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# Management and Outcome of 50 Traumatic Gut Injury Cases

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**Original Research Article** 

Introduction: Traumatic gastrointestinal tract perforation is one of the commonest abdominal emergencies. The number of admitted trauma patients just focuses the tip of the iceberg because a lion's share of these ill-fated people with abdominal trauma pass their last breathe on the way to the hospital. So what should we do to counter this epidemic and what necessary steps should be taken to reduce the mortality and improve the morbidity was our aim of the study. Although this small study cannot draw a valid conclusion in comparison to the large series of western situations. This study was designed to present the experience of 50 patients with traumatic gastrointestinal tract perforation who were admitted to the surgery department, at Dhaka Medical College Hospital from July 2007 to December 2007. Cases were selected randomly. Standard protocol was followed for analysis and studying of the factor modifying morbidity and mortality. Aim of the study: The aim of the study was to observe the management and outcome of 50 gut injury cases in a tertiary-level hospital in Dhaka, Bangladesh. Methods: This cross-sectional observational study was conducted at the Department of Surgery, Dhaka Medical College Hospital, Dhaka, Bangladesh. The study duration was 1 year, from January 2007 to December 2007. A total of 50 cases were selected for the purpose of this study from those admitted to the study hospital due to traumatic gut injury. Result: The majority of the patients was male and was of the young group. Penetrating groups (60%) predominate over the blunt group (40%). Penetrating injuries were mainly caused by stab and gunshot injuries on the other hand road traffic accidents were mainly responsible for blunt trauma. 58% of patients were in shock on admission and 48% had associated extra-abdominal injury. 52% of patients were resuscitated successfully by means of blood and I/V fluid and most of them were resuscitated within 1-4 hours. The diagnosis was mainly based on clinical presentation and with the aid of very limited investigation. The majority of patients (72%) were operated on within 24 hours of admission. The small intestine was the main organ involved. A number of procedures were adopted for operative management but the most common procedure was simple repair and resection with end-to-end anastomosis. Overall mortality was 6%. Finally, factors influencing morbidity and mortality were studied where cause and severity of the injury, the time lag from injury to treatment, blood loss and shock state of the patient, and multiple organ injuries were found to be the main factors responsible for morbidity and mortality in patient with traumatic gastrointestinal tract perforation. *Conclusion:* Through this study, an attempt was made to find out the factors that influence morbidity and mortality in the management of traumatic gastrointestinal tract perforation. The important factors that caused significant morbidity and mortality were the cause and severity of the injury, delay to resuscitate the patient, delay in starting definitive treatment, shock on admission, multiple organ injury, and intensive care facility.

Keywords: Trauma, Penetrating, Gastrointestinal, Abdominal, Stomach.

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# **INTRODUCTION**

The human body is subjected to an increasing number and variety of external forces including fall, blow, penetrating injuries by sharp-pointed weapons, firearm injuries, industrial accidents, and not the least road traffic accidents. The abdomen encompasses a large area of the body and suffers a lack of protection unlike the chest and as it is within approachable height so is more susceptible to various injuries [1]. Though the wounding agents seldom respect anatomical boundaries in causing injuries to the abdomen as well as injuries to the head, chest, and other areas of the trunk and extremities. Abdominal trauma is a very common surgical emergency and the number of admission with abdominal trauma is increasing in our country due to rapid urbanization and increased social unrest even in rural areas. Thousands of people, the majority of them are young, active groups of our population are becoming disabled or losing their lives to this sort of injury each year. It has been calculated that 1,20,000

