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CLINICAL TRIAL REPORT

# Improved Quality of Life and Emotional Well-Being after Diathermy Ablation for Cervical Intraepithelial Neoplasia: A Prospective Study

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**Abstract:** This study aimed to analyze the changes in quality of life (QOL) and emotional well-being of patients undergoing diathermy ablation for cervical intraepithelial neoplasia 2/3 (CIN). A total of 40 patients were recruited for a prospective clinical trial, and the European Organization of Research and Treatment for Cancer (EORTC)-QLQ-C30 and EORTC-QLQ-CX24 questionnaires were used to assess QOL before surgery and at 3 and 6 months postoperatively. Friedman and Wilcoxon tests were employed for statistical analysis. The results showed significant improvements in emotional functioning, body image, symptom experience, and physical functioning after surgery. Vaginal discharge and abnormal bleeding decreased over time, indicating improved symptom control. Sexual activity was temporarily affected but eventually returned to preoperative levels at 6 months after surgery. This study highlights the positive impact of diathermy ablation on psychological well-being and QOL, and emphasizes the importance of patient-centered care in CIN treatment. These survey questionnaires will eventually enable us to compare global QOL assessments between patients undergoing various cervical cancer treatments, such as trachelectomy, and those with precancerous lesions.

**Keywords:** clinical trial, CIN, diathermy, quality of life, EORTC-QLQ-C30 and -CX24, questionnaires

## Introduction

Cervical cancer is the eighth most prevalent cancer in women and the ninth most frequent cause of global cancer deaths in this population, with an estimated 661,044 new cases and 348,186 deaths per year.[1]

Notably, the number of patients with high-grade precursor lesions of cervical cancer is estimated to be 20 times higher.[2] Active surgical intervention for precursor lesions can contribute to the prevention of cervical cancer. One popular approach for preventing invasive cancer involves the use of minimally invasive methods to remove lesions through local resection or cervical ablation. This method is particularly advantageous for preserving fertility, especially in patients of reproductive age. In developed countries, procedures such as the Large Loop Excision of the Transformation Zone (LLETZ) or Loop Electrical Excision Procedure (LEEP) have become the standard of care.[3–6] Alternatively, diathermy or ablation can be used as a minimally invasive and potentially curative method to avoid the risk of preterm delivery.[7] Patients in their 20s to early 40s who wish to preserve their fertility may therefore opt for this alternative method.[8] While ablation is considered to be less invasive than excision, the extent and progression of the lesion as well as the patient's preferences have to be considered. To date, no reports have been conducted to evaluate the emotional well-being or quality of life (QOL) of patients who undergo this surgery. We had the opportunity to perform diathermy ablation during a prospective clinical trial with carefully selected patients.[9] In brief, we recruited patients who were diagnosed as cervical intraepithelial neoplasia 2/3 (CIN) by punch biopsy with concordant cytological interpretation, where the lesions did not entirely occupy the cervix in colposcopic findings, and followed them up for two years postoperatively. In this paper, we analyzed changes in the patients' QOL and emotional well-

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being before and after surgery during the clinical trial. This data could be beneficial for future surgical patients seeking information about QOL changes. There is an internationally standardized European Organization of Research and Treatment for Cancer (EORTC) questionnaire for the treatment of cervical cancer, and many different translations, including those in Japanese and Portuguese, have been published. We therefore used this questionnaire to conduct a paper-based survey on patient QOL before and after surgery, and analyzed the changes in their physical and emotional well-being.

## Materials and Methods

Patients underwent ablation in the outpatient ward. The eligibility criteria of the patients in this clinical trial were as follows:[9]

1. Patients were between 20 and 50 years old at the time of consent. Considering that the average age of menopause in Japanese women is 51 years, and the squamocolumnar junction of the cervix becomes invisible after menopause, the upper age limit was set at 50 years.
2. The transformation zone (TZ) was either entirely or partially visible (TZ1 or TZ2, respectively), and colposcopic analysis indicated that high-grade abnormal lesions did not entirely occupy the cervix. Patients with low-grade lesions that occupied the entire cervix were still deemed eligible. The patients must be diagnosed with CIN2 or CIN3 based on histological findings, and must be free of concomitant glandular lesions as evidenced by colposcopic-directed biopsy. Eligible cytology classifications were NILM, ASC-US, LSIL, ASC-H, AGC, or HSIL.
3. Patients had a performance status of 0 or 1.

