

GUIDELINES

Perioperative antibiotic prophylaxis in adults

Outline of the principal recommendations

National reference guidelines

F. CALISE¹, L. CAPUSSOTTI², S. CATERINO³, A. DELITALA⁴, P. TERRAZZI⁵, M. FRANCUCCI⁶, A. GASPARI⁷, M. LANGER⁸, A. M. MARATA⁹, C. MARTELLI¹⁰, M. L. MORO¹¹, A. PANTOSTI¹², D. PASSALI¹³, N. PETROSILLO¹⁴, R. POLASTRI², G. M. ROSSOLINI¹⁵, W. SANTANIELLO¹, F. SCAGLIONE¹⁶, V. ZIPARO¹⁷

¹Unit of Hepatobiliary Surgery and Liver Transplantation, Cardarelli Hospital, Naples, Italy; ²I Division of Surgery, Mauriziano Umberto I Hospital, Turin, Italy; ³Unit of Pediatric Surgery, S. Andrea Hospital, Rome, Italy; ⁴Unit of Neurosurgery, San Camillo Forlanini Hospital, Rome (SINch), Italy; ⁵Departement of Cardiovascular Surgery, Ospedali Riuniti, Bergamo, Italy; ⁶Unit of Day Surgery, S. Maria Hospital, Terni, Italy; ⁷Departement of Surgery, Tor Vergata University, Rome (SICADS - S.I.C.), Italy; ⁸Department of Anesthesia and Resuscitation, University of Milan, National Cancer Institute, Milan, Italy; ⁹CeVEAS, Modena, Italy; ¹⁰Division of Orthopedics and Traumatology, Polyclinic S. Orsola-Malpighi, Bologna, Italy; ¹¹Infective Risk Program Agency, Regional Division, Emilia-Romagna, Bologna, Italy; ¹²Istituto Superiore di Sanità - ISS, Rome, Italy; ¹³Departement of Otolaryngology, University of Siena, Siena (SIO e Ch CF), Italy; ¹⁴National Institute for the Infectious Diseases Lazzaro Spallanzani, Rome (SIMIT), Italy; ¹⁵Departement of Molecular Biology, University of Siena, Polyclinic Le Scotte, Siena (AMCLI), Italy; ¹⁶Departement of Pharmacology, University of Milan, Milan (SIC), Italy; ¹⁷II Faculty of Medicine, University La Sapienza, Rome, Italy

The current guidelines are an update of the version published in 2003 by the *Programma nazionale linee guida*—Italian national guidelines programme (PNLG), now *Sistema nazionale linee guida*—Italian national guidelines system (SNLG). In comparison with the previous edition, the authors have updated the efficacy of trials and decided to make the guidelines more useful for individual operational units, adding a series of addenda providing more precise information on the choice of antibiotic for prophylaxis use, dosages and administration methods. As in all SNLG guidelines, the strength of the recommendations is indicated by alphabetic symbols (Table I).

The current guidelines deal with the following questions:

1. What are the risk factors for surgical site infections and how do they affect decision to choose antibiotic prophylaxis?
2. What are the benefits and risks of perioperative antibiotic prophylaxis?

3. For which operations is there evidence that antibiotic prophylaxis reduces the risk of surgical site infection?

4. What types of antibiotics are recommended for perioperative prophylaxis and specifically how and when should they be administered?

Issues linked to local implementation are then discussed.

In addition to antibiotic prophylaxis recommendations, general principles of prevention are also described, as they represent the indispensable starting point for limiting postoperative infectious complications. Antibiotic prophylaxis supports and completes such practices without replacing them.

General principles of prevention

Preoperative measures

1. Correct preparation of the patient
2. Correct preparation of the surgical team
3. Management of colonised or infected health-

TABLE I.— *Level of evidence and strength of the recommendation, from SNLG – Methodological manual.*

<i>Level of evidence</i>	
I	Evidence obtained from several randomized controlled clinical studies and/or systematic review of randomized studies
II	Evidence obtained from a single suitably designed randomized study
III	Evidence obtained from cohort non-randomized studies with simultaneous or historical controls or their meta-analysis
IV	Evidence obtained from retrospective case-control studies or their meta-analysis
V	Evidence obtained from case studies ("series of studies") without control groups
VI	Evidence based on the opinion of authoritative experts or committees as indicated in guidelines or consensus conferences, or based on the opinion of members of the working group responsible for these guidelines
<i>Strength of the recommendation</i>	
A	The execution of that particular procedure or diagnostic test is strongly recommended. It indicates a particular recommendation supported by good quality scientific evidences, not necessarily type I or II
B	Doubts exist about the fact that particular procedure or operation must always be recommended, but it is thought that its execution should be considered carefully
C	Substantial uncertainty exists in favour of or against the recommendation to execute the procedure or operation
D	The execution of the procedure is not recommended
E	The execution of the procedure is strongly advise against

care personnel to reduce at a minimum the infection transmission risk.

