

Cervical Er:YAG Laser in Low-Risk CIN Management: A Promising Option Compared to Expectant Management and Conservative Treatments — A Pilot Study

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Abstract

Purpose: To compare the colposcopic regression rates and genital HPV (gHPV) clearance of cervical Er:YAG laser versus expectant management (follow-up) and a silicon dioxide-based vaginal gel (DeflaGyn®) in patients with low-risk cervical dysplasia.

Methods: A retrospective observational cohort study of 118 HPV-vaccinated patients with CIN1 (age >25) or CIN2 (age 25–30) attending a single gynecology clinic. Patients were allocated to one of three groups: Er:YAG laser (n=46), conservative follow-up (n=41), or DeflaGyn® vaginal gel (n=31). Primary outcomes were histological regression and gHPV clearance at 4–6 months (laser/gel) and up to 27 months (follow-up). Multivariate logistic regression identified independent predictors of HPV clearance.

Results: Colposcopic regression was achieved in 91.3% of the laser group versus 64.5% in the gel group (p=0.014). Complete gHPV clearance was 52.2% (laser) versus 35.5% (gel) (p=NS, univariate). Multivariate analysis showed Er:YAG laser independently increased the likelihood of HPV clearance 3.26-fold compared to DeflaGyn® (aOR=3.26; 95% CI: 1.11–9.56; p=0.031). In the conservative follow-up group, 78% demonstrated spontaneous regression by 27 months, but 7% (n=3) progressed to CIN2/3 requiring excisional treatment.

Conclusions: Er:YAG cervical laser demonstrated superior colposcopic regression and HPV clearance compared to silicon dioxide-based vaginal gel in patients with low-risk cervical dysplasia. These preliminary findings support the need for prospective randomized trials.

1. Introduction

Genital human papillomavirus (gHPV) infection is among the most prevalent sexually transmitted viral infections worldwide [1]. In the vast majority of cases, the infection is cleared spontaneously by the immune system without medical intervention. Nevertheless, persistent gHPV infection is recognized as the principal etiological factor underlying cervical intraepithelial neoplasia (CIN), vulvar and anal intraepithelial lesions, and invasive cancers of the cervix, anus, and oropharynx [2, 3].

Colposcopy-directed targeted biopsy is the gold standard for diagnosis of cervical dysplasia. Although intraepithelial lesions carry a potential for progression to invasive cancer, the probability of progression in CIN1 is markedly low. Consistent with the current risk-stratified approach, the 2019 ASCCP and ACOG guidelines recommend surveillance as the primary strategy for CIN1 (LSIL), with excisional treatment (conization) appropriate only in limited high-risk scenarios [4, 5].

Regression rates for CIN2 in women under 30 range between 60–70%, and guidelines accordingly recommend a surveillance protocol in this age group. A recent analysis based on Norwegian national data reported 1-year risks of progression to CIN2 and CIN3 of 9.1% and 5.7%, respectively, in colposcopically confirmed CIN1 [2]. In women under 30 with CIN2, the risk of progression to CIN3 has been reported at 5–11% [2, 6].

In clinical practice, a substantial proportion of patients diagnosed with high-risk HPV, CIN1, or CIN2 under age 30 turn toward internet- and social media-sourced information and are inclined toward alternative therapies with limited or no scientific basis. DeflaGyn® gel belongs to this category; classified as a medical device, it contains silicon dioxide along with a combination of sodium selenite and citric acid ('Deflamin'). The silicon dioxide is purported to bind potentially pathogenic agents, while the sodium selenite–citric acid combination is claimed to exert potent antioxidant effects; through this dual action, the product is alleged to clear gHPV, with published studies claiming elimination of high-risk gHPV in 87% of cases. DeflaGyn® gel is self-administered into the vagina using an applicator daily for three months, except during menstruation [7, 8].

