

Laparotomy Wound Edge Protection Not an Effective Barrier to Prevent Surgical Site Infection

Noman Shahzad*, Khwaja Muhammad Inam Pal and Hasnain Zafar

Department of General Surgery, Aga Khan University Hospital Karachi, Pakistan

Abstract

Introduction: Surgical site infections (SSIs) after abdominal surgery are important cause of morbidity and even mortality. These are known to have social as well as economic impact upon individuals and society at large. Pathogens from gastrointestinal tract are responsible for majority of surgical site infections after laparotomy. So wound edge protection from these organisms during surgery can potentially reduce incidence of SSIs. Several previous studies have investigated the effect of wound edge protectors on SSI rates in abdominal surgery and reported mixed results.

Objective: To measure frequency of Surgical Site Infections in patients who underwent laparotomy wound edge protection by plastic sheet.

Methods: We conducted single arm prospective cohort study, in which modified polyethylene wound protector was used to protect wound during surgery. It is improvised form of commercially available wound protectors. Wound infection was assessed according to centre for disease control criteria within 30 days of surgery. Results were compared with reported rates from same institution.

Results: We recruited 76 patients for inclusion in the study. Seven of these patients (9.2%) developed surgical site infections. Three had superficial surgical site infections while four had deep surgical site infections. There was no statistically significant difference in infection rate from our data as compared to reported rate of 6.7% ($p=.81$). After adjusting for all predictor variables, degree of intra-operative contamination was the only independent predictor of acquiring surgical site infection.

Conclusion: Our study failed to show any benefit of wound edge protection. Randomized trial is recommended to consolidate the evidence.

Keywords: Surgical Site Infection; Wound Protector; Laparotomy

Introduction

Surgical site infections (SSIs) are one of the most common causes of Hospital Acquired Infections and are responsible for significant economic burden [1]. They account for considerable morbidity for the patients in terms of increased length of hospital stay, organ dysfunction and even mortality. On average SSIs increase hospital stay by 3 to 9.7 days and cost of care up to 30000 dollars per admission [2,3]. It is also associated with indirect cost in the form of abstinence from work and mental and social disturbance. In its guidelines to prevent SSIs, Centre for Disease Control and Prevention (CDC) has developed standardized criteria for defining and classifying SSIs [4]. According to these definitions SSIs have been divided into superficial incisional SSI, deep incisional SSI and organ/space SSI. Incidence of SSIs after open abdominal surgeries remains high despite adequate aseptic and antiseptic measures. It ranges from 0.5% in clean surgeries [5] to up to 32.1% in contaminated or emergency surgeries [6].

Micro-organisms from gastrointestinal tract are responsible for majority of surgical site infections after laparotomy [7], thereby wound edge protection from these organisms during surgery can potentially reduce incidence of SSIs. Several studies have been conducted to investigate the effect of application of plastic wound edge protection devices during laparotomy on rate of surgical site infection with varying results. Some of those studies failed to show additional benefit [8,9], while on the other hand significant reduction in SSI has been reported by other authors [10,11]. A recent meta-analysis comprising sixteen randomized controlled trials witnessed a significant reduction in surgical site infection after wound edge protection [12].

Commercially available devices to provide mechanical barrier to physical contact of intra-abdominal contents with laparotomy wound are costly and not available to every healthcare set up. An improvised way of protecting wound could be covering it with sterile plastic sheet. Though all available literature regarding outcome of wound protection has come from studies using these commercially available products, data on improvised methodology is lacking. So we planned to conduct this study to look at change in risk of laparotomy wound infection if wound is protected through sterile plastic sheet.

Objective

To measure frequency of Surgical Site Infections in patients who underwent laparotomy wound edge protection by plastic sheet.

Material and Methods

Study design

Single Arm Prospective Cohort Study

Received date: 16 Aug 2017; **Accepted date:** 09 Nov 2017; **Published date:** 15 Nov 2017.

***Corresponding author:** Noman Shahzad, Department of General Surgery, Aga Khan University Hospital Karachi, Pakistan, Tel: +923008833313; **E-mail:** drns01@hotmail.com

Citation: Shahzad N, Pal KMI, Zafar H (2017) Laparotomy Wound Edge Protection Not an Effective Barrier to Prevent Surgical Site Infection. J Surg Clin Interventions. 1(1)

Copyright: © 2017 Shahzad N, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Eligibility criteria

All surgical patients of age from 16 years to 70 years, who were scheduled for open abdominal surgery, were eligible for the study, given their ability to understand the nature of study and grant written informed consent.

