Last update: May ‘26

COLPOFIX®
Medical kit

Global Medical Brand Team

Laborest

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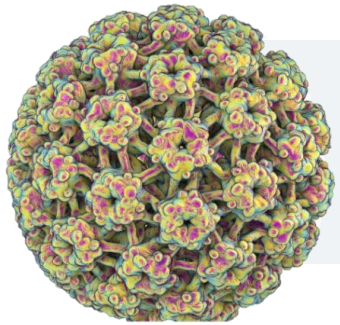
Introduction



Human papillomavirus (HPV) is a non-enveloped, double-stranded DNA virus.
Over **150 genotypes** have been identified, **each with characteristic tissue tropism**.

CUTANEOUS

HPV infection and virus replication in squamous epithelium of the skin

MUCOUS MEMBRANES

HPV infection and virus replication in the **genital mucosa**

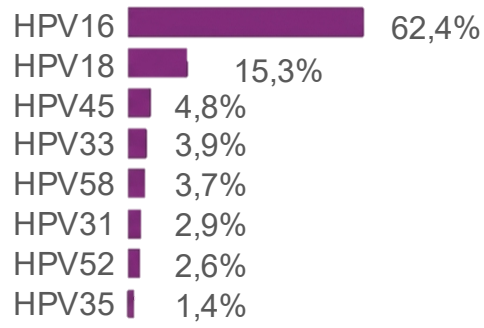
More than **150 types of HPV**, classified according to their oncogenic potential

- **High risk:** 16,18, **31, 33**, 35, 39, **45**, 51, **52**, 56, **58**, 59, 66
- **Low risk:** 6,11, 40, 42, 43, 44, 54, 61, 70, 72, 81

LOW-RISK HPV TYPES → **SKIN WARTS (genitals, anus, etc.)**

HIGH-RISK HPV TYPES → **PRECANCEROUS CERVICAL LESIONS AND CERVICAL CANCER (if persistent)**

Attributable Fraction of Key High Risk Types



Bzhalava, D., Eklund, C. & Dillner, J. *International standardization and classification of human papillomavirus types. Virology* (2015) doi:10.1016/j.virol.2014.12.028.
Jung, W.-W. *et al. Strategies against human papillomavirus infection and cervical cancer. J. Microbiol.* (2004)
Zur Hausen, H.: Nat Res Cancer, 2, 342 – 350, 2002

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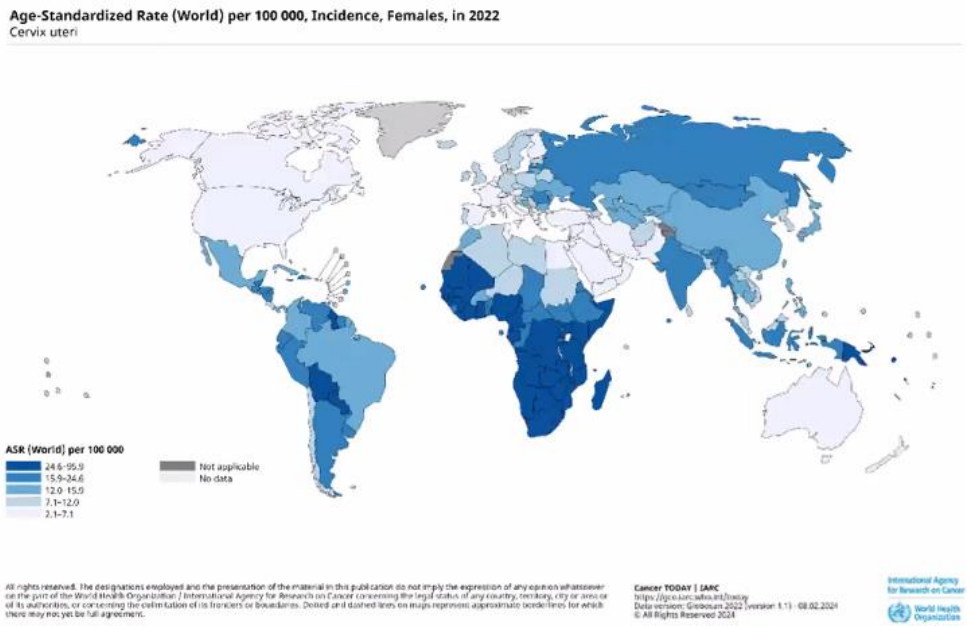
Epidemiology

HPV infection is highly prevalent, but **persistence** is the key clinical concern.

75-80%
of sexually active individuals may be exposed to HPV during their lifetime

One of the **most common** sexually transmitted infections (STI) worldwide

Cervical cancer
strongly associated with persistent high-risk HPV infection



- Highest prevalence in Africa and Central America; lowest in Europe and Asia.
- Cervical cancer is the 3rd most frequent in women between 25 – 64 years old
- Cervical cancer comprises 80% of cancers associated with HPV

Factsheet CDC 2014. 2. Weaver BA. Epidemiology and natural history of genital human papillomavirus infection. J Am Osreopath Assoc. 2006 Mar. 3. Documento de Consenso de las Sociedades Científicas: 2011. WHO. Human papillomavirus (HPV) and cervical cancer. World Health Organization fact sheet. (2019). Available at: https://www.who.int/news-room/fact-sheets/detail/human-papillomavirus-(hpv)-and-cervical-cancer. (Accessed: 27th September 2019) 2. ECDC. Human Papillomavirus Fact Sheet. European Centre for Disease Prevention and Control. (2018). Available at: https://ecdc.europa.eu/en/human-papillomavirus/factsheet. (Accessed: 26th September 2019)

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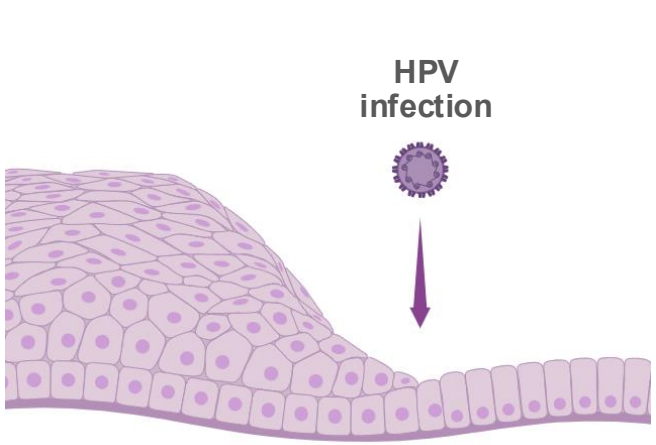
Natural history

Most HPV infections are transient, but persistent high-risk HPV infection is the key driver of cervical lesion progression.



Clearance
(85-90% of cases)

The immune system successfully eliminates the virus within 2 years.

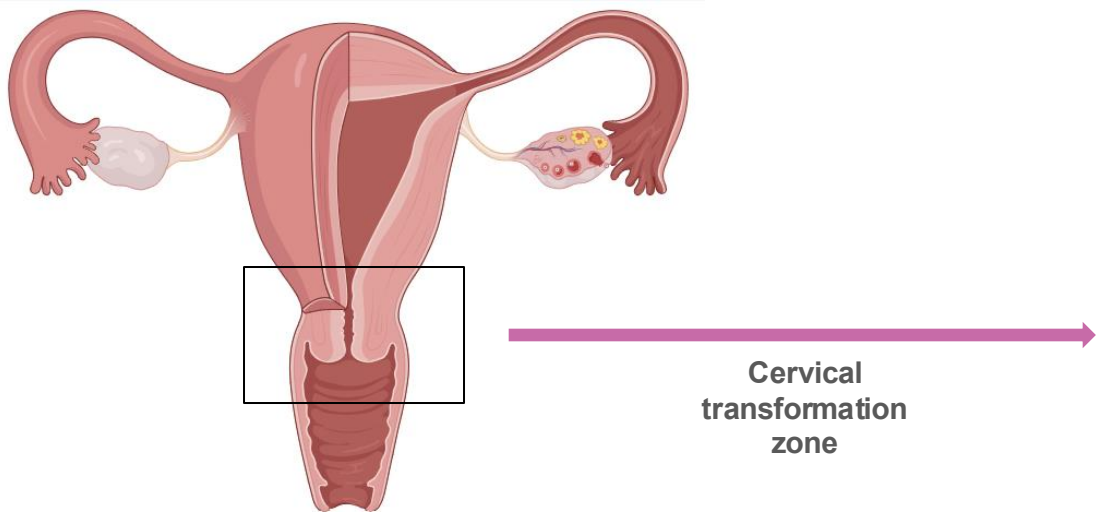
Persistence
(10-15% of cases)

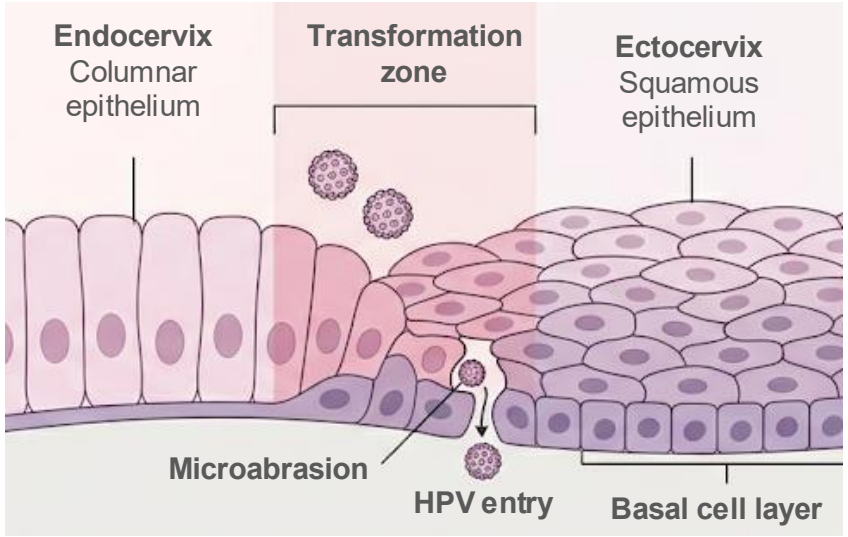
Low Grade Lesions (LSIL/CIN1) → **High Grade Lesions (HSIL/CIN2/3)** → Cervical cancer

Rositch, A. F. et al. Patterns of persistent genital human papillomavirus infection among women worldwide: a literature review and meta-analysis. Int. J. cancer (2013). doi:10.1002/ijc.27828 .2. Serrano, B., Brotons, M., Bosch, F. X. & Bruni, L. Epidemiology and burden of HPV-related disease. Best Practice and Research: Clinical Obstetrics and Gynaecology (2018). doi:10.1016/j.bpobgyn.2017.08.006

Natural history

HPV reaches the basal epithelial cells through microabrasions, especially in the cervical transformation zone.



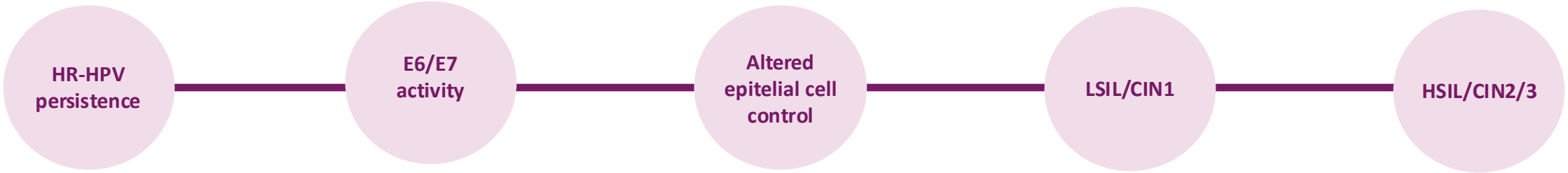


- The **transformation zone** is the **main site** of cervical HPV infection
- **Microabrasions** allow HPV to reach the basal cell layer.
- **Basal epithelial cells** are the initial site of infection.

Natural history

Why persistence matters: role of high-risk HPV and E6/E7

Persistent high-risk HPV infection can disrupt normal cell-cycle control, increasing the risk of cervical lesion progression.



Persistent HR-HPV infection
The virus remains active in the cervical epithelium instead of being cleared by the immune system

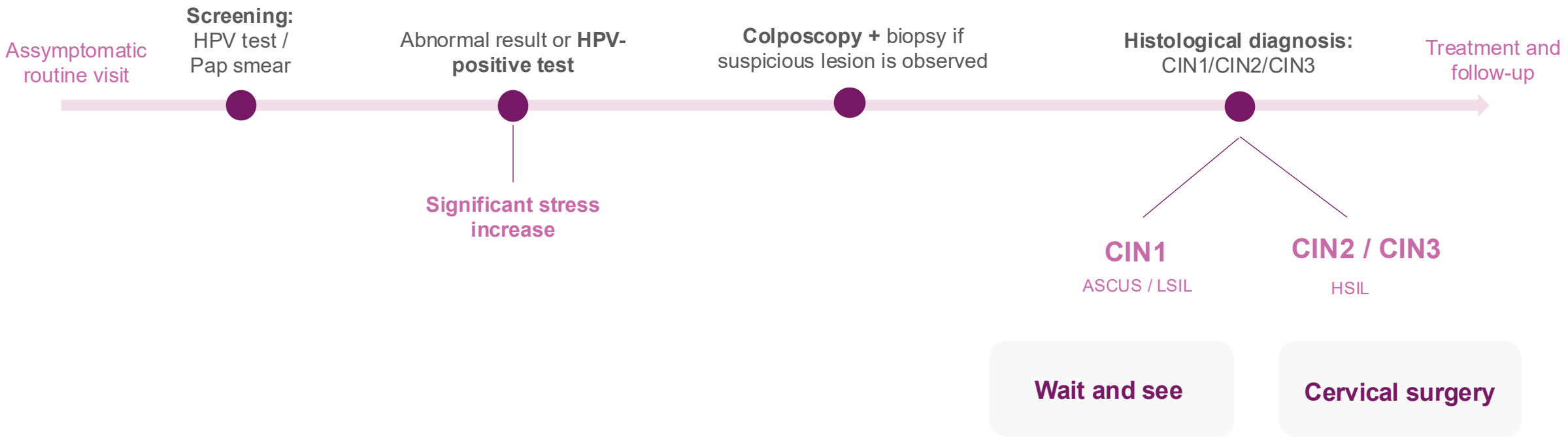
E6/E7 activity
High-risk HPV oncoproteins interfere with normal cell-cycle control mechanisms.

Progression risk
Sustained epithelial cell dysregulation may contribute to LSIL/CIN1 persistence and progression to HSIL/CIN2/3.

Diagnosis

Patient Journey

Screening tests identify women at risk, while histology confirms the grade of cervical lesion.



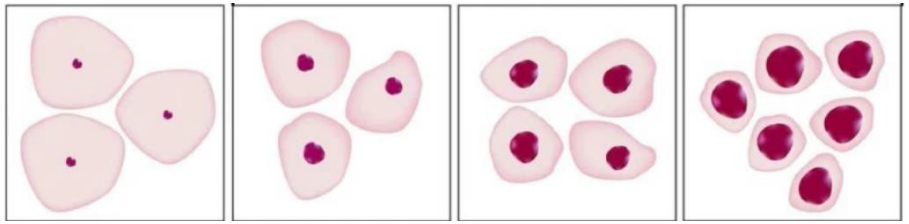
Diagnosis

HPV-related cervical lesions can be classified according to the sample evaluated: **cells** in **cytology** or tissue in histology.

CYTOLOGY

Bethesda system

Classifies the cytological **intraepithelial squamous lesions**



NORMAL

ASC-US: presence of **atypical squamous cells**

ASC-H: **atypical squamous cells** that raise concern for the **presence of H-SIL**

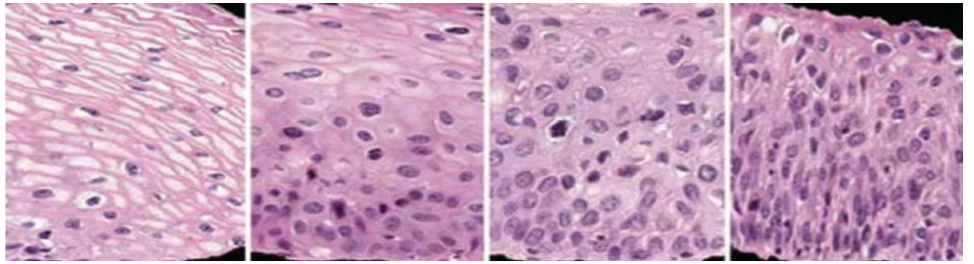
L-SIL: intraepithelial squamous **lesions of low grade**

H-SIL: intraepithelial squamous lesions of **high grade**

HISTOLOGY

CIN: Cervical Intraepithelial Neoplasia

Classifies the histological lesions by **their grade of neoplasia**



NORMAL

CIN1: cervical intraepithelial neoplasia of **low grade** considered light dysplasia

CIN2: lesions whose evolution **may progress** to neoplasia

CIN3: true intraepithelial neoplasms with a **high potential for progression**

LSIL usually corresponds to CIN1, whereas HSIL is more commonly associated with CIN2 and CIN3

. Baseman, J. G. & Koutsky, L. A. The epidemiology of human papillomavirus infections. Journal of Clinical Virology (2005). doi:10.1016/j.jcv.2004.12.008 2. De La Fuente, J. Verrugas genitales: estudio multicéntrico español. Spanish Work. Eurogin (2015). 3.Schianchi, R., Brena, M. & Veraldi, S. Treatment of common recalcitrant warts with topical formic acid. Int. J. Dermatol. (2018). doi:10.1111/ijd.13811 4. Valerio, E., Parata, F. & Cutrone, M. Handy paediatric dermatology. Archives of Disease in Childhood (2017). doi:10.1136/archdischild-2016-312358 . 1. Darragh, T. M. et al. The lower anogenital squamous terminology standardization project for HPV-associated lesions: Background and consensus recommendations from the college of American pathologists and the American society for colposcopy and cervical pathology. Int. J. Gynecol. Pathol. (2013). doi:10.1097/PGP.0b013e31826916c7 2. RICHART, R. M. NATURAL HISTORY OF CERVICAL INTRAEPITHELIAL NEOPLASIA. Clin. Obstet. Gynecol. (1967). doi:10.1097/00003081-196712000-00002; Jiang, P., Li, X., Shen, H. et al. A systematic review of deep learning-based cervical; cytology screening: from cell identification to whole slide image analysis. Artif Intell Rev 56 (Suppl 2), 2687–2758 (2023). https://doi.org/10.1007/s10462-023-10588-z; Researchgate.net. [citado el 18 de mayo de 2026]. Disponible en: https://www.researchgate.net/figure/CIN-grade-label-examples-highlighting-the-increase-of-immature-atypical-cells-from_fig1_283492620

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Risk factors

Main risk factors involved in HPV persistence

IMMUNE RESPONSE

VAGINAL MICROBIOTA

EPITHELIUM INTEGRITY

OTHER FACTORS: STRESS

Risk factors

IMMUNE RESPONSE

Key role in HPV clearence

An effective local immune response is essential for HPV recognition, clearance and prevention of persistence.