Citation: Mohammad Fazlul Haque, Mohammad Raisul Islam, Atikul Ahsan. Management and Outcome of 50 Traumatic Gut Injury Cases. SAS J Surg, 2022 July 8(7): 523-129. people die from trauma each year in the USA and 10% of them die from abdominal trauma. But statistics are not clear in our country [2]. Whatever may be the type of abdominal injury blunt, penetrating, or blast gastrointestinal tract is the most frequently affected organ, where the stomach accounts for 5%, Duodenum less than 1%, and the small intestine 20-25%. But all of them are curable traumatic conditions if detected early and managed promptly within the golden hour. Delay in their recognition often greatly impairs the chance of recovery and outcome. Traumatic gastrointestinal tract perforation is high on the list of curable traumatic conditions in patients sustaining multiple injuries. Exceptions are made when these are associated with other injuries (like head and chest) which require immediate particular attention. The history of surgery is as old as that of human beings. Many suggest that trauma was the main medical problem of early human beings. In ancient Egypt, Edwin Smith's papyrus has been found to deal with medicine, surgery, obstetrics & Gynecology and his writing between 3000 and 1600 BC describes 48 cases of trauma extending from head to foot "a capiteadcalceurn" [3]. Although there is no study of gut injury outcome only for mortality in traumatic gastrointestinal tract perforation but mortality for abdominal injuries was quite high in previous days (e.g. World War 1 -53.5% World War II -25%, Vietnam War 10%). But today the rate has been reduced to less than 5% [3, 4]. The primary factors that play a role in this decreasing mortality rates are modern diagnostic facilities, early recognition, and operation, proper management through better pre and post-operative care, etc. It has been seen that most of the factors influencing morbidity and mortality in traumatic gastrointestinal tract perforation can be prevented by early recognition and prompt management. It is only possible in a setting where there is a full range of diagnostic facilities and staff that is both knowledgeable and interested in trauma care. Although abdominal injuries usually fall within the training and experience of general surgeons, the extra-abdominal injuries should get ready access to both surgical and medical consultants, which are essential for optimal care. A broadly trained general surgeon serving as team captain should be responsible for the overall care of the patient. The present study was conducted to observe the management and outcome of gut injury in a present-day setting.

### **OBJECTIVE**

# **General Objective**

- To prompt diagnosis and accurate management of traumatic gut injured patient
- To find out the outcome of the patients

#### **METHODS**

This was a cross-sectional observational study that was conducted at the Department of Surgery, Dhaka Medical College Hospital, Dhaka, Bangladesh. The study duration was 1 year, from January 2007 to December 2007. A total of 50 cases were selected for the purpose of this study from those admitted to the study hospital due to traumatic gut injury. All cases present with trauma and distended abdomen meeting the enrollment criteria were consecutively selected and allocated into the groups based on acute cases. Informed written consent was taken from each patient and their privacy and confidentiality were maintained. Each patient in the surgery department was evaluated by taking a careful history, physical examination, and investigations. All findings were recorded in a prescribed data collection sheet. Ethical approval was obtained from the ethical review committee of the study hospital. A structured questionnaire addressing all the variables of interest was developed, and the questionnaire was pre-tested and modified according to the few backs review from field testing. Data was collected on variables of interest from the selected patients using the structured questionnaire. Collected data was checked, edited, and entered into the computer program Statistical Package for Social Science (SPSS). Both descriptive and inferential statistics were used in the process of data analysis.

#### **Inclusion Criteria**

- All patients present with traumatic gut injury irrespective of age and gender
- Patients who had given consent to participate in the study.

#### **Exclusion Criteria**

- Patient with traumatic gut injury alongside severe head injury
- Unable to answer the criteria question.
- Injury of the gut other than trauma like duodenal ulcer perforation, ischemic necrosis of the gut, typhoid ulcer perforation, etc.

# RESULTS

Condition		Number	Percentage (%)
Hemodynamic status	s Good/Stable		42
	Shock	29	58
Consciousness	Unconscious	01	02
	Semi-conscious	09	18
	Conscious	40	80

The majority of patients (58%) were in shock on admission. 42% were hemodynamically stable. 80% were conscious, 18% were semi-conscious and one was unconscious.

Variables	6	Number	Percentage (%)
Age grou	p(years)		·
0-10		04	08
11-20		14	28
21-30		23	46
31-40		06	12
41-50		02	04
51-60		01	02
Gender			
Male		45	90
Female		05	10
Type of T	[rauma		
Penetratir	ıg	30	60
Blunt		20	40
Associate	ed Injuries (n=	50)	
Head inju		01	3.84
Thoracic		03	11.53
Fracture	Upper limb	05	19.23
	Pelvis	03	11.53
	Lower limb	03	11.53
Soft tissue	e	11	42.30
None		24	48
Site of G	IT Involvemen	t	-
Stomach		03	06
Duodenui	n	03	06
Jejunum		20	40
Ileum		02	04
Caecum		04	08
Ascendin	g colon	10	20
Transvers	e colon	07	14
Descendin	ng colon	01	02

<b>Table 2: Characteristics</b>	of 1	the study	population (	(n=50)	)
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The age of the patients in this series ranged from 0-to 60 years. The highest incidence was noted between the ages of 21-30 years (465) followed by the age group 11-20 years (28%). 4patients were below 10 years of age and 1 patient was above 50 years of age. There were 45 male patients (90%) and female patients (10%). The male: female ratio was 9:1. Out of 50 patients, 30 (60%) sustained penetrating injury and 20 patients (40%) sustained blunt trauma. Among the 26 patients with an associated extra-abdominal injury.

