ORIGINAL ARTICLE

A prospective, non-randomized study to determine the role of intraperitoneal drain placement in perforation peritonitis

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ABSTRACT

BACKGROUND: Surgical site infection continues to be a major problem after laparotomy for perforation peritonitis, as it increases morbidity and hospital stay and decreases the quality of life. Intra-abdominal drain placement is a routine practice in perforation peritonitis. The aim of our study is to compare the incidence of surgical site infection in two groups of patients who were operated for perforation peritonitis: The first group received the intraperitoneal drain, while no drain was placed in the second group.

METHODS: The present single-center, prospective, non-randomized study was conducted in the Department of General Surgery at the Postgraduate Institute of Medical Education and Research, India. A total of 122 patients underwent exploratory laparotomy for gastroduodenal and small bowel perforation peritonitis, of which 100 participants were included in this study, based on specified criteria for inclusion and exclusion. A total of 50 participants each were included in the drain group and the no drain group, respectively. A drain was placed in every alternate patient with perforation peritonitis who received primary closure or resection anastomosis. Patients with diabetes, renal failure, and hemodynamic instability and those who presented more than 72 h since symptom onset were excluded from the study. Peritoneal fluids were cultured. The primary endpoint was to identify the incidence of surgical site infections (SSIs) in the two groups. We also compared the time taken for the return of bowel movements, duration for which a nasogastric tube was inserted, whether any intervention was performed under local or general anesthesia within 30 days of surgery, the duration of hospital stay, and the ease of diagnosing repair leak in the post-operative period in both the groups.

RESULTS: Demographics of participants in both the groups were matched. No significant difference was observed between the drain and no-drain groups with respect to the incidence of surgical site infection (p=0.779). The duration of surgery and length of hospital stay were significantly lower in the no drain group. A significant difference was observed between the two groups concerning the peritoneal culture growth, and increased bacterial growth was seen in the drain group. No significant difference in morbidity was noted between the two groups, which was classified according to the Clavien-Dindo classification.

CONCLUSION: Routine use of intra-abdominal drains was not found to be effective in preventing SSIs, but a selection bias cannot be ruled out. Patients with no drains had a significantly shorter duration of hospital stay.

Keywords: Drain; hospital stay; perforation peritonitis; surgical site infection.

INTRODUCTION

Peritonitis due to gastrointestinal perforation is one of the most common acute abdominal emergencies encountered in surgical practice.[1] Most occurrences are secondary bacterial peritonitis, as a result of perforation of the hollow viscus, duodenum, ileum, or large intestine. Peptic ulcer, perforation of the stomach or duodenum, tubercular or typhoid perforations of the ileum, and traumatic or ischemic gastrointestinal perforations are common causes of peritonitis.[1,2] Intraperi-

Cite this article as: Singh S, Tandup C, Singh H, Kumar H, Khare S, Sahu S, et al. A prospective, non-randomized study to determine the role of intraperitoneal drain placement in perforation peritonitis. Ulus Travma Acil Cerrahi Derg 2022;28:1397-1403.

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Ulus Travma Acil Cerrahi Derg 2022;28(10):1397-1403 DOI: 10.14744/tjtes.2021.45705 Submitted: 15.05.2021 Accepted: 28.12.2021

toneal cavity drainage after definite surgery for secondary bacterial peritonitis is a common practice employed to remove intraperitoneal collections, such as ascites, blood, bile, chyle, and pancreatic juice, and to reduce the incidence of surgical site infections (SSIs), which further helps in reducing morbidity and hospital stay.[3] However, drain placements are associated with complications such as increased rates of intra-abdominal and wound infections, increased abdominal pain, decreased pulmonary function, organ damage, prolonged hospital stay, and discomfort to the patients.[4]

SSIs are defined as wound infections following an invasive surgical procedure. In spite of advances in surgical technique and medical care, SSI is still a major concern for surgeons as well as patients.[5] Even in the era of evidence-based medicine, several randomized controlled trials failed to establish the value of prophylactic drainage after abdominal surgery.

The present research was undertaken to study the need, efficacy, and advantage, if any, of intra-abdominal drainage following primary closure or resection and anastomosis of the perforated bowel.