Comparative ex vivo studies on mucosal tissue have demonstrated that Er:YAG laser incisions produce a significantly narrower thermal damage zone than CO₂ laser, with the latter causing vacuolation and prominent carbonization at cutting margins [9]. Under equivalent conditions, CO₂ laser thermal damage width is approximately twice that of Er:YAG, highlighting Er:YAG laser as a rational option when the goal is to minimize thermal effects on cervical tissue.

The specific aim of this pilot study was to evaluate the clinical outcomes of Er:YAG laser therapy as an office-based, tissue-preserving option for patients with CIN1 or CIN2 under age 30 — a population for whom conventional surveillance is recommended but who often seek active intervention — by comparing it with expectant management and DeflaGyn® vaginal gel.

2 Materials and Methods

2.1 Study Design and Patient Selection

This retrospective observational cohort study compared different clinical approaches and the efficacy of cervical Er:YAG laser in the management of cervical dysplasia. Ethical approval was obtained from the Clinical Research Ethics Committee of the Istanbul Faculty of Medicine (Decision No: E-29624016-050.99-4016220). Data from 302 patients were initially screened; 118 patients who fully met the inclusion criteria were incorporated into the final analysis (Fig. 1). All patients had been vaccinated with 4-valent or 9-valent HPV vaccine. The study population was classified into three groups according to the treatment modality or surveillance decision applied (Table 1).

[Insert Figure 1 here]

2.2 Study Groups

Group 1 — Er:YAG Laser (n=46): Patients presenting between January 2023 and September 2025 with CIN1 (age >25) or CIN2 (age 25–30). Fifty-two eligible patients were initially evaluated; 46 who completed follow-up were included. Patients had no immunosuppressive systemic disease, were not taking immunosuppressive medications, were not pregnant, and provided informed consent.

Group 2 – Conservative Follow-up (n=41): Patients seen between January 2018 and September 2025 who declined any alternative treatment and chose standard clinical surveillance. Of 153 screened, 41 with complete gHPV typing, Pap smear, and colposcopic biopsy data who adhered to long-term follow-up were enrolled.

Group 3 – Vaginal Gel / DeflaGyn® (n=31): Of 97 patients with low-risk cervical dysplasia who preferred DeflaGyn® gel while declining Er:YAG laser, only 48.4% (n=47) used the gel continuously for 3 months. Of these, 31 patients with complete data were included.

2.3 Laser Procedure and Technical Parameters

Cervical Er:YAG laser was performed under colposcopic guidance in the lithotomy position, following visualization of the ectocervix with 3% acetic acid and Lugol's iodine solution. A Fotona SP Dynamis device with an R11 handpiece was used, with settings of 7 J/cm² fluence, 20 Hz frequency, SP (Short Pulse) mode, and a 3 mm spot size; the procedure was completed in a single session with 3 passes, without local anesthesia, at least one week prior to the expected menstrual period with pre-procedural coital restriction. HPV genotyping was performed using the geneMAP™ HPV HR & 6/11 Genotyping Kit for all participants.

2.4 Clinical Outcome Measures

Primary outcome measures were defined as cellular improvement (histological regression), gHPV clearance, and time to clearance in the conservative group. Post-intervention gHPV clearance responses were classified as: complete response (complete negativization of gHPV DNA); partial response (reduction in HPV types detected in multi-type infection); or no improvement (stable positivity). Partner change within less than 6 months (multi-partner status) or presence of genital warts in the patient's partner was incorporated as an additional risk factor.

2.5 Statistical Analysis

All statistical analyses were performed using IBM SPSS version 29.0 (IBM Corp., Armonk, NY, USA). Normality was examined using Kolmogorov-Smirnov and Shapiro-Wilk tests; continuous variables are reported as median (IQR) and categorical variables as frequency and percentage. Kruskal-Wallis test was used for between-group comparisons, with Dunn's test for post-hoc analysis. The chi-square test with Bonferroni correction was applied for categorical data. CIN1 clearance times in the conservative follow-up group were modeled by the Kaplan-Meier method. Statistical significance was set at $p < 0.05$.

