The Role of Antibiotic Prophylaxis in Prevention of Wound Infection After Lichtenstein Open Mesh Repair of Primary Inguinal Hernia

A Multicenter Double-Blind Randomized Controlled Trial

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PATIENTS AND METHODS

Three nonteaching and one teaching general hospital participated in this study. Surgical residents and surgeons in participating hospitals enrolled patients and performed the operations. The ethics committees of all hospitals approved the study and all patients gave informed consent.

Characteristics of the Patients

Patients with a primary uni- or bilateral inguinal hernia and an indication for Lichtenstein hernia repair were eligible for the study. Exclusion criteria were: age under 35, the need for antibiotics for a different reason, immunosuppressive disease (diabetes mellitus, malignancy, HIV) or medication (glucocorticoid therapy), allergy to the given antibiotic, recurrent hernia, or the inability to get an informed consent.

To get insight in a potential selection bias, all eligible patients in one of the 4 hospitals were registered.

➢**applicazione della “cecità”**

☛ singolo cieco il soggetto non sa a quale trattamento viene assegnato

☛ doppio cieco né il soggetto né il ricercatore conoscono l’assegnazione

Random Assignment to Treatment Groups

The patients were double-blinded randomly assigned to either intravenous placebo or antibiotic prophylaxis. A pharmacist carried out randomization according to a computer-generated list in blocks of 10 patients with stratification for each hospital.

1). Randomization was successful: there were no significant differences in patient or operation characteristics (Table 1).

TABLE 1. Baseline and Operative Characteristics of 1008 Patients With Primary Inguinal Hernia Randomized Between Antibiotic Prophylaxis and Placebo

Characteristic	Antibiotic Prophylaxis (n = 503)	Placebo (n = 505)
Age (years) (mean ± SD)	58.28 ± 12.9	58.22 ± 13.2
Sex [no. (%)]		
Male	481 (95.6)	490 (97.0)
Female	22 (4.4)	15 (3.0)
Characteristics of hernia [no. (%)]		
Direct	198 (39.4)	208 (41.2)
Indirect	221 (43.9)	233 (46.1)
Combined	76 (15.1)	60 (11.9)
Unknown	8 (1.6)	4 (0.8)
Surgeon [no. (%)]		
Resident	212 (42.1)	225 (44.6)
Certified surgeon	291 (57.9)	280 (55.4)
Anesthesia [no. (%)]		
Local	10 (2.0)	7 (1.4)
Spinal	180 (35.8)	191 (37.8)
General	311 (61.8)	303 (60.0)
Unknown	2 (0.4)	4 (0.8)
Bilateral hernia [no. (%)]	27 (5.4)	29 (5.7)
Disinfectant–iodine [no. (%)]	493 (98.0)	496 (98.4)
Operation in day surgery [no. (%)]	231 (46.1)	232 (45.9)
Use of drains [no. (%)]	11 (2.2)	4 (0.8)
Duration of surgery (minutes) [median (25%–75% quartiles)]	40 (30–50)	40 (28–51)
Incision length (cm) [median (25%–75% quartiles)]	8.0 (7.0–8.3)	8.0 (7.0–8.0)

DEFINIRE L'OBIETTIVO DELLO STUDIO

Esiti clinicamente rilevanti
Esiti secondari
Qualità della vita
Esiti indiretti

Endpoints

The primary endpoint of the study was wound infection as defined by the Centers for Disease Control and Prevention criteria.[18,19] In this definition, superficial infection occurs within 30 days after operation and involves only skin or subcutaneous tissue; deep infection involves fascial and muscle layers and, when related to an operation where an implant is used, may occur up to 1 year.

METODO DI ANALISI DEI RISULTATI

Intention to treat
Per-protocol

Data for all patients who were randomly assigned to a treatment group and underwent surgery were primarily analyzed on an intention-to-treat basis. A per-protocol analysis, which excluded patients with major protocol violations, was also performed. The third analysis performed was an as-treated analysis; that is, patients were assigned to a group based on whether they did actually get antibiotics or not. No interim analyses were performed. Continuous normally dis-

PIANIFICAZIONE DELLO STUDIO

- **Effetto atteso oppure precisione di una stima**
- **Probabilità di individuare un effetto dove realmente c'è (1-β)**
- **Probabilità di individuare un effetto dove non c'è (α)**

The power of the trial ($\alpha = 0.05$, $\beta = 80\%$, 2-sided) was based on the assumption that antibiotic prophylaxis reduces the wound infection rate from 4% (average in literature) to 1%. The sample size calculated was 978 patients. Since we expected a dropout of 5%, we randomly allocated 1040 patients.

EER (Experimental Event Rate)
Percentuale di eventi osservati nel gruppo randomizzato al trattamento

CER (Control Event Rate)
Numero percentuale di eventi osservato nel gruppo di controllo

ARR = CER – EER
(Absolute Risk Reduction)

NNT = 1/ARR
(Number Needed to Treat)

The number of wound infections was 8 (1.6%) in the antibiotic prophylaxis group and 9 (1.8%) in the placebo group ($P = 0.82$). There were 3 (0.3%) deep infections: 1 in the antibiotic prophylaxis group and 2 in the placebo group ($P = 0.57$). Statistical analysis showed an absolute risk reduction of 0.19% (95% confidence interval, −1.78%–1.40%) and a number needed to treat of 520 to prevent one infection. For the deep infection, the absolute risk reduction is 0.20% (95% confidence interval, −0.87%–0.48%) with a number needed to treat of 508 to prevent one infection.

Conclusions: A low percentage (1.7%) of wound infection after Lichtenstein open mesh inguinal (primary) hernia repair was found, and there was no difference between the antibiotic prophylaxis or placebo group. The results show that, in Lichtenstein inguinal primary hernia repair, antibiotic prophylaxis is not indicated in low-risk patients.

La profilassi antibiotica non è raccomandata in corso di:

I/D	Riparazione di ernia inguinale con o senza utilizzo di materiale protesico. Chirurgia laparoscopica dell'ernia con o senza utilizzo di materiale protesico.
✓	Laparoscopia diagnostica e/o lisi di aderenze. Biopsia escissionale di struttura linfatica superficiale.