2023

Congresso Nazionale A.GI.Co

5-6 Maggio 2023

Hotel Astra
Viale Cavour, 55 - Ferrara

A.Gi.Co.
Associazione Ginecologi Consultoriali

Ferrara, 5 Maggio 2023
Irene Piccolotti

Sindrome genitourinaria

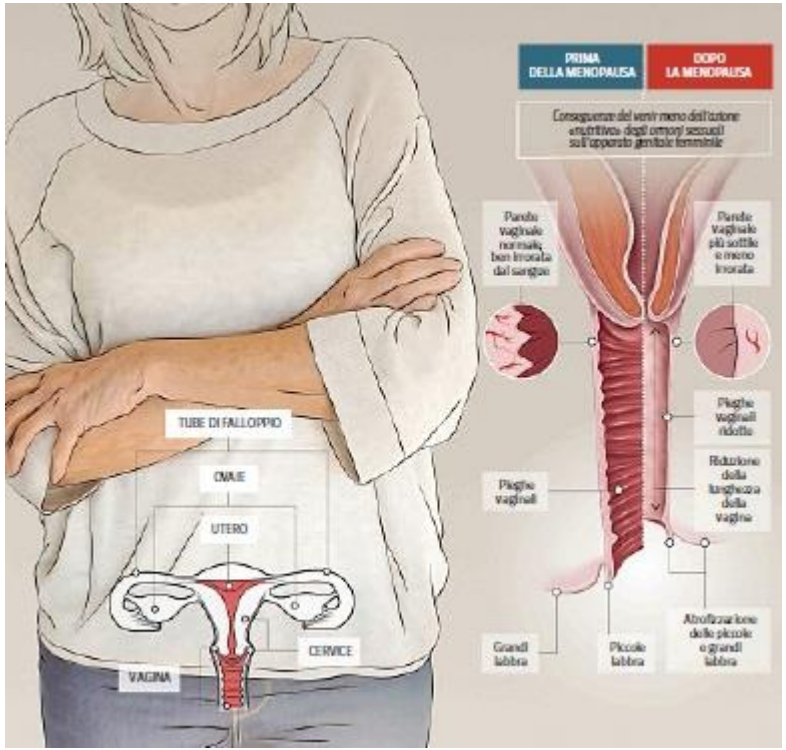
quale terapia?

Definizione

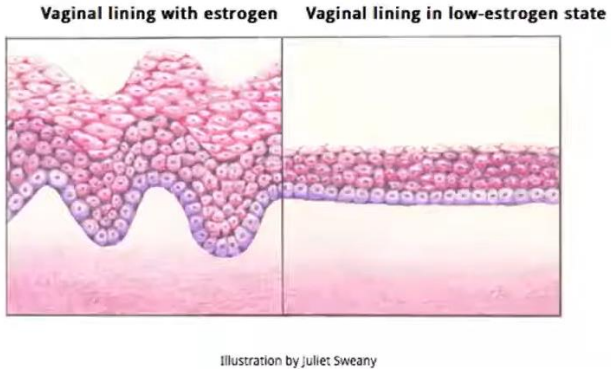
2014: **Genitourinary syndrome of menopause (GSM)**

Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and the North American Menopause Society.

Non solo **VVA!**



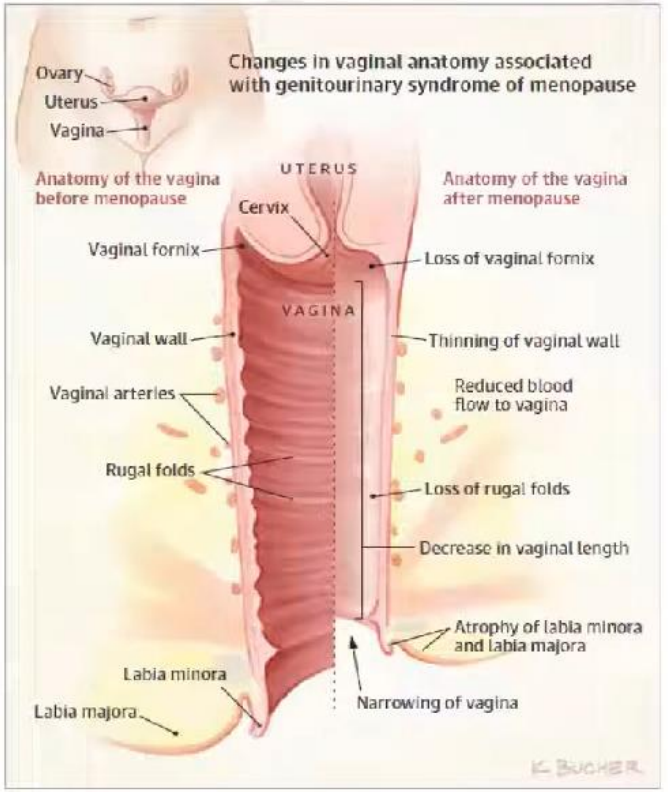
Patogenesi



➔ Carenza estrogenica post-menopausale
➔ Riduzione espressione recettori per gli estrogeni alfa e beta