The exclusion criteria for registration were as follows:

1. Previous treatment for cervical tumors, such as hysterectomy, cone resection, ablation, or radiation therapy.
2. Patients with multiple active cancers that were currently being treated.
3. Patients with psychosis or psychiatric symptoms that would make it difficult for them to participate in the study.
4. Patients who were pregnant or HIV-positive.

The colposcopy-guided diathermy ablation (Sabre GenesisTM, CONMED NY, USA) was conducted under local anesthesia with 1% lidocaine, and involved the use of a ball electrode. After the worst lesion was ablated, the squamocolumnar junction was circumferentially ablated. The survey methodology for this study was conducted as follows: Prior to their consultation with the physician at the outpatient department, patients were provided with a file containing a questionnaire. A clinical research coordinator was available to address any questions or concerns raised by the patients. The patients were then requested to complete the questionnaire on-site and submit the file to the designated location at reception. Participation conditions, such as the option to not answer the questionnaire, were clearly communicated in advance. Patients were asked to complete the identical EORTC-QLQ-C30 (version 3)[10–12] and EORTC-QLQ-CX24[13,14] questionnaires preoperatively and at 3 and 6 months after surgery.

### Scoring Procedures and Statistical Analysis

The EORTC-QLQ-C30 and -CX24 used during the study are questionnaires from the European Organization of Research and Treatment for Cancer that assess quality of life scales, including functional, symptomatic, and overall health status. The responses were scored based on the EORTC Scoring Manual[10,11] (*EORTC QLQ-C30 and QLQ-CX24 © EORTC Quality of Life Group. Used with permission*). The QLQ-C30 assesses functional scales (using 30 questions with 15 items), symptom scales, and overall health status, and the QLQ-CX24 assesses functional and symptom scales (using 24 questions with 9 items). These scales are scored from 0 to 100. For the functional scale and overall health status, higher scores indicate a higher QOL. For the symptomatic scale, higher scores indicate higher levels of symptoms and problems and lower QOL. The responses at the three time points of the study were scored based on the Scoring Manual,[15,16] and analyzed using the Friedman test and Wilcoxon signed-rank test for comparison. Questions regarding sexual activity were further analyzed separately.

# Results

## Trends in Significant Scales during Observation Period

Forty patients were recruited for the prospective clinical trial of diathermy for CIN2/3 in the outpatient clinic of Fujita Health University, Aichi, Japan, between January 2017 and October 2019. One patient was excluded from the analysis because she declined to participate. Patients aged 30–39 years accounted for 71.8% (28 individuals) of total registered cases. The median age was 36 years, and 71.8% (28 individuals) of patients had experienced childbirth. 92% (36 individuals) of patients were Japanese, while 7.7% (3 individuals) were Brazilian, as shown in Table 1. The median and interquartile range were calculated for all 24 items of the EORTC-QLQ-C30 and QLQ-CX24 preoperatively and at 3 and 6 months after surgery. Data for these three time points were then analyzed using the Friedman test, as shown in Table 2, revealing significant differences for four items. The first item was C30 Physical functioning, ie, having trouble with strenuous activities, taking a walk, staying in bed or a chair during the day, eating/dressing/washing oneself, or using the toilet ($p$=0.032). The second item was C30 Emotional functioning, ie, tension, worries, irritability, or depression ($p$=0.001). The third item was CX24 Symptom Experience, ie, abdominal cramps, difficulty in controlling bowels,

