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Review Article

Why are we still using antibiotic prophylaxis in elective laparoscopic cholecystectomy for the low-risk groups? a review of literature

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ABSTRACT

Gallstone disease is one of the most common gastrointestinal conditions requiring surgery and more than 90% of cholecystectomies are done laparoscopically. The major complications of laparoscopic cholecystectomy are major bleeding, Bile duct injury, and wound infection or surgical site infection. The incidence of Surgical site infection in laparoscopic cholecystectomy (0.4-1.13%) is significantly low compared to open cholecystectomy (3-47%) and the probable reasons are the smaller incision and the use of trocar along with almost nil to minimal wound contamination as compared to open cholecystectomy. Port site infection is a type of surgical site infection (1.8%) and the Umbilical port site is the most common site followed by the epigastric port site. In spite of the low-risk of surgical site infection, many surgeons still practice antibiotic prophylaxis in elective laparoscopic cholecystectomy for low-risk patients. Antibiotic prophylaxis is a debatable topic in the low-risk group undergoing elective laparoscopic cholecystectomy. Meticulous preoperative skin preparation is one of the established local factors to prevent the occurrence of SSI.

Keywords: Open cholecystectomy, Laparoscopic cholecystectomy, Antibiotic prophylaxis, Surgical site infection, Port site infection

INTRODUCTION

Gallstone disease is one of the most common gastrointestinal conditions requiring surgery and more than 90% of cholecystectomies are done laparoscopically.[1,2] Since 1990 LC has been stamped as the gold standard approach for uncomplicated gallstones and other benign gallbladder conditions and the reasons behind that are less postoperative pain, smaller incision and shorter hospital stay.[3,4] Though LC achieved the gold standard level it is not spared with complications. The major complications of LC are major bleeding, Bile duct injury, and wound infection or surgical site infection (SSI).[1] Before LC become the gold standard the incidence of SSI, related to open cholecystectomy (OC) was between 3 to 47%.[5] In LC the incision site is smaller and due to the use of the trocar, wound exposure and contamination are less common as compared to the OC resulting in a significant reduction in SSI.[6,7]

Cholecystectomy is classified as clean-contaminated surgery according to the surgical wound classification by the centers for disease control and prevention (CDC) with an estimated rate of SSI within 3-11%.[8-10] SSI is defined as an infection occurring within 30 days of surgery and can be superficial confining to the skin or deep involving the organs accessed during the surgical procedure.[11] Factors responsible for SSIs are 1) The proportion of

bacterial contamination while performing the surgery, 2) the duration of the procedure, and 3) associated pre-existing conditions of the patients like diabetes, malnutrition, and immune deficiency.[12]

Port site infection (PSI) is a type of SSI but restricted to laparoscopic surgeries. The infections in PSI are confined to superficial and deep surgical sites only.[13] PSI though a minor complication can cause discomfort, delays in the resumption of work and it is also a risk factor for Incisional hernia.[14] The Incidence of port site complication following laparoscopic surgery is approximately 21 per 100,000 cases, of which the incidence of PSI accounts for 1.8%. The Umbilical port site was the most common followed by the epigastric port site.[15] Samsal et al stated that the organisms responsible for PSI may be either endogenous (patient's skin, mucous membrane, or any of the viscera) or exogenous (any contamination sources present in the sterile environment like the surgery team, instruments, room air).[13]

PSI can be classified based on its time of presentation: 1. Within weeks- the organisms are either from the skin or infected surgical site. 2. 3-4 weeks-due to atypical mycobacterium.[13]

Antibiotic prophylaxis (ABP) is recognized as one of the essential steps to reduce the incidence of SSI. It is indicated in clean-contaminated and contaminated surgeries and in clean surgery with special considerations (e.g., implants related surgeries, surgery in immunosuppression status, and risky operative location such as neurosurgery and cardiac surgery).[16] Prophylactic antibiotics (PA) are meant to minimize the incidence of postoperative wound infection. They are usually indicated in all those procedures which are associated with a high infection rate, procedure with prosthetic implants involvement, or in procedures where the incidence of postoperative infection is low but consequences of any infective complications could be more grievous.[17,18] Ideal PA should be Bactericidal, well-tolerated, inexpensive, covers the common organism responsible for SSI in the cohort being treated concentration should be maintained throughout the procedure.[17,18]

