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Surveillance of Surgical Site Infection after Cholecystectomy Using the Hospital in Europe Link for Infection Control through Surveillance Protocol

Branko Bogdanic,[1] Zrinka Bosnjak,[2] Ana Budimir,[2] Goran Augustin,[1] Milan Milosevic,[3] Vanda Plecko,[2] Smilja Kalenic,[2] Zlatko Fiolic,[1] and Maja Vanek[1]

Departments of 1 Surgery and 2 Clinical and Molecular Microbiology, University Hospital Centre and School of Medicine University of Zagreb, Zagreb, Croatia.
3 School of Public Health ''Andrija Sˇ tampar,'' School of Medicine University of Zagreb, Zagreb, Croatia.

Abstract

Background: The third most common healthcare-associated infection is surgical site infection (SSI), accounting for 14%–16% of infections. These SSIs are associated with high morbidity, numerous deaths, and greater cost. Methods: A prospective study was conducted to assess the incidence of SSI in a single university hospital in Croatia. We used the Hospital in Europe Link for Infection Control through Surveillance (HELICS) protocol for surveillance. The SSIs were classified using the standard definition of the National Nosocomial Infections Surveillance (NNIS) system. Results: The overall incidence of SSI was 1.44%. The incidence of infection in the open cholecystectomy group was 6.06%, whereas in the laparoscopic group, it was only 0.60%. The incidence density of in-hospital SSIs per 1,000 post-operative days was 5.76. Patients who underwent a laparoscopic cholecystectomy were significantly younger (53.65 – 14.65 vs. 64.42 – 14.17 years; $p < 0.001$), spent roughly one-third as many days in the hospital (2.40 – 1.72 vs. 8.13 – 4.78; $p < 0.001$), and had significantly shorter operations by nearly 26 min (60.34 – 28.34 vs. 85.80 – 37.17 min; $p < 0.001$). Procedures that started as laparoscopic cholecystectomies and were converted to open procedures (n = 28) were reviewed separately. The incidence of SSI in this group was 17.9%. The majority of converted procedures (71.4%) were elective, and the operating time was significantly longer than in other two groups (109.64 – 85.36 min). Conclusion: The HELICS protocol has a good concept for the monitoring of SSI, but in the case of cholecystectomy, additional factors such as antibiotic appropriateness, gallbladder entry, empyema of the gallbladder, and obstructive jaundice must be considered.

Introduction

Patients acquire healthcare-associated infections during treatment for other conditions. The third most commonly reported healthcare-associated infection is surgical site infection (SSI), accounting for 14%–16% of infections reported. These SSIs are associated with high morbidity, mortality rate, and cost [1–5]. In Croatia, several epidemiologic projects are monitoring infections of surgical sites, but each has its own standards. We decided to use the Hospital in Europe Link for Infection Control through Surveillance (HELICS) protocol, as the majority of European Union countries employ it [6]. The HELICS protocol monitors surgical procedures in six categories: Coronary artery bypass graft, cholecystectomy, colon surgery, caesarean section, hip prosthesis placement, and laminectomy. We decided to monitor SSI after cholecystectomies, as that is one of the most common surgical procedures in our facility [6]. Incidence of SSI after cholecystectomy ranges from 1.3% to 4.4%. The several risk factors are male gender, older age, emergency procedure, prolonged surgery (> 2 h), high

American Society of Anesthesiologists (ASA) score, positive bile culture, open cholecystectomy, and multiple procedures [1–5, 7–10].