MATERIALS AND METHODS

Study Design

The present study was a single-center, prospective, non-randomized research carried out in the Department of General Surgery at the Postgraduate Institute of Medical Education and Research (PGIMER), a tertiary care hospital in India, from October 2019 to December 2020. The study was approved by the Institutional Ethical Committee (IEC no. INT/IEC/2019/002140) of the PGIMER, Chandigarh, India, on October 4, 2019, and is executed in compliance with the Declaration of Helsinki (as revised in 2013). Written informed consent was obtained from all participants, and they had full freedom to withdraw at any point during the study.

Patients

All patients included in the study belonged to the age group of 13–70 years and presented with perforation peritonitis, which was suspected clinically. They were diagnosed after a chest X-ray or contrast-enhanced computed tomography (CECT) confirmed the presence of free gas under the diaphragm. The patients included in this study underwent exploratory laparotomy and received either primary closure of perforation or resection anastomosis of perforated bowel segment. Informed consent was obtained from the patient. Patients with hemodynamic instability, renal failure, diabetes mellitus, and those who presented more than 72 h since the onset of symptoms were excluded from the study. Patients with temporary abdominal wall closure and those who received enterostomy at index surgery were also excluded from the study, as the role of drain could not be assessed in these cases.

Pre-operative Preparation

All the patients who presented with perforation peritonitis were optimized, and fluid resuscitation was carried out using intravenous crystalloid fluid though a wide bore intravenous cannula. All patients received nasogastric decompression, and a urinary catheter was placed to monitor the urine output. Routine blood investigation including the monitoring of arterial blood gas analysis was ensured. Broad-spectrum antibiotic (cefuroxime + metronidazole) was administered in all the patients. After optimum resuscitation, informed consent was obtained from the patient who was then prepared for surgery.

Surgery

All patients were explored under general anesthesia and prepping and draping from the nipple to mid-thigh was executed. A midline laparotomy was used to enter the peritoneal cavity. Peritoneal fluid sample was collected from the cavity and sent for culture and sensitivity in a sterile container. Exploration was carried out methodically from the gastroesophageal junction till the rectum to identify the site of perforation. Perforation was either repaired primarily or through resection anastomosis of the bowel segment, as feasible. Patients were divided intraoperatively into two groups. In one group, abdominal drain was placed during the surgery, while no drain was placed in the other group. To avoid selection bias, every alternate patient received drainage. Following the repair of the perforation, peritoneal lavage was done thoroughly with at least 5 L of normal saline, and the rectus sheath was closed.

Post-operative Management

All patients were kept nil orally with nasogastric tube (NGT) aspiration until the passage of flatus and/or resumption of bowel movement. All patients received the broad-spectrum antibiotic, which was then changed based on the intraoperative peritoneal fluid culture, usually by day 3 of the post-operative period. Both the groups were monitored in the post-operative period until discharge/mortality to compare for SSIs, intra-abdominal infections, and the risk of anastomotic/repair leak by looking for content in the drain or by eliciting the signs of peritonitis. Our primary endpoint was to compare the incidence of SSIs in the drain group and no drain group. The definition of SSI posited by the centers for disease control (CDC) was used for the present study: "Any infection of the superficial or deep tissues or the organ/space affected by surgery, which occurs within 30 days of surgery when no prosthesis has been implanted." According to this definition by the CDC, the presence of at least one of the following suggests infection: Purulent drainage, with or without laboratory confirmation, from the superficial incision; organisms isolated from an aseptically obtained culture of fluid from the superficial incision; at least one of the following signs or symptoms: Pain or tenderness, localized swelling, redness, and superficial incision deliberately opened

by the surgeon, unless the incision is culture negative; and a diagnosis of superficial incisional SSI by the surgeon.[6] In the secondary outcome, we compared the re-exploration rate, time of return of bowel movements, the duration for which NGT was inserted, any intervention under local or general anesthesia, and the duration of hospital stay. In case of SSI, intra-abdominal infection, or anastomotic/repair leak, medical management, or radiological/surgical intervention were carried out as clinically appropriate, and as necessitated by the individual cases, in both the groups.

Statistical Analysis

Statistical analysis was performed using the SPSS STATISTICS Version 21 software. Continuous variables were expressed as arithmetic mean±standard deviation or median (range), and compared using Mann–Whitney U-test. Categorical variables were compared using the χ^2 test or Fisher's exact test. P<0.05 was considered statistically significant.