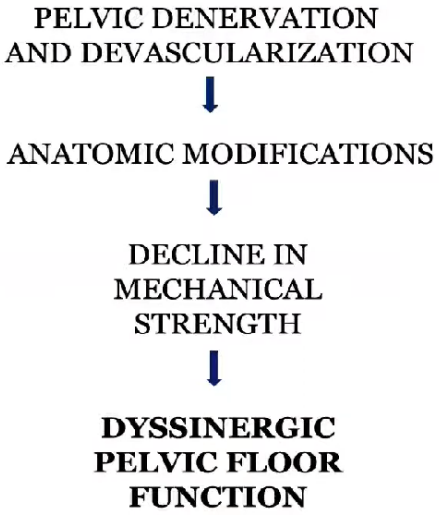
- ridotto turnover
- perdita di elasticità tissutale per fusione e ialinizzazione delle fibre collagene e frammentazione delle fibre elastiche
- perdita di idratazione per perdita di matrice intercellulare a base di mucopolisaccaridi e acido ialuronico

- Perdita rugosità vaginale –> assottigliamento e raccorciamento canale vaginale
- Assottigliamento mucosa –> pallore dei genitali esterni, scomparsa delle piccole labbra, restringimento dell'introito vaginale
- Dominanza cellule parabasali dell'epitelio con riduzione cellule intermedie e superficiali: **indice di maturazione vaginale**

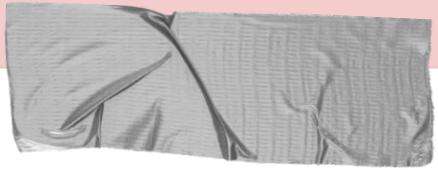


- Riduzione > 50% dei corpi cavernosi, involuzione delle fibre nervose –> perdita progressiva di sensibilità sessuale
- Riduzione del supporto vascolare –> riduzione trasudato –> ridotta lubrificazione
- Ipersensibilità delle fibre dolorose

- assottigliamento e perdita forza contrattile muscoli vaginali e perivaginali: prolasso pareti vaginali, prolasso dell'uretra, caruncola
- Assottigliamento dell'epitelio –> riduzione glicogeno –> riduzione lattobacilli –> aumento pH vaginale (tra 5,0 e 7,5) e una riduzione del perossido di idrogeno –> infezioni batteriche (stafilococco, streptococco di gruppo B, coliformi)
- Assottigliamento mucosa uretrale –> deficit continenza, sintomi urinari, UTI



Badiou W et al. Pelvic FloorDysfunct Int Urogynecol J 2008



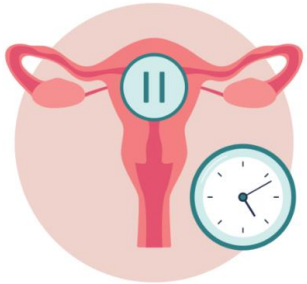
ALTRE CATEGORIE

- Allattamento
- Pillola EP a basso dosaggio di etinilestradiolo
- Ca mammario in terapia con inibitori dell’aromatasi
- Ca ginecologici sottoposti a chirurgia o radioTP

Sintomi

	Genitale	Sessuale	Urinario
Sintomi	Secchezza vaginale Irritazione, prurito, bruciore vaginale Dolore/peso vaginale/pelvico	Dispareunia Ridotta lubrificazione Riduzione del desiderio Perdite ematiche postcoitali	Disuria Urgenza minzionale Incontinenza da sforzo Nicturia
Segni	Atrofia labiale Perdita rughe vaginali Pallore mucosa vaginale Ridotta elasticità Incremento del pH Stenosi introitale		Prolasso/caruncola uretrale Ischemia del trigono Stenosi meato uretrale

