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IMPLEMENTING SURGICAL ANTIBIOTIC PROPHYLAXIS GUIDELINES; ROLE OF CLINICAL PHARMACIST

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Abstract: Surgical antibiotic prophylaxis (SAP) guidelines compliance evaluation of local SAP administration with surveillance of Surgical Site Infections (SSIs) incidence in patient undergoing surgery, many of the important conclusions can be carried out which leads to a substantial improvement in SAP administration practice. International recommendations include Scottish Intercollegiate Guidelines Network (SIGN), Antibiotic prophylaxis in surgery, Edinburgh: SIGN; 2008 [updated April, 2014]; and ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery, 1999 [updated September, 2013] provides evidence based regulations which can be used to establish local therapeutic guidelines for antibiotic prophylaxis administration in patients undergoing surgery. Besides establishment of evidence based SAP guidelines, implementation of these guidelines is of vital importance. Clinical pharmacist holds keystone kind of role in overall acceptance and implementation of these locally established guidelines, ultimately improving health related outcomes in patients as a result of reduction in post-operative SSIs development. As an important ally to practitioner clinical pharmacist plays a very important role in building a bridge between practitioner's decisions and health outcomes of patients. This role fulfilled by clinical pharmacist with the help of clinical pharmacy services like Drug utilization review, Drug utilization evaluations, Prescription event monitoring, clinical research studies, Drug information services, Therapeutic drug monitoring and clinical pharmacokinetics services. At the end, complete compliance with evidence based SAP guidelines leads to decrease in overall incidence of SSIs development and improvement in health related outcomes of patients undergoing surgery.

Key Words: Surgical antibiotic prophylaxis; Implementation; SAP Guidelines; Clinical Pharmacist; PharmD Skills

INTRODUCTION

Surgical site infections (SSI's) acquire 10% to 20% of all Hospital Acquired Infections (HAI's), but beside concurrent studies and use of preventive strategies like preoperative preparation of patient, antibiotic prophylaxis and proper wound care, there is no decrease in emergence of SSI's[1]. A 12 month European study in 2015 shows incidence of 3.2 SSI cases per 100 surgeries with overall compliance with published national Perioperative Antibiotic Prophylaxis (PAP) guidelines mere 12.9% and no other significant risk factor was identified in the study, thus indicates overall noncompliance with national PAP guidelines[2]. In 2012 another comparative study of cardiac procedure in neonates shown 6.21 cases of SSI's per 100 surgeries in no intervention group to 5.80 SSI's cases per 100 surgeries in group where strict protocols regarding SAP were intervened, depicts increased compliance after protocols implemented[3]. Study commenced from 2009-2011, had shown a massive 33% decrease in mean SSI rate from 27.3% before implementing special surgical protocols including enhancement of compliance with antibiotic prophylaxis to 18.2% in 12 months period[4]. A study from 2011, SSI rate with overall compliance with SAP guidelines were evaluated in patients of cardiac devices implantation and after a year of follow up SSI rate was found to be 2.3% and overall compliance with SAP guidelines was 45%; thus depicting the relation between the two[5]. In 2009 an American study shown significant reduction in infection after implementation of preoperative protocols for SAP in cesarean delivery in 533 women during 4 months, infection incidence came down from 5.4% to 2.5% and also an increase in overall compliance with SAP protocols[6]. On specific surgical basis a study of urological cancer surgery was done from 2007-2012 to evaluate incidence of *C. difficile* infection postoperatively, higher odds of incidence for *C. difficile* postoperative infection was found and it was related to a massive 20%-35% extended antibiotic prophylaxis postoperatively in these cases[7]. From 2011 to 2014 many different studies had shown reduced compliance with proper antibiotic prophylaxis protocols, this compliance ranges from 2% to 56.5% thus depicting that efforts have to be taken to increase this compliance for better postoperative outcomes[8-11]. In a study from 2008 -2013, compliance with local SAP guidelines were evaluated in a pediatric hospital; results from this study had shown increase in compliance with protocols after proper and strict regulation regarding SAP were intervened i.e. from 43.9% to 51.6% – 67%[12]. Thus these evidences depict a need for evaluation of compliance with SAP guidelines for better postoperative outcomes and thus a need of this review emerges.