RESULTS

A total of 122 patients were assessed for eligibility, of which seven patients did not gave consent. Out of the remaining 115 patients, 15 were excluded: 10 patients were diabetic, three patients required inotropic support for hemodynamic instability pre-intervention, and two patients received Bogota bag closure in the index surgery (Fig. 1).

The mean age of the 100 participants, who were equally divided into the two groups, was 38.50 years. The majority of the participants were in the age group of 31–40 years (n=32) (Table 1).

A preponderance of male patients was observed as they constituted 89% of the total number of participants, while the female patients constituted 11%. Both the groups were comparable with respect to age and sex. Body mass index (BMI) of each participant was measured and no significant difference was noticed between the two groups (Table 1).

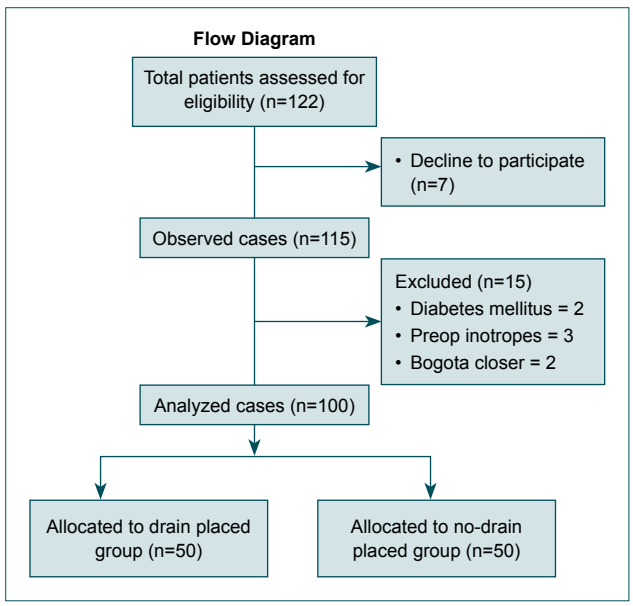

Figure 1. Consort diagram.

There was a significant difference between the two groups (p≤0.001) in terms of the distribution of the site of bowel perforation: 44% of the participants in the drain group had pre-pyloric perforation (n=22), while 76% of individuals in the no drain group presented with pre-pyloric perforation. Meanwhile, a total of 30% of participants in the drain group had ileal perforation, and all the ileal perforation peritonitis patients (n=15) received drain intraoperatively (Table 1).

In both the groups, primary repair of the perforation site was executed in 82% of the cases (n=41), and resection and anastomosis were done in the remaining 18% (Table 1). The majority of the participants, 90.8% in both the groups, had perforations of size that ranged 5–10 mm. As measured intraoperatively, 86% (n=43) of the patients in the drain group had a perforation of size 5–10 mm, while it was 95.8% (n=46) in the no drain group (Table 1). A total of 8 (8.2%) participants had a perforation size greater than 1 cm. The intergroup differences were insignificant (p=0.060) (Table 1).

We observed a significant difference (p=0.003) between the two groups in terms of the duration of the surgery. The mean operative time in the drain group was 1.75±0.37 h starting from skin incision to sheath closure. The mean duration of surgery in the no drain group was 1.57±0.37 h (Table 1).

Postoperatively, we followed the outcome for the development of SSI. Out of the 100 patients, 12 patients developed SSI – 6 (12%) in each group. No significant difference was recorded in the incidence of SSI between the two groups (p=0.779) (Table 2). Three patients in the drain group and five patients in the no drain group had developed superficial incisional SSI and were managed with intravenous antibiotics based on the culture report. Another three patients in the drain group who had developed deep incisional SSI and sheath dehiscence received Bogota bag application along with intravenous antibiotics. One patient in the no drain group developed deep incisional SSI and underwent ultrasound-guided percutaneous drainage. A Bogota bag was also applied for partial sheath dehiscence.

