that early Ryle's tube removal was possible in group A (MGO) as compared to group B (GO). The most common day of Ryle's tube removal in group A was Day 02 whereas in group B, Ryle's tube could most commonly be removed on days 03 and 04. The p value for Day of Ryle's tube removal was 0.045, which is statistically significant.

Average Daily Output (Subhepatic):-The Sub-hepatic drain output on various post-operative days were comparable in both the groups, and showed no statistically significant difference.

Average Daily Output (pelvic drain)

Table 4 Showing the average daily output of Pelvic abdominal drain. (GO- Graham's Omentopexy, MGO- Modified Graham's Omentopexy)

Abdominal Drain Output (Pelvic)	Surgery				p value
	GO		MGO		
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
Day 01	170.83 ± 86.62	150.00 (100 - 200)	135.83 ± 70.00	100 (100 - 150)	0.041
Day 02	142.67 ± 65.47	137.50 (100 - 185)	128.33 ± 70.02	100 (93.75 - 150)	0.137
Day 03	113.17 ± 39.75	100 (93.75 - 150)	99.33 ± 54.1	100 (68.75 - 100)	0.058
Day 04	109.31 ± 64.82	100 (75 - 125)	78.83 ± 51.19	50 (50 - 100)	0.015
Day 05	94.44 ± 54.76	100 (50 - 100)	56.04 ± 32.008	50 (30 - 100)	0.006
Day 06	59.05 ± 26.96	50 (40 - 87.5)	50.00 ± 26.46	50 (35 - 50)	0.426
Day 07	52.14 ± 29.40	50 (27.5 - 62.5)	43.33 ± 23.98	50 (30 - 50)	0.702
Day 08	37.50 ± 18.32	50 (10 - 50)	32.5 ± 20.62	35 (12.5 - 50)	1.000
Day 09	35.00 ± 17.32	35 (20 - 50)	30.00 ± 0.00	30 (30 - 30)	-
Day 10	20.0 ± 14.14	20 (10 - 30)	-	-	-

The Pelvic abdominal drain output on various post-operative days were comparable in both the groups and were mostly statistically insignificant, except on days 01,04 and 05 when group B (GO) had higher pelvic drain output as compared to group A (MGO). The p value for the aforementioned days was found to be 0.041, 0.015 and 0.006 respectively, all of which are statistically significant.

Day of Subhepatic Drain Removal: Majority of the drain in group A (MGO) patients was removed on days 03 and 04, whereas in group B(GO) the drain was removed on days 03,04 and 05. Three patients in both the groups had their sub-hepatic drain removed on day 06. Three patients in group B(GO) had biliary leak and were taken up for further management. One patient in group B(GO) had biliary leak after the removal of sub-hepatic drain. The p value for day of sub-hepatic drain removal was found to be 0.102, which is statistically insignificant.

Day of Pelvic Drain Removal: The pelvic abdominal drain was removed mostly on comparable days in both the groups. Majority of the drain in group A (MGO) patients was removed on days 04,05 and 07, whereas in group B(GO) the drain was removed on days 06,07 and 08. Four patients in group B(GO) had biliary leak and were taken up for further management. The p value for day of pelvic drain removal is 0.159 and is statistically insignificant.

Surgical Site Infections: In our study majority of the patients in both the groups did not develop surgical site infection. In group A (MGO) there were five cases of surgical site infection as compared to seven cases in group B(GO). The incidence of SSI in groups A and B were found to be 16.7% and 23.3% respectively. The p value for incidence of surgical site infection was found to be 0.519 and has no statistical significance.

Biliary Leak: In our study, four cases of biliary leak were observed among patients of group B(GO). No biliary leak was

observed in group A(MGO) patients. The incidence of biliary leak among patients undergoing Graham’s Omentopexy was found to be 13.3%. The p value for incidence of biliary leak was found to be 0.112, which is statistically not significant.

Mortality: The overall mortality among post-operative patients was low. A total of three mortalities occurred, of which one (3.3%) occurred in group A(MGO) and the remaining two (6.7%) occurred in group B(GO). The p value for mortality was 1.000, which is statistically insignificant

Length of Hospital Stay

Table 5 Showing the average duration of hospital stay in patients of perforated duodenal ulcer. (GO- Graham’s Omentopexy, MGO- Modified Graham’s Omentopexy)

	Surgery				p value
	GO		MGO		
	Mean ± SD	Median (IQR)	Mean ± SD	Median (IQR)	
Length of Hospital Stay (Days)	12.43 ± 5.59	11.00 (9.00 - 14.50)	8.10 ± 1.81	8.00 (7.00 - 9.25)	<0.001

In our study, we found that the length of hospital stay (days) was lesser among patients of group A (MGO) when compared to those of group B(GO). The mean number of days of hospital stay in group A was 8.10 with a standard deviation of ±1.81 and that in group B was 12.43 with a standard deviation of ±5.59. The p value for length of hospital stay (days) came out to be <0.001 and is statistically significant.