**Table 1** Patient Characteristics (N=39)

| Variables | | Percentage (%) |
|---|---|---|
| Age, N | | |
| 20-29 | 1 | 2.6 |
| 30-39 | 28 | 71.8 |
| 40-49 | 10 | 25.6 |
| Age, median (N=39) | 36 | |
| Age, mean (N=39) | 36.3 | |
| Parity, N | | |
| Nullipara | 11 | 28.2 |
| Parous (1–3) | 28 | 71.8 |
| Parous, median (N=28) | 2 | |
| Parous, mean (N=28) | 1.5 | |
| Marriage status, N | | |
| Single | 1 | 28.6 |
| Married | 38 | 97.4 |
| Ethnic group, N | | |
| Japanese | 36 | 92.3 |
| Brazilian (Portuguese) | 3 | 7.7 |

**Table 2** Subscale Scores of the EORTC QLQ-C30 and QLQ-CX24

| | | Median: Before | | | Median: After 3rd Month | | | Median: After 6th Month | | | *p*-value of Friedman Test |
|---|---|---|---|---|---|---|---|---|---|---|---|
| C30 | Physical functioning | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | $p$=0.032* |
| | | | 75%ile | 100.00 | | 75%ile | 100.00 | | 75%ile | 100.00 | |
| | Role functioning | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | $p$=0.756 |
| | | | 75%ile | 100.00 | | 75%ile | 100.00 | | 75%ile | 100.00 | |
| | Dyspnea | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | $p$=0.105 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Pain | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | $p$=0.123 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |

(*Continued*)


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**Table 2** (Continued).

| | | Median: Before | | | Median: After 3rd Month | | | Median: After 6th Month | | | *p*-value of Friedman Test |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Fatigue | 0.00 | 25%ile | 0.00 | 11.11 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.685 |
| | | | 75%ile | 11.11 | | 75%ile | 13.89 | | 75%ile | 22.22 | |
| | Insomnia | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.368 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Appetite loss | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.069 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Nausea and vomiting | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.368 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Constipation | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.895 |
| | | | 75%ile | 33.33 | | 75%ile | 33.33 | | 75%ile | 33.33 | |
| | Diarrhea | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.756 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Cognitive functioning | 100.00 | 25%ile | 83.33 | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 87.50 | *p*=0.226 |
| | | | 75%ile | 100.00 | | 75%ile | 100.00 | | 75%ile | 100.00 | |
| | Emotional functioning | 83.33 | 25%ile | 75.00 | 95.83 | 25%ile | 83.33 | 100.00 | 25%ile | 85.42 | *p*=0.001** |
| | | | 75%ile | 100.00 | | 75%ile | 100.00 | | 75%ile | 100.00 | |
| | Social functioning | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | 100.00 | 25%ile | 100.00 | *p*=0.084 |
| | | | 75%ile | 100.00 | | 75%ile | 100.00 | | 75%ile | 100.00 | |
| | Financial difficulties | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.444 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Global health status/QoL | 83.33 | 25%ile | 60.42 | 83.33 | 25%ile | 50.00 | 79.17 | 25%ile | 66.67 | *p*=0.992 |
| | | | 75%ile | 83.33 | | 75%ile | 91.67 | | 75%ile | 83.33 | |
| CX24 | Symptom Experience | 6.06 | 25%ile | 3.03 | 6.06 | 25%ile | 3.03 | 6.06 | 25%ile | 0.00 | *p*=0.016* |
| | | | 75%ile | 9.09 | | 75%ile | 10.61 | | 75%ile | 9.09 | |
| | Lymphedema | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.472 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Peripheral Neuropathy | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.449 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Menopausal Symptoms | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.276 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |
| | Body Image | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.002** |
| | | | 75%ile | 11.11 | | 75%ile | 11.11 | | 75%ile | 0.00 | |
| | Sexual Worry | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.455 |
| | | | 75%ile | 0.00 | | 75%ile | 0.00 | | 75%ile | 0.00 | |

(*Continued*)