HPV infection in cervical epithelium → Antigen capture by dendritic and Langerhans cells  → T-cell activation → **Clearance of infected epithelial cells**

If immune surveillance is impaired → Reduced antigen presentation → Reduced T-cell activation → **Higher risk of HPV persistence**

- Innate immunity is **the first line of defense** during early HPV infection.
- **Weakness** of the immune system appears to be the most significant factor for HPV progression and persistence
- Dendritic and Langerhans cells contribute to local immune activation by promoting **cytokine and chemokine secretion and supporting NK-cell and T-cell responses**.

Muntinga C et al. Importance of the Immune Microenvironment in the Spontaneous Regression of Cervical Squamous Intraepithelial Lesions(cSIL) and Implications for Immunotherapy. Journal of Clinical Medicine, 2022.

Risk factors

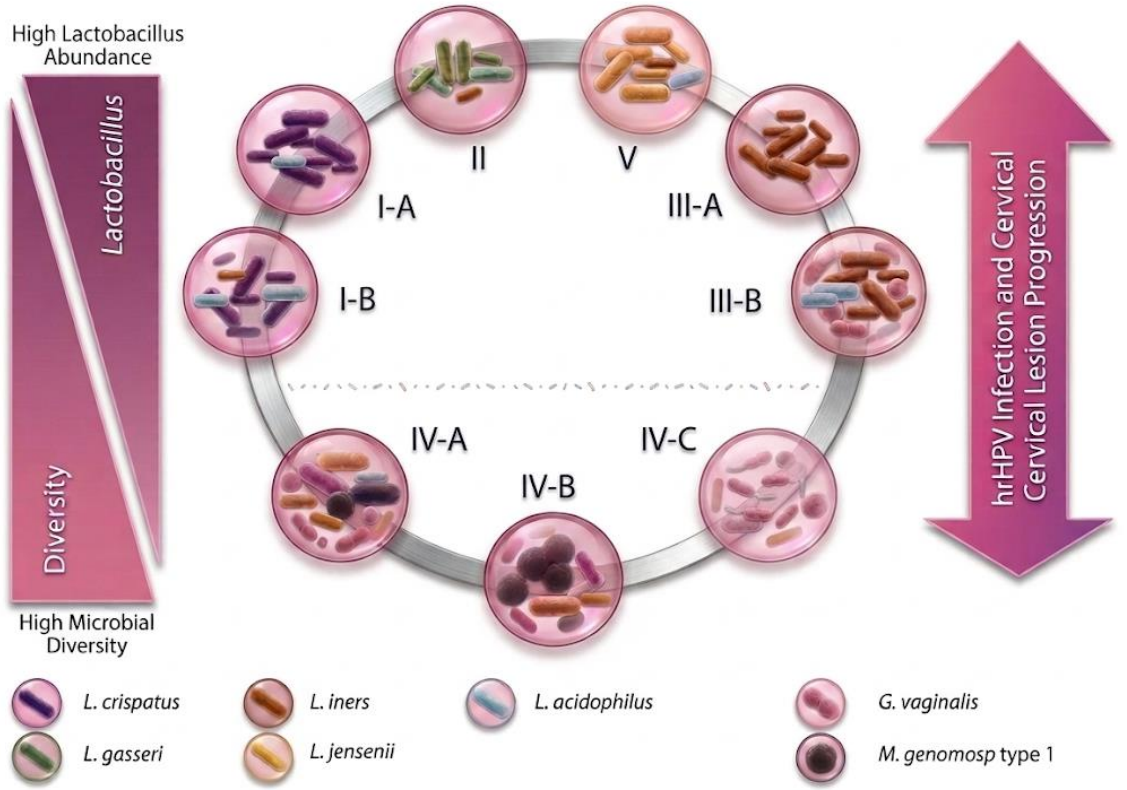
VAGINAL MICROBIOTA

The **vaginal microbiome (VM)** plays a functional role in **HPV acquisition and persistence**, influencing the cytokine profile of the cervical microenvironment.

HPV-positive women often show a **more diverse and altered vaginal microbiota** compared with HPV-negative women.

Rebalancing the microbiota may help create a **less favourable environment** for HPV persistence and support viral clearance.

The cervicovaginal microbiota can be classified into community state types (CSTs I–V), according to the dominant bacterial species. CST IV is typically associated with dysbiosis.



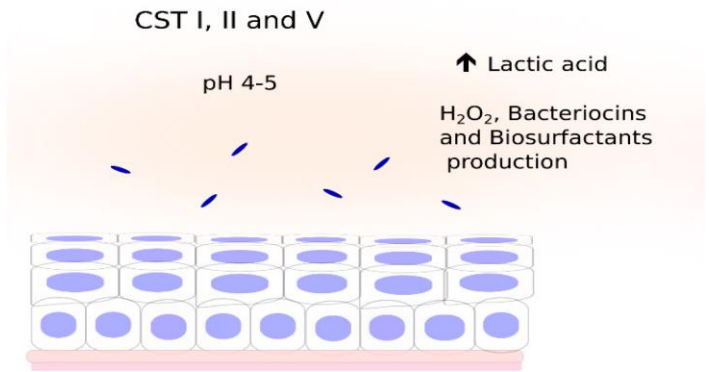
Kyrgioua M, Mitraa A, Moscickic AB. Does the vaginal microbiota play a role in the development of cervical cancer? DOI: https://doi.org/10.1016/j.trsl.2016.07.004

Risk factors

VAGINAL MICROBIOTA

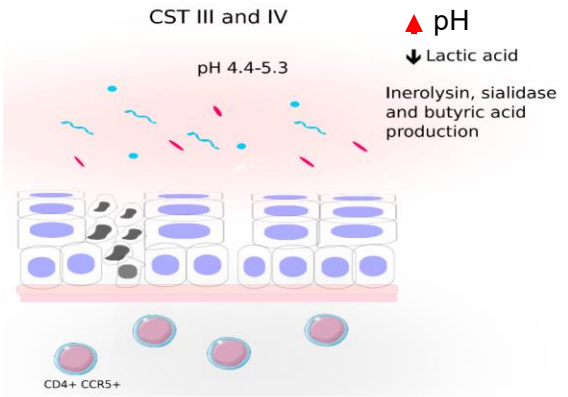
Protective microbiota profile
CST I, II and V

Dominated by non-iners Lactobacillus species associated with low vaginal pH
Produce high levels of lactic acid, hydrogen peroxide and protective bacterial bioproducts
Help maintain a more stable and protective cervicovaginal environment



Dysbiotic / less protective microbiota profile
CST III and IV

CST III is dominated by *Lactobacillus iners*
CST IV is characterized by high bacterial diversity and an increased frequency of anaerobic species
Both profiles produce less lactic acid
They may exhibit inerolysin, sialidase and butyric acid production
They can modulate the local immune response through pro-inflammatory cytokine production and recruitment of CD4+CCR5+ lymphocytes



Kyrgiou M, Mitra A, Moscicki AB. Does the vaginal microbiota play a role in the development of cervical cancer? DOI: https://doi.org/10.1016/j.trsl.2016.07.004; The Role of the Cervicovaginal Microbiome on the Genesis and as a Biomarker of Premalignant Cervical Intraepithelial Neoplasia and Invasive Cervical Cancer. *Int. J. Mol. Sci.* 2020, *21*(1), 222; https://doi.org/10.3390/ijms21010222. Bacterial bioproducts modulate cervical microenvironment. Bacterial cervical communities named CSTs (community state types) are displayed on the top of the Figure (A,B) in roman numerals (I, II, III, IV). (A) CST I, II, and V contain dominant *Lactobacillus* (non-*iners*) species (dark blue rods) and produce high level of lactic acid, hydrogen peroxide, and bacterial bioproducts (bacteriocins and biosurfactants). (B) CST III shows the *Lactobacillus iners*-dominant community (pink rods) and CST IV displays bacterial high diversity (light blue rods and circles) with increased frequency of anaerobic species. They both produce less lactic acid and exhibit inerolysin, sialidase, and butyric acid production. In addition, CST III and IV modulate immune responses by induction of proinflammatory cytokine production and recruitment of CD4+CCR5+ lymphocytes to the cervical region.

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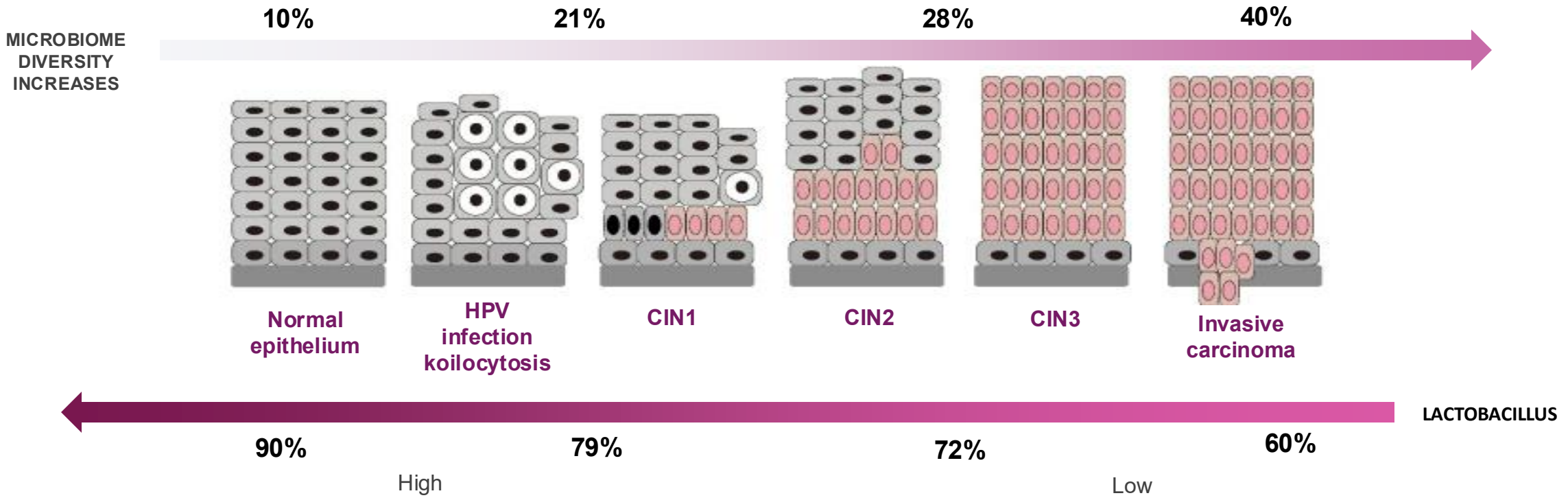
Risk factors

VAGINAL MICROBIOTA

Protective balance vs dysbiosis

A vaginal microbiota dominated by Lactobacillus helps maintain a protective low-pH environment, while dysbiosis is associated with HPV persistence and lesion progression.



Cervical intraepithelial neoplasia disease progression is associated with increased vaginal microbiome diversity A. Mitra, D.A. MacIntyre, Y.S. Lee, A. Smith, J.R. Marchesi, B. Lehne, R. Bhatia, D. Lyons, E. Paraskevaidis, J.V. Li, E. Holmes, J.K. Nicholson, P.R. Bennett & M. Kyrgiou; Avsaroglu, E., Kaleli, B., Kılıç, D., Kaleli, I., & Guler, T. (2023). A Decrease in Lactobacilli in the Vaginal Microbiota Is Independently Associated With HPV Persistence in Women With High-Risk HPV Infection. *Cureus, 15*. https://doi.org/10.7759/cureus.50907.

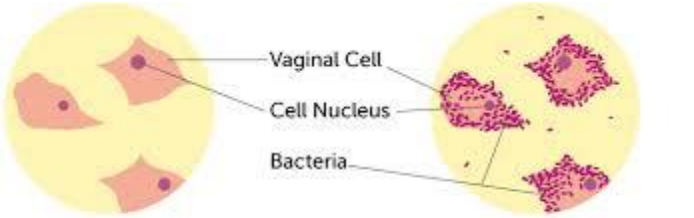
Risk factors

VAGINAL MICROBIOTA

Amsel Criteria

In clinical practice, Bacterial Vaginosis (BV) can be assessed using **Amsel criteria**, including:

- Leucorrhoea: Thin, white, yellow, homogeneous discharge
- Presence of clue cells
- pH of vaginal fluid **>4.5**
- Whiff test: amine odor , KOH
- **At least two of the four** criteria should be present for a confirmed diagnosis



Normal vaginal cells seen under a microscope.

"Clue Cells", vaginal cells with bacteria stuck to them.

Kenyon, C; Colebunders, R; Crucitti, T (December 2013). "The global epidemiology of bacterial vaginosis: a systematic review". *American Journal of Obstetrics and Gynecology*. 209 (6): 505–23. doi:10.1016/j.ajog.2013.05.006; 1. Amsel R, Totten PA, Spiegel CA, Chen KC, Eschenbach D, Holmes KK (1983). "Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations". *Am. J. Med.* 74 (1): 14–22. doi:10.1016/0002-9343(83)91112-9. PMID 6600371. 2. National guideline for the management of bacterial vaginosis (2006)". *Clinical Effectiveness Group, British Association for Sexual Health and HIV (BASHH)*. Archived from the original on 3 November 2008. Retrieved 16 August 2008.

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Risk factors

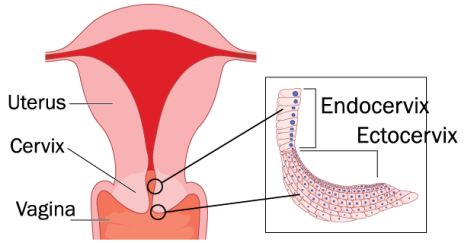
EPITHELIUM INTEGRITY

Cervical epithelium

Endocervix

Columnar cells, single layer epithelium

Lines the inner cervical canal and contains mucus-producing columnar cells, which can be exposed on the outer cervix in ectopy and later replaced by squamous cells in the transformation zone.

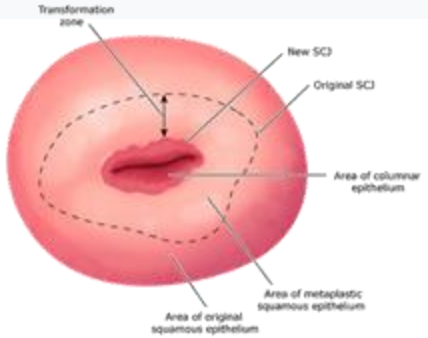


Transformation zone

The transformation zone is the area of the cervix where **columnar cells are replaced by squamous cells**.

Because cells are actively changing, it is the most common site for cervical abnormalities to develop.

*Its location can vary between women.



Ectocervix or exocervix

Squamous multilayer epithelium

Ectopy is the presence of columnar cells from the cervical canal on the outer surface of the cervix. It is a physiological condition, commonly seen in young women, during pregnancy, or in women using contraceptive pills.

Risk factors

EPITHELIUM INTEGRITY

Metaplasia

Squamous metaplasia in the cervix refers to the **physiological replacement of the everted columnar epithelium on the ectocervix** by a newly formed squamous epithelium.

Maintaining epithelial integrity is relevant because HPV infection begins when the virus reaches basal epithelial cells.