3 Results

3.1 Baseline Characteristics

No statistically significant differences were found between groups with respect to marital status, parity, or smoking. Age differed significantly among the three treatment groups ($p = 0.034$). Patients in the

Er:YAG laser group had a lower median age (31 years, IQR: 28–36) than those in the conservative treatment group (36 years, IQR: 30–44.5). The conservative follow-up group inherently differed in observation duration from the other two groups. The highest proportion of CIN2 at colposcopic biopsy (23.9%) was observed in the Er:YAG laser group. Detailed demographic and baseline clinical characteristics are presented in Table 1.

3.2 Conservative Follow-up Group

In the conservative follow-up group (median follow-up 18 months; findings reported at month 27), spontaneous CIN1 regression was observed in 78% of patients (Fig. 2). This group demonstrated a strong independent association with HPV clearance (aOR=9.51; 95% CI: 2.79–32.42; $p<0.001$) (Table 3). However, 7% of patients ($n=3$) progressed to high-grade dysplasia (CIN2/3) during follow-up and required LEEP conization.

[Insert Figure 2 here]

3.3 Colposcopic Regression

Clinical outcomes following all treatment approaches are summarized in Table 2. Colposcopic regression differed significantly among the groups ($p = 0.014$). Post hoc analysis showed that the Er:YAG laser demonstrated statistically and clinically significant superiority over DeflaGyn® vaginal gel in colposcopic regression. Despite harboring a higher proportion of CIN2 lesions at baseline, the colposcopic cellular improvement rate in the laser group reached 91.3%, compared to only 64.5% in the vaginal gel group. Representative colposcopic images before and after Er:YAG laser treatment are shown in Fig. 3.

[Insert Figure 3 here]

3.4 HPV Clearance

Complete HPV clearance occurred in 52.2% of the Er:YAG laser group versus 35.5% in the vaginal gel group. Although this difference was not statistically significant in univariate analysis, multivariate logistic regression demonstrated that Er:YAG laser independently increased the probability of HPV clearance 3.26-fold compared to DeflaGyn® vaginal gel (aOR=3.26; 95% CI: 1.11–9.56; $p=0.031$) (Table 3).

3.5 Independent Predictors of HPV Clearance

Univariate and multivariate logistic regression analyses for HPV clearance are presented in Table 3. The absence of additional risk factors (recent multi-partner status or presence of genital warts in the partner) was a strong independent predictor of HPV clearance (aOR=3.8; 95% CI: 1.40–10.33; $p=0.009$). Age, marital status, smoking, genital wart status, HPV 16/18 positivity, and obstetric history had no independent statistical effect. Single-type HPV infection positively influenced clearance in univariate

analysis (OR=2.70; p=0.011), but attenuated to borderline significance in multivariate analysis (aOR=2.32; p=0.066).

3.6 Adverse Events

No clinically significant adverse effects were documented in the Er:YAG laser group. Two patients experienced mild post-procedural vaginal bleeding, which resolved spontaneously; no additional complications were recorded. In the vaginal gel group, no adverse events such as mucosal irritation or allergic reactions were identified in retrospectively reviewed medical records.

4 Discussion

One of the most consistent principles in cervical dysplasia management guidelines is that expectant management is the primary approach for low-grade lesions, given the high spontaneous regression rate (60–70%) of CIN1 and CIN2 in women under 30. In our series, this rate was 78% at 27 months – confirming guideline recommendations.

However, with the widespread expansion of digital platforms, interest in 'alternative' treatment approaches lacking a scientific basis has increased markedly. Content circulating on social media reduces patient adherence to surveillance protocols and leads patients toward poorly evidenced, costly, and labor-intensive methods [10, 11].