**Table 2** (Continued).

| | | Median: Before | | | Median: After 3rd Month | | | Median: After 6th Month | | | *p*-value of Friedman Test |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sexual Activity | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | *p*=0.178 |
| | | | 75%ile | 33.33 | | 75%ile | 33.33 | | 75%ile | 33.33 | |
| | Sexual/Vaginal Functioning | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | 0.00 | 25%ile | 0.00 | (*p*=0.368) |
| | | | 75%ile | 4.17 | | 75%ile | 8.33 | | 75%ile | 4.17 | |
| | Sexual Enjoyment | 50.00 | 25%ile | 25.00 | 33.33 | 25%ile | 25.00 | 33.33 | 25%ile | 25.00 | (N/A) |
| | | | 75%ile | 50.00 | | 75%ile | 25.00 | | 75%ile | 25.00 | |

**Notes**: Open columns indicate Functional scales, Global health status / QoL (the higher, the better) and gray columns indicate Symptom scales / items (the lower, the better), **p*<0.05, ***p*<0.01 (significantly different). EORTC QLQ-C30 and QLQ-CX24 © EORTC Quality of Life Group. Used with permission.

blood in stool (motions), passing water/urine frequently, pain or a burning feeling when passing water/urinating, urine leakage, difficulty in emptying bladder, pain in lower back, irritation or soreness in vagina or vulva, discharge, or abnormal bleeding ($p$=0.016). The fourth item was CX24 Body Image, ie, feeling less physically attractive, less feminine, or dissatisfied with body image ($p$=0.002).

## Significant Scales among Different Time Points

To further validate the significant differences among the time points, we conducted a comparison using the Wilcoxon signed-rank test (Table 3). The results revealed a significant difference in C30 emotional functioning between the preoperative time point and 3 months after surgery ($p$=0.004) and also between the preoperative time point and 6 months after surgery ($p$=0.001). There were significant differences in CX24 Symptom Experience between the preoperative time point and 6 months after surgery ($p$=0.019) and also between 3 and 6 months after surgery ($p$=0.004). Similarly, for CX24 Body Image, significant differences were found between the preoperative time point and 6 months after surgery ($p$=0.003) and also between 3 and 6 months after surgery ($p$=0.005). In contrast, based on the Friedman test, there was a significant difference in C30 Physical functioning ($p$=0.032) between the preoperative time point and 3 months after surgery but only an equivocal difference between these time points based on the Wilcoxon signed-rank test ($p$=0.055).

**Table 3** EORTC QLQ Scales with Significant Differences on Friedman Test and Wilcoxon Signed-Rank Test

| EORTC Scales | Parameter | Before | After 3rd Month | After 6th Month | *p*-value of Friedman Test | *p*-value of Wilcoxon Signed-Rank Test |
|---|---|---|---|---|---|---|
| Emotional functioning score on C30 | Median<br>Mean<br>SD | 83.33<br>83.33<br>18.69 | 95.83<br>89.58<br>13.86 | 100.00<br>91.2<br>13.21 | *p*=0.001** | Before / After 3rd:*p*=0.004**<br>Before / After 6th:*p*=0.001**<br>After 3rd / 6th:*p*=0.602 |
| Symptom Experience score on CX24 | Median<br>Mean<br>SD | 6.06<br>7.13<br>6.97 | 6.06<br>8.35<br>7.33 | 6.06<br>5.08<br>4.41 | *p*=0.016** | Before / After 3rd:*p*=0.289<br>Before / After 6th:*p*=0.019*<br>After 3rd / 6th:*p*=0.004** |
| Body Image score on CX24 | Median<br>Mean<br>SD | 0.00<br>6.16<br>12.27 | 0.00<br>7.51<br>12.57 | 0.00<br>1.5<br>7.48 | *p*=0.002** | Before / After 3rd:*p*=0.389<br>Before / After 6th:*p*=0.003**<br>After 3rd / 6th:*p*=0.005** |
| Physical functioning score on C30 | Median<br>Mean<br>SD | 100.00<br>97.02<br>6.14 | 100.00<br>99.12<br>3.17 | 100.00<br>98.07<br>4.36 | *p*=0.032* | Before / After 3rd:*p*=0.055†<br>Before / After 6th:*p*=0.319<br>After 3rd / 6th:*p*=0.063 |

**Notes**: **p*<0.05, ***p*<0.01 (significantly different), †This was not statistically significant, although there was a trend for difference. EORTC QLQ-C30 and QLQ-CX24 © EORTC Quality of Life Group. Used with permission.