Inappropriate antibiotic prescription is rather frequent in surgical departments which lead to unnecessary increased cost of therapy and emergence of resistant bacteria strain[13]. Pharmacists on every level are very important for implementing rationality in medication use; qualified pharmacists with specialist technical skills facilitate implementation of evidence based antimicrobial prescribing[14]. In developed countries and in countries where pharmacists and physician collaborative efforts are being given responsibilities to control the flow of medication to patients, there antibiotics are handled with great care and responsibility as they should with very less influences by prescriber's behavior towards pharmacist integrated clinical practice[15]. Especially reduction of antibiotic resistance, that is very big of a problem now a day for whole mankind[16]. Antibiotic resistance is a result of many wrong chains of events that include irrational prescriptions, inappropriate monitoring and irrational dispensing[17-18]. Not only this,

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Inappropriate use of antibiotics for veterinary purposes is also making this problem even more difficult to be eradicated[19]. Relentless attitude towards the use of antimicrobials can lead to antimicrobial resistance and can become a very big problem in treatment of any condition in future[20]. Healthcare providers solely cannot get rid of this monster of a problem, there is a need of greater effort by all include patients, prescriber and dispensers[21]. Policies have to be formulated for strict regulations over antimicrobial use, and implementation of these policies with a cohesive effort of all[22]. Policies should be formulated keeping in mind many factors including practicality of implementation, local available facilities, expertise of implementers and at cost which most of population can afford[23-24]. Policies for prescriber should emphasize on rational prescription, proper sensitivity probing, rational dose, duration therapy and indication[25]. For dispenser policies including proper prescription filling, regulation on inventory, ethical practice and regular inspections of premises should be formulated[26]. For patient awareness programmes and education on medication use should be provided more often thus patient can understand potential hazards and benefits of antibiotic prophylaxis on his/her health[27].

Antimicrobials are now a day used for many indications like infective disease management, veterinary diseases and prophylaxis[28]. Antimicrobials for prophylaxis are used with much less evidences during practice, moreover antibiotic prophylaxis has to be administered in otherwise healthy persons thus have a great impact on development antibiotic resistance[29]. Short and brief antibiotic used during prophylaxis without any evidence can lead to development of resistant strains of microorganism[30]. On a complete note, Surgical antibiotic prophylaxis (SAP) used without any guideline can lead to both increased risk of surgical site infections (SSIs), post operative development of antibiotic resistance and increased hospital stay as well as cost of therapy[31]. SAP guidelines should be formulated for every setting whatever patient potential it might have. Formulation of SAP guidelines for any setting should be done keeping in mind some potential factors like available facilities, expertise available and practicality of implementation there[32]. SAP guidelines for a general hospital setting with every type of surgical procedure potential should be formulated with strong evidences, recommendations and local setting factors leads to improvement in practice[33].

International recommendations like antibiotic prophylaxis guidelines for surgical procedure drafted by American Society of Health-system Pharmacists (ASHP) with recommendations from Infectious Diseases Society of America (IDSA), Surgical Infection Society (SIS) and Society of Healthcare Epidemiology of America (SHEA), these guidelines are updated version of previously given ASHP guidelines and are greatly accepted by the world of healthcare providers as primary evidence on SAP[34]. Besides formulated guidelines, implementation of these guidelines is a bigger problem, in developing countries like ours; Physicians are bounded by many factors including patient burden, competitive business strategies and pharmaceutical companies[35]. These factors are somewhat biggest barrier in the way of implementation of these guidelines[36]. Even after these factors, more factors include patient related like BMI and diabetes which can lead to SSIs even after compliance with guidelines[37]. Clinical pharmacist holds the key for formulation and implementing antibiotic guidelines and eliminating all factors that are not in the influence of prescriber, as clinical pharmacist plays a bridging role between prescriber and patient, clinical pharmacist can implement guidelines from assisting prescription to rational use in patient[38].