42.03% suffered soft tissue injury, 19.23% patients had associated upper limb fracture, 11.53% patients had a pelvic fracture, 11.53% patients had lower limb fracture, and 11.53% patients had a thoracic injury. Only one (3.84%) patient in this series had an associated head injury. Per operative injury to the jejunum was found in the highest number (20 cases) of the patient followed by Ascending colon (10), transverse colon (07) stomach (03), and Duodenum (03), caecum (04), Descending colon (01), ileum.

Table 3: Types of trauma among the participants (n=50)						
Туре	Number	Percentage (%)				
Penetrating (n=30)						
Stab	12	40				
Gunshot	10	33.34				
Assault by a sharp instrument	02	06.67				
Bomb blast	01	03.33				
RTA	04	13.33				
Attack by a domestic animal	01	03.33				
Blunt (n=20)						
RTA	10	50				
Blow/Kick	08	40				
Fall from height	02	10				

Table 3: Types of trauma among the participants (n=50)				
Туре	Number	Percentage (%)		
Penetrating (n=30)				
Stab	12	40		
Gunshot	10	33.34		

Among the 30 patients with penetrating injury highest incidence was due to stab injury in 12 patients (40%), followed by Gunshot injury in 10 patients (33.34%), assault by a sharp instrument in 02 patients (6.67%), RTA 04 patients (13.34%), Bomb blast 01 patient (3.33%) and attack by domestic animal 01 patient (3.33%). Among the 20 cases of blunt trauma, 10 patients (50%) sustained injury from RTA, 08 patients (40%) suffered assault (Blow/kick), and 02 patients 10% were injured by a fall from height.

Table 4: Clinical presentations among the participants						
Symptoms and Signs		Penetrati	ng Group (n=30)	Blunt trauma group (n=20)		
		Number	Percentage (%)	Number	Percentage (%)	
Abdominal Pain		28	93.33%	16	80.00%	
Bleeding		21	70.00%	0	0.00%	
Vomiting		17	56.67%	12	60.00%	
Dehydration		15	50.00%	10	50.00%	
Hypotension		16	53.33%	13	65.00%	
Anaemia		10	33.33%	8	40.00%	
Unconsciousness		0	0.00%	1	5.00%	
Abdominal distension		9	30.00%	12	60.00%	
Rigidity		15	50.00%	14	70.00%	
Tenderness		17	56.67%	14	70.00%	
Shifting dullness		12	40.00%	10	50.00%	
Obliteration of liver dull	ness (upper border)	0	0.00%	12	60.00%	
Absent bowel sound		10	33.33%	9	45.00%	
Evisceration	Omentum	7	23.33%	0	0.00%	
	Gut	1	3.33%	0	0.00%	
Extra abdominal injury		12	40.00%	14	70.00%	
Skin Abrasion and Bruis	ses	0	0.00%	5	25.00%	
Asymptomatic		0	0.00%	4	20.00%	

30 patients out of 50 had sustained a penetrating injury in the series and their presentation was quite obvious. Abdominal pain was the main symptom (93.30%) followed by bleeding 70% and abdominal distension 30%. Important signs were dehydration (50%), hypotension (53.33%), shifting dullness 40%, anemia (33.30%), signs of peritonitis (Tenderness &rigidity), evisceration of omentum (23%) and gut (3%). 20 patients in this study sustained blunt trauma and their clinical presentation was not clear-cut. But a majority (80%) had mild to severe abdominal pain 60% had vomiting and 20% were asymptomatic. Physical examination raveled dehydration in 50% of patient's hypotension in 60%, and signs of peritonitis (Tenderness and rigidity) in about 70% of patients.