A total of four patients developed anastomosis/primary repair leak in the post-operative period. A comparison was made between the two groups in terms of the number of days taken for the detection of the leak and it was not found to be significant. In the drain group, a total of 3 patients (6%) developed the leak, which was detected on day 2 as the drain content was bilious in nature and clinically apparent (Table 2). Two patients in the drain group were re-explored on post-operative day 3. Ileal perforation was noted in one case in which primary closure was done in the index surgery, and

Table 1. Demographics and comparison of intra-operative findings and mean operative time

Parameters	Drain Group (n=50)	No-Drain Group (n=50)	p value
Age (years)	39.80±12.98	37.20±12.51	0.310
Gender, n (%)			0.749
Male	44 (88.0)	45 (90.0)	
Female	6 (12.0)	5 (10.0)	
Body mass index (kg/m^2)	22.12±2.31	21.84±1.87	0.645
Site of perforation, n (%)			<0.001
Prepyloric	22 (44.0)	39 (78.0)	
Duodenal	7 (14.0)	0 (0.0)	
Jejunal	4 (8.0)	5 (10.0)	
Ileal	15 (30.0)	0 (0.0)	
Appendicular	2 (4.0)	6 (12.0)	
Size of perforation, n (%)			0.060
<5 mm	0 (0.0)	1 (2.1)	
5–10 mm	43 (86.0)	46 (95.8)	
>10 mm	7 (14.0)	1 (2.1)	
Type of surgery, n (%)			1.000
Primary repair	41 (82.0)	41 (82.0)	
Resection anastomosis	9 (18.0)	9 (18.0)	
Intraoperative culture, n (%)			0.002
Bacterial growth present	22 (44.9)	8 (16.3)	
Sterile	27 (55.1)	41 (83.7)	
Comparison of mean operative time (hours)			
Mean (SD)	1.75 (0.37)	1.57 (0.20)	0.003
Median (IQR)	1.5 (1.5–2)	1.5 (1.5–1.5)	

SD: Standard deviation; IQR: Interquartile range.

one patient expired after the re-exploration. One patient in the drain group was not re-explored for leak and peritonitis given that he was hemodynamically unstable from septicemia and died on post-operative day 3. In the no drain group, 1 patient (2%) developed a leak in the primary repair done for the perforation of the first part of the duodenum, and it was detected on day 3 through clinical and radiological parameters. The patient was re-explored but later succumbed to sepsis.

There was a significant difference (p=0.028) between the two groups in terms of the duration of NGT indwelling. While NGT in the drain group remained for a mean duration of 3.04±1.16 days, the mean duration in the no drain group was 2.7±1.28 days.

The mean duration of hospital stay for patients in the drain group was 6.9±1.98 days, and for patients in the no drain group, the mean duration of hospital stay was 5.8±1.93 days which was statistically significant (p<0.001) (Table 2).

Peritoneal fluids of all the patients were sent for culture and sensitivity to laparotomy, and a significant difference was observed between the drain group and the no drain group (p=0.002). Participants in the drain group had a larger proportion (44.9%) of bacterial growth in the peritoneal fluid, whereas more of sterile culture was noted in the peritoneal fluid collected from the participants in the no drain group (83.7%) (Table 1). The culture report of one patient in each group was contaminated; hence, the report was excluded from the final analysis.

All post-operative complications were graded according to the Clavien-Dindo classification,[7] and no significant difference was recorded between the two groups (p=0.308). A total of 15 patients in the study had post-operative complications (Table 2). Grade II complication was noticed in three patients in the drain group and in five patients in the no drain group, who had developed superficial SSI and received culture-based I.V. antibiotics. Grade III complication was noticed in four patients in the drain group: Three patients had superficial SSI and sheath dehiscence for which Bogota bag was applied under local anesthesia, and one patient was re-explored for the leak. On the other hand, only one patient in the no

Table 2. Postoperative outcomes in the two groups

Parameters	Drain		p-value
	Drain Group (n=50)	No-Drain Group (n=50)	
Surgical site infection (present), n (%)	6 (16.0)	6 (14.0)	0.779
Nasogastric tube duration	3.04±1.16	2.65±1.28	0.028
Return of bowel movements, n (%)			0.078
Day 1	20 (40.8)	31 (62.0)	
Day 2	23 (46.9)	17 (34.0)	
Day 3	6 (12.2)	2 (4.0)	
Duration of hospital stay (days)	6.91±1.98	5.84±1.93	<0.001
Clavien-Dindo Classification, n (%)	(n=10)	(n=7)	0.308
Grade 2	3 (30)	5 (71.4)	
Grade 3	4 (40)	1 (14.2)	
Grade 5	3 (30)	1 (14.2)	
Mortality (present), n (%)	3 (6.0)	1 (2.0)	0.617
Number of patients with anastomotic leak, n (%)	3 (6)	1(2)	Not applicable
Day of detection of leak (mean)	2 days	3 days	0.065

drain group had a Grade III complication – a deep incisional SSI for which Bogota bag application under local anesthesia and ultrasound pigtail insertion was needed. Grade V complication/mortality was observed in 3 patients (6%) in the drain group and in 1 patient (2%) in the no drain group.

