

FACTORS THAT INFLUENCE SURGICAL MARGIN STATE IN PATIENTS UNDERGOING COLD KNIFE CONIZATION – A SINGLE CENTER EXPERIENCE

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ABSTRACT

Aim: To evaluate the factors that influence the surgical margin state in patients undergoing cold knife conization at the University Clinic of Gynecology and Obstetrics in Skopje, Republic of Macedonia

Materials and methods: We have retrospectively analyzed the medical records of all patients that underwent a cold knife conization at our Clinic in 2015. We cross-referenced the surgical margin state with the histopathological diagnosis (LSIL, HSIL or micro-invasive/invasive cancer), menopausal status of the patients, number of pregnancies, surgeon experience, operating time and cone depth. The data was analyzed with the Chi square test, Fisher’s exact test for categorical data and Student’s T test for continuous data and univariate and multivariate logistical regressions were performed.

Results: A total of 246 medical records have been analyzed, out of which 29 (11.79%) patients had LSIL, 194 (78.86%) had HSIL and 23 (9.34%) patients suffered micro-invasive/invasive cervical cancer. The surgical margins were positive in 78 (31.7%) of the patients. The average age of the patients was 41.13 and 35 (14.23%) of the patients were menopausal. The multivariate logistic regression identified preoperative forceps biopsy of micro-invasive SCC, HSIL or higher cone specimen histology and shorter cone depth as independent predictors of surgical margin involvement in patients undergoing cold knife conization.

Conclusion: In the current study, we have found no association between the inherent characteristics of the patient and the surgeon and the surgical margin state after a CKC. The most important predictors for positive margins were the severity of the lesion and the cone depth.

Keywords: Cold knife conization, residual disease, surgical margin

INTRODUCTION

Since the wide implementation of cervical cancer screening programs that utilize cervical cytological smears, the rates of cervical cancer in the developed western countries have dropped substantially [1]. The effect of these early detection programs depends not only on the sensitivity of the cytological smears, but also on the ability to successfully treat the precancerous lesions identified by the screening tests. At the same time, this improvement led to rising incidence rates of pre-

cancerous lesions of the uterine cervix, especially among women of reproductive age [2, 3]. Ting et al. has systematically reviewed 103 studies with data from more than 12 million patients [4]. The authors have found that the incidence of high-grade squamous intraepithelial lesions (HSIL) in European women peaks in women between the age of 30 and 40. The peak age of incidence of low-grade lesions (LSIL) is much lower than HSIL.

Because of the 5-12% chance of progression to squamous cell cancer, management guidelines recommend treatment for women with moderate-to-severe dysplasia [5]. Surgical treatment irrespective of the type, be it LEEP/LLEETZ, laser or cold knife cone biopsy, reduces the volume of cervical tissue and the length of the cervical canal, leading to specific local immunologic and fibrotic tissue reactions, cervical stenosis, preterm delivery and infertility [6]. In young women desiring future pregnancies, excisional procedures are balanced between complete excision of the lesion and minimal cervical damage in an attempt to reduce the risk of unfavorable obstetric outcomes. Bearing in mind that most women in this age group have not completed their reproduction at the time of diagnosis, one could certainly see the challenge this imposes on the surgeons. Surgical margin involvement is associated with an increased risk of residual/recurrent disease. A comprehensive meta-analysis [7] included data from 35109 patients, 8091 of which (23.04%) had at least one disease-involved excisional margin. The authors calculated that, following incomplete excision, the relative risk (RR) of post treatment disease of any grade was 5.47 (95% CI 4.37-6.83) and RR of high-grade disease (HSIL) was 6.09 (3.87-9.60) compared with the reference group who had a complete excision [7]. Oliveira et al. in their meta-analysis found the relative risk of persistent/recurrent HSIL one year after treatment to be 11.36 in patients with positive margins, compared to patients with negative margins [8]. Older patients [9], patients with higher parity [10], higher CIN grade [11] and/or smaller cone depth [12] have been reported to be at an increased risk of having positive surgical margins.

AIM

The aim of the study is to evaluate the factors that influence the surgical margin state in patients undergoing cold knife conization at the University Clinic of Gynecology and Obstetrics in Skopje, Republic of Macedonia.