Resuscitation	Number	Percentage	Means of resuscitation		
Resuscitation	Number	(%)	I.V. Fluid	Both (Blood and I/V fluid)	
Done & responsive	26	52	12	14	
Not done	21	42	Not resuscitated		
Done but not responsive	03	06	Both I/V fluid and blood		

Table 5: Requiren	ent and means	of resuscitation	(n=50)
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Most of the patients (58%) were hemodynamically unstable at presentation. So adequate resuscitation was done before commencing definitive treatment. Out of 50 patients, 12 patients (24%) were resuscitated with intravenous fluid only and 14 patients (28%) required both blood and intravenous fluid for resuscitation, 21 patients (42%) did not require any resuscitative measure while 03 patients (6%) could not be resuscitated even after using both intravenous fluid and blood.

Table 0. Time required for resuscitation (n=20)					
Time required(Hour)	Number	Percentage (%)			
<1 hour	0	0.00%			
1-2	9	34.62%			
3-4	13	50.00%			
4-6	4	15.38%			
>6	0	0.00%			

Table 6: Time require	ed for resu	scitation (n=	26)

Among the 26 cases who needed and were responded with resuscitation, the majority (50%) responded within 2-4 hours. Among the remaining cases, 09 cases (34.62%) and 04 cases (15.35%) were stable within 1-2 hours & 4-6 hours respectively. None of the patients could be resuscitated within one hour.

Table 6: Distribution of the nature of in	vestigations among	participants (n=50)

Nature of investigations	Total	Percentage (%)
Plain X-ray Abd.in erect posture	50	100
Chest X-ray P/A& Lateral view	30	60
X-ray pelvis A/P view	03	06
X-ray upper limb &neck	05	10
X-ray lower limb	03	06
Ultra-sonogram of the whole abdomen	07	14
Blood grouping	50	100
Complete blood count	20	40
RBS	10	20
ECG	05	10
Serum creatinine	02	04
Blood urea	01	02
Serum electrolyte	01	02
Urine routine microscopic examination	10	20

Diagnostic aid was very much limited in this series. Abdominal X-rays in erect posture A/P view including both domes of diaphragms and blood group were done in every case (100%) CBC was done for 20 cases, urine Routine Microscopic Examination for 10 cases. Another investigation was x-ray chest P/A view

(30 cases), x-ray pelvis (3 cases), x-ray upper limb and neck (5 cases), x-ray lower limb (3 cases), ultrasonogram of the whole abdomen (7 cases), RBS (10 cases) and ECG (5 cases). Fluid requirement depends upon pulse, blood pressure, and urine output.

Procedure	Number	Percentage		
	Positive	(%)		
Done	11	03	14	28
Not done	36			72

A diagnostic peritoneal tap was performed in 14 cases (28%). Among these, 11 showed positive tap. Peritoneal tap was not done in 36 cases (72%).

Time laps(Hour)	Number	Percentage
2-6	10	20
7-12	21	42
13-24	15	30
25-36	02	04
37-48	02	04

Table 8: Time laps between admission and definitive procedure (n= 50)

21 cases were operated within 7-12 hours of admission. 15 operations were done within 13-24 hours of admission and 10 operations were done within 6

hours of admission. Operations were delayed for more than 36 hours for 4 cases.

Table 9: Indication for operation (n=50)					
Indication	Number	Percentage (%)			
Penetrating					
1. Peritoneal penetration proved by					
a. Exploration-Digital/instrumental	20	40			
b. Evisceration	08	16			
2. Signs of surgical abdomen					
a. Rigidity and tenderness with or without distension	28	56			
b. Rebound tenderness	22	44			
c. Absent bowel sound	19	38			

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3. Refractory shock	01	02
Non-penetrating group		
1. Signs of acute abdomen	13	26
2. Sub diaphragmatic gas shadow	10	20
3. Positive peritoneal tap	11	22
4. Refractory shock	02	04

Among the penetrating group peritoneal penetration was the main indication for the operation which was proved by exploration of abdominal wounds in 20 cases (40%) and by evisceration, in 8 cases (16%). Other indications in this group (penetrating) were signs of the surgical abdomen and 01 patient was operated on for refractory shock. Among the non-penetrating group, operations were indicated for signs of acute abdomen in 13 cases (26%), positive peritoneal tap in 9 cases (18%), and refractory shock in 2 cases (4%).