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## Time Course for Discharge and Abnormal Bleeding

Significant differences were seen for the Symptom Experience of the QLQ-CX24 (Table 2 and Table 3), which contains an important set of questions related to disease-specific symptoms. Since this scale contained various symptoms, we pinpointed the ones that were specifically different for eleven question items. Two of the 11 items, vaginal discharge and abnormal bleeding, showed significant differences, as shown in Tables S1 and 4. There was a significant difference in vaginal discharge between 3 and 6 months after surgery ($p$=0.004). Additionally, there was a significant difference in abnormal discharge between the preoperative time point and 3 months after surgery ($p$=0.003) and also between the preoperative time point and 6 months after surgery ($p$=0.001).

## Time Course for Sexual Activity

For the question regarding sexual activity, 33.3% (13/39) of patients (CX-24, Question 49) responded that they did not have sex during the 4 weeks before surgery (Table 5). The frequency of patients not having sex reached 76.9% (30/39) and 43.6% (17/39) at 3 and 6 months after surgery, respectively. This data point had almost recovered to normal levels at 6 months after surgery. When asked if they enjoyed sex (Question 54), 53.8% (21/39) of patients responded that they had enjoyed sex "a little" or "quite a bit" before surgery. Only 10.3% (4/39) of patients responded the same way at 3 months after surgery. However, at 6 months after surgery, this data point had recovered to normal levels, with 43.6% (17/39) of patients responding this way. Notably, only 5.1% (2/39) of patients responded that they had "enjoyable sexual activity" at 6 months after surgery.

**Table 4** EORTC QLQ-CX24 Symptom Experience with Significant Differences on Friedman Test and Wilcoxon Signed-Rank Test

| CX24 Symptom Experience Single Items | Parameter | Before | After 3rd Month | After 6th Month | $p$-value of Friedman Test | $p$-value of Wilcoxon Signed-Rank Test |
|---|---|---|---|---|---|---|
| Discharge | Median<br>Mean<br>SD | 33.33<br>23.42<br>17.33 | 33.33<br>31.53<br>31.37 | 0.00<br>17.12<br>18.63 | $p$=0.011** | Before / After 3rd:$p$=0.062<br>Before / After 6th:$p$=0.052<br>After 3rd / 6th:$p$=0.004** |
| Abnormal bleeding | Median<br>Mean<br>SD | 0.00<br>1.80<br>7.64 | 0.00<br>12.61<br>19.80 | 0.00<br>0.90<br>5.48 | $p$=0.0001** | Before / After 3rd:$p$=0.003**<br>Before / After 6th:$p$=0.001**<br>After 3rd / 6th:$p$=0.564 |

**Notes**: **$p$<0.01 (significantly different). EORTC QLQ-C30 and QLQ-CX24 © EORTC Quality of Life Group. Used with permission.

**Table 5** Sexual Activity for Questions 48–54 in QLQ-Cx24

| | Description Score | Not at All 1 | A Little 2 | Quite a Bit 3 | Very Much 4 | No Response | Total |
|---|---|---|---|---|---|---|---|
| Q48 | Pre-treatment | 26 (66.7%) | 10 (25.6%) | 0 (0%) | 1 (2.6%) | 2 (5.1%) | 39 |
| | After 3 months | 20 (51.3%) | 12 (30.8%) | 2 (5.1%) | 0 (0%) | 5 (12.8%) | 39 |
| | After 6 months | 25 (64.1%) | 11 (28.2%) | 1 (2.6%) | 0 (0%) | 2 (5.1%) | 39 |
| Q49 | Pre-treatment | 13 (33.3%) | 25 (64.1%) | 0 (0%) | 0 (0%) | 1 (2.6%) | 39 |
| | After 3 months | 30 (76.9%) | 7 (17.9%) | 0 (0%) | 0 (0%) | 2 (5.1%) | 39 |
| | After 6 months | 17 (43.6%) | 20 (51.3%) | 1 (2.6%) | 0 (0%) | 1 (2.6%) | 39 |
| Q50 | Pre-treatment | 17 (43.6%) | 9 (23.1%) | 0 (0%) | 0 (0%) | 13 (33.3%) | 39 |
| | After 3 months | 6 (15.4%) | 1 (2.6%) | 0 (0%) | 0 (0%) | 32 (82.1%) | 39 |
| | After 6 months | 15 (38.5%) | 5 (12.8%) | 1 (2.6%) | 0 (0%) | 18 (46.2%) | 39 |
| Q51 | Pre-treatment | 26 (66.7%) | 0 (0%) | 0 (0%) | 0 (0%) | 13 (33.3%) | 39 |
| | After 3 months | 7 (17.9%) | 0 (0%) | 0 (0%) | 0 (0%) | 32 (82.1%) | 39 |
| | After 6 months | 21 (53.8%) | 0 (0%) | 0 (0%) | 0 (0%) | 18 (46.2%) | 39 |