Exclusion criteria

1. Re-laparotomy within 30 days of primary surgery due to reasons other than related to wound infection
2. Midline for transverse laparotomy within 60 days of registration for study
3. Abdominal operation without midline or transverse laparotomy (For Example, appendectomy)
4. Concurrent Abdominal wall infections
5. Severe Immunocompromised state
 - a) After organ or bone marrow transplantation
 - b) Concurrent Steroid Treatment with > 10 mg Prednisolone daily (or an equivalent dose of any other steroid)
 - c) Chemotherapy within last two weeks
 - d) Pre-operative Neutropenia <math><0.5 \times 10^9 \text{ Cells/L}</math>
6. ASA >3

Sample size

Sample size was calculated based upon evidence from study of Pinkney TD et al who reported incidence rate of surgical site infection to be 24.7% in laparotomy patients [13]. Keeping level of significance to be 5% and precision to be 10%, sample size calculated turned out to be 72 patients. Expecting loss to follow up rate upto 10%, we included 80 patients in our study.

Settings

The study was conducted at the General Surgical Units of The Aga Khan University Hospital (AKUH) Karachi. AKUH is a 550 bed tertiary care hospital with eight general surgeons. All the patients who fulfilled eligibility criteria were approached to be included in the study. If consent was granted, the patient was included in the study.

Sampling technique

Non probability consecutive sampling.

Surgical technique

In patients participating in the study, a sterile circular non-adhesive plastic sheet was applied circumferentially to wound edges before application of abdominal wall retractors. This sheet was taken from C Arm cover. In its original form, it is tubular cover of diameter of about 20 Inches, made up of polyethylene. 8-10 Inches length of this was cut and used as wound protector. It is improvisation of commercially available wound protectors. This sheet acted as physical barrier to direct contact of intra-abdominal contents with laparotomy wound edges.

Data collection procedure

All patients who fulfilled the eligibility criteria were included in the study. Pre-operative and post-operative antibiotics were given as per protocol. Standard aseptic and anti-septic preparation was done.

Data regarding the demographics of the patients was collected on specifically designed questionnaire. Wound was assessed daily from second day onwards during the hospital stay and on clinical follow up

after discharge from hospital to detect surgical site infection according to CDC criteria. Either of the superficial and deep SSI was considered as positive outcome. Last assessment was made 30 days after the surgery.

Statistical analysis

Data was entered and analysed using SPSS version 19 [14]. Continuous variables i.e. age, White Blood Cells count, duration of surgery and duration of hospital stay are reported as means +/- standard deviation. Categorical variables i.e. gender and Surgical Site Infection are reported as percentages and proportions. Reported infection rate of 6.7% after laparotomy in previously reported data from our institution was used as standard to compare our results with [15]. One sample proportion comparison test was used to detect statistically significant difference from reported rate of surgical site infection. Chi-Square test was applied as test of significance to detect change in risk of surgical site infection. "p" value of less than 0.05 was considered as significant. To detect independent predictors of surgical site infection, we used univariate and multivariable binomial logistic regression analysis.

Criteria for defining surgical site infection (SSI)

Surgical site infection was defined using criteria laid down by Centre for Disease Control and Prevention [4]. Salient features of these criteria are given below and outcome was considered positive if any one of both criteria was fulfilled.

Superficial incisional SSI: Infection that occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician based on above findings.

Deep incisional SSI: Infection occurs within 30 days after the operation if no implant is left in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician based on above findings.

Laparotomy wound edge

Laparotomy wound edge was defined as surgical incision margin on anterior abdominal wall from skin to peritoneum.