The IPVS announced at Eurogin 2026 that they will formally evaluate alternative methods in gHPV treatment [12]. To date, only 5 human studies on DeflaGyn® have been published [13]. The core evidence derives from three studies from the same patient population as a single prospective RCT, reporting cytological regression of 72.2% vs. 25% in LSIL/HSIL; 76% vs. 25% in p16/Ki-67-positive patients; and 83% vs. 18% p16/Ki-67 regression with 51% vs. 9% hr-HPV clearance at 3 months. These results are impressive under controlled conditions.

In contrast, a review of retrospective records revealed that only 48.4% of patients completed the full 3-month course continuously. Financial constraints, application difficulty, and loss of motivation were the most frequently cited reasons. This real-world compliance gap has not been previously documented in the literature. Even among the compliant per-protocol subgroup analyzed here, treatment response rates for both cervical cytology and gHPV clearance were inferior to those of Er:YAG laser (aOR=3.26; 95% CI: 1.11–9.56; p=0.031). It should be acknowledged that the DeflaGyn® arm was evaluated using a per-protocol approach including only compliant patients, and no intent-to-treat analysis was performed.

Cervical Er:YAG laser application offers a rational and clinically feasible response to the need for active intervention. Under equivalent conditions, CO₂ laser thermal damage width is approximately twice that of Er:YAG, and CO₂ laser produces prominent carbonization in tissue [9]. Consequently, Er:YAG laser causes considerably less cervical tissue damage while achieving highly effective evaporation – particularly relevant for young patients who have not completed their reproductive plans. Kyrgiou et al.'s meta-

analysis reported a relative risk of preterm birth of 1.56 for cryotherapy/CO₂ laser ablation techniques. Although studies specifically addressing the obstetric impact of cervical Er:YAG laser are still needed, clinical assessment of the tissue damage produced demonstrates considerably less cervical tissue loss than either CO₂ laser or cryotherapy.

To our knowledge, this is the first study to evaluate Er:YAG laser efficacy in low-risk CIN in comparison with alternative management strategies. The study has several important limitations. The non-randomized mixed retrospective design increases the risk of selection bias and limits causal inference. The case groups are small and retrospective selection was performed over a very wide time span. The follow-up duration of 4–6 months is too short to evaluate recurrences in HPV-related dysplasias. Furthermore, the extended recruitment window of the conservative and gel groups (2018–2025) introduces a potential temporal bias, as HPV genotype distributions and vaccination coverage may have shifted over time. Future prospective randomized studies are warranted.

In conclusion, this pilot study suggests that Er:YAG laser treatment is a promising option that may be offered to patients with low-grade cervical lesions seeking alternative management strategies, within the framework of evidence-based medicine and without compromising gynecologic oncology principles.

Declarations

Information note: The findings of this pilot study were previously presented at the EUROGIN 2026 meeting in Vienna (Abstract Book FC 24-6).

Funding: No funding was received for this study.

Competing Interests: The authors declare no competing interests.

Ethics Approval: Ethical approval was obtained from the Clinical Research Ethics Committee of the Istanbul Faculty of Medicine (Decision No: E-29624016-050.99-4016220). All patients provided written informed consent.

Data Availability: The datasets used are available from the corresponding author upon reasonable request.

Clinical Trial declaration: This study is a retrospective observational cohort study and does not constitute a clinical trial; therefore, clinical trial registration is not applicable.