Diagnosi



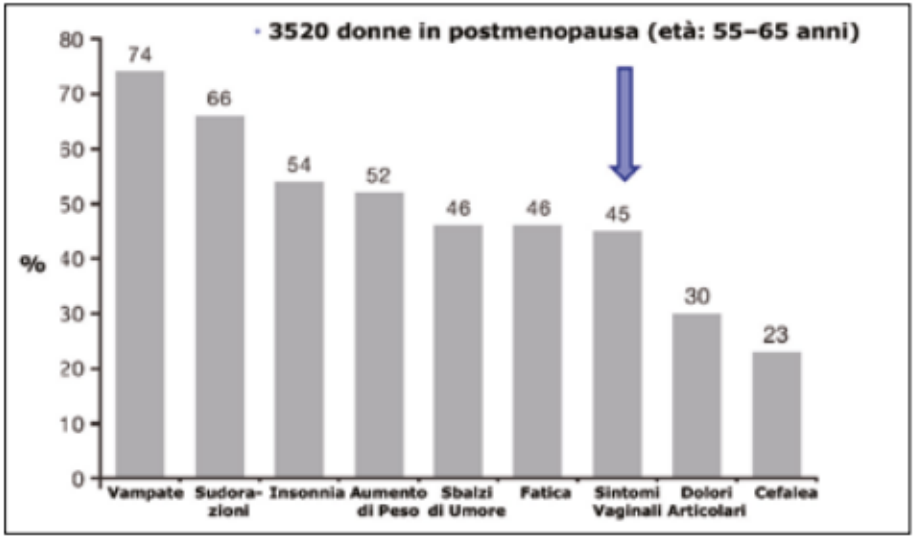
GSM-like symptoms may be also be present in **15% of premenopausal women** due to the hypoestrogenic state

50-70% of postmenopausal women suffering from symptomatic GSM.

Symptoms of menopause - global prevalence, physiology and implications

Patrizia Monteleone [1], Giulia Mascagni [1], Andrea Giannini [1], Andrea R Genazzani [1], Tommaso Simoncini [1]

Diagnosi



VIVA

- ➔ 45% delle donne in postmenopausa
- ➔ il 55% ha atteso più di 3 anni prima di affrontare l'argomento col medico

- ➔ 80% effetto negativo sulla QOL
- ➔ 75% impatto sulla sessualità
- ➔ 33% effetti negativi su relazioni e matrimonio

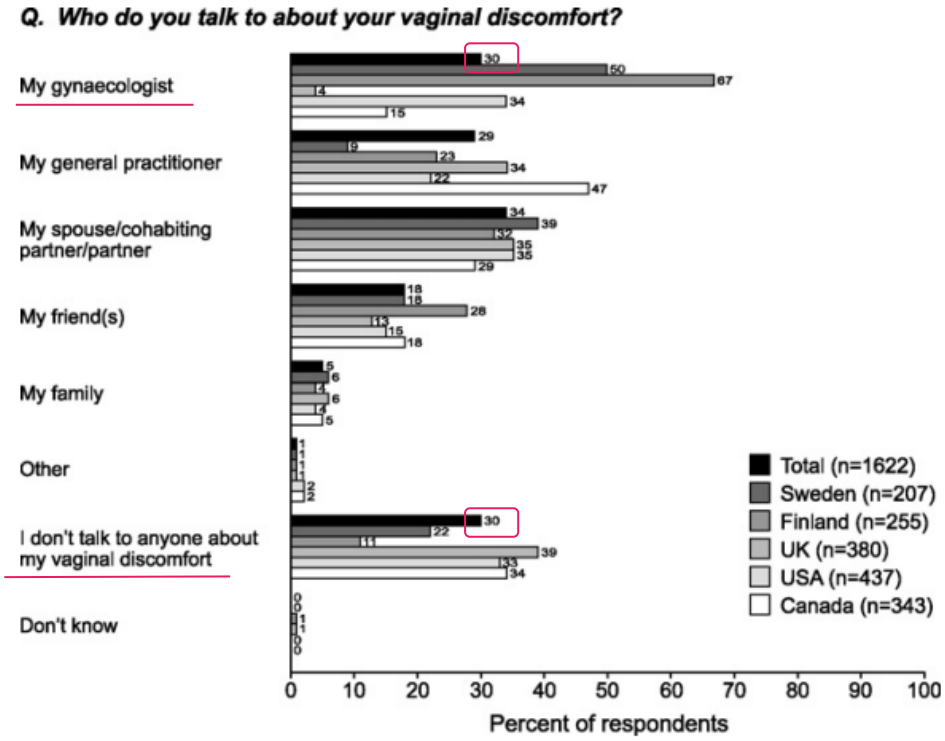
Contents lists available at ScienceDirect