Portion of G.I.T.	Procedure	Number	Percentage (%)
Stomach	Primary anatomical repair	06	16
Duodenum	Primary anatomical repair	06	12
Small gut	Primary anatomical repair		40
Sillall gut	Resection & anastomosis	11	22
	Primary anatomical repair	02	04
	Repair & proximal colostomy	10	20
Large gut	Repair & proximal defunctioning illeostomy	04	08
	Resection & anastomosis with proximal defunctioning colostomy	05	10
	Exteriorization as a loop colostomy	05	10

Table 10•	Operative	nrocedure	followed in	n the series	(n=50)
Lable IV.	Operative	procedure	Ionoweu n	I the series	(II-30)

Table 11: Recovery and hospital stay affected by organ involvement (n=50)					
Recover Duration Organ Number Percentage					
Rapid with mild complication	<15 days	No organ, small gut alone	20	40	

Recover	Duration	Organ	rumber	1 ci centage
Rapid with mild complication	<15 days	No organ, small gut alone	20	40
Slow with moderate complication	.15 days	Stomach with other organ	16	32
Very slow with complication	>30 days	Colon withother organ	11	22
Death			03	06

Those patients who had only a small gut injury and no other associated injury (40%) left the hospital within 15 days with rapid recovery and minimum complications. Patients who had stomach or duodenum injury with other organs (32%) cases gained slow recovery with moderate complications. A patient who suffered colonic with other organs injuries.22% of cases gained very slow recovery with complications and stayed in the hospital for more than 30 days.

Time between trauma &	No.	Cured (n=32)		Morbidity (n=16)		Mortality (n=3)	
present action in casualty		Total	%	Total	%	Total	%
2-6 hour	10	9	90.00%	1	10.00%	0	0.00%
7-12 hour	21	14	66.67%	8	38.10%	0	0.00%
13-24 hour	15	9	60.00%	5	33.33%	1	6.67%
25-36 hour	2	0	0.00%	1	50.00%	1	50.00%
37-48 hour	2	0	0.00%	1	50.00%	1	50.00%

Table 12: Relationship	between morbidity	& mortality with hosp	oital delay (n=50)

The cure rate was high (90%) who were operated on within 2-6 hours and was low for those who were operated on within 37-48 hours. Morbidity was low (10%) for those who were operated on earlier and high (50%) for those who operated within 37-48 hours. Mortality was also high (50%) for this group of patient

# DISCUSSION

Morbidity and mortality of traumatic gastrointestinal tract perforation have undergone spectacular changes during the whole length of the twentieth century. Interest in this subject was aroused during world war-II and since then the morbidity and mortality rates for abdominal trauma have fallen steadily [5]. But a dramatic fall in morbidity and mortality has occurred in 1988 when the Royal College of Surgeons of England reported that at least one in five and possibly as many as one in three trauma death in the hospital were avoidable by introducing Advance Trauma Life Support (ATLAS). Realizing this fact, they have started the Advance Trauma Life Support course (ATLAS), followed by the Advanced Trauma Nursing Course (ATNC), and at the same time, they have introduce the Pre-Hospital Trauma Life Support