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Tables

Table 1 Demographic and baseline clinical characteristics of the study groups

Variable	Total (n=118)	Conservative* (n=41)	Er:YAG Laser (n=46)	Vaginal Gel** (n=31)	p
Age, years, median (IQR)	34 (28–39)	36 (30–44.5) ^{abc}	31 (28–36) ^{ab}	34 (30–39) ^{abc}	0.034
Follow-up, months, median (IQR)	6 (5–14)	18 (14–31.5) ^{ab}	5 (4–6) ^a	6 (5–8) ^a	<0.001
Parity, n (%)					0.143
No	83 (70.3)	27 (65.9)	37 (80.4)	19 (61.3)	
Yes	35 (29.7)	14 (34.1)	9 (19.6)	12 (38.7)	
Marital status, n (%)					0.086
Single	73 (61.9)	21 (51.2)	34 (73.9)	18 (58.1)	
Married	45 (38.1)	20 (48.8)	12 (26.1)	13 (41.9)	
Smoking, n (%)	40 (33.9)	18 (43.9)	13 (28.3)	9 (29.0)	0.257
Genital warts, n (%)	20 (16.9)	5 (12.2)	10 (21.7)	5 (16.1)	0.473
Smear cytology, n (%)					NA
Negative	20 (16.9)	6 (14.6)	7 (15.2)	7 (22.6)	
ASC-H	3 (2.5)	1 (2.4)	1 (2.2)	1 (3.2)	
ASCUS	37 (31.4)	15 (36.6)	13 (28.3)	9 (29.0)	
LSIL/CIN 1	56 (47.5)	19 (46.3)	25 (54.3)	12 (38.7)	
HSIL/CIN 2	2 (1.7)	0 (0.0)	0 (0.0)	2 (6.5)	
Colposcopic biopsy, n (%)					0.015
CIN 1	102 (86.4)	40 (97.6) ^{ab}	35 (76.1) ^a	27 (87.1) ^{abc}	
CIN 2	16 (13.6)	1 (2.4) ^a	11 (23.9) ^{ab}	4 (12.9) ^{ab}	
HPV 16 and/or 18 (+), n (%)	53 (44.9)	14 (34.1)	22 (47.8)	17 (54.8)	0.193
Single-type HPV, n (%)	53 (44.9)	23 (56.1)	19 (41.3)	11 (35.5)	0.162
Additional risk†, n (%)	40 (33.9)	16 (39.0)	19 (41.3)	5 (16.1)	0.057

Superscript letters (a,b,c) indicate statistically homogeneous subsets (Dunn's test with Bonferroni correction).

*Conservative management: active surveillance with repeat testing and colposcopy/treatment only if persistence or progression occurs. **Vaginal gel formulation containing silicon dioxide, sodium selenite, and citric acid (DeflaGyn®). †Additional risk: patients with multiple sexual partners within the preceding 6

months or whose sexual partner has genital warts. Statistically significant *p* values (*p* < 0.05) are shown in bold. NA: Not applicable

Table 2 Clinical outcomes after therapeutic intervention and subsequent surveillance

Variable	Total (n=118)	Conservative (n=41)	Er:YAG Laser (n=46)	Vaginal Gel* (n=31)	<i>p</i>
Follow-up smear result, n (%)					NA
Negative	95 (80.5)	32 (78.0)	41 (89.1)	22 (71.0)	
ASCUS	5 (4.2)	0 (0.0)	2 (4.3)	3 (9.7)	
LSIL/CIN 1	14 (11.9)	6 (14.6)	3 (6.5)	5 (16.1)	
HSIL/CIN 2	4 (3.4)	3 (7.3)	0 (0.0)	1 (3.2)	
Smear regression (cytology improvement), n (%)	95 (80.5)	32 (78.0)	41 (89.1)	22 (71.0)	0.130
Colposcopic regression, n (%)	94 (79.7)	32 (78.0) ^{abc}	42 (91.3) ^a	20 (64.5) ^b	0.014
Follow-up HPV 16/18 positivity, n (%)	15 (12.7)	3 (7.3)	5 (10.9)	7 (22.6)	0.139
HPV clearance, n (%)					0.005
Complete clearance	67 (56.8)	32 (78.0) ^a	24 (52.2) ^a	11 (35.5) ^a	
Partial clearance [†]	25 (21.2)	4 (9.8) ^a	12 (26.1) ^a	9 (29.0) ^a	
No clearance	26 (22.0)	5 (12.2) ^a	10 (21.7) ^a	11 (35.5) ^a	
HPV improvement (combined), n (%)					0.001
Complete clearance	67 (56.8)	32 (78.0) ^a	24 (52.2) ^a	11 (35.5) ^a	
Partial or no clearance	51 (43.2)	9 (22.0) ^a	22 (47.8) ^a	20 (64.5) ^a	

Superscript letters (a,b) indicate statistically homogeneous subsets (Dunn's test with Bonferroni correction).