Risk factors

Other factors influencing HPV infection and persistance: Stress

WORRIES

- Afraid of developing cervical cancer
- Loss of reproductive capacity
- Negative reactions from partners, family, and friends
- Infidelity

CHANGES

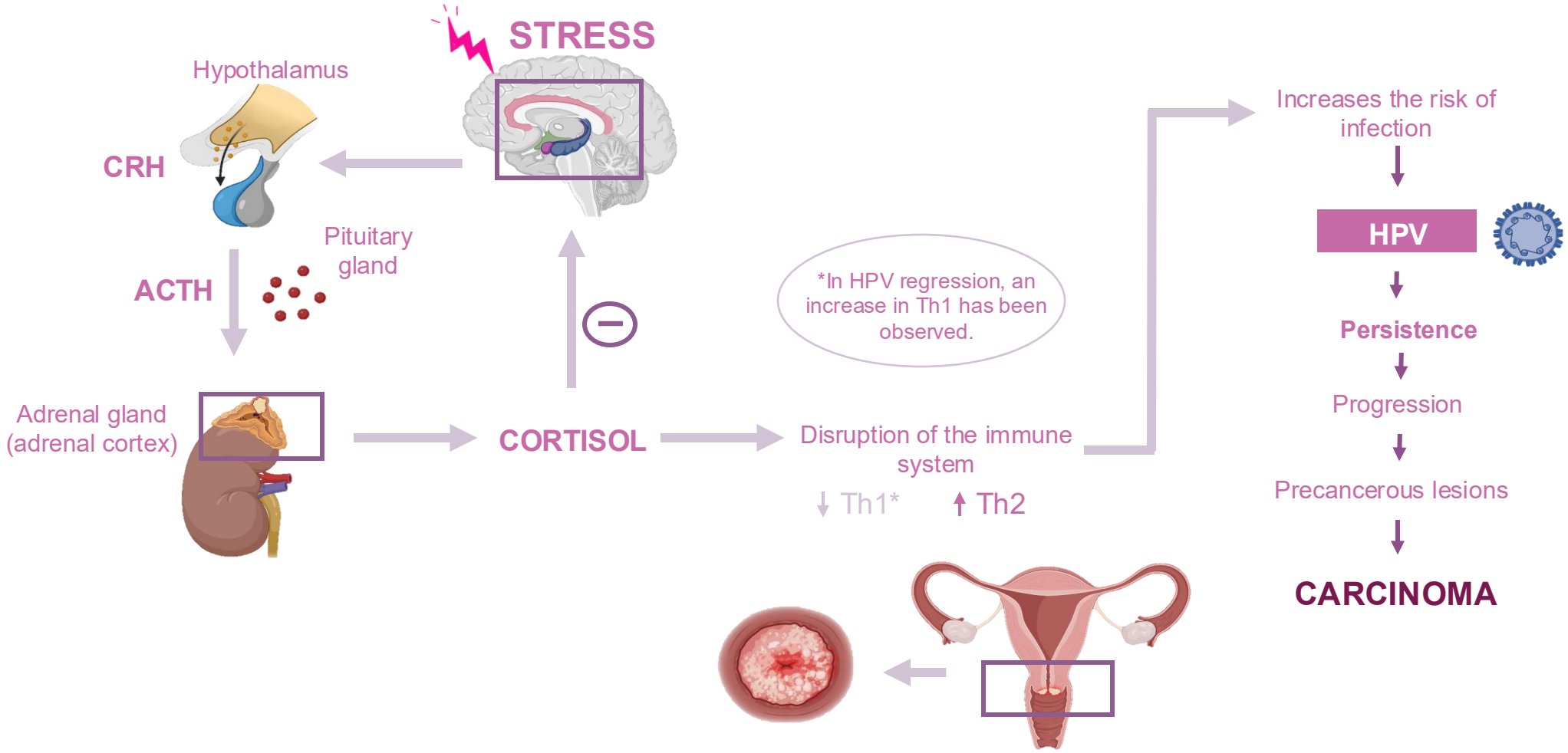
- Body image (undesirable)
- Sexual activity: **Spontaneity, Frequency, Satisfaction**

REACTIONS

Angriness	Depressive feelings	Shame	Anxiety	Guilt
78%	**76%**	**86%**	**82%**	**80%**

Risk factors

Other factors influencing HPV infection and persistance: Stress

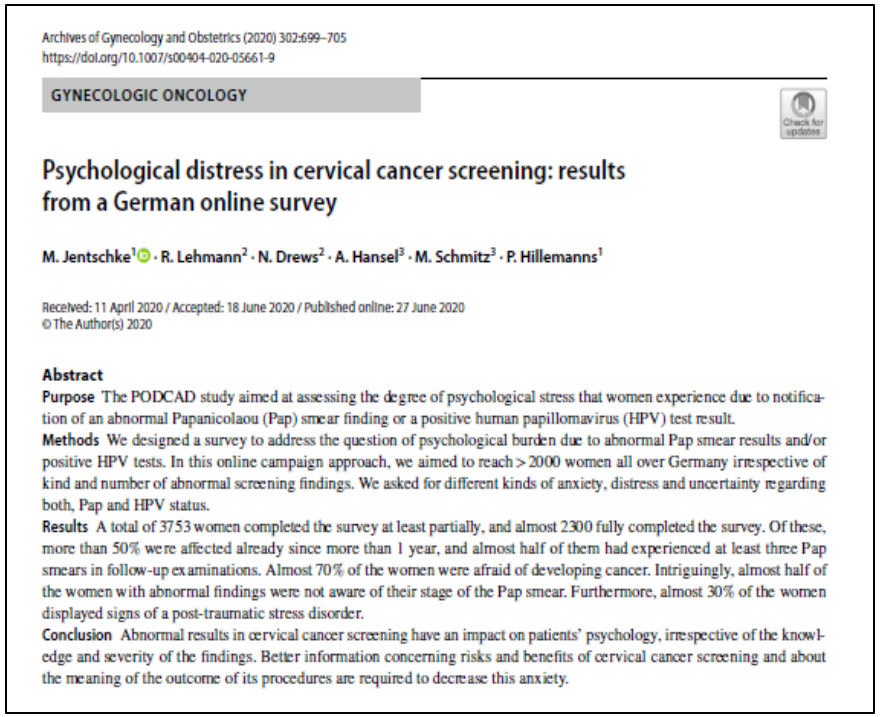


Liborija LM, et al. The Influence of Psychological Stress on HPV Infection Manifestations and Carcinogenesis. Cellular Physiology and Biochemistry. 2021 Jul 10;55(S2):71–88.

Risk factors

Other factors influencing HPV infection and persistance: Stress

- 30% post-traumatic stress and 50% afraid to die of cancer
- Psychological distress in cervical cancer screening: results from a Germany online survey (2020)



Archives of Gynecology and Obstetrics (2020) 302:699–705
https://doi.org/10.1007/s00404-020-05661-9

GYNECOLOGIC ONCOLOGY

Psychological distress in cervical cancer screening: results from a German online survey

M. Jentschke[1] · R. Lehmann[2] · N. Drews[2] · A. Hansel[3] · M. Schmitz[3] · P. Hillemanns[1]

Received: 11 April 2020 / Accepted: 18 June 2020 / Published online: 27 June 2020

Abstract

Purpose The PODCAD study aimed at assessing the degree of psychological stress that women experience due to notification of an abnormal Papanicolaou (Pap) smear finding or a positive human papillomavirus (HPV) test result.

Methods We designed a survey to address the question of psychological burden due to abnormal Pap smear results and/or positive HPV tests. In this online campaign approach, we aimed to reach > 2000 women all over Germany irrespective of kind and number of abnormal screening findings. We asked for different kinds of anxiety, distress and uncertainty regarding both, Pap and HPV status.

Results A total of 3753 women completed the survey at least partially, and almost 2300 fully completed the survey. Of these, more than 50% were affected already since more than 1 year, and almost half of them had experienced at least three Pap smears in follow-up examinations. Almost 70% of the women were afraid of developing cancer. Intriguingly, almost half of the women with abnormal findings were not aware of their stage of the Pap smear. Furthermore, almost 30% of the women displayed signs of a post-traumatic stress disorder.

Conclusion Abnormal results in cervical cancer screening have an impact on patients' psychology, irrespective of the knowledge and severity of the findings. Better information concerning risks and benefits of cervical cancer screening and about the meaning of the outcome of its procedures are required to decrease this anxiety.

N=3.753 women in Germany
Mean age of 31.8 years old
Survey from May to June 2018

- **Abnormal results** in cervical cancer screening have an **impact** on patients' **psychology**, **irrespective** of the knowledge and **severity** of the findings
- The **psychological outcome** of women with cervical intraepithelial neoplasia was **similar** to those of women with abnormal cytology

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2. Clinical management

- Prevention
- Screening
- Treatment

Prevention

Primary Prevention

- **Vaccination** ♂ → ♀

  - It covers HPV types: 6, 11, 16, 18, 31, 33, 45, 52, 58
- Absolute abstinence
- Mutual monogamy for life
- Condom use
- Circumcision only partially protect

Secondary Prevention

- Screening for cervical cancer
- Cytology / HPV test

♀

Precancerous lesions are usually **asymptomatic**, for this reason **screening** helps **detect lesions early and prevent progression**.

WHO recommends screening from **30 years of age.**

WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention www.who.int/reproductivehealth/publications/cancers/screening_and_treatment_of_precancerous_lesions/en/index.html

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Screening

WHO recommendation for HPV screening (on a routine basis)

HPV TEST

CYTOLOGY

COLPOSCOPY

BIOPSY

VISUAL INSPECTION WITH ACETIC ACID (VIA)

LUGOL'S IODINE OR SCHILLER'S IODINE

WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention www.who.int/reproductivehealth/publications/cancers/screening_and_treatment_of_precancerous_lesions/en/index.html

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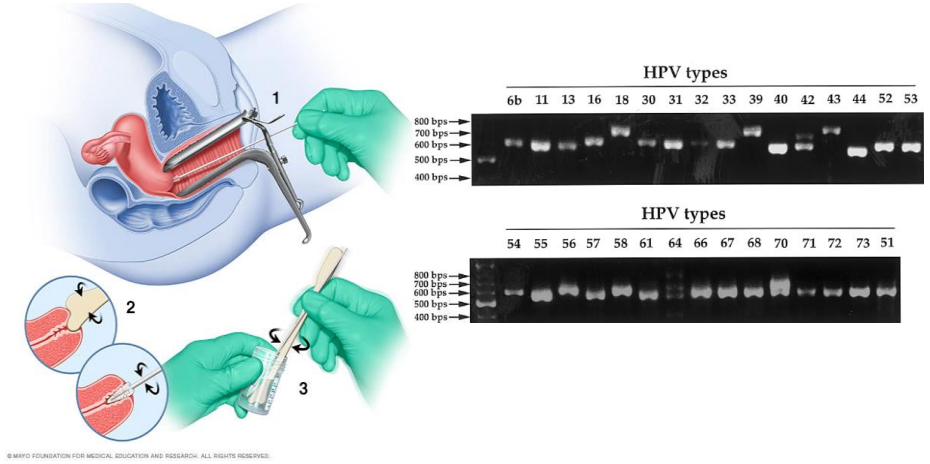
Screening

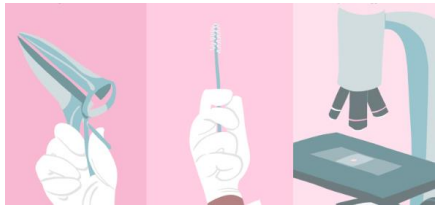
HPV Test

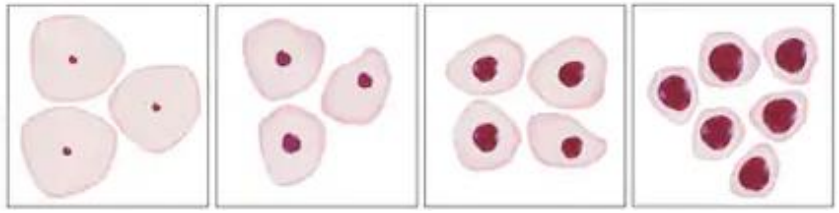
Detection of the viral DNA by PCR.
Positive: HPV DNA detected.



Cytology

PAPANICOLAU OR PAP TEST:
Conventional cytology of cervical tissue





Screening

Colposcopy

Colposcopy is a diagnostic procedure used to visually examine the cervix with a colposcope after a positive screening result. Since visual assessment is subjective, a biopsy is needed to confirm the diagnosis.

Biopsy

CIN diagnosis is confirmed by **histopathological examination of a cervical biopsy or excision specimen**. The CIN grade is determined by histological features such as cell differentiation, maturation, stratification and nuclear abnormalities. Women with a positive colposcopy may undergo biopsy for confirmation or receive immediate treatment.

Visual inspection with acetic acid (VIA)

Inspection of the cervical tissue, appropriate only in women whose zone is visible (typically, in those younger than 50).

Negative

Positive

Thick well-defined acetowhite areas

Lugol's iodine or Schiller's iodine

Iodine stains glycogen and turns dark brown. Normal squamous epithelium is rich in glycogen

Positive: premalignant squamous epithelium is deficient, so **non-staining areas are suspectful** of premalignant disease

Screening

HPV test as primary screening: superior protection vs cytology

Superior cancer prevention

Women screened with primary HPV testing had a 17–28% lower risk of invasive cervical cancer compared to cytology-screened women over 8 years of follow-up
(Wang et al., Lancet Public Health, 2024)

Higher CIN3+ detection

Primary HPV screening detected 58% fewer CIN3+ lesions at 48 months compared to cytology-based screening
(Ogilvie et al., HPV FOCAL RCT, JAMA, 2018)

Longer safe interval

A single HPV-negative result provides very low cervical cancer risk for up to 7 years, versus cytology-negative intervals of 3-5 years
(Yao et al., PLOS Med, 2024)

Adapted for vaccinated cohorts

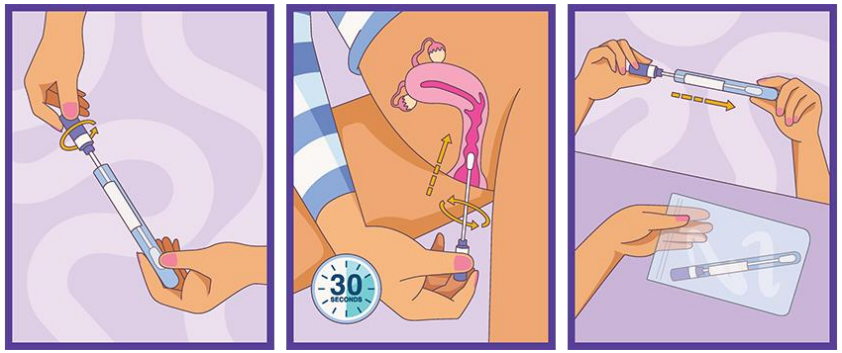
HPV partial genotyping (HPV16/18) allows stratification of risk in vaccinated women, enabling program adaptation
(Canfell et al., BMJ Open, 2018)

Wang J, et al. HPV-based cervical screening and long-term cervical cancer risk: a randomised health-care policy trial in Sweden. Lancet Public Health. 2024.Ogilvie GS, et al. Effect of Screening With Primary Cervical HPV Testing vs Cytology Testing on High-grade CIN at 48 Months: The HPV FOCAL RCT. JAMA. 2018;320(1):43–52.

Screening

Guidelines

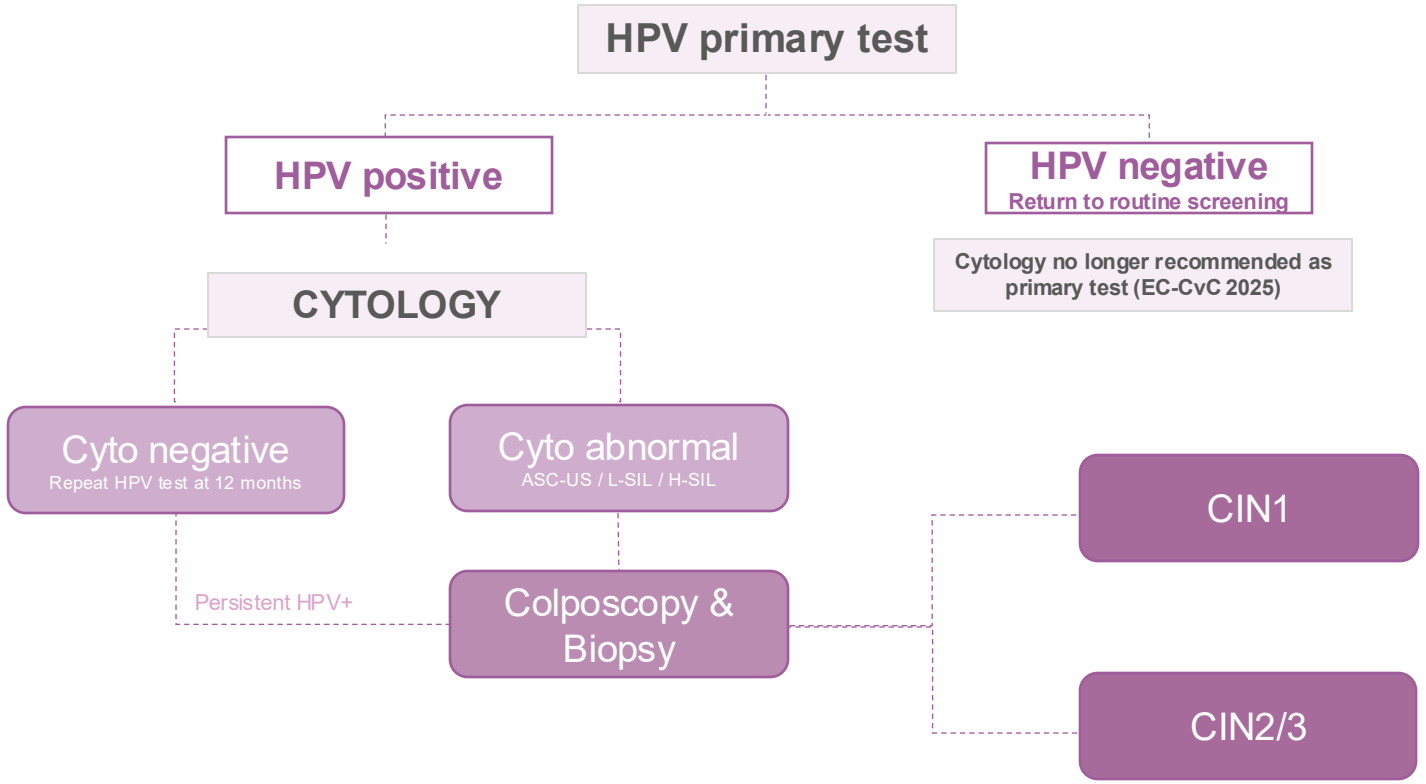
- **No differences** in the results compared with a test taken **by an HCP**
- **High acceptance rate in women**: easy to use, painless, comfortable, and time-saving
- **Higher coverage** in the screening program than the current one
- It does not replace the concept of screening; rather, it is a way to collect the sample for the HPV test.



Polman N, Ebisch R, Heideman D et al. Performance of human papillomavirus testing on self-collected versus clinician-collected samples for the detection of cervical intraepithelial neoplasia of grade 2 or worse: a randomised, paired screen-positive, non-inferiority trialThe Lancet Oncology, 2019; 20, 229-238

Screening

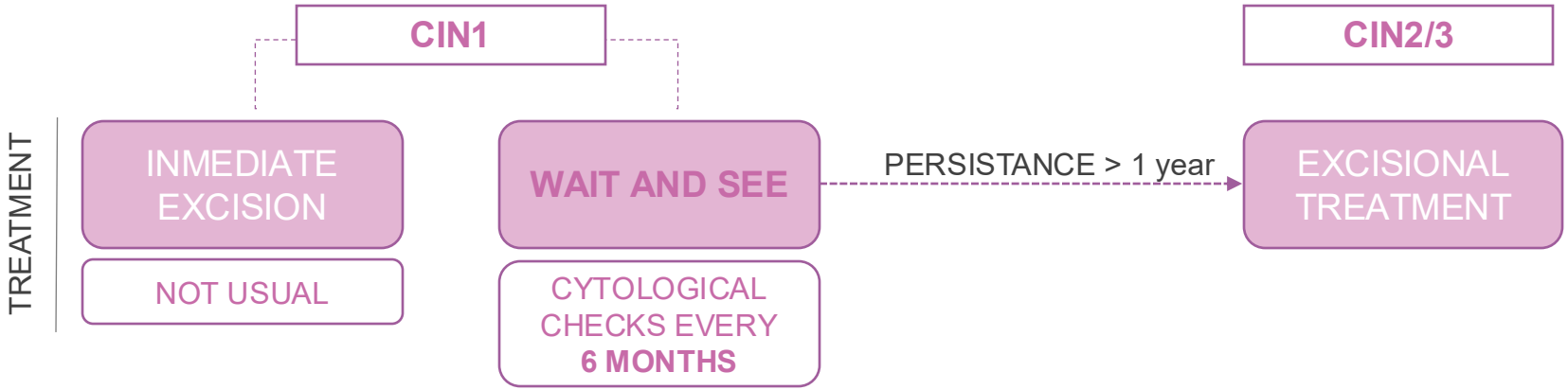
What does the guidelines say?