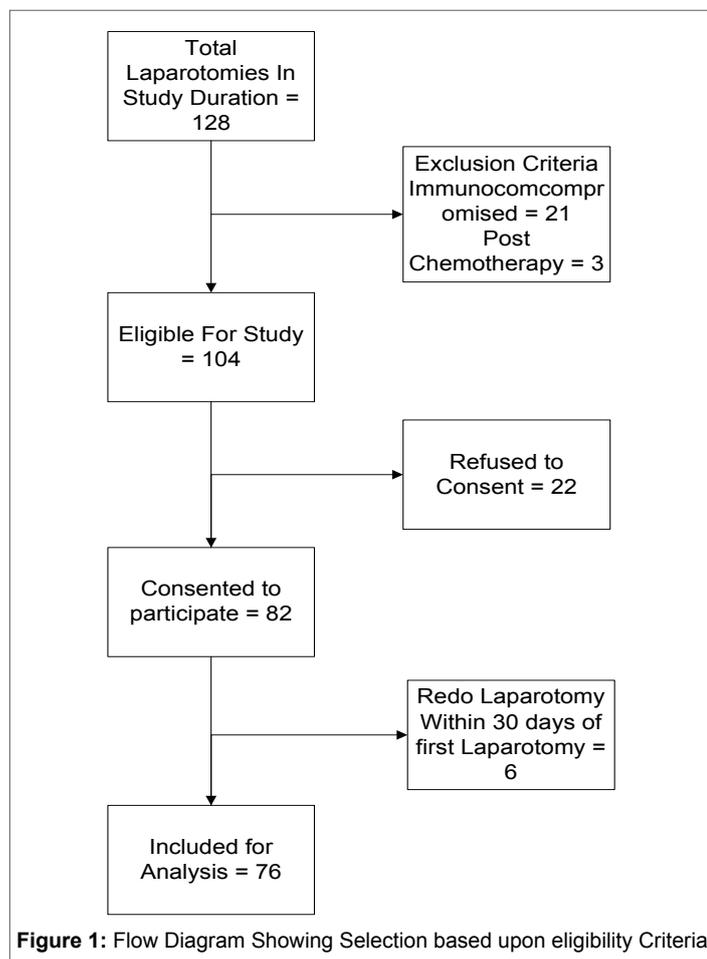
Results

Data collection was started from April 2016 to Nov 2016. All consecutive patients who were planned for laparotomy and met our inclusion criteria were invited to participate in the study. During data collection period, a total of 128 laparotomies were done. A detail of these laparotomies is given in the following flow diagram figure 1.

Mean age of the patients included for study was 48.8 +/- 15.8 years. Of the participants 49 (64.5%) were males and 27 (35.5%) were females. In our study, laparotomy was done after elective admission in 49 (64.5%) patients, while rest of 27 (35.5%) had admission through emergency. Systemic Inflammatory Response Syndrome or Sepsis was present in 39 (51.3%) patients before undergoing operation. Categorizing based upon degree of intra-operative contamination, 17 (22.3%) patients had contaminated or dirty operation. Mean duration of operation was 190 +/- 115 minutes and 27 (35.8%) patients were having > 2 American Society of Anesthesia (ASA) category.

In our study, 7 (9.2%) patients developed laparotomy wound infection. Out of these 7 patients, 3 had superficial surgical site infection while 4 had deep surgical site infection.

We checked if our infection rate was different from previously reported infection rate after abdominal surgery by Pishori et al from the same hospital [16]. In report of that surveillance surgical site infection was reported to be 6.7% after abdominal surgeries. One sample proportion comparison test was used to test if our infection rate was significantly different from 6.7%. No statistically significant difference was found in our infection rate from reported rates (p=0.81).



Individual predictor variables were checked for association with development of surgical site infection. For binomial categorical variables, results are as given in table 1.

Results showed that mode of admission and SIRS or Sepsis present before admission were significantly associated with development of surgical site infection. There was no association of gender with development of surgical site infection.

For polynomial categorical predictor variables association was checked as follows.

It was found that degree of intra-operative contamination was significantly associated with development of surgical site infection (P < 0.05). Categories based upon degree of contamination and their frequencies of developing surgical site infection along with percentages are as given in table 2.

Results of analysis of association between degree of intra-operative contamination and development of surgical site infection showed that greater the degree of contamination more are the chances to develop surgical site infection.

Frequency of developing surgical site infection according to ASA categories are given in table 3.

Results of analysis of ASA categories showed that greater the ASA category, more are the chances for a patient to develop surgical site infection.

Results of analysis of quantitative predictor variables showed that age, TLC count before surgery and length of hospital stay were not significantly associated with development of surgical site infection. Results showed that those who developed surgical site infection had significantly shorter duration of operation as compared to those who did not develop surgical site infection.

In order to see the effect of individual variables adjusting for other predictor variables, binomial logistic regression was done. All the variables which turned out to be significant at univariate analysis were considered for inclusion in multivariable binomial logistic regression analysis. Model building was done adopting forward regression technique, including variables in the model in order of their significance level. Variables considered for multivariable regression analysis included, mode of admission, SIRS / Sepsis before operation, degree of intra-operative contamination, ASA category and duration of operation. Results of final model obtained are as shown in table 4.