*Vaginal gel formulation containing silicon dioxide, sodium selenite, and citric acid (DeflaGyn®). †Partial clearance: in patients initially infected with multiple gHPV genotypes, a reduction in the number of HPV

types testing positive was classified as partial clearance. Statistically significant *p* values (*p* < 0.05) are shown in bold. NA: Not applicable

Table 3 Univariate and multivariate binary logistic regression analysis for HPV clearance

Variable	Univariate Analysis OR (95% CI)	p	Multivariate Analysis aOR (95% CI)	p
Age	1.02 (0.97–1.07)	0.410	1.01 (0.95–1.08)	0.695
Marital status				
Married	1.95 (0.90–4.21)	0.091	1.98 (0.77–5.10)	0.159
Single (Ref.)	1.0	—	1.0	—
Smoking				
No	0.82 (0.38–1.78)	0.613	1.03 (0.40–2.63)	0.950
Yes (Ref.)	1.0	—	1.0	—
Genital wart				
Yes	0.92 (0.35–2.41)	0.860	2.18 (0.62–7.63)	0.223
No (Ref.)	1.0	—	1.0	—
HPV type				
16/18	0.75 (0.36–1.55)	0.435	1.21 (0.51–2.86)	0.668
Other (Ref.)	1.0	—	1.0	—
HPV single/multiple				
Single type	2.70 (1.26–5.78)	0.011	2.32 (0.94–5.72)	0.066
Multiple (Ref.)	1.0	—	1.0	—
Additional risk				
None	2.07 (0.95–4.48)	0.066	3.80 (1.40–10.33)	0.009
Present (Ref.)	1.0	—	1.0	—
Parity				
Yes	1.43 (0.64–3.21)	0.388	1.20 (0.43–3.30)	0.727
No (Ref.)	1.0	—	1.0	—
Study group				
Conservative follow-up	6.46 (2.28–18.35)	<0.001	9.51 (2.79–32.42)	<0.001
Er:YAG Laser	1.98 (0.78–5.06)	0.152	3.26 (1.11–9.56)	0.031
Vaginal Gel (Ref.)	1.0	—	1.0	—

OR: Odds ratio; aOR: Adjusted odds ratio; CI: Confidence interval; Ref.: Reference category. Additional risk: patients with multiple sexual partners within the preceding 6 months or whose sexual partner has genital warts. Statistically significant *p* values (*p* < 0.05) are shown in bold.