Polman N, Ebisch R, Heideman D et al. Performance of human papillomavirus testing on self-collected versus clinician-collected samples for the detection of cervical intraepithelial neoplasia of grade 2 or worse: a randomised, paired screen-positive, non-inferiority trialThe Lancet Oncology, 2019; 20, 229-238

Treatment

There was no medication indicated to fight HPV infections



ARE RESERVED FOR MORE SEVERE CASES

These destructive therapies are only indicated in case of CIN2 and CIN3, and women exhibiting CIN1 are often kept without any treatment.

If the infection progresses, **excisional or destructive treatments** are performed that require surgical intervention, intended to eliminate altered tissue considered a pre-cancerous lesion

These procedures can negatively affect the quality of life of patients

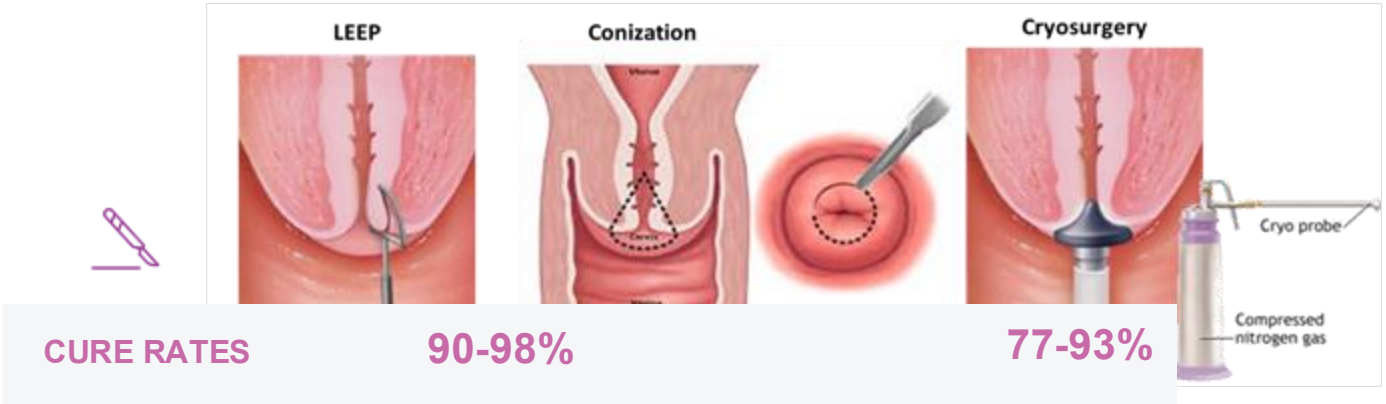
Consequences on reproduction: premature births

Excisional and ablative treatment further increases that risk. The frequency and severity of adverse sequelae increases with increasing cone depth and is higher for excision than for ablation.

1. Furugori, M., Asai-Sato, M., Katayama, K., Hirahara, F. & Miyagi, E. Short- and long-term complications and the impact on quality of life after cervical conization by harmonic scalpel. J. Obstet. Gynaecol. Res. (2017). doi:10.1111/jog.13273; 1. Adverse obstetric outcomes after local treatment for cervical preinvasive and early invasive disease according to cone depth: systematic review and meta-analysis. *BMJ* 2016; 354 doi: https://doi.org/10.1136/bmj.i3633 (Published 28 July 2016)Cite this as: *BMJ* 2016;354:i3633

Treatment

Excisional or destructive treatments



CURE RATES	90-98%	77-93%

HPV infection rate post-excisional surgery may remain high.[2]

Most studies assessed HPV persistence after loop excision (42%), followed by conization (7%), cryotherapy (11%), laser treatment (4%), interferon-alpha, therapeutic vaccination, and photodynamic therapy (2% each) and mixed treatment (38%).

Types of excisional treatments for the management of cervical neoplasia. LEEP uses a small, electrically charged wire loop to remove tissue, it can also remove tissue samples for further analysis. Cold knife cone biopsy (conization): a cone-shaped piece of tissue containing

1. Furugori, M., Asai-Sato, M., Katayama, K., Hirahara, F. & Miyagi, E. Short- and long-term complications and the impact on quality of life after cervical conization by harmonic scalpel. J. Obstet. Gynaecol. Res. (2017). doi:10.1111/jog.13273 2. Hoffman, S. R. *et al.* Patterns of persistent HPV infection after treatment for cervical intraepithelial neoplasia (CIN): A systematic review. *International Journal of Cancer* (2017). doi:10.1002/ijc.30623

1. Laborest approach: Colpofix®

- Introduction
- Indication
- Mode of use
- International footprint

Laborest

Introduction

COLPOFIX® is an innovative vaginal spray gel for the **prevention and treatment of cervical lesions caused by Human Papillomavirus (HPV)**

It acts through the control of physiological conditions on the cervico-vaginal transformation zone

Introduction

Innovative medical device

Colpofix® is a **vaginal spray gel** based on two complementary components:

Carboxymethyl β-glucan

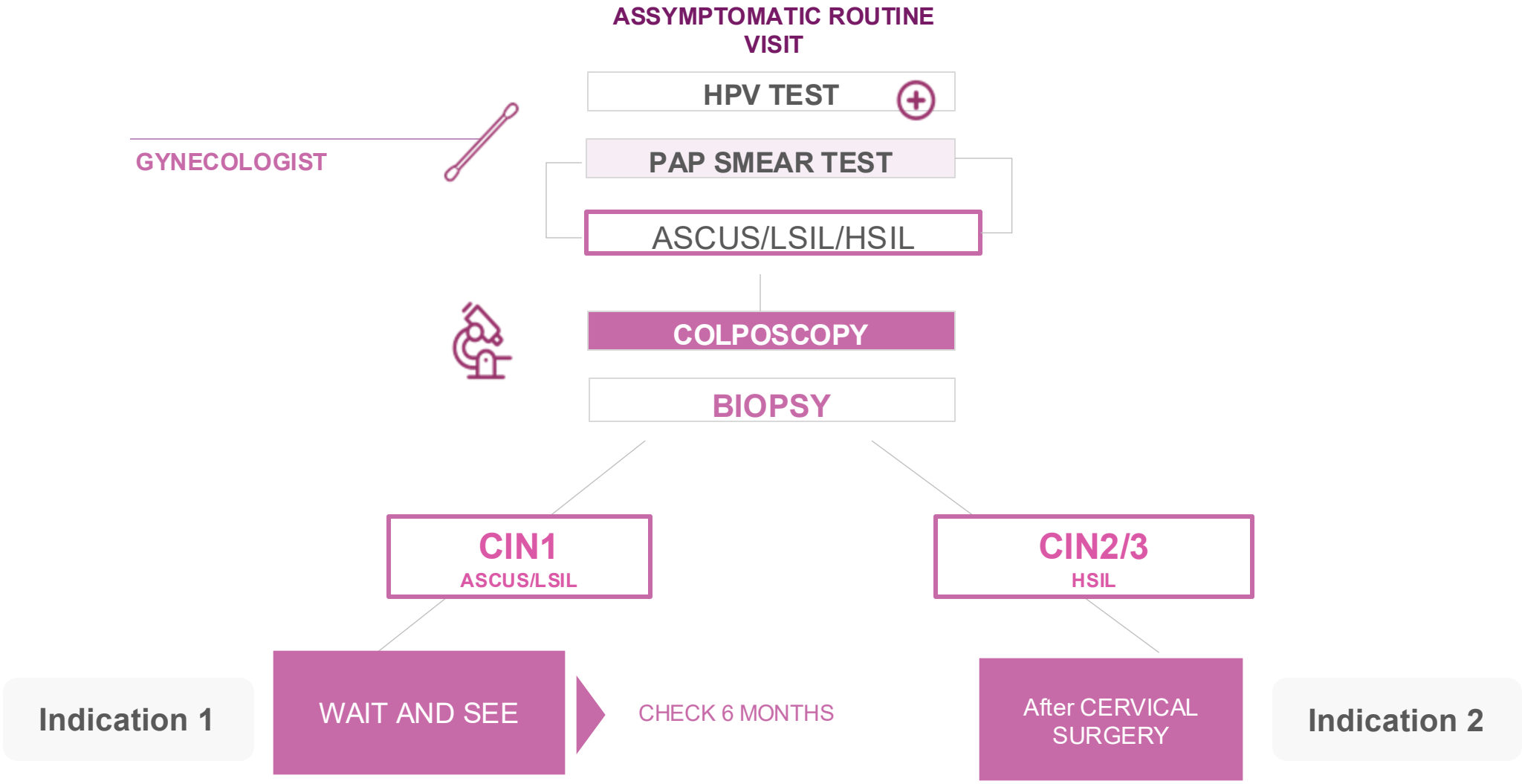
✓ **Supports local immune response**, **tissue repair** and **epithelial recovery**.

Polycarbophil

✓ Forms a **mucoadhesive protective film** and helps maintain **an acidic vaginal environment**.

Its spray delivery system allows **a uniform distribution of the gel over the cervical-vaginal mucosa**.

Indication


ASSYMPTOMATIC ROUTINE VISIT
HPV TEST
GYNECOLOGIST
PAP SMEAR TEST
ASCUS/LSIL/HSIL
COLPOSCOPY
BIOPSY
CIN1
ASCUS/LSIL
CIN2/3
HSIL
Indication 1
WAIT AND SEE
CHECK 6 MONTHS
After CERVICAL SURGERY
Indication 2

Indication

Colpofix indication 1: HPV+/ low grade cervical lesions

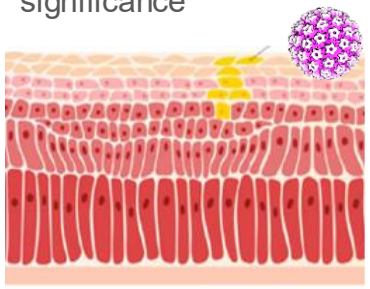
Colpofix® is an alternative to **"Wait and see" on low grade cervical lesions**

CIN1
ASCUS/LSIL

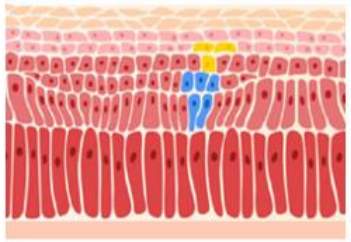
COLPOFIX AND SEE

CHECK 6 MONTHS

ASCUS:
presence of **atypical squamous cells** of undetermined significance



CIN1:
cervical intraepithelial neoplasia of **grade 1** considered light dysplasia



L-SIL:
intraepithelial squamous **lesions of low grade**

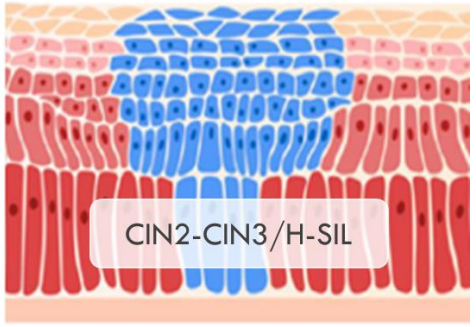
Colpofix indication 2: After cervical surgery

Colpofix® helps to restore the damaged tissue by **its reepithelialization** capacity. Its action on the **vaginal immunity help to decrease the risk of reinfection.**

CIN2/3
HSIL

CERVICAL SURGERY

AFTER 1 MONTH EXCISIONAL TREATMENT



Mode of use

1. Remove a vaginal applicator (single use) from its protective cover
2. Remove the cap from the bottle
3. Insert the applicator into the bottle dispensing nozzle
4. Activate dispensing by first pressing the button until the product appears
5. Insert the applicator deep into the vagina
6. Perform 5 sprays
7. Discard the applicator after use
8. Close the bottle with the lid

1 application a day
└ 5 sprays

20 days per month*

3-6 months

International footprint

+23 markets launched

+5 markets under registration

+10 planned launches in 2026

Key considerations

- Established presence across Europe and Asia-Pacific markets.
- New launches planned in Nordic and Central American markets in 2026.
- Registration processes ongoing in Asia and Kazakhstan.
- Local strategies should be adapted according to regulatory status and market dynamics.

2. Colpofix® ingredients

- Polycarbophil
- Carboxymethyl beta-glucan

Laborest

Polycarbophil

A key component supporting the cervical-vaginal mucosa

- ✓ High molecular-weight **acrylic acid polymer**
- ✓ High **bio-adhesivity** and gel consistency
- ✓ This gel forms non-covalent bonds with mucus secreted by tissues
- ✓ **It contains a high density of available hydrogen bonding that combines strongly with mucins** (glycoproteins secreted by epithelial cells of the mucous membrane)

Polycarbophil associated with mucin forms a mucoadhesive protective film

de Souza Ferreira, S. B., da Silva, J. B., Borghi-Pangoni, F. B., Junqueira, M. V., & Bruschi, M. L. (2017). Linear correlation between rheological, mechanical and mucoadhesive properties of polycarbophil polymer blends for biomedical applications. *Journal of the Mechanical Behavior of Biomedical Materials*, *68*, 265–275. https://doi.org/10.1016/J.JMBBM.2017.02.016

Polycarbophil

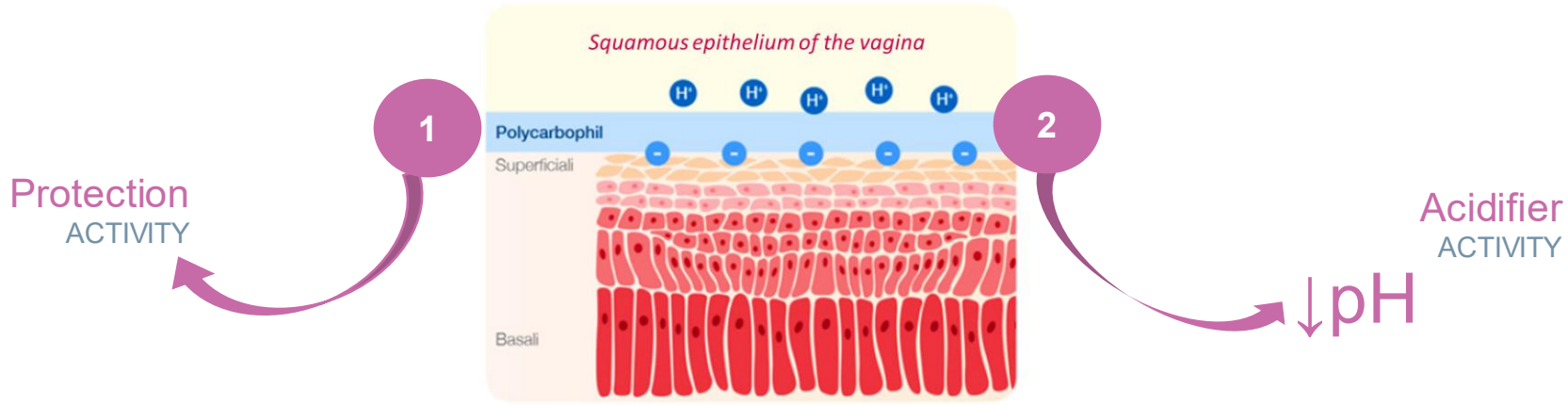
Mechanisms of Action (MoA)

1 EPITHELIUM INTEGRITY
(difficult HPV access to basal layer)

Mucoadhesive film formation allows the maintenance of **epithelium integrity** and works as a **protective barrier** (mechanic barrier)

2 OPTIMAL VAGINAL MICROBIOTA
(*decrease infection and persistence risk)*

Once attached to the mucous, polycarbophil releases H+ ions which contribute to **reducing pH in the vaginal environment** **(pH acid) for an optimal vaginal microbiota**



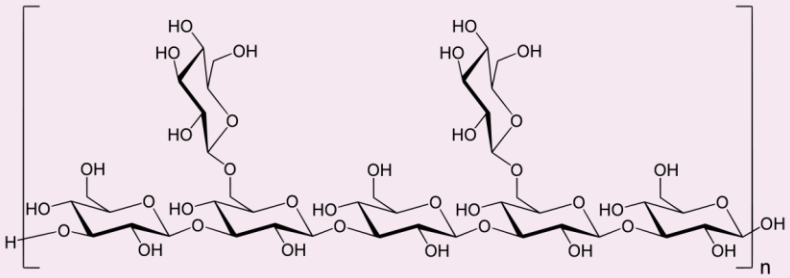
Laborest

Carboxylmethyl betaglucan

Key component supporting local immune response and epithelial recovery

Carboxymethyl β-glucan is a linear glucose polysaccharide obtained from the cell wall of *Saccharomyces cerevisiae*

- ✓ Known for its **immunomodulatory properties**
- ✓ Supports **local immune activation** involved in HPV clearance.
- ✓ Helps promote **tissue repair and epithelial recovery.**
- ✓ Contributes to maintaining a more favourable **cervical-vaginal environment**.



Amer, E., Saber, S., Markeb, A., Elkhawaga, A., Mekhemer, I., Zohri, A., Abujamel, T., Harakeh, S., & Abd-Allah, E. (2021). Enhancement of β-Glucan Biological Activity Using a Modified Acid-Base Extraction Method from Saccharomyces cerevisiae. *Molecules, 26*. https://doi.org/10.3390/molecules26082113.