MATERIAL AND METHODS

We conducted a retrospective cross-sectional study on the data from the registers of University Clinic for gynecology and obstetrics, University "Ss. Cyril and Methodius", Skopje, Republic of

Macedonia in the timeframe January – December 2015. We only included patients that underwent cold knife conization that had pathohistological reports that clearly defined cone margin state. We identified a total of 253 patient records; where 246 patients (97.23%) met the inclusion criteria, while 7 patients were excluded due to inadequate pathohistology reports (fragmented cone samples and/or inability to evaluate cone margin state). The following variables were recorded from the medical charts for each patient: age, parity, menopausal status, pre-treatment biopsy results, surgeon experience (defined as experienced if he/she had performed at least 200 cold knife conizations, otherwise inexperienced) and operating time. All specimens were analyzed at the Institute of Pathology, University "Ss. Cyril and Methodius", Skopje, Republic of Macedonia. The extent of the lesion, cone base length and width, cone depth (height) and margin status were recorded from the final pathology report for each patient. The volume of each specimen was approximated using the elliptic cone volume formula (using the cone base length and width and the cone depth from the pathology report).

We formulated the following hypotheses:

Hypothesis 1: the severity of the disease in the preoperative forceps biopsy and the cervical conization specimen increases, so does the percentage of patients who have positive surgical margins.

Hypothesis 2: advanced patient age and/or menopause increases the risk of disease-involved margins in the cone sample.

Hypothesis 3: Precancerous lesions of the uterine cervix tend to recur even after complete resection of the initial lesion (i.e. the surgeon has achieved clear margins) because of the viral etiology of the lesion. The persistence of viral infection after the surgery increases the risk of recurrent disease and/or de novo lesion formation.

All statistical calculations were done using IBM SPSS Statistics software package, version 20.0. A probability value of $p \leq 0.05$ was considered significant. The differences between discrete variables were tested using Chi-square test and Fisher's exact test (where appropriate). Student's t test was used to test the statistical significance of the differences between the continuous variables. A multivariate logistic regression was carried out to identify the independent risk factors and odds ratios (ORs) with 95% confidence intervals were calculated for each outcome.

RESULTS

We identified a total of 246 patient records that met the inclusion criteria. The average age of the patients was 41.13 years (± 10.76 years) with a range from 21 to 78 years. The patients had 2.31 pregnancies (± 1.72 , range 0-10) and 1.66 deliveries (± 1.19 , range 0-8) on average. Thirty-five (14.2%) of the patients were menopausal, while the rest of the patients were premenopausal. The preoperative colposcopy-guided forceps biopsy revealed HSIL lesions in 238 (96.75%) of the patients, while 8 (3.25%) patients had micro-invasive squamous cell carcinoma. 51 (21.43%) of the patients with HSIL lesions, had moderate cervical dysplasia, 110 (46.22%) had severe cervical dysplasia and 77 (32.35%) had in situ squamous cervical carcinoma. 168 patients (68.3%) had negative cone margins, while 78 (31.7%) had at least one disease-involved margin (endocervical or exocervical). The postoperative histology verified LSIL lesions in 29 (11.79%) of the patients, HSIL lesions in 194 (78.86%) of the patients [of which 49 (25.26%) patients had moderate cervical dysplasia, 76 (39.18%) had severe cervical dysplasia and 69 (35.56%) had in situ squamous cervical carcinoma], while 23 (9.34%) patients had invasive squamous cell carcinoma. The average cone depth was 15.28mm (range 4-30mm) with a standard deviation of 5.8mm, while the average

cone volume was $3.51\text{cm}^3 \pm 2.9\text{cm}^3$ (range 0.19-13.67 cm^3). One hundred and fifty-five (63.01%) conizations were performed by experienced surgeons, 91 (36.99%) were performed by inexperienced surgeons with an average operating time of 35.33 ± 10.43 minutes for all surgeons. Table 1 summarizes the patient characteristics, while table 2 presents the histopathologic results from the conizations.