(*Continued*)

**Table 5** (Continued).

| | Description Score | Not at All 1 | A Little 2 | Quite a Bit 3 | Very Much 4 | No Response | Total |
|---|---|---|---|---|---|---|---|
| Q52 | Pre-treatment | 24 (61.5%) | 2 (5.1%) | 0 (0%) | 0 (0%) | 13 (33.3%) | 39 |
| | After 3 months | 6 (15.4%) | 1 (2.6%) | 0 (0%) | 0 (0%) | 32 (82.1%) | 39 |
| | After 6 months | 20 (51.3%) | 1 (2.6%) | 0 (0%) | 0 (0%) | 18 (46.2%) | 39 |
| Q53 | Pre-treatment | 19 (48.7%) | 6 (15.4%) | 1 (2.6%) | 0 (0%) | 13 (33.3%) | 39 |
| | After 3 months | 6 (15.4%) | 1 (2.6%) | 0 (0%) | 0 (0%) | 32 (82.1%) | 39 |
| | After 6 months | 16 (41.0%) | 4 (10.3%) | 0 (0%) | 0 (0%) | 18 (46.2%) | 39 |
| Q54 | Pre-treatment | 3 (7.7%) | 17 (43.6%) | 4 (10.3%) | 0 (0%) | 15 (38.5%) | 39 |
| | After 3 months | 2 (5.1%) | 3 (7.7%) | 1 (2.6%) | 0 (0%) | 33 (84.6%) | 39 |
| | After 6 months | 2 (5.1%) | 11 (28.2%) | 4 (10.3%) | 2 (5.1%) | 20 (51.3%) | 39 |

**Notes**: 48; Have you worried that sex would be painful?, 49; Have you been sexually active during the past 4 weeks?, 50; Has your vagina felt dry during sexual activity?, 51; Has your vagina felt short?, Has your vagina felt tight?, 53; Have you had pain during sexual intercourse or other sexual activity?, 54; Was sexual activity enjoyable for you? EORTC QLQ-C30 and QLQ-CX24 © EORTC Quality of Life Group. Used with permission.

## Discussion

We examined the emotional well-being, physical changes, and sexual activity of CIN patients before and after surgical intervention. Numerous reports have investigated similar outcomes in cervical cancer and CIN. However, since different survey questionnaires have been used and reported in cancer[17,18] and CIN,[19,20] it remains unclear how beneficial CIN interventions can be. The purpose of this study was to comprehensively analyze the well-being of CIN patients using survey questionnaires that are typically employed for cancer patients. Then, by administering the same survey questionnaire to future cancer patients, we can potentially determine how advantageous CIN treatment can be compared to disease progression. The EORTC initiated a research program to develop an integrated, modular approach for evaluating the QOL of patients participating in international clinical trials.[21] The EORTC-QLQ-C30 has proved to be a reliable and valid measure of the QOL of cancer patients. The EORTC-QLQ-CX24 was developed for patients with cervical cancer to supplement the EORTC-QLQ-C30 core questions.[22] Both questionnaires have subsequently been used for cervical cancer patients undergoing surgery, chemotherapy, or radiation therapy.[23–28]