Mortality

A post-operative leak from the repaired or anastomosed perforation was the main cause of mortality in the present study. Four cases of mortality (n=4) were reported in our study. Two of the 3 (6%) patients in the drain group died due to a leak and 1 patient (2%) expired due to acute pulmonary thromboembolism. One patient in the no drain group also had a leak and was re-explored but died in the post-operative period.

DISCUSSION

Intraperitoneal drains are placed after perforation peritonitis to drain collections such as blood, bile, and intestinal contents.[8] The rationale behind the placement of drains is to reduce the potential source of infection and avoid SSI, and to detect post-operative bleeds or anastomotic leakage. Theodor Billroth was convinced that prophylactic drainage of the peritoneal cavity saved many lives after GI surgery.[9,10] However, other contemporaries believed that drainage of the peritoneal cavity was impossible and, therefore, prophylactic drainage served no purpose.[11]

The result of the present study clearly demonstrates that prophylactic placement of intraperitoneal drain is not beneficial. It does not help in reducing the incidence of SSI but contributes toward a prolonged hospital stay and increased operative time. In the present study, the clinical profile of the patients in the two groups matched in terms of age, sex, BMI, site and size of perforation, and the operative procedure performed. Statistically insignificant difference was observed in the incidence of SSI between the drain and no drain groups (p=0.779), which indicates that the placement of the drain does not reduce the incidence of SSI (Table 1). The difference in the duration of surgery between the two groups was statistically significant (p=0.003), as the mean duration of surgery (1.75±0.37 h) was more in the drain group (Table 1). The duration of hospital stay (6.9±1.98 days) was significantly less (p<0.001) in the no drain group (Table 1). Our observations are in agreement with various studies[8,11–16] documented in the existing literature.

The findings of a study by Khan et al.[15] suggested a statistically significant (p<0.001) difference between the drainage and no drainage groups in terms of SSI in wounds that were dirty. The SSI rates in dirty wounds with drains were found to be more than 3 times higher than those without drains. It has been debated that non-drainage may lead to a delay in the diagnosis of the anastomotic leak which increases morbidity and mortality. Thus, surgeons generally prefer intra-abdominal drains. In the present study, three patients in the drain group and one patient in no drain group developed anastomotic/primary repair leak which was suspected clinically on the basis of a deterioration in the general condition of the patients and signs of peritonitis. In the drain group participants, it was confirmed through the presence of bilious content in the drain, while in the no drain group participant, it was confirmed through a CECT of the abdomen. Only two cases in the drain group could be re-explored on post-operative day

3, as one patient expired before the exploration and one after the exploration. Whereas, one patient in the no drain group was re-explored on day 3, but later succumbed to sepsis. Thus, the theory that only the placement of a drain helps in the early diagnosis of the leak does not stand corrected in our study. Furthermore, our data are not large enough to support the proposition that an alert surgeon can suspect a leak clinically and confirm it through radiological investigations/interventions.

In addition, we studied the bacterial growth in both the groups: Participants in the drain group (44.9%) had a larger proportion of bacterial growth in the peritoneal fluid, whereas a more sterile culture was noted in the peritoneal fluid collected from participants in the no drain group (Table 1). The most common organisms isolated were *E. coli* and *K. pneumoniae*. A similar observation was recorded by Pai et al.[12] where, in addition to the above organisms, they also isolated *Staphylococcus aureus*.

Conclusion

The present study found that the incidence of SSI in the drain and no drain groups was comparable, and the routine use of intraperitoneal drains was not effective in preventing SSI. However, since all the patients in the study with fecopurulent contamination received drainage, the role of the drain cannot be assessed in cases with severe contamination. Furthermore, prolonged hospital stay in the case of perforation peritonitis patients with drains warrants more research and standard guidelines for practice.

Limitations

This study has potential limitations as it is a unicentric, prospective observational study. Therefore, it is subject to biases and confounding that may have influenced the study and the outcome.

Ethics Committee Approval: This study was approved by the Postgraduate Institute of Medical Education and Research, Chandigarh, Clinical Research Ethics Committee (Date: 15.10.2019, Decision No: IEC no. INT/IEC/2019/002140).