Table 3 outlines the differences between the patients with negative cone margins and the patients with disease-involved surgical margins.

In our series, patients were more likely to have disease involved margins if they were older ($p < 0.001$), menopausal ($p = 0.001$), had more pregnancies ($p = 0.03$), had a lesion of higher grade both on the preoperative biopsy and in the cone specimen ($p = 0.001$ and < 0.001 , respectively) and if they had shallower and smaller blocks of tissue excised ($p < 0.001$ and 0.04, respectively). The differences in parity, surgeon experience and operating time between the groups were not statistically significant.

Next, we included the identified potential risk factors (age, number of pregnancies, menopausal status, preoperative biopsy, cone histology, cone depth and cone volume) in a multivariate logistic regression analysis. The following independent risk factors for disease-involved surgical margins were identified: preoperative forceps biopsy of micro-invasive SCC (OR=17.97; 95%CI

Table 1. Summary of patient characteristics

Characteristic	
Age (mean \pm SD)	41.13 \pm 10.76 years
No. of pregnancies (mean \pm SD)	2.31 \pm 1.72 pregnancies
Parity (mean \pm SD)	1.66 \pm 1.19 deliveries
Menopausal status	
Premenopausal (n, %)	211 (85.77%)
Postmenopausal (n, %)	35 (14.23%)
Preoperative forceps biopsy histology	
HSIL (n, %)	238 (96.75%)
Squamous cell carcinoma (n, %)	8 (3.25%)
Surgeon experience	
Inexperienced (n, %)	91 (36.99%)
Experienced (n, %)	155 (63.01%)
Operating time (mean \pm SD)	35.33 \pm 10.43 minutes

Table 2. Pathological features of the specimens

Characteristic	
Cone specimen histology	
LSIL (n, %)	29 (11.79%)
HSIL (n, %)	194 (78.86%)
Squamous cell carcinoma (n, %)	23 (9.34%)
Surgical margin state	
Negative (n, %)	168 (68.3%)
Positive (n, %)	78 (31.7%)
Cone depth (mean \pm SD, [range])	15.28 \pm 5.8mm [4-30mm]
Cone volume (mean \pm SD, [range])	3.51cm ³ \pm 2.9cm ³ [0.19-13.67cm ³]

Table 3. Distribution of the analyzed variables with regard to surgical margin state

Variable	Margin state		p
	Negative (n=168)	Positive (n=78)	
Age (mean)	39.47 years	44.72 years	<0.001 [‡]
No. of pregnancies (mean)	2.13	2.69	0.027 [‡]
Parity (mean)	1.56	1.87	0.084 [‡]
Menopausal status			0.001 [‡]
Premenopausal	153 (72.5%)	58 (27.5%)	
Postmenopausal	15 (42.9%)	20 (57.1%)	
Preoperative forceps biopsy histology			0.001 [‡]
HSIL* (n, %)	167 (70.5%)	70 (29.5%)	
SCC* (n, %)	1 (11.1%)	8 (88.9%)	
Surgeon experience			0.671 [‡]
Inexperienced (n, %)	64 (70.3%)	27 (29.7%)	
Experienced (n, %)	104 (67.1%)	51 (32.9%)	
Operating time (mean)	35.12min	35.77min	0.65 [‡]
Cone specimen histology			<0.001 [‡]
LSIL* (n, %)	25 (86.2%)	4 (13.8%)	
HSIL* (n, %)	137 (70.6%)	57 (29.4%)	
SCC* (n, %)	6 (26.1%)	17 (73.9%)	
Cone depth (mean)	16.34mm	13mm	<0.001 [‡]
Cone volume (mean)	3.79cm ³	2.91cm ³	0.04 [‡]

*LSIL - low-grade squamous intraepithelial lesions; HSIL - high-grade squamous intraepithelial lesions; SCC- micro-invasive/invasive squamous cell carcinoma. [‡]Chi-square test; [‡]Student's t-test.