Interestingly, Klügel et al conducted a questionnaire survey using scores on the Hospital Anxiety and Depression Scale (HADS) and health-related QOL (SF-12) for patients with CIN2. Their depression or anxiety symptoms were significant compared with those of healthy women, and the intervention did not lead to any symptom improvement.[29] Others reported that CIN interventions led to improvements in self-assessment, based on the use of their original questionnaire.[30,31] The standardized questionnaires should be used worldwide for objective evaluation and comparison across languages and regions. Even when the intervention methods differ, using the same questionnaire allows for easier comparison and examination of different treatment approaches. The EORTC-QLQ-C30 and QLQ-CX24 have already been used for patients undergoing trachelectomy,[32] so their results can eventually be compared with the findings of this study.

Previous reports have assessed patients who experience emotional instability upon receiving a CIN diagnosis.[29,33–35] Feelings of sadness, anger, disappointment, and fear are common, as well as anxiety associated with colposcopy examinations.[36] Understanding the physical and psychological changes that patients undergo before and after treatment is particularly crucial for healthcare professionals providing patient-centered care. However, limited information is available regarding these aspects, which underscores the need for further research.[31,34] Since ablation was considered to be minimally invasive and did not significantly affect the patient's daily activities, little attention was paid to the patient's emotional and physical changes before and after the procedure. Thus, data related to this particular aspect of ablation is lacking. To address this issue, during our clinical trial for ablation, the questionnaire survey was administered to patients before and after surgery. As anticipated, there were almost negligible variations noted in the questionnaire items between the pre- and postoperative assessments. However, we found that emotional functioning, body image,

symptom experience, and physical functioning were statistically different before and after surgery. Analysis of the relationship between body image (including attractiveness, femininity, and body dissatisfaction) and emotional functioning (such as tension, worries, irritability, and depression) revealed that surgery had a positive impact on women's mental health, by restoring body confidence and reducing anxiety. The symptom experience, ie, discharge and abnormal bleeding, also improved after treatment. There was a significant difference in discharge between 3 months and 6 months after surgery. The discharge may be partially attributed to the CIN but could also have been caused by cervical erosion due to surgery. Discharge levels gradually decrease after surgery, thereby contributing to improved QOL. Additionally, there was a significant difference in abnormal bleeding levels between the preoperative time point and 3 months after surgery, while no difference was found between 3 months and 6 months after surgery. This suggests that wound healing is achieved within at least 3 months post-surgery. Generally, patients do not report any bleeding beyond 2 months after surgery, which is in line with both the survey results and clinical observations. An equivocal difference in physical functioning was also noted between the preoperative time point and 3 months after surgery. This could be attributed to the patients' subjective perception of feeling less active or experiencing difficulty in movement after surgery, rather than being an indication of any actual physical issues.

Regarding the sexual activity question, about one-third of patients reported that they did not have any sexual intercourse during the last 4 weeks before surgery. In this particular group, there was a delay between diagnosis confirmation and treatment initiation, so during that time, they may not have wanted to engage in sexual intercourse. At 3 months after surgery, 4 out of 5 patients were not having sex, presumably due to their symptoms. These findings make sense since it usually takes 1 or 2 months for the surgical wound to heal. Since ablation is less invasive than excision, we expected that there would be fewer complaints of pain during sexual intercourse. Our results from Q53 of QLQ-CX24 indicated that the postoperative pain score at 6 months was the same as the preoperative score (Table 5). Six months after surgery, data related to the frequency of intercourse had also recovered to preoperative levels. Since there were no comparisons conducted with healthy couples, it remains unclear how much sex is impacted by the disease, but this study was the first to demonstrate that sexual activity conditions had returned to preoperative levels at least 6 months after surgery. These findings may also have direct clinical implications. Gynecologists can use this information to counsel patients who are considering fertility-preserving treatment for CIN, by explaining that diathermy ablation is associated with improvements in emotional functioning, body image, and symptom relief, with sexual activity returning to preoperative levels within 6 months. Such data may help alleviate patient anxiety and support shared decision-making.