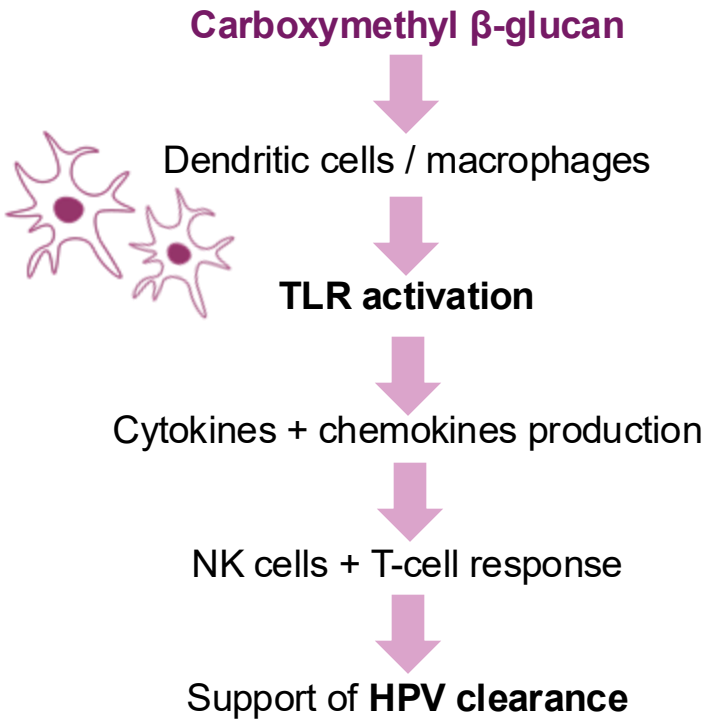
Carboxylmethyl betaglucan

Immune stimulation action

Carboxymethyl β-glucan can interact with immune cells such as macrophages and dendritic cells, helping activate local immune responses and cytokine production.

How it works

- ✓ **Targets innate immune cells**, mainly macrophages and dendritic cells.
- ✓ May interact with **pattern-recognition receptors**, such as Toll-like receptors.
- ✓ Activates intracellular signalling pathways.
- ✓ Promotes **cytokine and chemokine secretion**.
- ✓ Supports activation of immune effector cells, including **NK cells and T lymphocytes**



Carboxylmethyl betaglucan

Mechanisms of Action (MoA)

1

IMMUNE STIMULATION

↓

IMPROVES HPV CLEARANCE
Immune system fights against HPV infection

↓

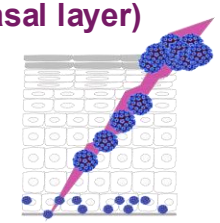
HELPS LESIONS REGRESSION
As HPV is cleared, lesions are improve

TISSUE REPAIRING ACTION

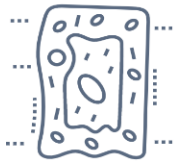
Macrophages, keratinocytes and fibroblasts are considered the main target of β-glucans during wound healing

β-glucans enhance wound repair by increasing the infiltration of macrophages, which stimulates tissue granulation, collagen deposition and **re-epithelialization.**

EPITHELIUM INTEGRITY (Difficult HPV Access to basal layer)



HELPS REPAIRING TISSUE after excisional treatment



Majtan, J. & Jesenak, M. β-Glucans: Multi-functional modulator of wound healing. Molecules (2018). doi:10.3390/molecules23040806

Carboxylmethyl betaglucan

Mechanisms of Action (MoA)

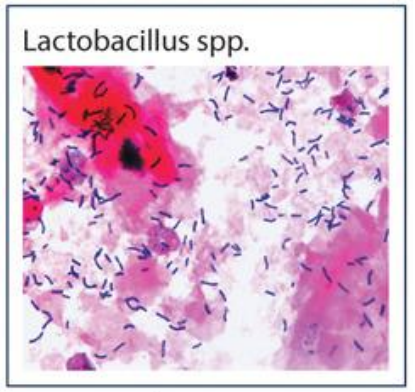
2

PREBIOTIC ACTION

Maintenance and/or restoration of the vaginal microbiota by a specific prebiotic effect

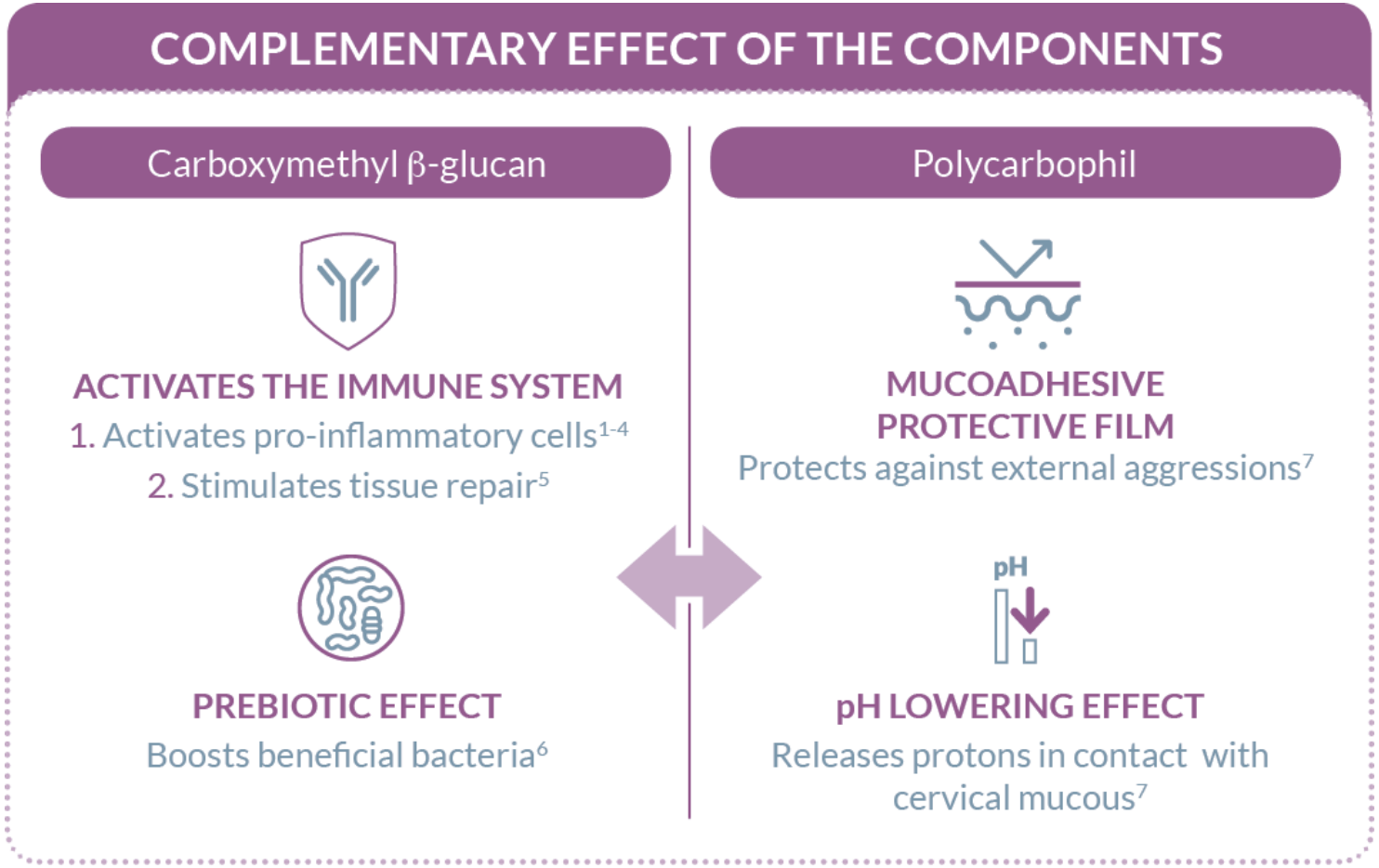
Betaglucan vaginal application provides a **specific source of energy for Lactobacillus sp., promoting their growth and domination of the vaginal microbiota**

Lactobacillus sp., the most abundant genus of bacteria found in the vaginal ecosystems, is critical for its role in maintaining a **low pH, which prevents pathogens overgrowth.**



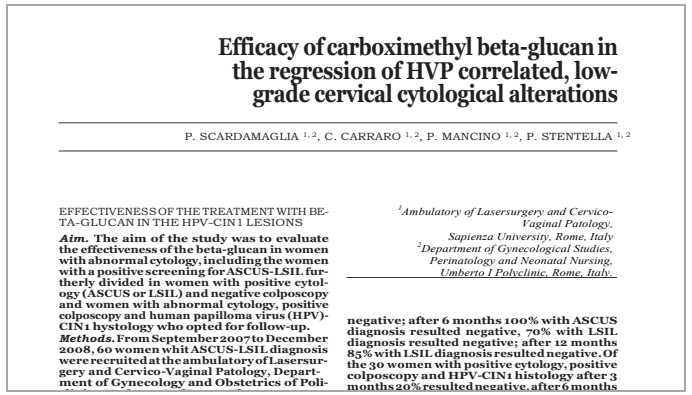
PREBIOTIC ACTION → **OPTIMAL VAGINAL MICROBIOTA** → **DECREASE INFECTION AND RISK OF PERSISTENCE**

Complementary effect of the components



2. Clinical evidence of Colpofix®

Overview of clinical studies



Efficacy of carboximethyl beta-glucan in the regression of HVP correlated, low-grade cervical cytological alterations

P. SCARDAMAGLIA [1, 2], C. CARRARO [1, 2], P. MANCINO [1, 2], P. STENTELLA [1, 2]

[1] *Ambulatory of Lasersurgery and Cervico-Vaginal Patology, Sapienza University, Rome, Italy*
[2] *Department of Gynecological Studies, Perinatology and Neonatal Nursing, Umberto I Polyclinic, Rome, Italy*

EFFECTIVENESS OF THE TREATMENT WITH BETA-GLUCAN IN THE HPV-CIN 1 LESIONS

Aim. **The aim of the study was to evaluate the effectiveness of the beta-glucan in women with abnormal cytology, including the women with a positive screening for ASCUS-LSIL furtherly divided in women with positive cytology (ASCUS or LSIL) and negative colposcopy and women with abnormal cytology, positive colposcopy and human papilloma virus (HPV)-CIN1 hystology who opted for follow-up.**

Methods. **From September 2007 to December 2008, 60 women whit ASCUS-LSIL diagnosis were recruited at the ambulatory of Lasersurgery and Cervico-Vaginal Patology, Department of Gynecology and Obstetrics of Poli-**

negative; after 6 months 100% with ASCUS diagnosis resulted negative, 70% with LSIL diagnosis resulted negative; after 12 months 85% with LSIL diagnosis resulted negative. Of the 30 women with positive cytology, positive colposcopy and HPV-CIN1 histology after 3 months 20% resulted negative, after 6 months

- ✓ Retrospective study
- ✓ N = **60 women Mean age of 24 (aged 18-35)**
- ✓ T = **12 months**
- ✓ Inclusion criteria
  - ✓ Women with an abnormal cytology (ASCUS/LSIL lesions)

Scardamagalia, 2010

DESIGN

Women with cytological diagnosis of **ASCUS/LSIL** (N=60)

Group 1 N=30
Negative colposcopy

Group 2 N=30
Positive colposcopy
HPV-CIN1histology

Colpofix® treatment*

Colpofix® treatment*

Colpofix® 1st month

Colpofix® 2nd month

1st month

3rd month

6th month

12th month

Follow-up
Cytology
Colposcopy

Follow-up
Cytology
Colposcopy

Follow-up
Cytology
Colposcopy

*One application per day (5 doses) for 20 days, followed by a 10-day suspension, for 2 months.

Scardamaglia P, Carraro C, Mancino P, Stentella P. Efficacia del carbossimetilbetaglucano nella regressione delle alterazioni citologiche cervicali di basso grado HPV correlate [Effectiveness of the treatment with beta-glucan in the HPV-CIN 1 lesions]. Minerva Ginecol. 2010 Oct;62(5):389-93. Italian. PMID: 20938424.

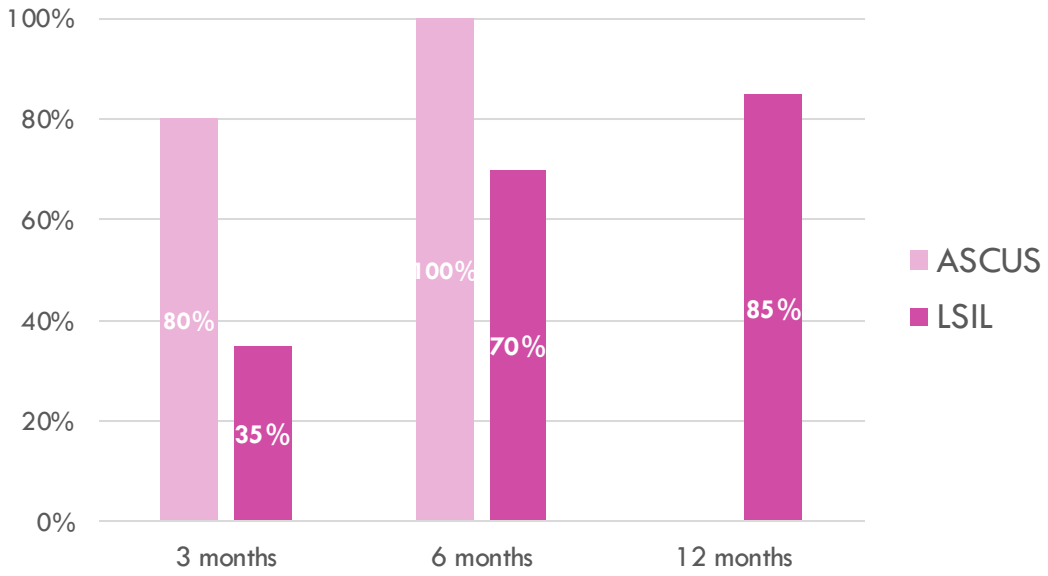
Overview of clinical studies

Scardamagalia, 2010

RESULTS

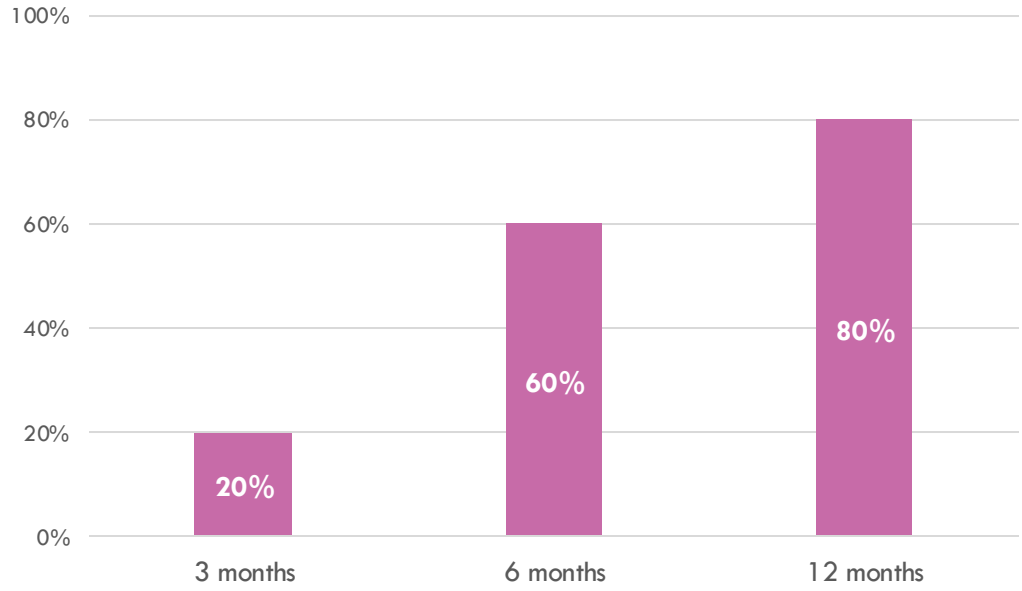
Group 1

Group 1: Colpocytological negative examinations



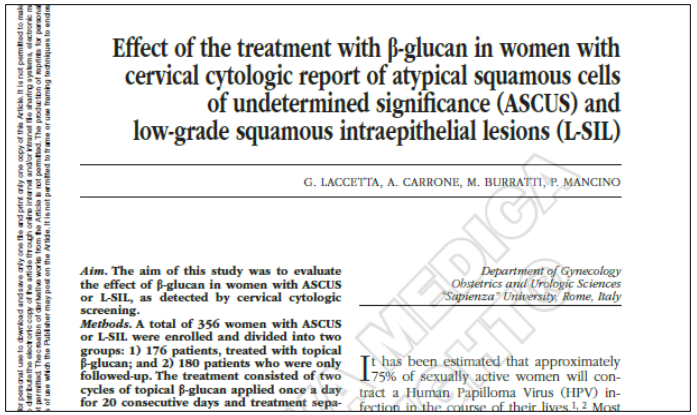
Group 2

Group 2: Colpocytological negative examinations



Scardamaglia P, Carraro C, Mancino P, Stentella P. Efficacia del carbossimetilbetaglucano nella regressione delle alterazioni citologiche cervicali di basso grado HPV correlate [Effectiveness of the treatment with beta-glucan in the HPV-CIN 1 lesions]. Minerva Ginecol. 2010 Oct;62(5):389-93. Italian. PMID: 20938424.