Figures

Fig. 1

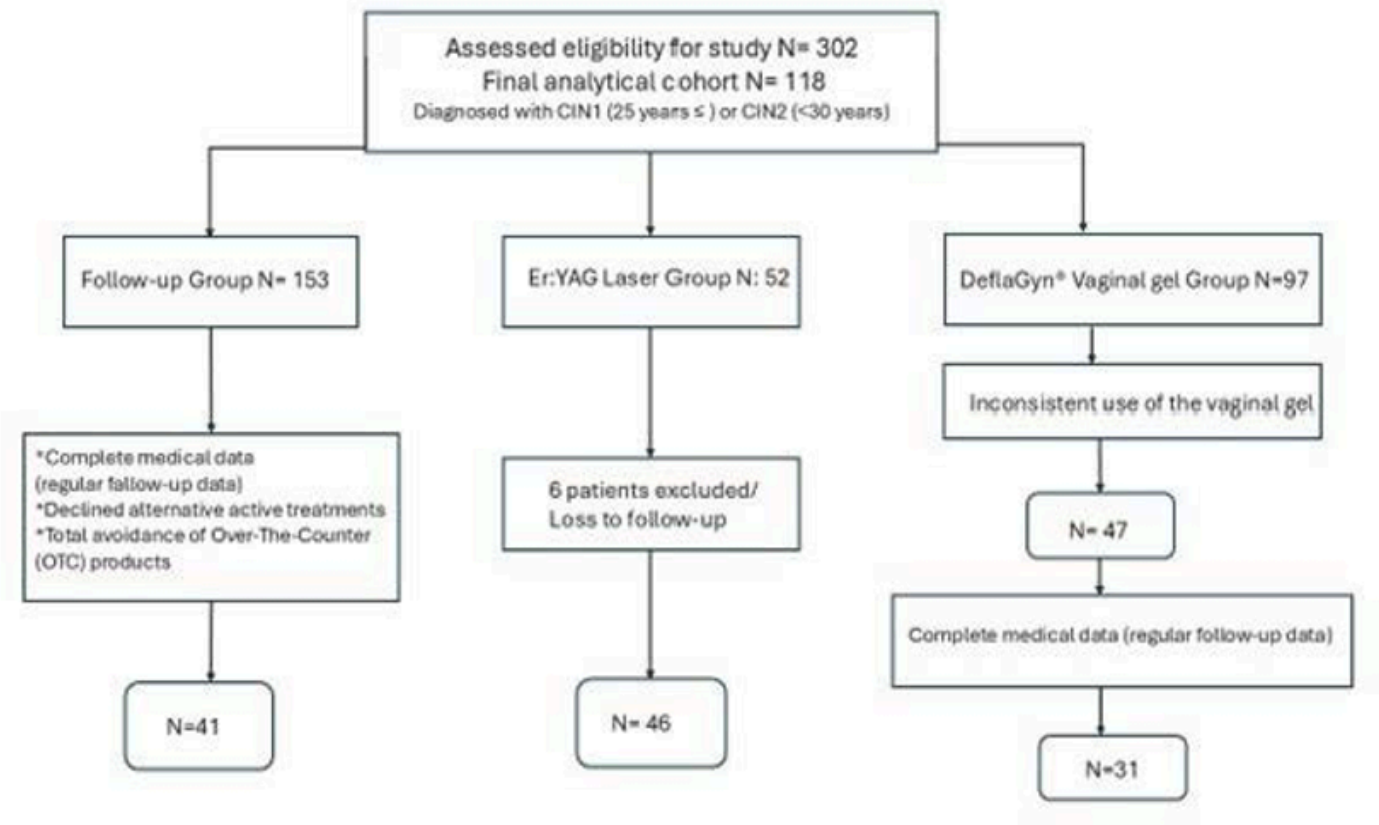


Figure 1

Study flow diagram. Of 302 patients initially screened, 118 met inclusion criteria and were allocated to three groups: Er:YAG laser (n=46), conservative follow-up (n=41), and DeflaGyn® vaginal gel (n=31)