DISCUSSION

In this study 60 patients of perforated duodenal ulcer were included out of them 48 (80%) were males and 12 (20%) were females (male: female 4:1) similar to other studies by Nishikant Gujar *et al*, male were (86%), female (14%) where the M: F ratio ranged from 6.15 : 1 to 9 : 1.^{28,29}

The mean age of presentation was 43.30 ± 15.59 in group A (MGO) and it was 43.80 ± 14.70 in group B (GO) which is similar to the study Jat *et al* ^[032], however significantly different from other studies from Africa that had an average of 64.8 +/- 11.4 years and from India highest incidence was between 40 – 60 years.^{6,7}

We noted that there was a significant difference in the day of Ryle’s tube removal in both the groups. The most common day for Ryle’s tube removal was day 02 for Group A(MGO) whereas for group B (GO) it was days 03 and 04. This suggests that the incidence of ileus was more among the patient who underwent Graham’s Omentopexy as compared to those who underwent Modified Graham’s Omentopexy. This result of our study differs from Abdallah *et al* ²⁶ wherein the incidence of ileus was similar among both the groups Modified Graham’s Omentopexy and Graham’s Omentopexy.

In this study we placed two abdominal drains Sub-Hepatic and Pelvic in all patients irrespective of the type of repair. We noted that the mean drain outputs sub-hepatic and pelvic in both the groups were mostly comparable and statistically insignificant except the pelvic drain output on post-operative days 04 and 05 which was significantly higher in group B(GO) as compared to group A (MGO). This could be explained by the fact that cases of biliary leak happened on the said days which may have led to an increase in the mean daily output.

The days of abdominal drain removal were also similar and statistically insignificant in both groups. Majority of the sub-hepatic drain in group A(MGO) patients was removed on days 03 and 04, whereas in group B (GO) the drain was removed on days 03,04 and 05. Three patients in both the groups had their subhepatic drain removed on day 06. The pelvic abdominal drain in group A (MGO) patients was removed mostly on days 04,05 and 07, whereas in group B (GO) the drain was removed on days 06,07 and 08. Four patients in group B(GO) had biliary leak and were taken up for further management, however no biliary leak was found in patients of group A (MGO). Similar incidence of biliary was reported in other studies by Jat *et al* ²⁶ and Abdallah *et al*.²⁷

In our study the major postoperative complications in group B Graham’s omentopexy was surgical site infection in 07 cases (23.33%), biliary leakage in 04 cases (13.33%) whereas in group A Modified Graham’s omentopexy surgical site infection was noted in 05 cases (16.67%) however there was, no biliary leakage. The similar results of post -operative complications were also shown in other studies by Rajput *et al* ^[122] and Satapathy *et al*.³⁰

In this study mortality rate is less, 1 (3.33%) in group A and 2 (6.67%) in group B . The overall mortality rate was 5% while in other studies by A Nuhu *et al* ¹⁰ it was 16.4% and Satapathy *et al* ³⁰ was 4.09%. In another study by Umran Muslu *et al*, the mortality rate was 5 patients (3.9%).³¹ Mortality rate in literature varies with the range of 6.5 – 20%.³²

In our series the average length of hospital stay was significantly higher among patients who underwent Graham’s Omentopexy. The average duration was 8.10 ± 1.81 days in group A and 12.43 ± 5.59 days in group B . In other series like Satapathy *et al* ³⁰ the average hospital stay was 9 ± 1.2 days and 10.0 days (Modified Graham’s Omentopexy) and 11.5 days (Graham’s Omentopexy) in Jat *et al*.³³ The hospital stay varies with the size of perforation, duration of illness and the condition of the patient on arrival.³⁴

Several literatures support the role of therapy for *H. pylori* in post-operative period.³⁵ *H. pylori* eradication speeds up healing and decrease the relapse rate of ulcer disease as reported by Sebastian *et al*.³⁶ Therefore, post-operatively, all patients were prescribed a 2-week course of standard triple drugs anti-*H. Pylori* therapy.

The most important factors predisposing to complications are delay in admission to the hospital, general condition of the patient, associated diseases and shock on admission. Mortality and morbidity can be reduced by early admission, prompt resuscitation, and treatment of associated diseases, early surgical intervention and prophylaxis for complications.

CONCLUSION

Hence, it is concluded from our study that Modified Graham’s Omentopexy can be considered as a safe and effective alternative to the standard Graham’s Omentopexy in patients with perforated duodenal ulcers.

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