Overview of clinical studies



Effect of the treatment with β-glucan in women with cervical cytologic report of atypical squamous cells of undetermined significance (ASCUS) and low-grade squamous intraepithelial lesions (L-SIL)

G. LACCETTA, A. CARRONE, M. BURRATTI, P. MANCINO

Department of Gynecology Obstetrics and Urologic Sciences "Sapienza" University, Rome, Italy

Aim. **The aim of this study was to evaluate the effect of β-glucan in women with ASCUS or L-SIL, as detected by cervical cytologic screening.**

Methods. **A total of 356 women with ASCUS or L-SIL were enrolled and divided into two groups: 1) 176 patients, treated with topical β-glucan; and 2) 180 patients who were only followed-up. The treatment consisted of two cycles of topical β-glucan applied once a day for 20 consecutive days and treatment sepa-**

It has been estimated that approximately 75% of sexually active women will contract a Human Papilloma Virus (HPV) infection in the course of their lives.[1, 2] Most

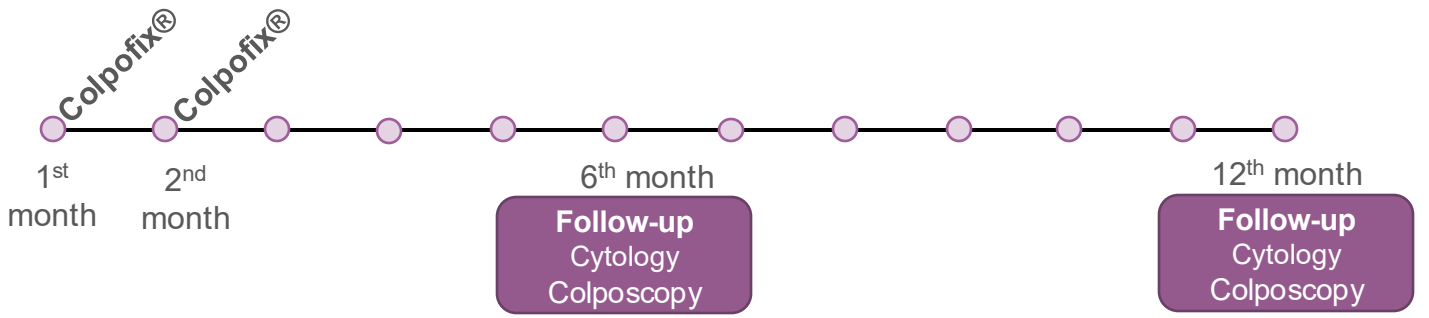
- Prospective, Randomized 1:1, Case-control study
- N = **356 women** between **16 to 75** years old (mean age of **33.3 years old**)
- T = **6 and 12 months**
- Inclusion criteria:
  - Women HPV+
  - Women diagnosed with ASCUS/LSIL

Laccetta, 2015

DESIGN

Women with cytologic report of ASCUS/L-SIL (N=356)

	GRUPO 1	GRUPO 2	GRUPO 3	GRUPO 4
Case – **Grupo 1** N=176 Colpofix®	N=34 Women with **ASCUS lesion and negative Colposcopy**	N=59 Women with **L-SIL lesion and negative Colposcopy**	N=25 Women with **ASCUS lesion and positive Colposcopy**	N=58 Women with **L-SIL lesion and positive Colposcopy**
Control – **Grupo 2** N=180 Wait & See	N=42 Women with **ASCUS lesion and negative Colposcopy**	N=61 Women with **L-SIL lesion and negative Colposcopy**	N=18 Women with **ASCUS lesion and positive Colposcopy**	N=59 Women with **L-SIL lesion and positive Colposcopy**



Laccetta G, Carrone A, Burratti M, Mancino P. Effect of the treatment with β-glucan in women with cervical cytologic report of atypical squamous cells of undetermined significance (ASCUS) and low-grade squamous intraepithelial lesions (L-SIL). Minerva Ginecol. **2015** Apr;67(2):113-20. Epub 2015 Feb 5. PMID: 25668505

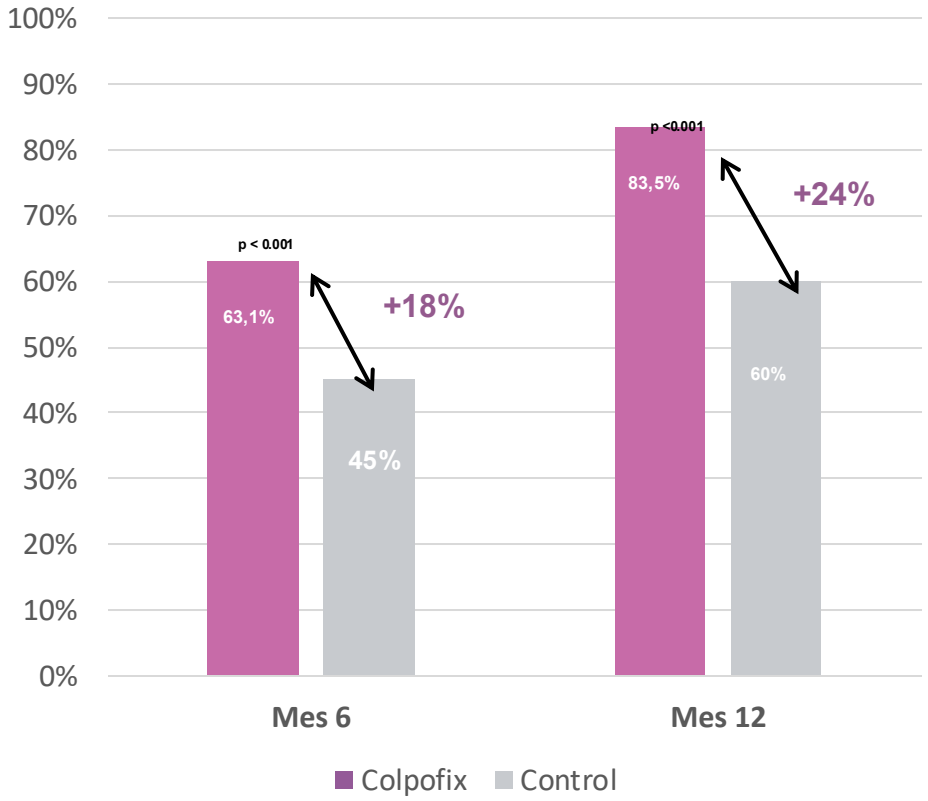
Laborest

Overview of clinical studies

Laccetta, 2015

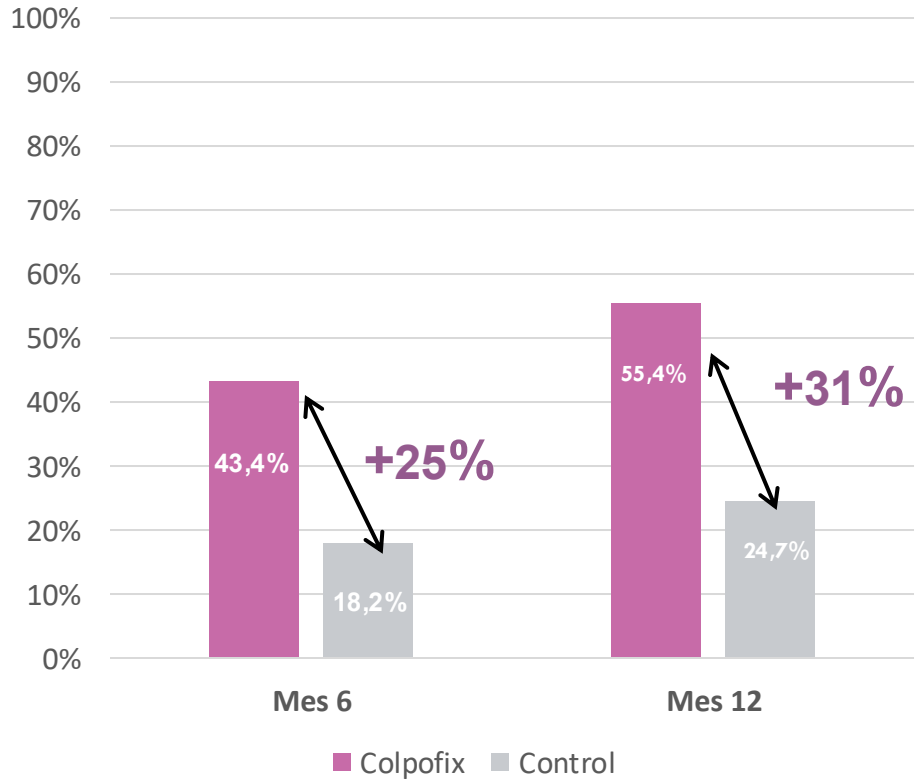
+24% negative cytology and +31% negative colposcopy at 12 months

Negative Cytology



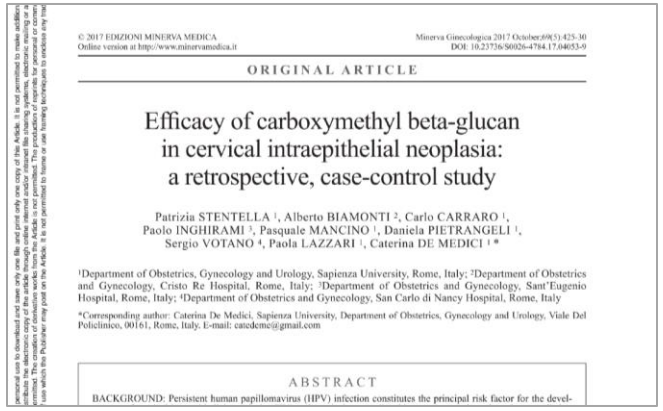
No adverse events reported in the treated group

Negative Colposcopy
In women with ASCUS/LSIL and positive colposcopy



Laccetta G, Carrone A, Burratti M, Mancino P. Effect of the treatment with β-glucan in women with cervical cytologic report of atypical squamous cells of undetermined significance (ASCUS) and low-grade squamous intraepithelial lesions (L-SIL). Minerva Ginecol. **2015** Apr;67(2):113-20. Epub 2015 Feb 5. PMID: 25668505

Overview of clinical studies



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Minerva Ginecologica 2017 October;69(5):425-30
DOI: 10.23736/S0026-4784.17.04053-9

ORIGINAL ARTICLE

Efficacy of carboxymethyl beta-glucan in cervical intraepithelial neoplasia: a retrospective, case-control study

Patrizia STENTELLA [1], Alberto BIAMONTI [2], Carlo CARRARO [1], Paolo INGHIRAMI [3], Pasquale MANCINO [1], Daniela PIETRANGELI [1], Sergio VOTANO [4], Paola LAZZARI [1], Caterina DE MEDICI [1] *

[1]Department of Obstetrics, Gynecology and Urology, Sapienza University, Rome, Italy; [2]Department of Obstetrics and Gynecology, Cristo Re Hospital, Rome, Italy; [3]Department of Obstetrics and Gynecology, Sant'Eugenio Hospital, Rome, Italy; [4]Department of Obstetrics and Gynecology, San Carlo di Nancy Hospital, Rome, Italy

*Corresponding author: Caterina De Medici, Sapienza University, Department of Obstetrics, Gynecology and Urology, Viale Del Policlinico, 00161, Rome, Italy. E-mail: caterinademedici@gmail.com

ABSTRACT

BACKGROUND: Persistent human papillomavirus (HPV) infection constitutes the principal risk factor for the devel-

- **Retrospective case-control study**
- **Multicentric** (4 hospitals)
- N = **999 women with mean age of 36.1 (+/- 10) (18-65 years old)**
- T = **12 months**
- Inclusion criteria:
  - Patients attending Colposcopy for abnormal Pap Test

Stentella, 2017

DESIGN

Case-arm

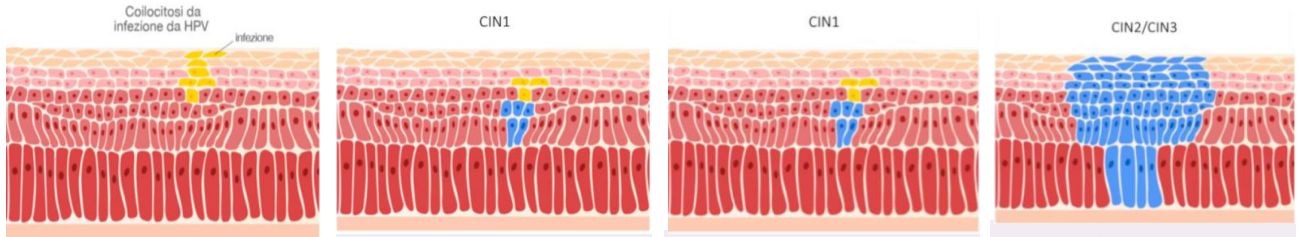
Patients who **received** Colpofix® treatment

Group 1	Group 2	Group 3	Group 4
N=187	N=168	N=99	N=81

Control-arm

Patients who did **not receive** Colpofix® treatment

Group 1	Group 2	Group 3	Group 4
N=124	N=144	N=98	N=98



Group 1
ASCUS/LSIL
Negative colposcopy

FOLLOW-UP

Group 2
ASCUS/LSIL
Positive colposcopy
Histology CIN1

FOLLOW-UP

Group 3
ASCUS/LSIL
Positive colposcopy
Histology CIN1

ABLATIVE THERAPY

Group 4
HSIL
Positive colposcopy
Histology CIN2/3

LEEP

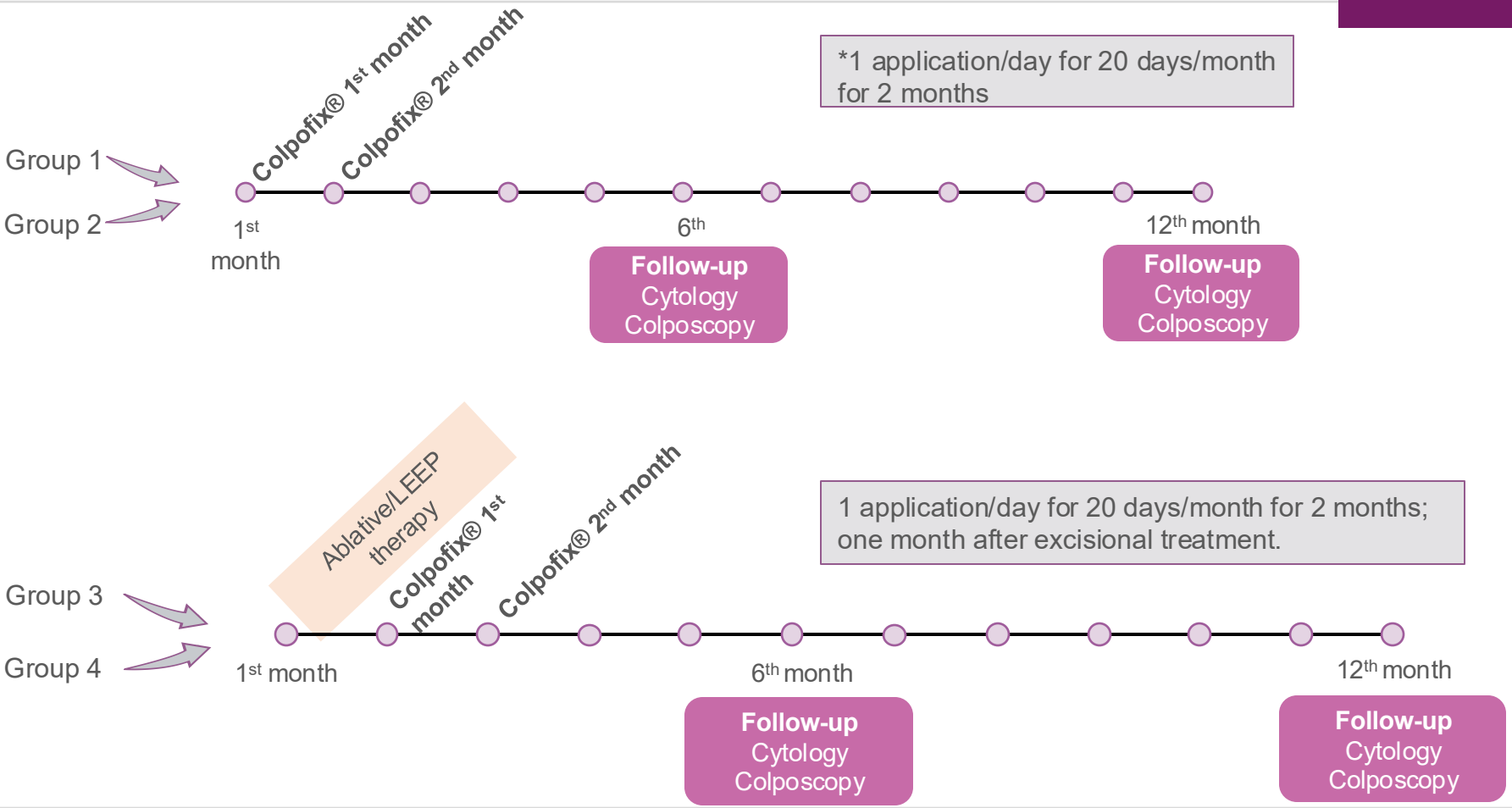
Stentella P, Biamonti A, Carraro C, Inghirami P, Mancino P, Pietrangeli D, Votano S, Lazzari P, DE Medici C. Efficacy of carboxymethyl beta-glucan in cervical intraepithelial neoplasia: a retrospective, case-control study. Minerva Ginecol. 2017 Oct;69(5):425-430. doi: 10.23736/S0026-4784.17.04053-9. PMID: 28675291.

Laborest

Overview of clinical studies

Stentella, 2017

TIMELINE



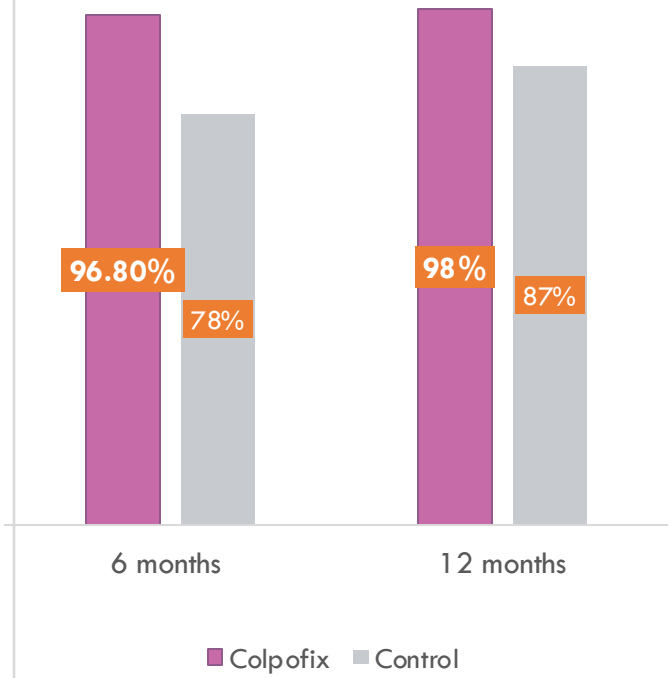
Stentella P, Biamonti A, Carraro C, Inghirami P, Mancino P, Pietrangeli D, Votano S, Lazzari P, DE Medici C. Efficacy of carboxymethyl beta-glucan in cervical intraepithelial neoplasia: a retrospective, case-control study. Minerva Ginecol. 2017 Oct;69(5):425-430. doi: 10.23736/S0026-4784.17.04053-9. PMID: 28675291.

