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Original research

Randomized clinical trial comparing cold knife conization of the cervix with and without lateral hemostatic sutures

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HIGHLIGHTS

- Cold knife conization of the cervix is a safe procedure when performed without lateral hemostatic sutures.
- Perform this procedure without paracervical sutures does not increase the intraoperative bleeding.
- Lateral Haemostatic Sutures does not avoid intraoperative bleeding.

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ABSTRACT

Objective: Compare blood loss during cold knife conization of the cervix with and without lateral hemostatic sutures in the cervical branches of the uterine arteries.
Design: Randomized clinical trial.
Setting: Hospital de Clínicas de Porto Alegre (HCPA).
Population: 102 patients that underwent cold knife conization.
Methods: Women that underwent cold knife conization of the cervix were randomized to undergo the procedure with or without lateral hemostatic sutures.
Main outcome measures: Primary outcome measure: blood loss measured in grams. Secondary outcome measures: operative time and postoperative intervention. Only the participants were blinded to group assignment.
Results: From March 2009 to August 2012, patients were randomly assigned to one of the study groups. There were no differences in amount of blood loss between patients that underwent the procedure with and without sutures ($p = 0.39$). Operative time was shorter in the group without suture ($p = 0.020$). There were no differences in intervention due to bleeding ($p = 0.20$). Blood loss was greater among menstruating women than for menopausal women ($p = 0.011$). There were no differences in amount of blood lost between smoking and nonsmoking patients ($p = 0.082$).
Conclusions: Lateral hemostatic sutures do not affect the amount of intraoperative bleeding or the number of postoperative interventions. Their use is not necessary because they result in longer operative time, have a higher cost due to the use of suture material and pose the risk of ureter lesion in case the sutures are not placed at a lower position in the cervix.
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1. Introduction

Cervical cancer, in its initial stage, is a highly curable condition when patients are accurately staged and an adequate treatment

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plan is made [1]. In many developing countries, cervical cancer is the most common type of cancer among women and the most common cause of lost life years. This cancer is very often diagnosed around the fifth decade of life, that is, several years earlier than the mean age for breast, lung or ovary cancer [2].

The terms cervical intraepithelial neoplasia (CIN) 2 and 3 are used to define lesions previously described as moderate dysplasia (CIN 2) and severe dysplasia/carcinoma in situ (CIN 3) [3]. The treatment of high grade CIN (CIN 2, 3) is defined according to the colposcopic evaluation of the patient. In case of colposcopy findings are satisfactory (visible squamocolumnar junction), both ablative and excisional methods are adequate [4]. Ablative methods include cryotherapy, laser vaporization, electrocautery, diathermy and cold coagulation, whereas excisional treatments are loop electrosurgical excision procedures (LEEP), laser conization and cold knife conization. Abdominal hysterectomy may be indicated in well-selected cases if the results of conization rule out an invasive lesion.

The descending branches of the uterine arteries provide the main blood supply to the cervix. In the middle of the 20th century, lateral hemostatic sutures were added to the cold knife conization surgical technique to reduce blood loss [5]. Although not obligatory, lateral hemostatic sutures are recommended by most authors [6–8]. Before the incision of the cone using the scalpel, two absorbable suture stitches are applied laterally to the cervix at 3 and 9 o'clock to hold the descending branches of the uterine arteries [6].

For some decades, some authors have questioned the effectiveness of lateral hemostatic sutures in the cervix [8–13]. Their questions arose from the fact that lateral hemostatic sutures have failed to reduce blood loss considerably [11,14], in addition to having increased operative time and costs because of the use of one or more sutures. Moreover, there is the theoretical risk of ureter lesion in case the sutures are applied too cranially at the level of the cervix.

This study compared blood loss during cold knife conization of the cervix with and without lateral hemostatic sutures.

2. Material and methods

This randomized clinical trial was conducted in Hospital de Clínicas de Porto Alegre (HCPA), Porto Alegre, Brazil. From March 2009 to August 2012, all patients referred to cold knife conization of the cervix were invited to participate in the study. The variable under study was the use or not of lateral hemostatic sutures during cold knife conization (Figs. A.1, A.2 and A.3). The primary outcome was intraoperative bleeding measured in grams (g) by weighing the gauze sponges used to absorb blood during the procedure. The secondary outcomes were: operative time and postoperative interventions. Also we compare the surgery results according to year of residency in obstetrics and gynecology.

