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Surgical site infection: An observer-blind, randomized trial comparing electrocautery and conventional scalpel

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ABSTRACT

Aim: To evaluate the incidence of surgical site infection (SSI) based on the type of scalpel used for incisions in the skin and in subcutaneous tissues.
Methods: Observer-blind, randomized equivalence clinical trial with two arms (electrocautery versus conventional scalpel) which evaluated 133 women undergoing elective abdominal gynecologic oncology surgery. A simple randomization stratified by body mass index (BMI: 30 kg/m^2) was carried out. Women were evaluated at 14 and 30 days following the operation. A multivariate analysis was performed in order to check whether the type of scalpel would be a risk factor for SSI.
Results: Group arms were balanced for all variables, excepted for surgical time, which was significantly higher in the electrocautery group (mean: 161.1 versus 203.5 min, $P = 0.029$). The rates of SSI were 7.4% and 9.7%, respectively, for the conventional scalpel and electrocautery groups ($P = 0.756$). The exploratory multivariate model identified body mass index $\geq$30 kg/m^2 (OR = 24.2, 95% CI: 2.8–212.1) and transverse surgical incision (OR = 8.1, 95% CI: 1.5–42.6) as independent risk factors for SSI. The type of scalpel used in surgery, when adjusted for these variables and the surgery time, was not a risk factor for SSI.
Conclusion: This study showed that the SSI rates for conventional scalpel and electrocautery were not significantly different. These results were consistent with others reported in the literature and would not allow a surgeon to justify scalpel choice based on SSI.
Trial number: NCT01410175 (Clinical Trials – NIH).

1. Introduction

Since World War I, medicine has evolved considerably, and the development of new instruments has produced better results in surgical treatments [1]. Surgical instruments have been modified to become increasingly more specific based on the types of procedures and their individual requirements. In 1926, William Bovie developed the first electrocautery, which offered the possibility of coagulation and tissue cutting using a source of energy [2,3]. Careful dissection and manipulation of tissues is essential to reduce tissue trauma during surgery. When used improperly or above the recommended charge, electrocautery can result in significant tissue devitalization.

Among all postoperative complications, surgical site infection (SSI) is the most common infection acquired during hospitalization [4,5]. Approximately two-thirds of these infections involve superficial incisions, and the remaining infections involve muscle tissue, organs or deep spaces. According to the Centers for Disease Control and Prevention (CDC), SSI can occur up to 30 days after the surgical procedure and up to one year when prostheses are implanted [6].

The aim of this study was to evaluate the incidence of SSI based on the type of scalpel used for incisions in the skin and in subcutaneous tissues (electrocautery versus conventional scalpels) in gynecologic oncology surgeries and evaluate whether the type of