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Course (PHTLS) which all together radically altered the management and outcome of injured patients [6]. But the situation is not always the same all over the globe. Many attempts have already been taken to improve the skills of our surgeons concentrating on ATLAS, ATNC, and PHTLS, but no definite results can be observed as of yet. Our study was conducted to detect the factors modifying morbidity and mortality in traumatic gastrointestinal tract perforation which will hopefully reflect the recent improvement in trauma care in our country. According to the findings of our study, Young patients were the common victims and incidence decreased with advancing age. The highest incidence was in the age group 21-30 years (46%) followed by 11-20 years (28%), and 31-40 years (12%). The above figures indicate that the affected people were those who were most mobile and active in their daily life. This finding was quite similar to a few other studies [7, 8]. An extremely high male prevalence was observed in the present study. The male predominance may be due to the fact that male is mainly involved in outdoor work, more hospital beds are available for male, or may be due to more awareness of the male patient. All of these factors reflect the male dominant society of the country. The high male prevalence was also supported by the findings of Richardson et al., as well as a few other studies [8-11]. Regarding the nature of trauma, the present series showed that 60% had penetrating trauma and 40% had blunt trauma, but this picture was different in western countries, where bunt trauma had a higher prevalence among the participants [12, 13]. Out of the cases of penetrating trauma 40% comprised stab injury 33.34% by gunshot. These two causes comprised 73.34% of penetrating injuries. Other causes like a bomb blast, assault by a sharp instrument, road-traffic accidents, and attacks by domestic animals were very infrequent. Out of the cases of blunt trauma, road traffic accidents accounted for 50%, assault (Blow/kick) for 40%, and fall from height 10%. These findings had little similarities with western studies, where the incidence of a gunshot wound as a cause of penetrating injury was much higher [14]. Another western study showed a higher incidence of stab injuries as a cause of penetrating injuries [15]. But in regards to blunt trauma injury causes, our study findings were similar to these Western studies [14, 15]. Time lapse from initial injury to treatment plays a big role in the morbidity and mortality rates of such patients. In this series, 21 cases were operated within 7-12 hours of admission. 15 operations were done within 13-24 hours of admission and 10 operations were done within 6 hours of admission. Operations were delayed for more than 36 hours for 4 cases. In this series, 58% of patients were in shock at the time of admission. A majority (52%) were effectively managed either by I/V fluid or blood or by both. Resuscitation had failed for 3 patients due to concealed hemorrhage (per operative findings) and persistent shock was the indication for operation for them. Extra abdominal injuries were associated in 52% of cases, the majority being soft tissue injury (42.30%)

followed by upper limb fracture (19.25%)pelvic fracture (11.53%), thoracic injury (11.53%), and head injury (3.84%). These findings were quite similar to a study by Everad et al., [15]. In this series morbidity was 50% and mortality was 11.53% for patients with the associated extra-abdominal injury which had some dissimilarity with the study conducted by Fitagenald et al., [16], where associated injury-related mortality was 22%. This dissimilarity reflected the recent adoption of advanced trauma life support care in the management of trauma patients. Most of the patients (52%) needed and responded to width resuscitation by I/V fluid alone or in combination with blood following the ABCDE principle of primary survey and resuscitation step (ATLAS). Optimum resuscitation time was 2-4 hours in 44.82% of cases and 1-2 hours in 34.61% of cases. This indicates that 79.43% of patients were resuscitated within 1-4 hours of time. Detailed clinical presentation and findings of the cases were studied for both penetrating and blunt groups. The commonest mode of presentation was pain (93.3%) for a penetrating group. Abdominal distension was more frequent in the blunt group (60%) and less in the penetrating group (30%). Major clinical signs were tenderness 56.6% for the penetrating group, 70% for the blunt group, rigidity 50% for the penetrating group and 70% for the blunt group, hypotension 46.60% for the penetrating group, 60%1 for the blunt group, anemia 33.30%0 for penetrating group 40% for the blunt group. Absent bowel sound 33.30% for penetrating group and 45% for blunt group indicating paralytic ileus. In this study, 42% of cases had surgery within 7-12 hours where morbidity was 38.09% and mortality was absent. 30% of patients had surgery within 13-24 hours and morbidity was 33.33% and mortality was 6.66% 20% of patients had surgery within 6 hours of admission where morbidity was 10% and mortality was 00%, 04% of patients received definitive treatment within 25-36 hours where morbidity was 50% and mortality was also 50%. 04% of patients had surgery within 37-48 hours where morbidity & mortality was 50%. So it has been seen from the study that delay in starting definitive treatment influenced morbidity and mortality. Robbs et al., showed that mortality was 47.2% in patients who were operated on after 24 hours, which was almost similar to our study [17]. Recovery and hospital stay were also influenced by the organ affected. 40% of patients had rapid recovery with minimum complications that had only a small gut injury and stayed for less than 15 days. 22% of patients had very slow recovery that had colon injury with other organs and stayed for more than 30 days. The death rate was 06% in this series.

#### Limitations of the Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

### **CONCLUSION**

Through this study, an attempt was made to find out the factors that influence morbidity and mortality in the management of traumatic gastrointestinal tract perforation. The important factors that caused significant morbidity and mortality were the cause and severity of the injury, delay to resuscitate the patient, delay in starting definitive treatment, shock on admission, multiple organ injury, and intensive care facility.

#### FUNDING

No funding sources.

# CONFLICT OF INTEREST

None declared.

#### ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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