Intraoperative measures

1. Correct ventilation systems in the operating theatre
2. Correct room cleaning and disinfection
3. Environmental microbiological sampling only during specific epidemiological investigations (not as routine)
4. Correct sterilisation of surgical instruments
5. Use of surgical clothing and cloths able to reduce the infection transmission risk at a minimum
6. Observance of asepsis and correct surgical techniques
7. Correct wound-medication methods

List of principal recommendations

QUESTION 1: *What are the risk factors for surgical site infections and how do they affect the decision to choose antibiotic prophylaxis?*

Numerous factors influence the occurrence of surgical site infection. Independent but linked factors are represented by: type of operation, implantation of prosthetic material, duration of hospitalisation prior to operation, duration of operation, concomitant diseases.

The duration of the operation and concomitant diseases have a significant impact on the infection risk and, together with the operation type, contribute to define a risk index.

QUESTION 2: *What are the benefits and risks of perioperative antibiotic prophylaxis?*

The final decision concerning the benefits and risks of antibiotic prophylaxis for each individual patient will depend on:

- the risk of surgical site infection, which will take into account the risks linked to the operation and the risks linked to the patient;
- the potential seriousness of possible surgical site infection;
- the effectiveness of prophylaxis for the specific operation;
- the consequences of prophylaxis for the specific patient (for example an increased risk of colitis or diarrhea associated with *Clostridium difficile*).

QUESTION 3: *For which operations is there evidence that antibiotic prophylaxis reduces the risk of surgical site infection?*

Below is a list of the operations for which it is possible to formulate a recommendation about the effectiveness of antibiotic prophylaxis, based on clinical studies. The panel has also given an opinion (**in grey**) on the advisability of carrying out prophylaxis during certain common operations for which clinical studies are not available.

Cardiac and thoracic surgery

Antibiotic prophylaxis is **recommended** during:

- I/A Insertion of pacemaker/cardiac defibrillator
- Open-heart surgery, including aorta-coro-

nary bypass and prosthetic valve implantation

II/A Lung resection

Ear, nose and throat surgery

Antibiotic prophylaxis is **recommended** during:

I/A Head and neck surgery (clean-contaminated and contaminated)

Antibiotic prophylaxis is **not recommended** during:

I/C Adenotonsillectomy

I/D Ear surgery (clean and clean-contaminated) including myringoplasty

II/D Nasal and paranasal sinus surgery (septoplasty and rhinoseptoplasty)

VI/D Head and neck surgery (clean)

General surgery

Antibiotic prophylaxis is **strongly recommended** during:

I/A Colorectal surgery

Antibiotic prophylaxis is **recommended**, but those in charge of antibiotic policy at a local level must make a decision that considers infection rates at the level of their own situation, during:

I/A Oncological breast surgery

Reduction mammoplasty

II/A Endoscopic gastrostomy

Stomach and duodenum surgery

VI/B Clean-contaminated procedures not specifically mentioned elsewhere

Esophageal surgery

Small intestine surgery

Antibiotic prophylaxis is **recommended** during:

I/A Appendectomy

Open biliary surgery

Liver resection surgery

Pancreatic surgery

Augmentation mammoplasty

Antibiotic prophylaxis is **not recommended** during:

I/D Inguinal hernia repair with or without the use of prosthetic material

Laparoscopic hernia surgery with or without the use of prosthetic material

Diagnostic laparoscopy and/or lysis of adhesions

Excisional lymph node biopsy

Antibiotic prophylaxis is **not recommended**, but during local implementation exceptions could be identified, during:

I/D Laparoscopic cholecystectomy

Neurosurgery

Antibiotic prophylaxis is **recommended** during:

I/A Craniotomy

Internal cerebrospinal fluid diversion

Obstetrics and gynecology

Antibiotic prophylaxis is **recommended**, but those in charge of antibiotic policy at a local level must make a decision that considers infection rates at the level of their own situation, during:

I/A Induced abortion

II/A Abdominal hysterectomy

Vaginal hysterectomy

Antibiotic prophylaxis is **recommended** during:

I/A Caesarean section

Antibiotic prophylaxis is **not recommended** during:

Bilateral salpingo-oophorectomy

Monolateral salpingo-oophorectomy

Local excision or destruction of ovarian lesion or tissue

Orthopedic surgery

Antibiotic prophylaxis is **strongly recommended** during:

I/A Implantation of ankle prostheses[§]

III/A Implantation of knee prostheses

Antibiotic prophylaxis is **recommended** during:

I/A Closed fracture fixation

Fitting of a prosthetic device when a direct trial is not available.

Ankle fracture repair

II/A Spine surgery

Antibiotic prophylaxis is **not recommended** during:

V/D Orthopedic surgery without prostheses (elective): excision/suture/incision of lesion of muscle, tendon and fascia of hand; other local excision or destruction of lesion or cutaneous or subcutaneous tissue; other operations of repair, section or plastic surgery on muscle, tendon and fascia; arthroscopic meniscectomy; arthroscopic synovectomy.

[§]Independently of the use of antibiotic-impregnated cement.