In spite of the low risk of SSI (0.4 to 1.13%) many surgeons still practice ABP in elective LC for low-risk patients.[19,20] The High-risk factors are, the patients with acute cholecystitis, presence of obstructive jaundice, pregnancy, antibiotic intake within one week prior to surgery, immunosuppression disease/steroid use and age above 60 years.[20,21] Previous biliary tract surgery, diabetes mellitus, conversion to OC, evidence of cholangitis, previous ERCP, BMI more than 30, ASA more than 2, pancreatits20, coagulopathy and portal hypertension.[1]

ABP is a debatable topic in the low-risk group undergoing elective LC due to the low incidence of SSI.[20-22] Those in favour of ABP argued that patients who received ABP did better in terms of SSI, reoperations, and mortality whereas those who are against ABP justified their stand based on the development of antibiotic resistance, change of normal bile flora, increase nosocomial infection, and SSI, increasing rates of Clostridium difficile infection (diarrhoea), high cost and increase the workload for the hospital staff.[1,11,20-23] In OC, ABP is a standard practice to minimize the infective complications postoperatively, but there are differences regarding ABP in elective LC in low-risk patients.[24]

DISCUSSION

The ABP in low-risk groups, planned for elective laparoscopic cholecystectomy is like a disputed-land. There are two schools of thought for it.

Those who are against ABP

Society of American gastrointestinal endoscopic surgeons (SAGES) guidelines and the Scottish intercollegiate guidelines network (SIGN) recommend that ABP is not required in the low-risk group and single doses for the high-risk patient that too within one hour of the skin incision.[25,26] Second dose if surgery continues for more than 4 hours. Six randomized control trials (RCT) have been published since the publication of the SIGN recommendations, all dealing with elective LC and all concluding that no prophylactic antibiotics are required.

Cochrane review also shares the same opinion and stated that there is no evidence supporting the role of prophylactic antibiotics in minimizing the SSI in the low-risk groups who underwent elective LC and ABP selectively should be advised in patients of the medium or high-risk group.[27]

The national institute for health and care excellence (NICE) guidelines are based on high-level RCT and they recommend ABP in clean contamination surgeries. Though the elective LC related RCTs reviewed under NICE guidelines suggested that ABP is unneeded, NICE guideline broadly recommended ABP in clean contaminated surgeries.[28]

Based on a meta-analysis that analysed 15 RCT involving 2961 patients, Zhou et al stated that antibiotic prophylaxis has no significant role in reducing wound infection, major infection, distant and other infective complications in elective LC.[21]

Chong et al based on their retrospective analysis in 534 patients found out that ABP has no benefit in minimizing SSI and are not necessary for elective LC but it should be considered in patients with poor nutritional status with low albumin level.[29]

Passos et al observed that the infective complication is equal and statistically insignificant when compared ABP group and the no-ABP group in their study. No ABP is

required in any clean or contaminated surgeries where the chance of SSI is up to 5%. They also quote from the CDC guidelines that a significant incidence of post-surgical infections is acquired during the surgical process and can be prevented by adapting good surgical practice.[19]

Graham conducted auditing amongst 111 surgeons in Great Britain and Ireland involving over 7,000 laparoscopic cholecystectomies. In spite of the SIGN, SAGES, and NICE guidelines, 80% of surgeons used ABP due to the intraoperative bile spillage. According to these guidelines, intraoperative bile spillage automatically shifts the low-risk patients into high-risk groups. The author stated that further study needs to shed light on this matter as few articles also reported that bile spillage does not increase the risk of SSI. Their audit concluded that non-adherence of current guidelines leads to the misuse of 20,000 doses of antibiotics (AB) and misspent £100,000.[30]

Current consensus doesn't support ABP in low-risk patients undergoing LC due to the low risk of SSI and the unnecessary high cost of treatment. These are based on many recent meta-analyses. In spite of the above recommendations, between 20% and 80% of low and moderate risk patients undergoing LC still receive antibiotics in various studies.[23]

Antibiotic prophylaxis is recognized as one of the most important preventive measures to reduce the incidence of SSI. Both patients' intrinsic and extrinsic factors are usually responsible for the SSIs. Based on the retrospective analysis, Rodriguez-caravaca et al., concluded that the overall incidence of SSI was 1.96% and no significant differences were found in the incidence of SSI according to the adequacy of antibiotic prophylaxis.[16]