Patients and Methods

In this prospective study, data were collected on patients who underwent open or laparoscopic cholecystectomy from December 2009 to June 2011 in University Hospital Centre, Zagreb, Croatia. Patients who had another procedure along with a cholecystectomy (i.e., hernioplasty) were not included. We classified SSI using the definition of the National Nosocomial Infections Surveillance (NNIS) system [11]. A standard form was completed for each patient consisting of general data (hospital code, operative procedure, age at date of operation, gender, date of admission, date of operation, date of discharge or of last follow-up in hospital, discharge status, and NNIS operative code); stratification and preoperative data (endoscopic procedure, wound contamination class, duration of operation [min], urgent/elective operation, ASA physical status classification, peri-operative prophylactic antibiotic); and infection data (type of SSI, date of infection, microorganism isolated, antibiotic resistance pattern of microorganism) [6]. Procedures that started as laparoscopic cholecystectomies and were converted in an open procedure were classified in a third group. All patients were followed up for 30 days after hospital discharge. Normality of data distribution was assessed using the Smirnov-Kolmogorov test, and according to the results, appropriate parametric or non-parametric tests were applied. Differences between operative procedures were analyzed with the w2 test with Yates correction (categorical values) or independent t-test (quantitative values). Binary logistic regression was performed to assess the impact of a number of factors on the likelihood that patients would develop an infection. All p values < 0.05 were considered significant. Data analysis software STATISTICA version 9.1 (StatSoft, Inc., Tulsa, OK) was used.

Results

The incidence of SSI was 1.44% (12/832). The incidence density in-hospital SSI per 1,000 postoperative days was5.76. Table 1 gives the descriptive statistics and differences between the operations. Significant differences were noted in all investigated variables and suggested that laparoscopic cholecystectomy was performed more often on female patients (69.70% vs. 53.79%; $p < 0.001$). In comparison, most cases of laparoscopic cholecystectomy were elective, and the patients had lower ASA scores. Most antibiotic prophylaxis was administered when open cholecystectomy was preformed (75% vs. 12.7%). The percentage of infection in patients who underwent open cholecystectomy was 10 times hat of patients who had a laparoscopic cholecystectomy (6.06% vs. 0.6%; $p < 0.001$). Infections in patients having emergency open procedures occurred in 9.09% of cases, and in the emergency laparoscopic group in 3.57%. The open surgery group had a 2.27% rate of infections and the laparoscopic group 0.16%. Table 2 shows the descriptive statistics and differences in quantitative variables between operational procedures. Patients who had a laparoscopic cholecystectomy were significantly younger (53.65 – 14.65 vs. 64.42 – 14.17 years; $p < 0.001$), spent one-third as long in the hospital (2.40 – 1.72 vs. 8.13 – 4.78 days; $p < 0.001$), and had significantly shorter operations by 26 min (60.34 – 28.34 vs. 85.80 – 37.17 min; $p < 0.001$). Binary logistic regression was performed to assess the impact of a number of factors on the likelihood that patients would develop an infection. The model contained eight independent variables Gender: age, hospital length of stay, operation duration, emergency or not, ASA score, and antibiotic prophylaxis. The full model containing all predictors was statistically significant (w2 8; N= 832) = 50.59; $p < 0.001$, indicating that the model could distinguish between patients who had and did not have infection. The model as a whole explained 30.5% (Nagelkerke R2) of the variance in symptomatology and correctly classified 98.4% of cases. As Table 3 shows, four of the independent variables made a statistically unique contribution to the model. This indicated that male patients had 5.11 times the risk of developing SSI, patients who had an open cholecystectomy had 4.67 times the risk, and patients who had longer operations had 1.01 times the risk when controlling for all other factors in the model. Procedures that started as laparoscopic cholecystectomies and were converted in an open procedure were performed in 28 patients. The incidence of SSI in this group was 17.9%. The majority were procedures were elective at 71.4%, and, as expected, the operating time was significantly longer than in other two groups (109.64 – 85.36 min). The pre-operative hospital stay had no impact on the risk of infection. Overall, the pre-operative stay was 0.87 days. In the laparoscopic group, it was 1.06 days; in the open group, it was 0.57 days, and in the group having laparoscopic cholecystectomy converted to an open procedure, it was 0.82 days. Among patients having infections, the pre-operative stay in the laparoscopic group was zero days, in the open group 0.286 days, and in the third group 0.6 days. According to the distribution of risk index, the majority of patients were classified in NNIS 0 group (77.6%), the remainder being in NNIS 1 group (20.8%) or NNIS 2–3 (1.5%). Using the standard definition of the NNIS system (laparoscopic and open cholecystectomy), 66.67% of the SSIs (8/12) were superficial incisional, 8.33% (1/12) deep incisional, and 25% (3/12) organ/space. In the third group, 80% of the infections were superficial incisional (4/5) and 20% deep incisional. In ten cases, wound swabs were taken, and bacteria were isolated in five cases. In all patients, Escherichia coli was the organism recovered. In three patients, E. coli was combined with coagulase-negative staphylococci, Enterococcus faecium, or extended-spectrum beta-lactamase (ESBL)-positive Klebsiella pneumoniae. The other swabs were sterile. In two cases, E. coli was resistant to amoxicillin, and the ESBL K. Pneumoniae was sensitive to aminoglycosides and carbapenems.