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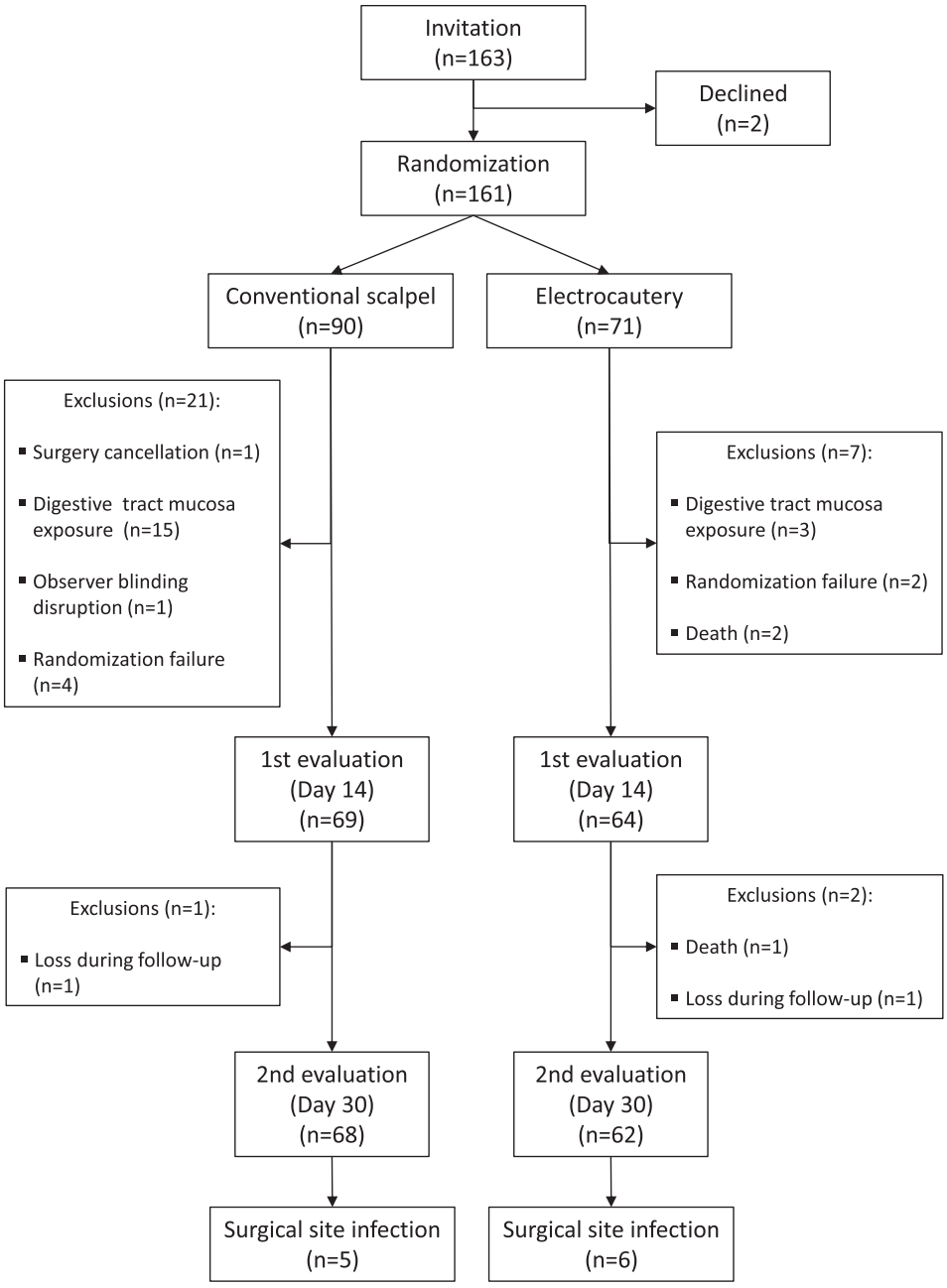

Fig. 1. Distribution of participants according to the study arm (Consort flowchart).

scalpel was a risk factor for infection. The hypothesis of this study was that the electrocautery and conventional scalpel would be equivalent in terms of SSI.

2. Methodology

This was an equivalence clinical trial in which only the observer was blinded. Patients were randomly allocated into two groups: conventional scalpel versus electrocautery. The study was conducted at Barretos Cancer Hospital [Hospital de Câncer de Barretos] from July 2010 to July 2012 on women undergoing elective abdominal gynecologic oncology surgery. The selection criteria included women older than 18 years of age who agreed to participate in the study and underwent elective abdominal gynecologic surgery via laparotomy for diagnosis and curative or palliative cancer treatment. Women who underwent surgery that involved exposure of the digestive tract mucosa, ostomies, re-operations or emergency surgeries were excluded. In total, 163 patients were invited to participate in the study; 2 patients declined to participate, resulting in 161 randomized patients. Overall, 90 patients were selected for the conventional scalpel group, and 71 patients were selected for the electrocautery group. After randomization but before the first observation, 28 women were excluded for the following reasons: 1 woman had her surgery suspended in the operating room; the digestive tract mucosa was manipulated during surgery for 18 women (accidental rupture of the intestine mucosa, intestinal anastomosis or ostomy); the randomization process failed for 6 patients (including 2 patients who were younger than 18 years of age; randomization was duplicated for 1 patient; 3 patients were excluded because the surgeon did not use