Overview of clinical studies

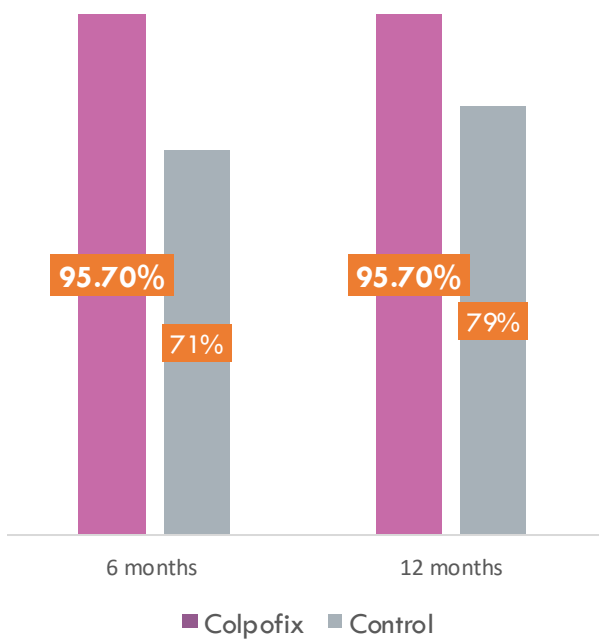
Stentella, 2017

RESULTS

ASCUS/LSIL regression **1,2 x**



CIN1 regression **1,3 x**



Post conization as reepithelialising

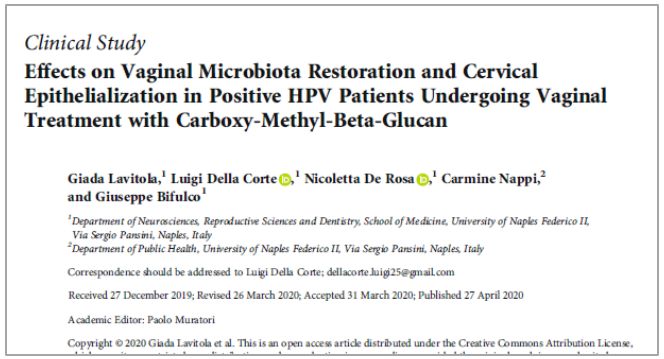
Group	6-month follow-up	12 month follow-up	P value
Group 3			
Colpofix®	91 (92%)	94 (95%)	NS
Control	88(90%)	94 (96%)	
Group 4			
Colpofix®	81 (100%)	78 (96.4%)	NS
Control	96 (98%)	94 (96%)	

Table 6. Negative histology (<CIN2+) at 6- and 12-months' follow-up in groups 3 and 4

There is no improvement in the regression rate due to removal of abnormal tissue by surgery

Stentella P, Biamonti A, Carraro C, Inghirami P, Mancino P, Pietrangeli D, Votano S, Lazzari P, DE Medici C. Efficacy of carboxymethyl beta-glucan in cervical intraepithelial neoplasia: a retrospective, case-control study. Minerva Ginecol. 2017 Oct;69(5):425-430. doi: 10.23736/S0026-4784.17.04053-9. PMID: 28675291.

Overview of clinical studies



Clinical Study

Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan

Giada Lavitola,[1] Luigi Della Corte,[1] Nicoletta De Rosa,[1] Carmine Nappi,[2] and Giuseppe Bifulco[1]

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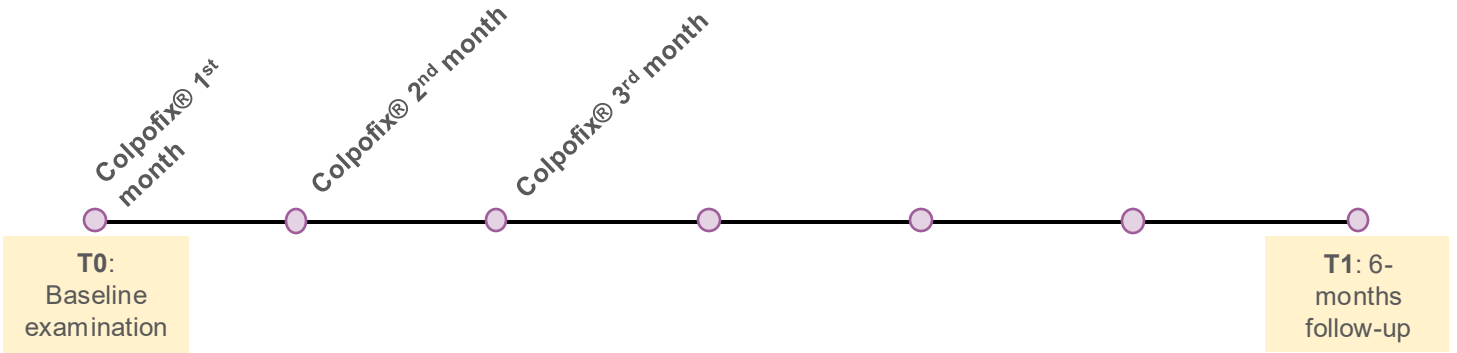
Academic Editor: Paolo Muratori

- **Retrospective case-control study**
- N = **784 women mean age of 34,11** (+/-6,35) years
- T = **6 months**
- Inclusion criteria
  - Women between 18 to 60 years old
  - **HPV-positive and/or CIN1 positive by punch biopsy**. Exclusion of CIN 2/3

Lavitola, 2020

DESIGN

- Group A: 392 treated women with **Colpofix®** (1 application/day for 20 days per month during 3 months).
- Group B: 392 untreated women (control group)



ENDPOINTS

Epithelialization and Vaginal health	Ectopia >2/3	Metaplasia >20%	Positive Lugol test	
	Vaginal pH>4,5	Positive Whiff test	Presence of leucohorrea	
Cytohistological, molecular and colposcopic tests	Positive pap test	Positive HPV test	Positive Colposcopy	Positive Biopsy

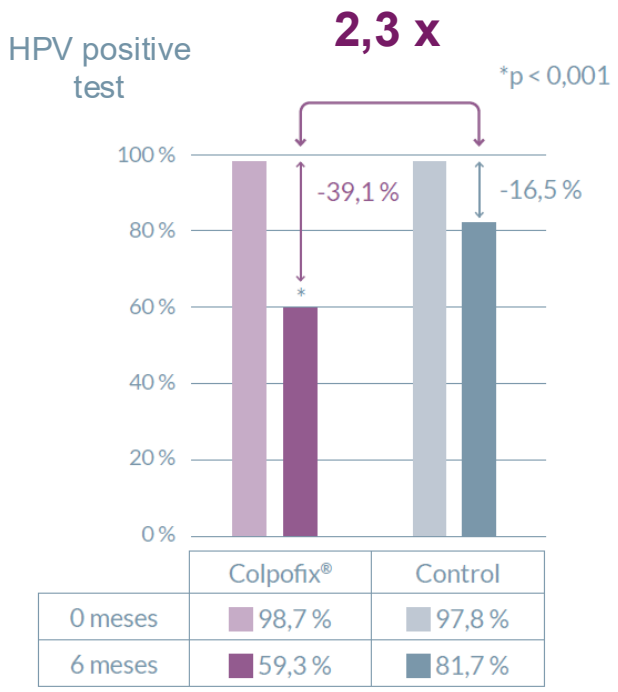
Lavitola G, Della Corte L, De Rosa N, Nappi C, Bifulco G. Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan. Biomed Res Int. 2020 Apr 27;2020:5476389. doi: 10.1155/2020/5476389. PMID: 32420349; PMCID: PMC7201736.

Overview of clinical studies

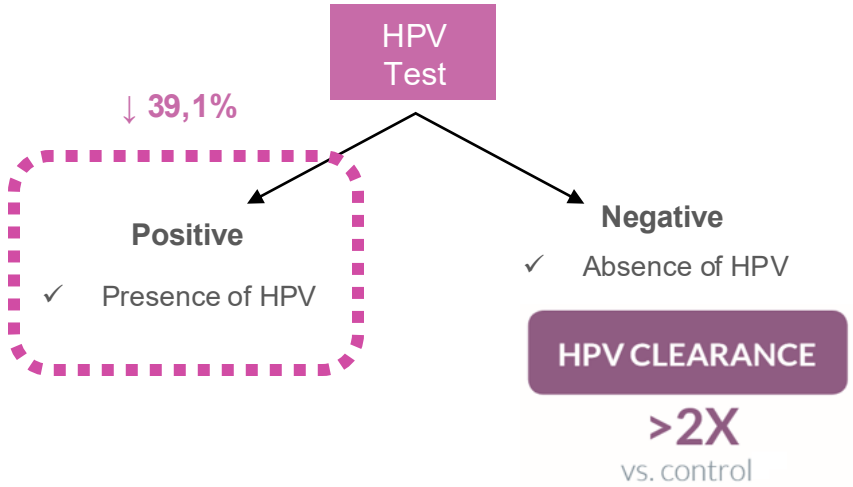
Lavitola, 2020

RESULTS: Colpofix doubles HPV clearance

- After 6 months of Colpofix® treatment, patients **decreased significantly (39,1%)** positive results for HPV-test.
- After Colpofix® treatment, **HPV clearance** is improved **twice** as much as control group.



	Colpofix®	Control
0 meses	98,7 %	97,8 %
6 meses	59,3 %	81,7 %



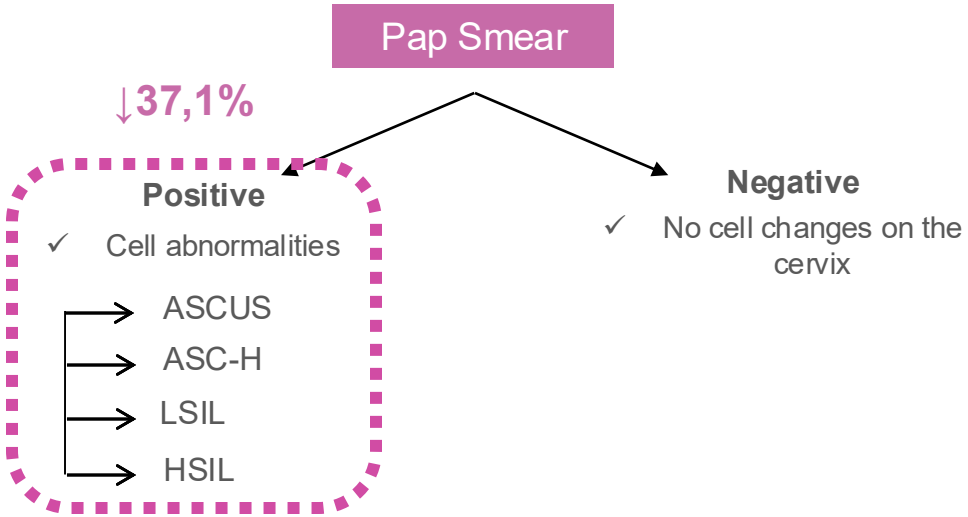
Lavitola G, Della Corte L, De Rosa N, Nappi C, Bifulco G. Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan. Biomed Res Int. 2020 Apr 27;2020:5476389. doi: 10.1155/2020/5476389. PMID: 32420349; PMCID: PMC7201736.

Overview of clinical studies

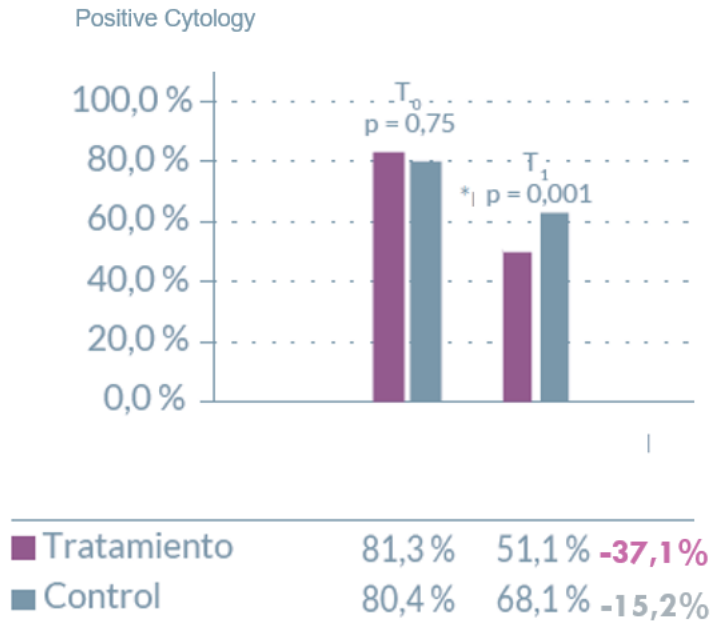
Lavitola, 2020

RESULTS: Colpofix doubles Negative Cytology

- After 6 months of Colpofix® treatment, patients **decreased significantly (37,1%)** positive results for Pap Test



2,4 x



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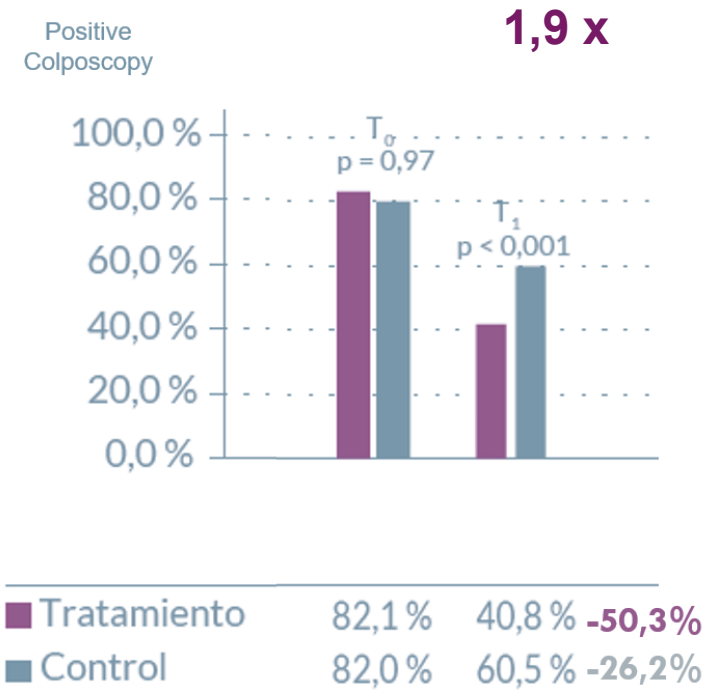
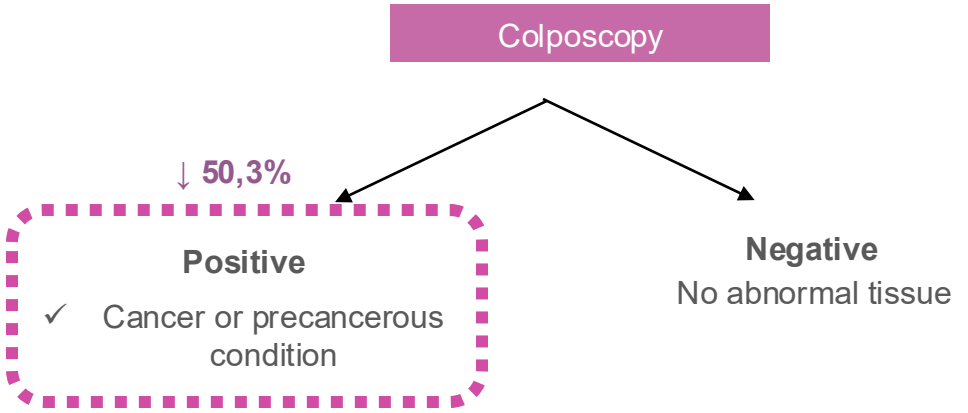
Overview of clinical studies

Lavitola, 2020

RESULTS: Colpofix decreases significantly the number of positive colposcopies



- After 6 months of Colpofix® treatment, patients **decreased significantly (50,3%)** positive results for colposcopy, which means that CIN1 lesions have regressed.



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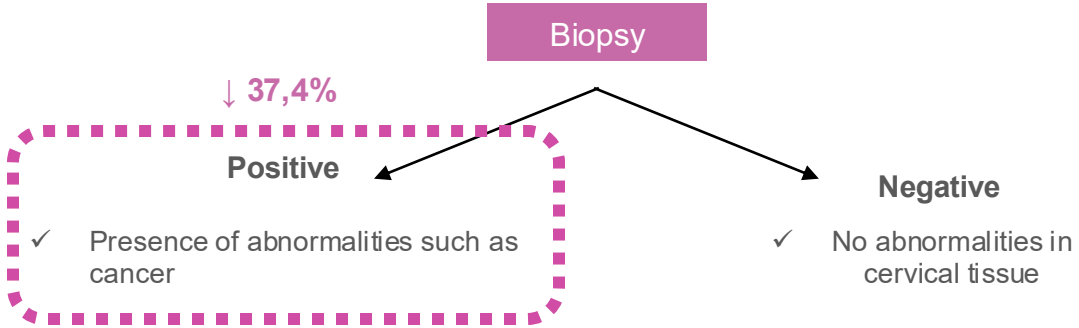
Overview of clinical studies

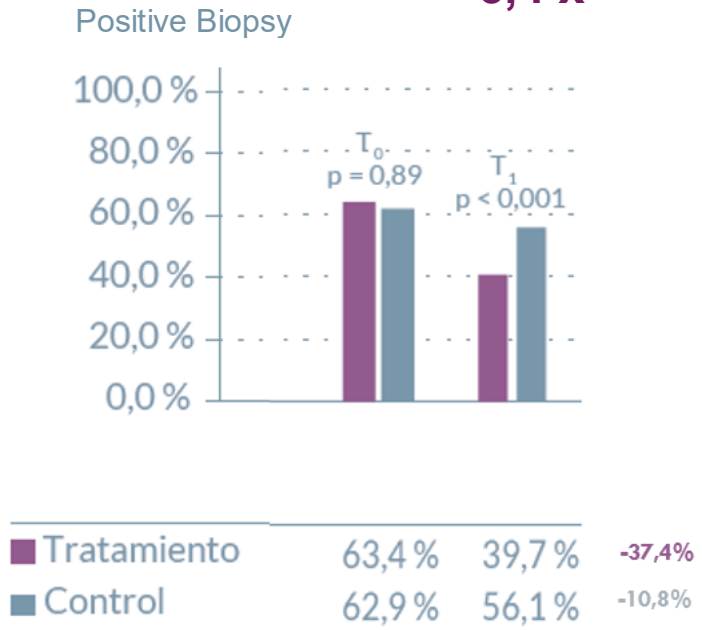
Lavitola, 2020

RESULTS: Colpofix triples the number of negative biopsies

- After 6 months of Colpofix® treatment, patients **reduced significantly (37,4%)** positive results for biopsy, indicating an **increased regression rate**.