Discussion

We surveyed the incidence of SSI after cholecystectomy using the HELICS protocol, as this operative procedure is one of the most common being performed in our facility [6]. Prior to conducting this surveillance, we did not have genuine insight into the incidence of SSI after cholecystectomy in our hospital because of the lack of systematic monitoring. This research has set clear criteria to define risk factors and mode of prevention. The overall incidence of SSI was 1.44%. The infection rate in open cholecystectomy was 6.06%, whereas in the laparoscopic group, it was only 0.6%. As in our study, Richards et al. concluded that SSI rates after cholecystectomy should be stratified by technique [8]. As expected, most laparoscopic cholecystectomies were elective, as those patients were younger, had lower ASA scores, and shorter mean duration of operation and thus a lower risk of developing SSI. Male patients were five times more likely to develop postoperative infections. We attribute this to their older age and higher ASA scores, although the differences were not statistically significant. Patients who had emergency procedures were more often treated with the open operation. In our emergency department, general surgeons rotate daily, and there is a variation in the extent of laparoscopic experience among them. Emergency patients often have complicated intra-operative findings, so the use of the open approach is not surprising. These patients had higher ASA scores, and thus a higher risk of SSI. In our study, emergency open procedures had the highest infection rate, at 9.09%,whereas elective open procedures had a 2.27% rate of SSI. There were nine patients between four and 18 years of age. All procedures in this group were elective and were performed laparoscopically. None of them developed infection. As Esposito et al. reported, pediatric patients are more demanding than adults because of possible congenital biliary abnormalities; nevertheless, the laparoscopic approach is as effective as open surgery [12]. Prophylactic antibiotics were administrated to all patients having emergency procedures, including those who had operations (open or laparoscopic) lasting longer than 120 min, and when the intra-operative finding was empyema of the gallbladder. In the 28 patients having laparoscopic cholecystectomies converted to open surgery, the incidence of SSI was 17.9%, the majority (71.4%) of the procedures were elective, and the operating time was significantly longer than in the other two groups (109.64 – 85.36 min). These procedures were performed more often on male patients (64.3 % vs. 35.7%), and prophylactic antibiotics were administrated to 53.6% of the patients. Five patients developed SSI, and of these, antibiotic prophylaxis had been administrated to only one. Although this is a small number of patients, we believe that at each converted laparoscopic cholecystectomy, antibiotic prophylaxis should be considered strongly [13]. Superficial incisional SSIs were the most often reported infection.We believe this type of SSI is underreported, because post-discharge surveillance is difficult, and surgeons tend to minimize the importance of this type of complication. Biscione et al. reported incomplete post-discharge follow-up in 50.5%of about 6,000 cholecystectomy cases,which indicates insufficient surveillance [14]. In our study, the post-discharge follow-up rate was 70.3%. Our patents were monitored within 30 postoperative days, which leaves open the question of unreported cases. In 2010 in Croatia, the rate of ESBL Klebsiella pneumoniae isolates resistant to third-generation cephalosporins was 34%. During 2010, a somewhat higher number of carbapenemresistant isolates (mostly resistant to ertapenem only) were recorded. The first metallo-beta-lactamase (NDM-1)-producing isolate of K. pneumoniae in Croatia was described in 2009, and during 2010, no further NDM-1 isolates were detected among the organisms sent to the Reference Center for re-testing for antibiotic resistance surveillance [15]. In the report Surveillance of Healthcare-Associated Infections in Europe, several countries report their results using the HELICS protocol. The overall cumulative incidence of SSIs was 1.43% and in our study 1.44%. The number of participating hospitals and data collected differed from one country to another (three vs. 296 hospitals; 152 vs. 10,020 operative procedures), which leaves unclear the real infection incidence. Hospitals performing at least 20 operative procedures could participate, but we believe that more procedures are required for relevant conclusions to be drawn. Interventions should be parsed according to the urgency, and when a laparoscopic procedure is converted to open surgery, a separate group should be formed [16]. Minimally invasive operations carry a lower risk of SSI than do similar procedures done in open fashion. Laparoscopic cholecystectomy has become the gold standard because of its safety, effectiveness, short hospitalization, and lower cost [7,17,18]. However, open procedures can be indicated for patients who have had abdominal surgery and thus have intra-abdominal adhesions and those with recent acute cholecystitis or obstructive jaundice [19,20]. By conducting this survey, we set a clear basis for SSI monitoring at our hospital. This study proved that male gender, open cholecystectomy or laparoscopic cases converted to open surgery, and prolonged procedures carry a higher risk. The HELICS protocol is a good concept for monitoring SSI, but in case of cholecystectomy, it requires consideration of additional elements such as antibiotic appropriateness, gallbladder entry, empyema of the gallbladder, obstructive jaundice, previous cholecystitis or pancreatitis, and previous abdominal operations. The ASA physical status classification is good to estimate the patients' overall health, but some diseases; for example, diabetes mellitus, or some drugs; for example, corticosteroids, have a big impact on the immune system and thus the defense against infection. When laparoscopic cholecystectomy has to be converted to open surgery, antibiotic prophylaxis should be considered seriously.