Table 1: Relationship of binomial predictor variables with development of Surgical Site Infection

Predictor Variable	Reference Category	Who did not Develop SSI (%)	Who Developed SSI (%)	Test Used	P Value
Gender	Male	43 (87.8%)	6 (12.2%)	Chi Square	0.41
Mode of Admission	Emergency Admission	46 (93.9%)	3 (6.1%)	Fischer Exact	0.048
SIRS / Sepsis	+ ve	35 (84.6%)	2 (5.4%)	Fischer Exact	0.039

Table 2: Frequency of Surgical Site infection according to degree of intra-operative contamination

Categories	Who did not Develop SSI (%)	Who Developed SSI (%)	Test Used	P Value
Clean (13)	12 (92.3%)	1 (7.7%)	Chi Square	0.03
Clean Contaminated (46)	43 (93.5%)	3 (6.5%)		
Contaminated (14)	12 (85.7%)	2 (14.3%)		
Dirty (3)	2 (66.7%)	1 (33.3%)		

Table 3: Frequency of Surgical Site Infection according to ASA Categories

ASA Categories	Who did not Develop SSI	Who Developed SSI (%)	Test Used	P Value
I (2)	2 (100%)	0 (0%)	Chi Square	0.004
II (47)	43 (91.5%)	4 (8.5%)		
III (23)	21 (91.3%)	2 (8.7%)		
IV (4)	3 (75.0%)	1 (25.0%)		

Table 4: Multiple Binomial Logistic Regression Analysis to adjust for co-variables

Variable	Reference Category	Slope Co-efficient	P Value	Log Likelihood
Degree of Intra-operative Contamination	Clean Surgery	1.40	0.002	-36.67

Final model included only Degree of intra-operative contamination to be significantly associated with development of surgical site infection.

In terms of relative risk, risk of developing surgical site infection for clean contaminated, contaminated and dirty surgeries as compared to clean surgeries turned out to be 2.5, 5.6 and 13.0 time in our data.

Discussion

Surgical site infections after abdominal operations prove to be a significant morbidity especially after clean abdominal operations. This is especially true of low income countries where morbidity is burden on the pocket as well. Aga Khan University reported its infection rates after various surgical procedures in 2001. This was made possible by establishing a surveillance system to monitor surgical site infections. Rate of abdominal wound infection overall was reported to be 6.7% [4].

In the last decade there has been some literature regarding effectiveness of wound protection during surgery, especially after laparotomy. There is lack of conclusive evidence yet regarding its true impact. Wound protectors are available commercially as well. Drawback of these wound protectors is that they are economically no affordable for low income country people. To overcome that problem, we devised a custom made wound protector. It was made from polyethylene tubular sheet used to cover fluoroscope during intra-operative fluoroscopy. We cut a length of 8-10 cm of that tubular sheet. One end of the sheet was placed inside the abdomen after doing laparotomy and the other end stayed outside. Self-retaining retractors were applied after placing in the wound protector. We checked effectiveness of this wound protector in preventing surgical site infection.

Our study reported infection rates after abdominal surgeries to be 9.2%. This infection rate is higher than previously reported rates from the same institution. This difference was not statistically significant.

Over a period of time, trend has been seen that, patients are referred to tertiary care hospital from remote areas usually when their disease either has become severe or they have tried modes of treatment other than allopathy. Immuno-compromization due to those treatments and severity of illness could be a factor for higher infection rates in our population, and worsening of these figures over time.

About one third of our patients had admission through emergency. Emergency operation is a known risk factor for surgical site infection [16].

Our study also showed that about one quarter of patients had contaminated or dirty operations. Degree of intra-operative contamination, which is also correlated with more emergency admissions, could be one of the underlying factors responsible for increased infection rates in our population.

While comparing our results with international literature, our result correlate with studies by Smith et al and Edward et al, who also demonstrated that wound protection has no advantage over no protection after abdominal surgeries [17,18]. These studies had used wound protectors that were commercially made for this purpose which functioned as protectors as well as retractors.

There have been prospective studies from various countries reporting effectiveness of barrier wound protection. Some of these studies claim that wound protection results in decrease in surgical site infection rate after wound protection [8,10].

A meta-analysis of published literature upon this topic analysed the combined data of similar prospective studies. This meta-analysis showed that there was significant difference between rate of surgical site infection after barrier wound protection [12].