There were some limitations to this study. First, the sample size was small. It should also be noted that, among the enrolled patients, 71.8% were parous women and 97.4% were married. It is important to acknowledge that different results may be obtained for patients who are unmarried and nulliparous. The QLQ-C30 questionnaire was originally prepared for cervical cancer, so it has not been completely adapted for CIN. However, a QLQ-CX24 questionnaire survey for CIN has been published in a previous study.[37] There is a questionnaire survey that is specific to dysplasia, known as the FACIT-CD,[38] but it currently has no Japanese translation and thus could not be used in this study. Furthermore, there is always the question of how honest patients will be when answering questions about their sexual activity. It may be necessary to take precautions in the future, such as sending survey questionnaires to a different clinical institution, in order to ensure the confidentiality of personal information. However, if surveys are conducted by mail, there is a risk of even lower response rates. In Japan, there are many people who consider it extremely embarrassing to answer questions about sexual activity. The actual response rate to such questions in this survey was low, and thus a statistical analysis was not conducted.

Additionally, in this survey, there were no direct questions regarding the recurrence of cervical neoplasms. Patients treated for high-grade cervical intraepithelial neoplasia reportedly have a higher risk of cervical or vaginal cancer compared to controls.[39,40] The persistence and recurrence of cervical dysplasia are known to be influenced by multiple factors, including host immunity, viral characteristics, and treatment modality.[41] Post-treatment HPV vaccination has been shown to reduce the risk of recurrence, and in the future, vaccination after treatment should be considered to promote mental stability in patients.[42–44] Recent systematic reviews have further confirmed the potential therapeutic role of HPV vaccination after conization in reducing the risk of recurrent high-grade cervical dysplasia.[45] The absence of a control group, such as healthy women or those treated with other modalities, restricts the generalizability of our findings. Future studies incorporating such comparison groups would provide stronger evidence for the external validity of our conclusions.

This study also has certain strengths. As a prospective clinical trial, we administered the questionnaire survey before and after surgery, so we were able to conduct the survey under protocol. The age group was narrowed down to 20–30 years of age. The use of a questionnaire that is employed worldwide will make it easy to compare the scores with those of other treatments, including radical hysterectomy and trachelectomy, in future studies.[32,46–48]

## Conclusion

In this prospective clinical trial, diathermy ablation for precancerous cervical lesions demonstrated a positive impact on the patients' psychological well-being, physical functioning, and symptom relief. Significant improvements were observed in emotional functioning, body image, and symptom experience after surgery.

Using internationally standardized QOL questionnaires, we confirmed that the patients' overall QOL and sexual activity conditions recovered to preoperative levels within six months after surgery.These findings underscore the importance of minimally invasive fertility-preserving treatments and highlight the value of standardized QOL assessments in future comparative studies across different cervical disease treatments.

## Registration of the Clinical Trial

This study was registered in the clinical trial registration system of the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR ID: UMIN000024483).

Trial open to the public through the website: 01/11/2016

First patient registration: 30/01/2017

## Data Sharing Statement

De-identified individual participant data, including baseline clinical characteristics and responses to the EORTC-QLQ-C30 and QLQ-CX24 questionnaires, that support the results reported in this article will be made available upon reasonable request. Additional study-related documents, such as the study protocol and statistical analysis plan, will also be accessible. Data will be available beginning 6 months after publication of this article and for a period of 3 years thereafter. Researchers who provide a methodologically sound proposal may request access by contacting the corresponding author (Takuma Fujii; fujiit44@fujita-hu.ac.jp).

## Statement of Ethics

All procedures involving human participants were performed in accordance with the ethical standards of the Institutional Research Committee and the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the Ethical Committee of Fujita Health University (HM20-096). Written informed consent was obtained from the patients.

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We received the EORTC Item Academic Access agreement via email to S.B. (DocuSign Envelop ID: A5C27FC5-7180-4BF1-A974-EFE51AD1E718). We received the Japanese and Portuguese (Brazil) questionnaires via email from EORTC (ID:62842 and 62868).

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## Disclosure

The authors declare that they have no conflicts of interest for this work.

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