Author Disclosure Statement
No competing financial interests exist.

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Address correspondence to:
Dr. Branko Bogdanic
Department of Surgery
University Hospital Centre and School
of Medicine University of Zagreb
Kispaticeva 12
10 000 Zagreb, Croatia
E-mail: dr.bogdanic@gmail.com

Table 1. Categorical Values by Operative Procedure

	Operative procedure			
	Cholecystectomy N = 132 (%)	Laparoscopic cholecystectomy N = 700 (%)	χ^2 value with Yates correction	p value
Gender				
Male	61 (46.21)	212 (30.30)	12.78	<0.001
Female	71 (53.79)	488 (69.70)		
Urgency				
Emergency	88 (66.67)	56 (8.00)	267.07	<0.001
Elective	44 (33.33)	644 (92.00)		
ASA score				
1	5 (3.79)	136 (19.50)	78.40	<0.001
2	70 (53.03)	473 (67.70)		
3	57 (43.18)	89 (12.70)		
4	0 (0)	1 (0.10)		
Antibiotic prophylaxis				
No	33 (25.00)	611 (87.30)	246.30	<0.001
Yes	99 (75.00)	89 (12.70)		
Infection				
No	124 (93.94)	696 (99.40)	23.50	<0.001
Yes	8 (6.06)	4 (0.60)		

ASA = American Society of Anesthesiologists.

Table 2. Comparison of Quantitative Values of Cholecystectomies

Factor	Procedure	N	Min	Max	Mean	Median	Standard deviation	Standard error	p value[a]
Age (years)	Open	132	27	92	64.42	67.0	14.17	1.23	<0.001
	Laparoscopic	700	4	86	53.65	55.0	14.65	0.55	
Hospital length of stay (days)	Open	132	1	33	8.13	7.0	4.78	0.42	<0.001
	Laparoscopic	700	1	33	2.40	2.0	1.72	0.06	
Duration of operation (min)	Open	132	35	250	85.80	78.0	37.17	3.23	<0.001
	Laparoscopic	700	18	190	60.34	55.0	28.34	1.07	

[a]Independent *t*-test.

Table 3. Binary Logistic Regression Model for Prediction of Infection during Hospital Surveillance

Factor	Odds ratio	95% Confidence interval	p value
Cholecystectomy	4.67	1.04–20.95	0.044
Age of patients (years)	0.97	0.93–1.00	0.072
Male	5.11	1.49–17.57	0.010
Length of hospital stat (days)	1.11	1.01–1.22	0.026
Duration of operation (min)	1.01	1.00–1.03	0.033
Elective operation (not emergency)	0.63	0.11–3.63	0.601
American Society of Anesthesiologists score	1.77	0.64–4.88	0.269
Antibiotic prophylaxis	0.77	0.12–4.85	0.779