On the other hand, those who are in support of ABP, argue that

Brahmall et al stated that they still practice ABP before elective LC. They quote the long waiting list of elective LC in the UK, loss of follow-up, and the higher cost of treatment of complications than the cost of ABP as the reasons. ABP in patients with risk factors will become worthless if they receive it and have to wait for long.[18]

Kim SH et al based on their meta-analysis concluded that ABP in low-risk patients prevents SSI and superficial SSI but not the deep SSI.[3]

Matsui et al concluded that 24 hours schedule 3 doses perioperative ABP reduces infective complications in low-risk patients who underwent elective LC. They reported that elimination of ABP did not reduce the cost and on the other hand prolong hospitalization for the treatment of postoperative infective complications increases the medical cost as seen in the no-AB group in their study. The author also mentioned that the meta-analyses not supporting ABP are underpower and included mostly small sample-sized randomized trials.[31]

Marsui et al reported that ABP significantly decreases the postoperative SSI rate, distant infections, and overall infections. The facts regarding the development of AB resistance and increase medical cost remained unsolved and suggested a large-scale RCT. They argue that AB resistance develops after prolong use of AB and medical cost increases more once the patient develops complications.[32]

Liang et al concluded that ABP is beneficial in reducing the risk of SSI and global Infection during hospitalization and after discharge as well, hence lesser hospital stays. They also reported that 2 doses or 3-10 doses of AB significantly reduced the SSI compared to the placebo or no AB group whereas the single-dose AB has no benefit over the placebo or no AB group.[33]

As the debate is on, we came across one article by Chauhan et al which directed the topic towards medico-legal aspects. The author stated that in view of the low incidence of SSI, prolonged postoperative ABP in simple and straightforward cases is not necessary and beneficial, still, many surgeons continue with it due to the older trend or habit or due to medico-legal issues.[23] Similarly, Pai et al reported that prolonged post-operative ABP doesn't reduce the risk of SSI in LC, where the incidence of SSI itself is low. Still, the use of ABP is being practiced probably due to the usual old habit or/and medico-legal reasons. The author suggested that in a clean case of cholelithiasis, whether it's single or 3 doses ABP, it should be stopped.[34]

Development of SSI in case of positive bile culture, bile and/or stones spillage due to intraoperative gallbladder perforation is still a controversial topic.[24] Uludag et al reported no relationship between the organisms isolated from the bile and the subsequent SSI. In spite of using a retrieval bag (RB) while extractive the GB; they observed that all the SSI happened in the GB extracting port. They used gloves for retrieving GB and umbilical port as the extraction site. They suggested that trauma due to the first port opening technique and mechanical stretching while retrieving the GB specimen compared to the other port could lead to SSI.[20] Harling et al conducted a study related to wound infection in LC by comparing the ABP group and retrieval bag group. Out of 76 patients, 6 developed SSI, 3 in each group, and all at the GB extracting port site. They stated that the organisms isolated were all skin commensals and concluded that ABP in LC has no advantage because the source of infection is from the skin rather than the colonized diseased GB.[22] Regina et al found that there was no strong evidence supporting the use of RB in preventing SSI. From a practical point of view, RB is helpful while extracting the GB for spilled stones. They also stated that lack of association between the bile and causing WI organisms suggests that WI does not depend on direct

contact of the GB while extraction, instead the skin commensals play a part in it.[35]

Neri et al compared two groups for PSI with and without topical AB and found out that the incidence of umbilical port site infection is less compared to the non-topical AB groups. In their trial, they applied Rifamycin after the closure of the wound at the end of the surgery and at 12, 24, 36, 48 and 72 hours maintaining full sterility. The questionable thing in this study was that both the groups received 3 doses of ABP (preoperatively, intra-operatively, and third dose after 24 hours). They stated that though topical ABP is beneficial in reducing the chances of PSI, it should not replace the systemic ABP.[14] Kiff et al conducted a study where they compared the incidence of SSI between two groups who are planned for biliary surgery; the first group received 1 gm ceftriaxone before induction and for the second group, 1% povidone Iodine was sprayed over all the three layers of the surgical wound after the closure of the peritoneum. Only 1 patient from the ceftriaxone group (n=100) developed SSI compared to 9 patients from the povidone-iodine group (n=100) hence they concluded that ABP before induction significantly reduced the incidence of SSI compared to local application of povidone Iodine into the wound before closure.[36]