Conclusion

Our study failed to show any benefit of laparotomy wound edge protection in reducing rate of surgical site infection. We recommend prospective randomized controlled trial to evaluate rote of barrier wound edge protection.

Limitations

We conducted a single arm prospective study comparing our results with historical cohort of patients for which infection rates are reported. Limited information available of patient population of historical cohort and along with limited follow up is the main limitation of the study.

Conflict of Interest

We have no conflict of interest.

Funding

Funding for the project was provided from Faculty Research Fund.

References

- Jenks PJ, Laurent M, McQuarry S, Watkins R (2014) Clinical and economic burden of surgical site infection (SSI) and predicted financial consequences of elimination of SSI from an English hospital. *J Hosp Infect* 86(1): 24-33.
- Lissovoy GD, Fraeman K, Hutchins V, Murphy D, Song D, et al. (2009) Surgical site infection: incidence and impact on hospital utilization and treatment costs. *Am J Infect Control* 5: 387-397.
- Coello R, Charlett A, Wilson J, Ward V, Pearson A, et al. (2005) Adverse impact of surgical site infections in English hospitals. *J Hosp Infect* 2: 93-103.
- Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR (1999) Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *Am J Infect Control* 2: 97-132.
- Dumville JC, McFarlane E, Edwards P, Lipp A, Holmes A (2013) Preoperative skin antiseptics for preventing surgical wound infections after clean surgery. *Cochrane Database Syst Rev* 3(3).
- Watanabe M, Suzuki H, Nomura S, Maejima K, Chihara N, et al. (2014) Risk factors for surgical site infection in emergency colorectal surgery: a retrospective analysis. *Surg Infect (Larchmt)* 15(3): 256-261.
- Misteli H, Widmer AF, Rosenthal R, Oertli D, Marti WR, et al. (2011) Spectrum of pathogens in surgical site infections at a Swiss university hospital. *Swiss Med Wkly* 140: 13146.
- Kercher KW, Nguyen TH, Harold KL, Poplin ME, Matthews BD, et al. (2004) Plastic wound protectors do not affect wound infection rates following laparoscopic-assisted colectomy. *Surg Endosc* 1: 148-151.

9. Anthony T, Murray BW, Sum-Ping JT, Lenkovsky F, Vornik VD, et al. (2011) Evaluating an Evidence-Based Bundle for Preventing Surgical Site Infection : a randomized trial. *Arch Surg* 3: 263-269.
10. Gheorghe A, Calvert M, Pinkney TD, Fletcher BR, Bartlett DC, et al. (2012) Systematic review of the clinical effectiveness of wound-edge protection devices in reducing surgical site infection in patients undergoing open abdominal surgery. *Ann Surg* 6: 1017-1029.
11. Edwards JP, Ho AL, Tee MC, Dixon E, Ball CG (2012) Wound Protectors Reduce Surgical Site Infection: a meta-analysis of randomized controlled trials. *Ann Surg* 1: 53-59.
12. Mihaljevic AL, Müller TC, Kehl V, Friess H, Kleeff J (2015) Wound edge protectors in open abdominal surgery to reduce surgical site infections: a systematic review and meta-analysis. *PloS one*. 10(3): e0121187.
13. Pinkney TD, Calvert M, Bartlett DC, Gheorghe A, Redman V, et al. (2013) Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI Trial). *BMJ*. 347.
14. IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.
15. Pishori T, Siddiqui AR, Ahmed M (2003) Surgical wound infection surveillance in general surgery procedures at a teaching hospital in Pakistan. *Am J Infect Control*. 31(5): 296-301.
16. Mohammad D, Begum M, Talukder AR, Salam MA (2017) Rate of Wound Infection of Non-traumatic Emergency Laparotomy at a Teaching Hospital in Bangladesh: Experience of 100 cases. *Bangladesh J Infect Dis*. 2(1): 9-12.
17. Arnaud JP, Bellissant E, Boissel P, Carlet J, Chastang C, et al. (1992) Single-dose amoxicillin-clavulanic acid vs. cefotetan for prophylaxis in elective colorectal surgery: a multicentre, prospective, randomized study. The PRODIGE Group. *J Hosp Infect* 22(Suppl A): 23-32.
18. Psaila JV, Wheeler MH, Crosby DL (1977) The role of plastic wound drapes in the prevention of wound infection following abdominal surgery. *Br J Surg* 64: 729-732.