1.6-20.17; $p=0.019$), HSIL or higher cone specimen histology (OR=3.76; 95%CI 1.58-8.92; $p=0.003$) and cone depth (OR=0.87 for every mm of cone depth; 95%CI 0.8-0.95; $p=0.002$). Since cone depth was a continuous variable in the logistic regression, we used the regression analysis to extrapolate the optimal cone depth from the logit function. The minimal cone depth that achieves a negative margin rate of 90% in the analyzed series was 21.56mm.

DISCUSSION

Cervical cancer is the second most common malignancy affecting women in the Republic of Macedonia, but the mortality rate has declined with the organized efforts to detect precancerous lesions earlier via cytological smears [13]. This, in turn increased the need for more conservative treatment, as most of these precursor lesions are identified in women in their twenties [14], which means the treatment choice will impact the future reproductive health of the patients.

The aim of our study was to assess the factors that influence the surgical margin state in patients undergoing cold knife conization at our center.

In the analyzed series, 31.7% of the patients had positive surgical margins. The rate of margin involvement varies greatly in the published studies: 7.2 -42.5% [15-17], and is mostly dependent on the margin type. Authors that consider endocervical margins regardless of the ectocervical margin involvement, approximate the margin involvement rate at 10% [15, 16, 18]. Studies that analyzed hysterectomy specimens have estimated the rates of disease recurrence and residual disease at 5-10% and 20-35%, respectively. It is more than clear from the published data that patients with incomplete excision of intraepithelial cervical lesions must be treated and that these lesions recur even after a complete resection of the initial lesion (i.e. the surgeon has achieved clear margins). This is due to the viral etiology of the lesion; even though the surgery is sufficient to treat the lesion itself, it does nothing for the treatment of the pathogen. The persistence of the viral infection, increases the risk of recurrence and/or de novo lesion formation. Furthermore, the authors have shown that the follow-up of patients after an excisional procedure is paramount for the

early detection of residual and/or recurrent disease [15, 18, 19]. Still, recurrence and/or persistence of CIN is more frequent in patients with positive surgical margins after an excisional procedure (conization, LEEP/LEETZ...) [19]. However, one should always bear in mind that the majority of patients with positive margins remain disease-free throughout the entire follow-up period [15]. Therefore, most published studies recommend that the managed of patients with margin involvement be tailored to the patient's individual needs, taking into consideration the age, patient preference, reproductive plans, risk of potential complications from further treatment and the desire to eradicate the potential residual lesion.

In the current series, the descriptive statistics found significant differences between patients with positive and negative surgical margins on the basis of age, parity and menopausal status. This is probably due to the fact that the squamocolumnar junction of the cervix tends to be retracted within the cervical canal in postmenopausal women, which increases the risk of positive stromal margins. However, the subsequent logistic regression failed to identify these factors as independent risk factors for positive cone margins, which is in concordance with literature data [20].

We found that as the severity of the disease in the preoperative forceps biopsy and the cervical conization specimen increases so does the percentage of patients who have positive surgical margins. Patients with micro-invasive SCC on the preoperative forceps biopsy had an OR of 17.97 (95%CI 1.6-20.17; $p=0.019$), positive surgical margins, while patients with HSIL or higher on the cone specimen had an OR of 3.76 (95%CI 1.58-8.92; $p=0.003$), margin involvement.

Chang et al. [21] also published similar results. In their study, patients with HSIL, micro-invasive SCC and invasive SCC identified in the conization specimen had positive surgical margins in 23%, 23.8%, and 43.8% of the cases, respectively.

Our data showed that the average cone depth was significantly different between patients with negative and positive margins (16.34 mm vs. 13mm) and the subsequent logistic regression analysis identified this parameter as an independent risk factor for margin involvement. We found that the minimal cone depth that achieves a negative margin rate of 90% in the analyzed series was 21.56 mm.

Klieamnn and colleagues found that the mean depth of the cone specimens were 17.1mm

and 22.4mm in patients with positive and negative surgical margins [22]. On the other hand, Papoutsis et al. [23] calculated that the optimal cone depth to achieve clear surgical margins was 10 mm, while Milinovic and colleagues [24] found that cone depth of 15mm for nulliparous and 18mm for multiparous women were sufficient to achieve a negative endocervical margin. It is important to note, however, that the last two cited studies analyzed data from younger patients and did not include patients with carcinoma in situ, micro-invasive SCC or SCC lesions on the conization specimen histology. It should be noted, however, that deeper cone specimens are associated with a greater risk of cervical canal stenosis [25], intraoperative bleeding [26] and subsequent obstetric complications (cervical incompetence) [27]. Therefore, one should always weigh the potential of positive surgical margins and/or residual disease against the potential risk of complications and the reproductive plans of the patient.