3,4 x



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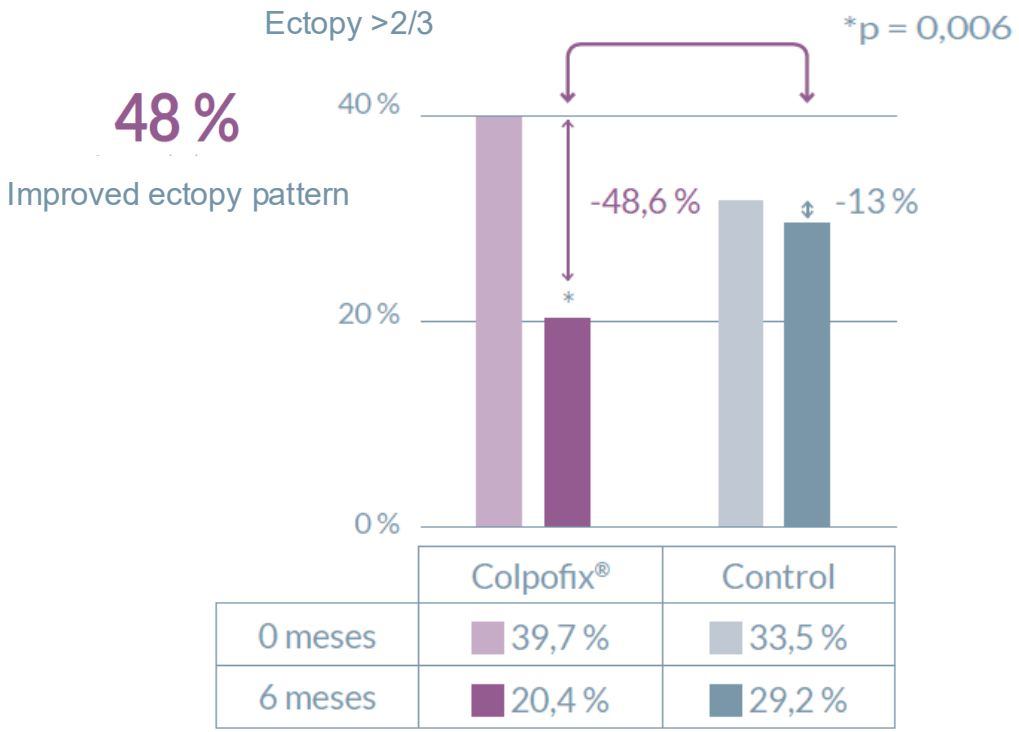
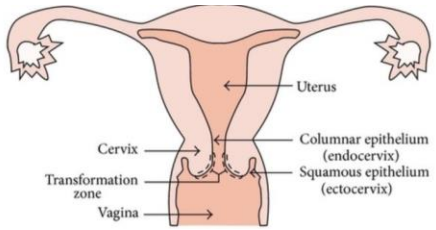
Overview of clinical studies

Lavitola, 2020

RESULTS: Colpofix improves by 48% ectopy pattern



	Colpofix®	Control
0 meses	39,7 %	33,5 %
6 meses	20,4 %	29,2 %



HEALTHY CERVIX

CERVICAL ECTROPION

Presence of **endocervical columnar epithelium on the ectocervix.**

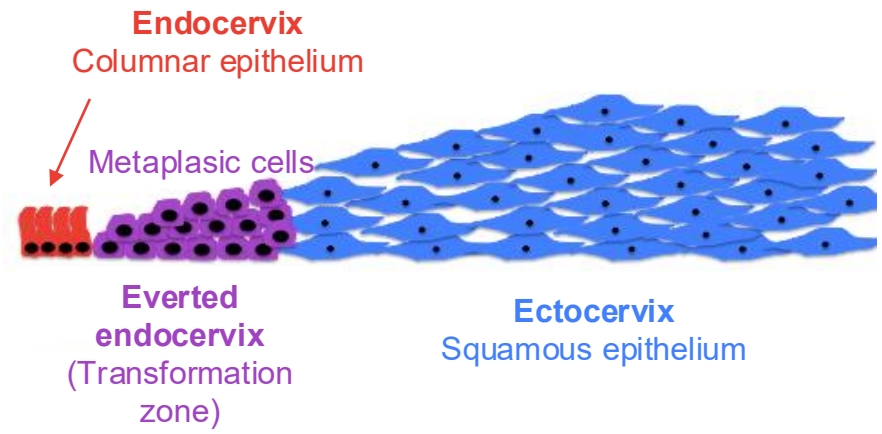
- After 6 months of Colpofix® treatment, patients **reduced significantly (48,6%)** ectopia.
- Colpofix® treatment reduced 4 times the presence of endocervical cells in the ectocervix compared with control.

Lavitola G, Della Corte L, De Rosa N, Nappi C, Bifulco G. Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan. Biomed Res Int. 2020 Apr 27;2020:5476389. doi: 10.1155/2020/5476389. PMID: 32420349; PMCID: PMC7201736.

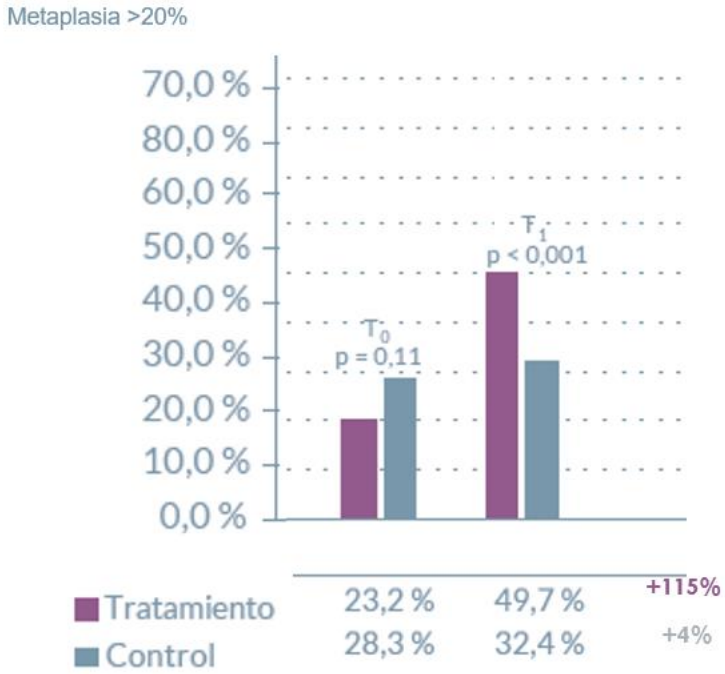
Overview of clinical studies

Lavitola, 2020

RESULTS: Colpofix increases by 115% metaplasia



Physiological replacement of columnar epithelium to squamous epithelium in the everted endocervix to the ectocervix.



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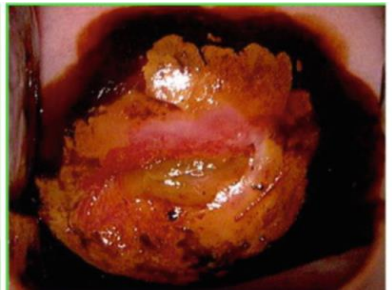
Overview of clinical studies

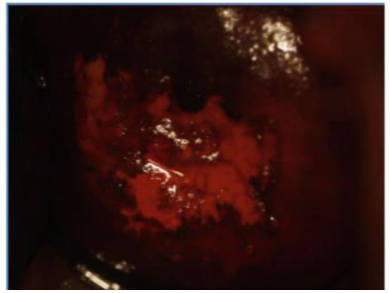
Lavitola, 2020

RESULTS: Colpofix improves reduced by 36,3% Lugol test

Lugol Test



CIN1 before treatment with Colpofix®



Transformation zone after treatment with Colpofix®

Lugol detects epithelial lesions.

Squamous epithelium is glycogenated, but other epithelial lesions contain little/no glycogen.

Glycogen of squamous epithelium stains brown as it uptakes Lugol; while columnar epithelium or epithelial lesions do not stain due to their lack of glycogen.

Lugol Test (non-captive)

	Colpofix ®	Control
0 months	85.50%	85.60%
6 months	54.20%	74.10%

- After 6 months of Colpofix® treatment, patients **reduced significantly (36,3%)** non-captive Lugol Test, which indicates **less epithelial lesions** and higher presence of resistant **squamous epithelium**.

Lavitola G, Della Corte L, De Rosa N, Nappi C, Bifulco G. Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan. Biomed Res Int. 2020 Apr 27;2020:5476389. doi: 10.1155/2020/5476389. PMID: 32420349; PMCID: PMC7201736.

Overview of clinical studies

Lavitola, 2020

RESULTS Colpofix decreased 73,5% positives in Whiff Test

Colpofix reduced by 67,4% leucorrhoea

Whiff Test

Whiff test detects amine odor that occurs in dysbiosis. A positive result is abnormal.

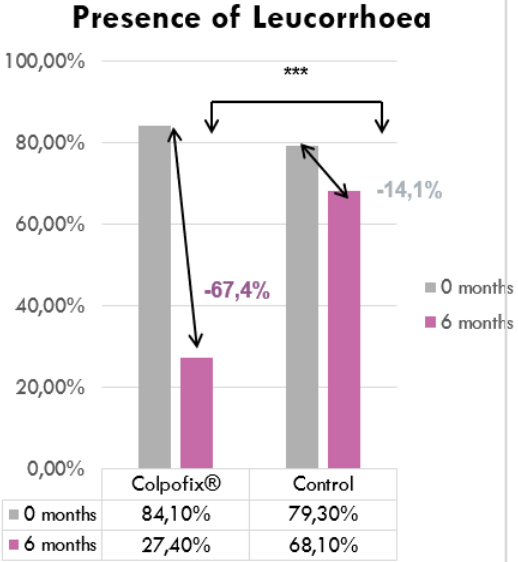
- After 6 months of Colpofix® treatment, patients **decreased significantly (73,5%)** positives in Whiff Test.
- This results indicates an improvement in **vaginal microbiota**, a more **acidic environment** and therefore, an improved **HPV clearance** and **vaginal health**.

	Colpofix ®	Control
0 months	47,50%	44,40%
6 months	12,60%	42,20%

Presence of Leucorrhoea

Leucorrhoea refers to a thick, whitish or yellowish vaginal discharge, usually due to vaginal infection.

- After 6 months of Colpofix® treatment, patients **reduced significantly (67,4%)** leucorrhoea, which indicates a **vaginal health improvement.**
- Colpofix treatment reduced **5 times** the presence of Leucohorrea compared with control group.



	Colpofix®	Control
0 months	84,10%	79,30%
6 months	27,40%	68,10%

Lavitola G, Della Corte L, De Rosa N, Nappi C, Bifulco G. Effects on Vaginal Microbiota Restoration and Cervical Epithelialization in Positive HPV Patients Undergoing Vaginal Treatment with Carboxy-Methyl-Beta-Glucan. Biomed Res Int. 2020 Apr 27;2020:5476389. doi: 10.1155/2020/5476389. PMID: 32420349; PMCID: PMC7201736.

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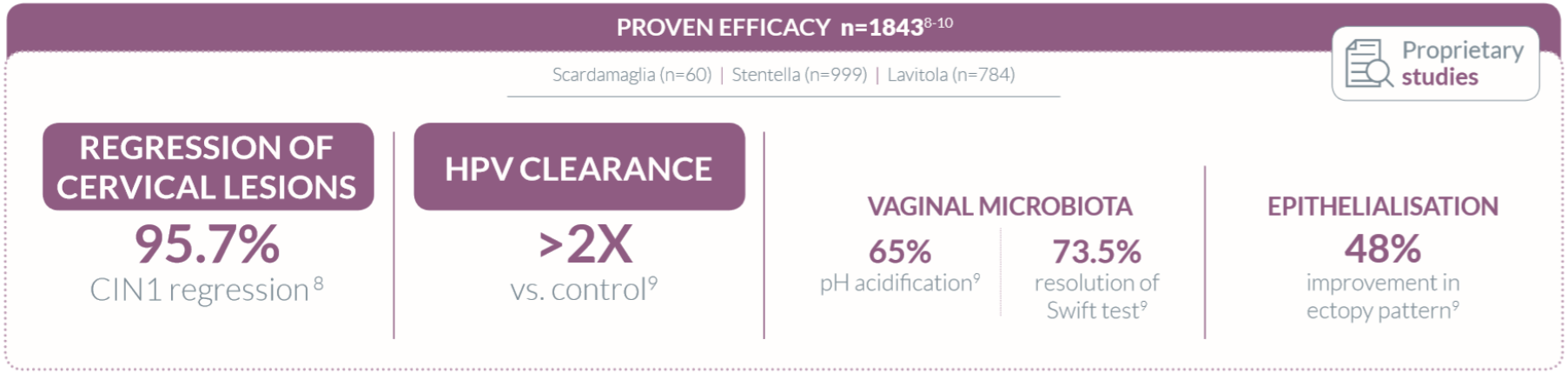
Conclusions



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Colpofix new study under publication

Objective:
Evaluate the efficacy and safety of the local treatment of Carboxymethyl beta-glucan and Polycarbophil in patients with normal cytology/ASCUS/LSIL (CIN1) with HPV+ PCR determination

Real World Evidence
Women from **25 to 65 years old**
N= 533 patients

533 patients finished the study

PI: Dr. Carmen Pingarrón
29 Spanish KOLs

First visit → Final visit

Colpofix for 3 months
6 month Follow up: HPV test

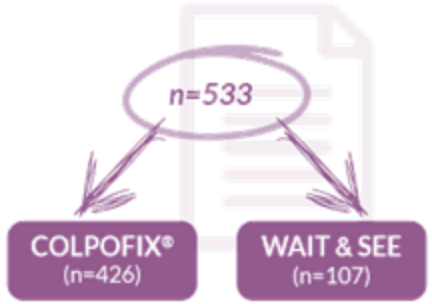
Colpofix new study under publication

METHODOLOGY

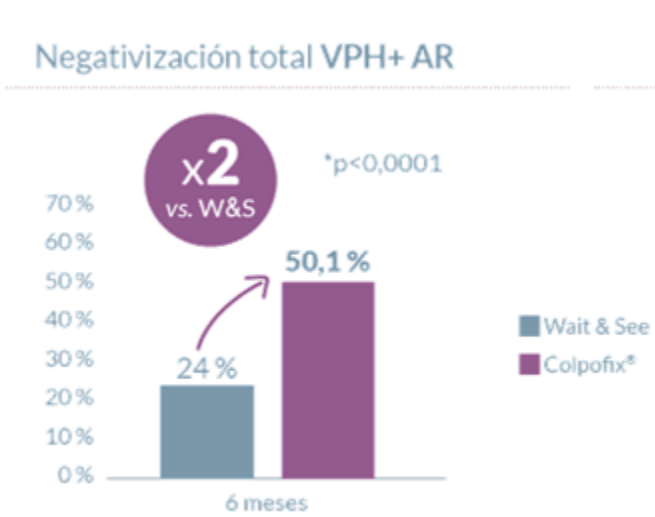
- Observational, Prospective, Control Group, Multicentric in Real Clinical Practice
- Population: Women between 25 – 65 years old with **Normal/ASCUS/LSIL cytology and +HPV-HR**

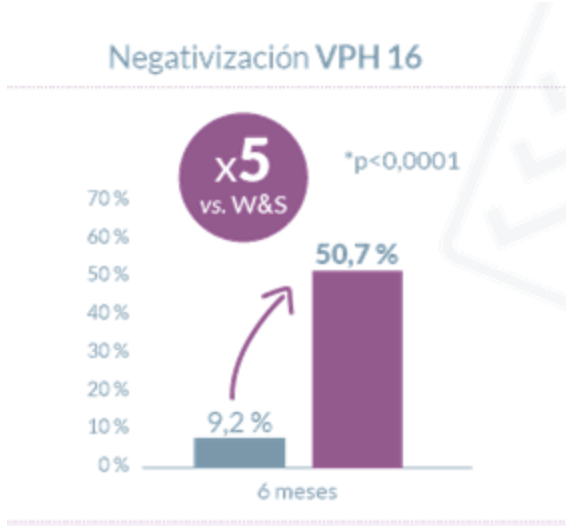
Genotypes:
16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 y 68

- **44,1%** of women were **vaccinated against HPV**



RESULTS AT 6 MONTHS





Total **+HPV-HR negativisation** was **DOUBLE (50,1%)** in **Colpofix** group vs. 24% of W&S at 6 months

HPV 16 negativisation was **5 times higher (50,7%)** in **Colpofix** group vs. 9,2% of W&S at 6 months

Laborest

Colpofix effects

- ✓ Colpofix® improves HPV CLEARANCE
- ✓ Colpofix® increases REGRESSION OF CERVICAL LESIONS
- ✓ Colpofix® helps EPITHELIALIZATION
- ✓ Colpofix improves VAGINAL MICROBIOTA

Thank you!