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REVIEW

Could antibiotic prophylaxis be not necessary to implant totally implantable venous access devices? Randomized prospective study

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Abstract
Background: The growing use of totally implantable venous access devices (TIVAD) has caused the simultaneous increase of various complications. Among these, one of the most encountered is the infection of the subcutaneous pocket in which the device is positioned, or the infection of TIVAD itself. The aim of this study is to evaluate the role of the antibiotic in the prevention of the infection of both the surgical site and the TIVAD within 30 days after the implant.
Methods: The authors enrolled one hundred eight consecutive patients divided into two randomized arms each of 54 patients: group A (antibiotic), group B (no antibiotic). All patients were affected by solid tumors needing chemotherapy continuously. TIVADs were implanted surgically in cephalic vein. On the first, third, and seventh postoperative days, the following manifestations were considered as signs or symptoms of infection: pain, localized swelling, redness, and heat; white blood cell count was performed in the in-hospital laboratory. Body temperatures were checked twice a day for 7 days. A statistical analysis of the results was performed.
Results: No sign of infection was recorded in both groups. Body temperatures and white blood cell counts remained within normal limits in both groups. One month after the procedure no patients recorded any sign of skin infection or body temperature increase.

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Conclusions: The study suggests that, following strict methods of pre- and postoperative care, TIVADs in patients with solid tumors may be surgically implanted without any antibiotic prophylaxis.

Contents

Introduction

The growing use of totally implantable venous access devices (TIVAD) has caused the simultaneous increase of various complications. TIVAD's infection or the infection of the subcutaneous pocket in which the device is positioned is one of the most encountered complications [1]. In studies which consider both surgical approach and nursing management the rate of this complication ranges between 0.3% [2] and 9.0% [3] with *Staphylococcus aureus* as the most implicated agent. Surgical site infection following central venous catheter placement is rare (less than 1%); on the opposite, pocket infection is slightly higher but almost always associated to nursing problems in the device management and not strictly related to initial surgery.

Antibiotic therapy is not recommended in literature when a central venous catheter (CVC) is inserted [4] and some studies clearly underline the uselessness of antibiotic prophylaxis for these patients [5,6]. However no study has been performed to assess the role of antibiotic prophylaxis after implanting a TIVAD. Structural differences exist between TIVAD and CVC; in fact the catheter, that is the unique component of CVC, represents only a part of the TIVAD in which the port is the most relevant component. Moreover, the technique of implant of TIVAD is different from CVC, especially when cutdown is used to insert the catheter in cephalic or external jugular vein. Surgical cutdown consists of a 4—5 cm skin incision, a tissue dissection with hemostasis and sutures, unlike the simple puncture used for percutaneous approach.

The indiscriminate use of antibiotic prophylaxis can lead to adverse effects for patients as well as the emerging of resistant organism, and these complications may represent a dreadful problem in patients immunosuppressed or undergoing chemotherapy.

The aim of this study is to evaluate the role of the antibiotic in the prevention of the infection of the surgical site of TIVAD's pouch within 30 days after the implant.

Patients and methods

From January 2004 to December 2008, one hundred eight patients were enrolled for the present study. Criteria for enrollment were: good performance status, more than 18 years of age, diagnosis of solid tumors, white blood cells (WBC) count between 4×10^9/L and 10×10^9/L, body temperature lesser than 37 °C. Clinical symptoms of infection were considered as criteria of exclusion. All patients provided an informed consent before to be enrolled in the trial.

In all patients, the TIVAD was necessary to infuse chemotherapy continuously. The device utilized in all patients was composed of a catheter of polyurethane and a titanium portal reservoir covered with polysulfone (PORT-A-CATH, Smiths Medical Inc., MN).

Patients were divided into two arms (A and B) each of 54 patients. The main difference we expected to find by comparing the two groups was an increased rate of early postoperative local infections in patients who did not underwent antibiotic prophylaxis. On the contrary the null hypothesis was that no difference exists between patients who undergo antibiotic administration and patients who do not. Patients were randomized using sealed envelopes that were opened only in the operating room 30 min before starting the procedure. Group A included patients submitted to the short-term prophylaxis with 1 g of ceftazidime (Glazidim®, Glaxo, Verona, Italy) administered i.v. 10 min before the skin incision; group B included patients without any antibiotic prophylaxis. For all patients were evaluated: age, gender, associated risk factor like diabetes or nicotinism, number of chemotherapeutical cycles before the surgical procedure, type of tumor, type of vascular access, experience of surgeons (resident or skilled surgeon), preparation of the skin of the patients, duration and modality of surgeon's hand scrub, class of antibiotic used, and time of administration. All devices were implanted in the operating room using the left or right cephalic vein or the right external jugular vein dissected surgically. All patients were hospitalized the night after the surgical procedure.

On the first, third, and seventh postoperative days, WBC count was performed in the in-hospital laboratory. Body temperature was checked twice a day for 7 days. Eight days after the surgical procedure, sutures of the skin were removed. The skin wound was covered with a sterile drape