Fig. 2

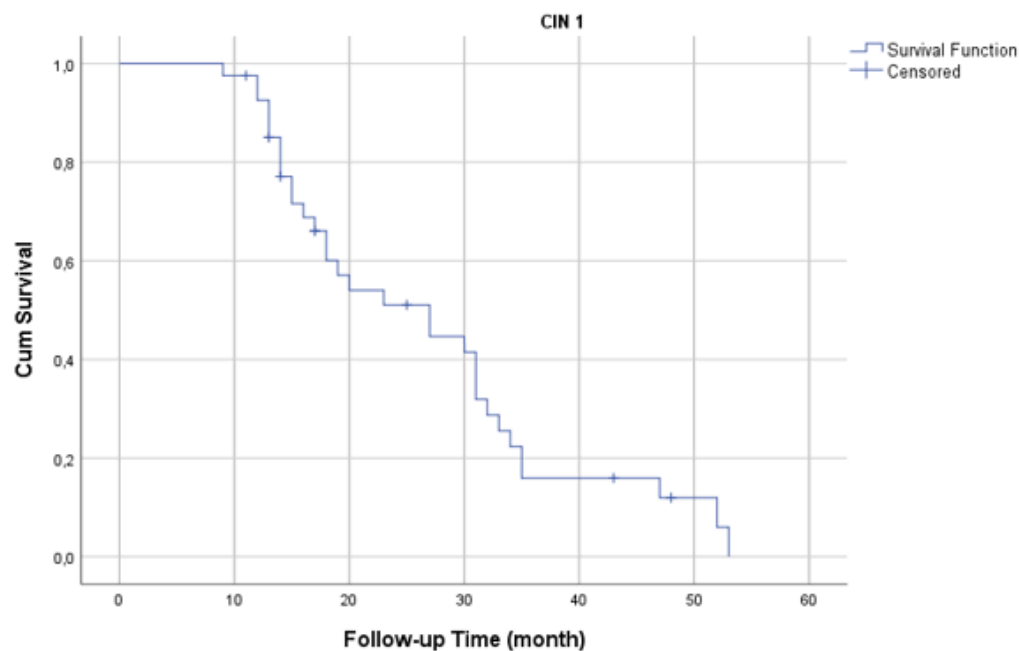


Figure 2

Kaplan-Meier survival curve for CIN1 clearance in the conservative follow-up group. The estimated median clearance time was 27 months (SE=5.46).

Fig. 3

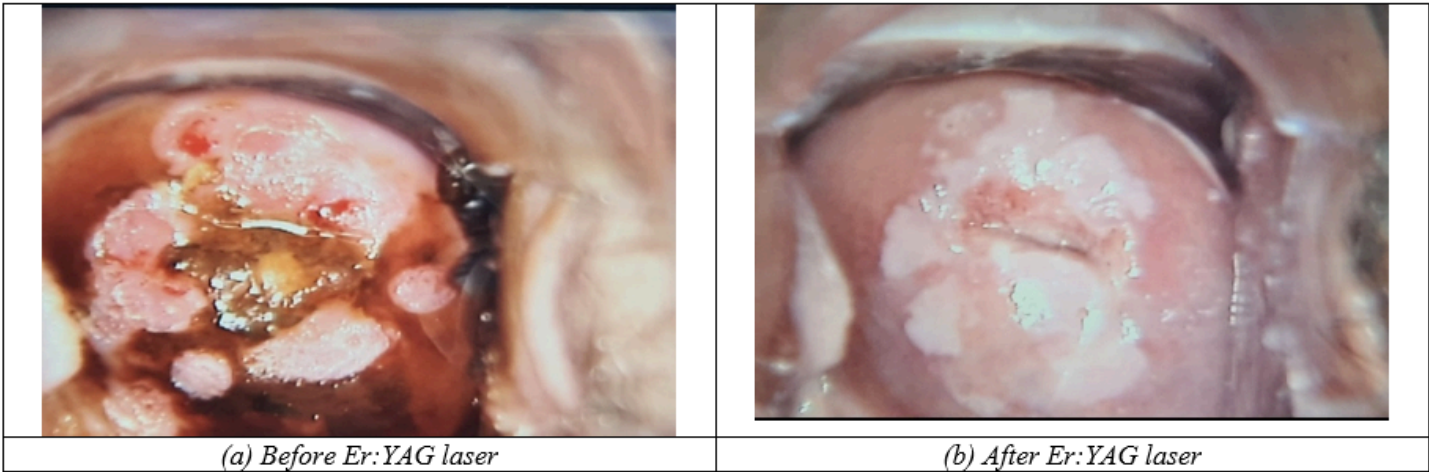


Figure 3

Representative colposcopic images of a 26-year-old patient with HPV 16 positivity and CIN2 on colposcopic biopsy (Pap smear: CIN1). (a) Pre-treatment acetowhite lesion at the cervical transformation zone. (b) Complete colposcopic regression 5 months after a single session of cervical Er:YAG laser ablation