Urology

Antibiotic prophylaxis is **recommended** during:

- I/A Transurethral resection of the prostate
- II/A Transrectal prostate biopsy
- Radical prostatectomy
- Radical cystectomy
- Operations on the renal parenchyma (nephrotomy and nephrostomy)
- Nephrectomy
- Removal of hydrocele (in the vaginal tunic)

Antibiotic prophylaxis is **recommended**, but those in charge of antibiotic policy at a local level must make a decision that considers infection rates at the level of their own situation, during:

- I/A Shock wave lithotripsy

Antibiotic prophylaxis is **not recommended** during:

- VI/D Transurethral resection of bladder tumours

Vascular surgery

Antibiotic prophylaxis is **recommended** during:

- II/A Lower limb amputation
- Arterial surgery in the abdomen or lower limbs

Antibiotic prophylaxis is **not recommended** during:

- VI/D Carotid thrombendarterectomy (TEA)
- Endarterectomy
- Ligation/stripping of varicose veins
- Other surgical occlusion of vessels

QUESTION 4: *What types of antibiotics are recommended for perioperative prophylaxis and, in particular, how and when should they be administered?*

VI/B The antibiotic chosen must have a spectrum of action that guarantees its effectiveness against probable contaminants.

- 1) It is advisable that the bacteria species responsible for postoperative infectious complications and their sensitivity to the antibiotics used in prophylaxis are monitored in every local surgery location. This will be possible only if material from each surgical site infection (SSI) is sent to a microbiology laboratory for a culture test and antibiogramme.

IV/B Patients with a history of anaphylaxis, urticaria or exanthema occurring immediately following treatment with penicillin

are at greater risk of developing immediate hypersensitivity reactions and should not undergo prophylaxis with beta-lactam antibiotics.

- 1) When the operational guidelines for perioperative antibiotic prophylaxis recommend the use of beta-lactam antibiotics as a first choice, an alternative should always be provided for patients with allergies to penicillin or cephalosporins.
 - 2) Third- and fourth-generation cephalosporins, monobactams, carbapenems and piperacillin/tazobactam are not recommended for prophylactic use.
 - 3) It is preferable to reserve these antibiotics, which are effective against multiresistant pathogens, for therapeutic use.
 - 4) Antibiotics of proven effectiveness for prophylactic use should be used for prophylaxis, and they should be used therapeutically only for the treatment of infections by pathogens that are not particularly resistant.
 - 5) The majority of available efficacy trials do not demonstrate the superiority of glycopeptides in preventing surgical site infections caused by Staphylococci. The excessive use of such drugs risks hindering their efficacy in the treatment of nosocomial Staphylococcus and Enterococcus infections. The decision to use a glycopeptide for prophylaxis should be made only under certain circumstances and in any case only during major operations involving the implantation of prosthetic material (cardiac surgery, orthopaedic surgery, vascular surgery, neurosurgery) and only in the presence of a colonisation or infection by MRSA or a high incidence of SSI caused by methicillin-resistant Staphylococci, verified through clinical and microbiological surveillance of the SSIs at a local level. Such a decision should be made in accordance with local antibiotic policy strategies.
 - 6) In the majority of cases, the single dose of antibiotic used for prophylactic purposes corresponds to a medium-high therapeutic dose.
 - 7) Antibiotic prophylaxis should be administered intravenously.
- II/A In the majority of cases, antibiotic prophylaxis should begin immediately prior to anaesthesia and in any case 30 to 60

minutes prior to the first skin cut.

- I/A Antibiotic prophylaxis should be limited to the perioperative period and should be administered immediately prior to the start of the operation. There are no trials that show greater effectiveness in prolonged prophylaxis; in the majority of cases administration of a single dose of antibiotics is sufficient (specifically the one administered within 30 and 60 minutes of the first skin cut). The decision to continue prophylaxis beyond the first 24 hours after the operation is not justified.
- 1) In the case of long operations, despite a lack of unequivocal data, the majority of guidelines suggest the administration of an intraoperative dose if the operation is still ongoing, following a period of time from the start of the operation equal to double the half-life of the drug used.
- IV/B The administration of an additional intraoperative dose of antibiotic (to be carried out following fluid replacement) is advised in adults if during the course of the operation a loss of more than 1 500 mL of blood

is verified or if a hemodilution of more than 15 mL per kg has been carried out.

- 1) The extension of the prophylaxis to the first 24 hours following the operation can be justified in defined clinical situations when the postoperative infection risk index is high. Any decision to prolong the prophylaxis beyond the period established by the local guidelines should be explained in the medical record.

Local implementation of the guidelines

The implementation strategies whose effectiveness has been most documented are: sharing the prophylaxis protocol with surgeons, anesthetists and operating room personnel; paying attention to organisational problems; assigning specific responsibilities regarding the protocol's application; the preparation of prepackaged kits by the dispensary.

- VI/A Recording a minimum set of data in the medical record and the treatment form facilitates audits to evaluate the appropriateness of perioperative antibiotic prophylaxis.

Received on January 19, 2009 - Accepted for publication on February 2, 2009.

Corresponding author: F. Calise, Unit of Hepatobiliary Surgery and Liver Transplantation, Cardarelli Hospital, Naples, Italy.
E-mail: fulvio.calise@ospedalecardarelli.it