The Most common antiseptic solutions are iodinated solutions, alcohol with chlorhexidine (CH), or CH. According to the food and drugs administration (FDA) these antiseptic solutions can reduce the number of transient and permanent microorganisms in the surgical field rapidly (10 minutes after the painting) and suppresses its growth until 6 hours.[37]

Frantizides et al reported that SSI mostly causes by the skin commensals predominately gram-positive *cocci*. They compared two groups; one received ABP, and the other group had skin preparation with CH. They found that there was no infection in the CH group. They suggested that careful patient selection with thorough preoperative evaluation for intrinsic factors is crucial and those who had risk factors should be given ABP and on the other hand meticulous antiseptic skin preparation is sufficient for prevention of post-surgical infection in a low-risk group.[38]

Charehbili et al stated that the efficacy of chlorhexidine-alcohol and iodine-alcohol with respect to minimizing the risk of developing an SSI is similar.[39] Darouiche et al reported that preoperative skin preparation with chlorhexidine-alcohol reduced the incidence of SSI by 41% as compared to aqueous povidone-iodine which is most commonly used in the United States of America. Though both are broad-spectrum antimicrobial, chlorhexidine-alcohol's more rapid action, persistent activity despite exposure to bodily fluids, and residual effect provides better protection. As two-thirds of surgical-site infections are limited to the incision site, optimum preoperative skin preparation could result in a significant clinical benefit.[40] Paocharoen et al reported that chlorhexidine has better coverage against the predominant organism of the skin i.e., gram-positive bacteria compared to povidone-iodine.[12]

Meticulous preoperative skin preparation is one of the important local factors to prevent the occurrence of SSI.[12,39]

Alvarezl et al stated that the aim of the skin preparation is to paint rather than washing the patient with the antiseptic solution. The duration of the application of antiseptic solution depends on the nature of the solution and manufacturer's recommendation but the general consensus is to prepare the skin for at least 3 minutes or allow it to dry completely before incision. The skin preparation and paint should cover a larger area keeping in mind additional incisions, converting the minimally invasive procedure to an open procedure, an extension of the incision, and potential sites for drains. The deep and narrow umbilicus should be cleaned with applicators to ensure proper cleaning and removal of debris. Any excess accumulation of the antiseptic solution in the umbilicus should be removed as it will take a longer duration to evaporate and dry. The applicator and the gauze or sponge should be discarded after a single-use. The use of adhesive dressings over the incision site may decrease the risk of contamination with residual flora of the skin.[37]

Samsal et al communicated with the ten commandments for preventing PSI: (1) Whenever possible use disposable trocars and instruments, and adequate stock of properly sterilized reusable trocars as stand-by or to cover all the surgical procedures for the day where disposable trocar and instruments are not available, (2) Use of Laparoscopic hand instruments which are autoclave compatible, (3) Instruments with limited joints, and provision to clean the debris collected in its crevices should be used, (4) Proper cleaning of the instrument after dismantling, (5) The concentration and the contact time with a liquid sterilizing agent, and cycles of use for sterilizing instruments should be followed properly according to the protocol,(6) In case of long OT line-up, instrument sterilization to be done with either plasma sterilizer or ethylene oxide,(7) Separate instrument sets for all the different subject specialties and avoiding sharing of instruments, (8) Surgical steps should be executed meticulously so as to avoid bile spillage in the operative area/port site, (9) Use of non-porous specimen retrieval bags, and (10) Meticulous cleaning of the port site before closure.[13]

The PSIs will present as a seropurulent discharge from the port sites along with inflammatory changes in and around the port site. Clinical assessment, microbiological analysis, daily cleaning, and dressing of the wound along with the empirical antibiotic are the mainstay of treatment. Drainage and debridement of necrotic tissue required when associated with an abscess and necrosis.[13]

CONCLUSION

For years the debate of antibiotic prophylaxis was going for low-risk patients scheduled for laparoscopic cholecystectomy but in the end, meticulous antiseptic skin preparation was the Victor Ludorum. One thing was common between the two groups, and that was the need for a well-designed large scale RCT to address the problem. Till then proper history to categorize the patient and meticulous skin preparation is what we can do to prevent surgical site infection without any disagreement. Single-dose antibiotic prophylaxis may not affect the cost factor or emergence of antibiotic resistance but cumulatively if we see for all the low-risk patients, we believe it's a huge burden from the financial point of view and also unnecessary wastage of nursing staff time which we could have saved.

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