The technique of measuring the amount of bleeding during cold knife conization was that reported in the study by Awobusuyi et al. [15]. Blood loss was quantified as follows: sterile gauze sponges were weighed on a sensitive laboratory scale separately, before the procedure, Weight 1 (W1). At HCPA, gauze sponge weight is standardized at 2 g each. The cold knife conization procedure was performed ensuring that all blood lost during the procedure was absorbed with gauzes. Used pieces of gauze were weighed and the weight was noted, Weight 2 (W2). The amount of blood loss (ABL) during the procedure was then obtained using the following equation: $ABL = W2 - W1$. We took care to clean all the bleeding with gauze obtained during the procedure.

To calculate the sample size was considered bleeding during cold-knife conization of the cervix with stitches (48 ml) and without stitches (26 ml), the study by Gilbert and colleagues [11]. Sample size was calculated using the WINPEPI software: for an alpha of 5% and a power of 80%, at least 102 patients should be included, 51 in each group (Fig. A.4). The inclusion criterion was the surgical treatment indication of CIN 2/3 by cold knife conization. Exclusion criteria were: (a) conization using techniques other than the cold knife; (b) previous cervical conization using any other technique; (c) previous pelvic radiotherapy; (d) pregnancy; and (e) refusal to participate in the study.

The *RANDOMIZATION.COM* website (http://www.randomization.com) was used to generate a random list for inclusion, separating patients into two groups (group WITH stitches and group WITHOUT stitches). The randomization was created by including two different treatments, in two groups (51 patients per group). All patients signed an informed consent term after reading it and receiving verbal explanations about their questions. The surgeons were 2nd year residents (seven) of the Medical Residency Program in Obstetrics and Gynecology of HCPA, under the supervision of only one professor/staff surgeon of the Service of Obstetrics and Gynecology of HCPA, and were only told about whether the procedure was with or without stitches moments before the operation. Only the participants were blinded to group assignment. All procedures were performed under general anesthesia. The procedure of cold knife conization of the uterine cervix was performed by surgical excision of the specimen with cold scalpel based on the Schiller test. After the removal of the specimen and marking at 12 h, the conization bed was cauterized with *valleylab* cautery (40 w of power). Besides that, two lateral sutures with 2-0 vicryl thread were performed to approximate the anterior and posterior lips. It was not used Monsel solution during the procedures.

Data collected were: age (in years) at time of surgery, skin color (according to the Brazilian Geography and Statistics Institute), parity, hormonal status, smoking, use of anticoagulation agents. Preoperative test results were also collected: colposcopy (satisfactory or not), lesion site according to colposcopy and cervical biopsy before conization. All data were collected by one single person, the principal investigator.

The following surgery variables were collected: operative time (in minutes), blood loss (in grams) and surgeon's qualifications. All blood lost during surgery was absorbed with gauze sponges, which were weighed after the operation using a scale (model 9094-II TOLEDO, Brazil, 1999) in a room next to the operating room. At the end, the number of sponges used was discounted. The specimens of cervical conization were examined, and the following variables were collected: type of lesion according to histopathology examination, invasion of lymphovascular spaces in cases of invasive lesion, height and base diameter of the cone (in millimeters), and surgical margins.

Postoperative data were evaluated during the follow-up visits and by reviewing emergency visit records. The patients usually left the surgery room with a vaginal pack and were told to remove it at home on the following day. Outpatient return visits for review were scheduled for one week and 30 days after operation. The rest of the clinical surveillance was defined according to the result of histopathology examination of the conization specimen. The patients were instructed to seek care in the Emergency Service of HCPA in case of complications. Postoperative interventions due to bleeding were defined as the need to replace vaginal pack, to suture the cervix or to receive blood transfusion any time in the first 30 days after the operation.

All data were entered in an Excel spreadsheet and later exported to the SPSS (*Statistical Package for the Social Sciences*) 18.0