In conclusion, we found that preoperative forceps biopsy of micro-invasive SCC, HSIL or higher cone specimen histology and shorter cone depth were independent predictors of surgical margin involvement after a cold knife conization. The optimal cone length to achieve a negative surgical margin in 90% of the cases was 21.56mm. The inherent characteristics of the patient (age, parity, menopausal status) and surgeon experience did not influence the surgical margin state after a cold knife conization.

Ethics Committee Approval: the study has received approval from the ethics committee of the Medical faculty, University “Ss. Cyril and Methodius”, Skopje, Republic of Macedonia.

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Authors' contributions

AI designed the study, collected the data, reviewed the data and wrote the manuscript, MT collected the data, did the data analysis and wrote the manuscript. PG reviewed the data, JR reviewed the data, KKS collected the data. All authors have read and approved the final manuscript.

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Резиме

ФАКТОРИ ШТО ВЛИЈААТ ВРЗ СОСТОЈБАТА НА ЕКСЦИЗИОНИТЕ ХИРУРШКИ РАБОВИ КАЈ ПАЦИЕНТКИ КАЈ КОИ Е ИЗВЕДЕНА КОНИЗАЦИЈА СО КЛАСИЧНА ХИРУРШКА ТЕХНИКА – ИСКУСТВО ОД ЕДЕН ЦЕНТАР

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Цел: Да се евалуираат факторите што влијаат врз состојбата на ексцизионите рабови на препаратот добиен кај пациентки со изведена оперативна хируршка техника – конизација на Универзитетската клиника за гинекологија и акушерство во Скопје, Македонија.

Материјал и методи: Направена е ретроспективна анализа на медицинските досиеја на сите пациентки кај кои е спроведена класична техника на конизација на нашата клиника во текот на 2015 год. Направивме компарација меѓу состојбата на ексцизионите рабови на конизатот со добиените хистопатолошки дијагнози (LSIL, HSIL или микроинвазивен/инвазивен карцином), менопаузалниот статус на пациентките, бројот на бремености, искуството на хирургот, времетраењето на операцијата и длабочината на конусот. Добиените податоци беа анализирани со χ^2 -тест, Фишеров егзактен тест и Стутентов т-тест, како и спроведување на униваријантна и мултиваријантна регресивна анализа.

Резултати: Вкупно беа анализирани 246 медицински досиеја. Од тоа, кај 29 (11,79%) пациентки утврдена е LSIL промена, кај 194 (78,86%) утврдена е HSIL и кај 23 (9,34%) од пациентките утврден е микроинвазивен/инвазивен карцином. Ексцизионите хируршки рабови на конизатот беа позитивни кај 78 (31,7%) од пациентките. Просечната старост на пациентките изнесува 41,13, а 35 (14,23%) од пациентките се во менопауза. Мултиваријантната логистичка регресивна анализа ги идентификуваше: предоперативниот хистолошки наод на микроинвазивен карцином на грлото на матката добиен со биопсија, постоперативен хистолошка наод на HSIL или понапредната дијагноза на препаратот добиен со конизација и помалата длабочина на конизатот, како независни предиктори за инволвирање (позитивни) ексцизионите хируршки рабови на конизатот, добиен кај пациентки кај кои е спроведена класична техника на конизација со скалпел.

Заклучок: Во оваа студија не е утврдена поврзаност меѓу карактеристиките на пациентките и искуството на хирургот со инволвираноста на ексцизионите хируршки рабови на конизатот. Најважни предиктори за позитивни рабови на препаратот (конизатот) претставува тежината на лезијата на грлото на матката, потврдена преку хистопатолошкиот наод и длабочината на конизатот.

Клучни зборови: конизација, резидуална болест, хируршки маргини