Peer-review: Internally peer-reviewed.

Authorship Contributions: Concept: S.S., C.T., S.K.; Design: S.S., C.T., H.S., H.K.; Supervision: C.T., H.S., H.K., S.K., L.K.; Resource: C.T., S.S., A.L., A.L.N; Materials: C.T., S.K., H.S., A.S.; Data: S.S., C.T.; Analysis: S.S.; Literature search: C.T., H.S., L.K.; Writing: S.S., C.T.; Critical revision: L.K., A.S., S.Sa.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study has received no financial support.

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ORİJİNAL ÇALIŞMA - *ÖZ*

Perforasyona bağlı peritonitte intraperitoneal dren takılmasının rolünü belirlemeye yönelik prospektif, randomize olmayan bir çalışma

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AMAÇ: Perforasyona bağlı peritonitte laparotomi sonrası cerrahi alan enfeksiyonu, morbiditeyi ve hastanede kalış süresini arttırdığı ve yaşam kalitesini düşürdüğü için önemli bir sorun olmaya devam etmektedir. Perforasyona bağlı peritonitte karın içi dren yerleştirilmesi rutin bir uygulamadır. Çalışmamızın amacı perforasyona bağlı peritonit nedeniyle ameliyat edilen iki grup hastada cerrahi alan enfeksiyonu insidansını karşılaştırmaktır: Birinci grupta karın içi dren yerleştirilmişken, ikinci gruba dren yerleştirilmedi.

GEREÇ VE YÖNTEM: Mevcut tek merkezli, ileriye yönelik, randomize olmayan çalışma, Hindistan'da Yüksek Lisans Tıp Eğitimi ve Araştırma Enstitüsü Genel Cerrahi Anabilim Dalı'nda yürütülmüştür. Gastroduodenal ve ince bağırsak perforasyonuna bağlı peritonit için keşif amaçlı laparotomi uygulanan toplam 122 hastadan 100'ü, belirtilen dahil edilme ve hariç tutulma kriterlerine göre bu çalışmaya alındı. Dren grubuna ve drensiz gruba her birinde 50 katılımcı olacak şekilde hasta alındı. Primer kapama veya rezeksiyon-anastomoz yapılan perforasyon peritonitli her alternatif hastaya bir dren yerleştirildi. Diyabet, böbrek yetmezliği ve hemodinamik instabilitesi olan hastalar ve semptom başlangıcından bu yana 72 saatten fazla zaman geçtikten sonra başvuranlar çalışma dışı bırakıldı. Periton sıvılarından kültür alındı. Birincil son nokta, iki grupta cerrahi alan enfeksiyonlarının insidansını belirlemekti. Ayrıca her iki grupta da bağırsak hareketlerinin geri dönüşü için geçen süreyi, nazogastrik sondanın (NGS) takılma süresini, ameliyattan sonraki 30 gün içinde lokal veya genel anestezi altında herhangi bir müdahale yapılıp yapılmadığını, hastanede kalış süresini ve postoperatif dönemde onarım kaçağı tanısının konulma kolaylığını karşılaştırdık.

BULGULAR: Her iki gruptaki katılımcıların demografik özellikleri eşleştirildi. Cerrahi alan enfeksiyonu insidansı açısından drenli ve drensiz gruplar arasında anlamlı bir fark gözlenmedi (p=0.779). Dren olmayan grupta ameliyat süresi ve hastanede kalış süresi anlamlı olarak daha kısaydı. Peritoneal kültürde üreme açısından iki grup arasında anlamlı fark gözlendi ve dren grubunda bakteri üremesinde artış görüldü. Clavien-Dindo sınıflamasına göre sınıflandırılan iki grup arasında morbidite açısından anlamlı bir fark görülmedi.

TARTIŞMA: Karın içi drenlerin rutin kullanımı cerrahi alan enfeksiyonlarını önlemede etkili bulunmadı, ancak seçim yanlılığı göz ardı edilemez. Dren olmayan hastaların hastanede kalış süreleri önemli oranda daha kısaydı.

Anahtar sözcükler: Cerrahi alan enfeksiyonu; dren; hastanede kalış süresi; perforasyona bağlı peritonit.

Ulus Travma Acil Cerrahi Derg 2022;28(10):1397-1403 doi: 10.14744/tjtes.2021.45705