Also besides implementation, evaluation of SAP and its impact on heath of patient is an important asset, and follow up programmes for evaluating SAP can substantially increase SAP efficiency and reduced cost of therapy[39]. Evaluation of practice compliance with guidelines can be done by prescription review and because main purpose of guidelines is to reduce variability of clinical practice behavior amongst practitioners, this purpose can be fulfilled by sharing guidelines to fellow healthcare personnel[40]. Impact on patient health can be evaluated by SSI incidence surveillance[41].

Surgical antibiotic prophylaxis guidelines

Antibiotic prophylaxis in surgical procedure is mainly given to prevent patient from post operative infections[42]. Surgical Site Infections (SSIs) are most common type of post operative infection in surgery patient. Occurrence of these post operative infections is influenced by many factors like type of surgical procedure, preoperative preparation of patient, elective/emergency, and type of wound, hospital premises and wound care given to patient, thus if there are these many influencing factors, then there is much more care healthcare providers must take before selecting SAP for a particular patient for reduction in overall risk of development of SSI's[43].

SAP can be illustrated by different protocols carried out simultaneously for a particular patient of surgery; include selection of appropriate antimicrobial agent, selection of right dose for that particular patient, selection of right dosing time for that particular agent, selection of right route of administration, selection of second dose and time of that dose, if needed and post operative duration of that prophylaxis in that particular patient and to carry out these steps in appropriate way, there has to be complete compliance with SAP guidelines[44]. SAP protocols if followed appropriately for an individual patient leads to an optimal plasma concentration of that particular antimicrobial agent, in other words meeting the proper MIC (minimum inhibitory concentration) needed for probable invasion and development of susceptible microbe[45].

Guidelines for any hospital setting should be prepared with keeping some factors in mind like available facilities, expertise available and practicality in implementation, implementation of these local protocols can help to decrease variations in SAP administration amongst different providers in utilization of resource[46].

These guidelines should be evidence based and also on the principles recommended by internationally accepted norms or standards. Such internationally accepted standards

like Scottish Intercollegiate Guidelines Network (SIGN), Antibiotic prophylaxis in surgery, Edinburgh: SIGN; 2008 [updated April, 2014]; and ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery, 1999 [updated September, 2013]. Some of the important recommendations from these guidelines are as illustrated below:

Recommendation for surgical antibiotic prophylaxis in cardiac surgeries, SIGN guidelines recommend SAP in open heart procedures and pacemaker insertion and ASHP guidelines recommend cefazolin, Cefuroxime, clindamycin and Vancomycin for the same including ventricular assist devices implantation. In non-cardiac thoracic surgeries including lobectomy, pnuemonectomy, thoracotomy, video assisted thoracoscopic surgery and lung resection ASHP guidelines recommend cefazolin as primary agent of choice with alternative agents like Ampicillin-salbactam, clindamycin and Vancomycin; SIGN guidelines also recommend SAP in pulmonary resection. According to SIGN guidelines, in breast cancer surgery, breast reshaping procedures should consider administration of SAP and breast surgery with implants (aesthetic or reconstructive) with proper SAP is recommended; ASHP guidelines recommend Cefazolin as prime choice for SAP with alternatives like clindamycin or Vancomycin with aminoglycoside or Aztreonam or fluoroquinolones in plastic surgeries. In intracranial procedures including craniotomy SIGN guidelines recommend SAP administration and ASHP guidelines says Cefazolin to be the primary choice agent with alternates as clindamycin and Vancomycin in elective craniotomy, CSF shunt and intrathecal pumps implantation. In clean nonmalignant head and neck surgeries including tonsillectomy, adenoidectomy SIGN guidelines don't recommend any SAP administration, ASHP guidelines agrees with it. SIGN guidelines states SAP should be considered in clean malignant head and neck surgeries, but it recommend SAP in clean-contaminated and contaminated head and neck surgeries whereas ASHP recommends cefazolin, Cefuroxime and clindamycin in clean with prosthesis placements; cefazolin with Metronidazole, Cefoxitin, Cefotetan, ampicillin-salbactam in clean-contaminated cancer surgeries and other clean-contaminated procedures excludes tonsillectomy and fundoscopic sinus procedures of head and neck. In ophthalmic procedures including cataract surgery SIGN guidelines highly recommends SAP administration, also recommends SAP in glaucoma or corneal grafts, Lacrimal surgery; ASHP guidelines recommends topical neomycin-polymyxin B-gramicidin or fourth generation topical fluoroquinolones given as single drop every 5 to 15 minutes for 5 doses as a prime choice, additionally a post operative cefazolin 100mg subconjuctival injection or Intracameral cefazolin 1 to 2.5 mg or Cefuroxime 1mg can be given. In functional endoscopic sinus procedures both guidelines agrees on not recommending any SAP administration. SIGN guidelines recommends SAP in Gastroduodenale, Oesophageal and Gastric bypass surgeries and ASHP guidelines agrees with it, recommends cefazolin as primary agent with alternates like clindamycin or Vancomycin with aminoglycoside or Aztreonam or fluoroquinolone in both Gastroduodenale procedures involving entry into lumen of GIT or without entry into lumen of GIT. SAP is recommended in small intestine surgery as stated by SIGN guidelines and ASHP guidelines supports it, recommendations for SAP in Obstructed Small intestine procedures cefazolin plus Metronidazole as prime choice with alternates as Cefoxitin, Cefotetan and Metronidazole plus aminoglycoside or fluoroquinolone; in non-obstructed procedures cefazolin as primary choice, clindamycin plus aminoglycoside or Aztreonam or fluoroquinolone as alternates. In Open Hepatobiliary procedures including bile duct surgery, pancreatic surgery, liver surgery and gall bladder surgery SAP is recommended by SIGN guidelines and ASHP guidelines recommends cefazolin, Cefoxitin, Cefotetan, ampicillin-salbactam as prime choice and clindamycin or Vancomycin plus aminoglycoside or Aztreonam or fluoroquinolone as alternatives. As far as laparoscopic Hepatobiliary procedures goes both guidelines agrees on not to administer SAP for elective low risk patients but for high risk patients SAP should be considered says SIGN guidelines and ASHP guidelines recommends same agents as in open procedures with additional option of Metronidazole plus aminoglycoside or fluoroquinolone; high risk cases includes intraoperative cholangiogram, bile spillage, conversion to laparotomy, acute cholecystitis or pancreatitis, jaundice, pregnancy, immunosuppression and prosthesis insertion. For lower GIT procedures SIGN guidelines highly recommends proper SAP administration and ASHP guidelines recommends cefazolin plus Metronidazole, Cefoxitin, Cefotetan as primary agents, clindamycin plus aminoglycoside or Aztreonam or fluoroquinolone and Metronidazole plus aminoglycoside or fluoroquinolone as alternatives for appendectomy; for colorectal surgeries same primary agents with additional option like ampicillin-salbactam, Ceftriaxone plus Metronidazole and Ertapenam, alternatives are same as in appendectomy. For hernia repair SIGN guidelines do not recommend any SAP but ASHP guidelines do recommend cefazolin as prime choice with alternates like clindamycin and Vancomycin for hernioplasty as well as herniorrhaphy. In Gynecological surgeries including hysterectomy both vaginal as well as abdominal SAP is recommended and in Cesarean section delivery SAP is highly recommended according to SIGN guidelines; According to ASHP guidelines, for hysterectomy Cefazolin as prime choice and clindamycin plus aminoglycoside or Aztreonam or fluoroquinolone as alternative is recommended, for cesarean delivery Cefazolin as primary agent with clindamycin plus aminoglycoside as alternates are recommended. SIGN guidelines recommend SAP in all urogenital procedures specifically highly recommend appropriate SAP in transurethral resection of prostate; whereas ASHP guidelines recommend Cefazolin as prime choice agent clean surgery with or without entry into urinary tract, optional addition of aminoglycoside is also recommended in case of implantation of prosthesis; it says fluoroquinolone, Trimethoprim-sulphomethoxazole and cefazolin are primary agents in case of Transrectal prostate biopsy with alternates as aminoglycoside with or without clindamycin. In clean-contaminated urogenital surgery, it recommends combination of Cefazolin and Metronidazole as primary agent to use with alternatives like fluoroquinolones and aminoglycoside with or without clindamycin. In orthopedic surgeries including insertion of foreign material SIGN

guidelines highly recommends SAP administration, ASHP guidelines support this with recommendation of Cefazolin as primary agent to use with alternative options like clindamycin and Vancomycin. Both guidelines support the fact not to administer any SAP in clean orthopedic surgery without insertion of foreign material. As per vascular procedures goes SIGN guidelines recommends SAP administration in all procedures; ASHP recommends Cefazolin as prime choice with alternates like clindamycin and Vancomycin in heart, lung, heart-lung, pancreas and pancreas-kidney transplant with special consideration of including Fluconazole as prime choice with additional options like aminoglycoside, Aztreonam or fluoroquinolone in Pancreas transplantation in high risk patient. ASHP guidelines also recommend standard dosing of SAP agents in adults as well as pediatric patients with half-life in adults with normal renal function and recommended perioperative Redosing, for example recommended adult dose of Cefazolin is 2g (3g for patients weighing more than 120kg) and pediatric dose of 30mg/kg with adult half-life of 1.2-2.2 hrs and perioperative Redosing time is 4 hrs from initiation of SAP[47-48]. Reference from evidence based recommendations leads to establishment of better protocols and improved patient outcomes[49].

Role of clinical pharmacist

Implementation of SAP guidelines is a work of great responsibility, and inclusion of clinical pharmacist in this area holds the key to success of these guidelines by implementing them to patient level[50]. Implementation of SAP guidelines includes understanding both needs of patient and medical practitioner; clinical pharmacist with proper interprofessional corresponding command can maneuver situations evolving during communicating about implementation issues with other healthcare professionals and can play an important role in implementing decisions[51]. Pharmacy practice in hospitals leading to an effective strategy to improve medication use, clinical services provided by practicing pharmacists include consultation about adjustment of dosage, antibiotic prescribing recommendations, pharmacokinetic evaluations and drug information and this study of United States in 2013 states growth of role played by pharmacists in rationale medication prescribing[52]. In English hospitals from 2005 to 2013, there is a tremendous improvement in specialist pharmacists and their skills in provision of antimicrobial formularies, empirical prescribing recommendations and surgical antimicrobial prophylaxis[53]. In a study published in 2012, Pharmacy Interns played a very important role in evaluating SAP administration compliance with SAP guidelines in Germany and results were only 70.7% of cases were compliant with guidelines[54]. Development of antibiotic prophylaxis guidelines for local settings on international recommendations with providing clinical pharmacist a key position in monitoring and intervention of antimicrobial prophylaxis may improve present prescribing practice[55].

DISCUSSION

Implementation of the SAP guidelines in any hospital setting is of much importance and has to be performed with responsible personnel. Implementation of these guidelines decreases risk of developing SSIs and antimicrobial resistance burden. For successfully implementing guidelines in a local setting, one must consider factors like practicality for application in local settings, available expertise and antimicrobial resistance burden in patients. These healthcare benefits to a patient undergoing surgery, decreases overall recovery time post operatively and cost of therapy. For these implementations, studies had shown that involvement of clinical pharmacist holds a vital position with all the necessary skills.

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