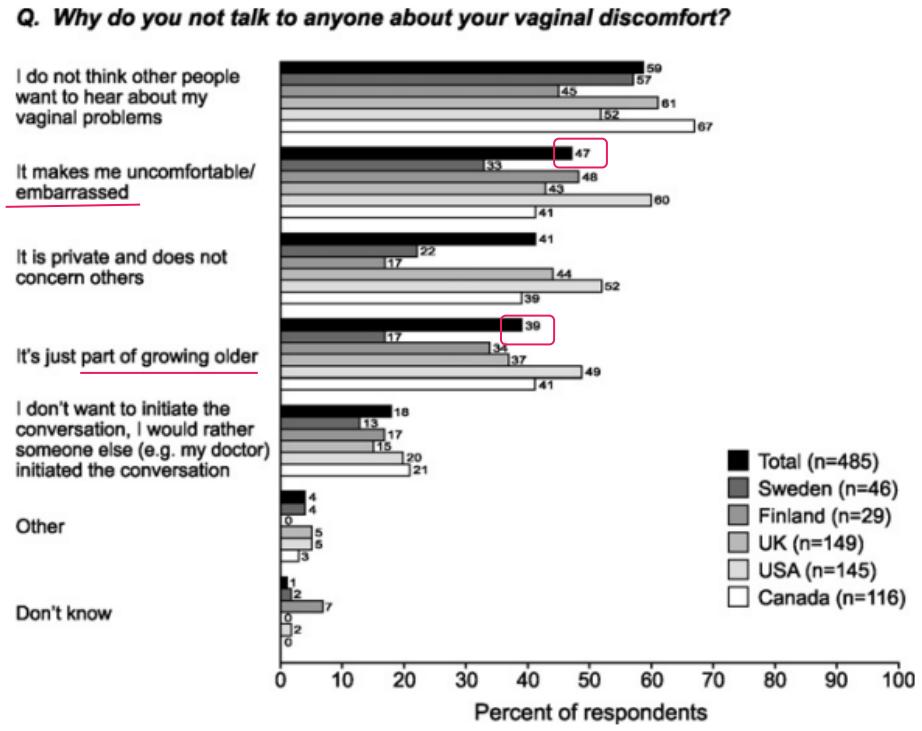
Maturitas

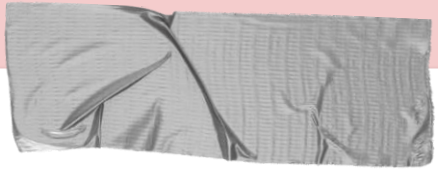
journal homepage: www.elsevier.com/locate/maturitas

Women's voices in the menopause: Results from an international survey on vaginal atrophy

Rossella E. Nappi[a,b,*], Marta Kokot-Kierepa[c]







“Women’s voices” take home messagge

- **70%** mai discusso la condizione con il ginecologo
- **31%** preferiva che fosse il medico a iniziare a parlare dell’argomento
- **42%** non conosceva l’esistenza di trattamenti locali specifici

Diagnosi

1. SINTOMI
2. SEGNI (VHI, VUHI)
3. Ph>5

	1	2	3	4	5
Elasticità complessiva	Nessuna	Scarsa	Discreta	Buona	Eccellente
Secrezione	Nessuna	Scarsa	Discreta	Buona	Eccellente
pH	6.1	5.6 - 6.0	5.1 - 5.5	4.7 - 5.0	< 4.6
Mucosa epiteliale	Petecchie presenti prima del contatto	Sanguina al contatto lieve	Sanguina allo sfregamento	Non friabile, mucosa sottile	Non friabile, mucosa normale
Idratazione	Assente mucosa infiammata	Assente mucosa non infiammata	Minima	Moderata	Normale

Raccomandazioni Congiunte per la Diagnosi ed il Trattamento dell'Atrofia Vulvo-Vaginale della donna in Peri- e Post-Menopausa della Società Italiana per la Menopausa (SIM) e della Società Italiana della Terza Età (SIGiTE), 2019

SIGITE
SOCIETÀ ITALIANA GINECOLOGIA TERZA ETÀ

Criteri AGATA

Sensazione di secchezza vaginale

+

pH>5

+

1 tra i seguenti segni:

- Secchezza Vaginale
- Pallore della Mucosa
- Appiattimento delle rughe
- Fragilità della mucosa
- Petecchie

Quale terapia?

medicina

MDPI

Review

New Innovations for the Treatment of Vulvovaginal Atrophy: An Up-to-Date Review

Vittoria Benini [1], Alessandro Ferdinando Ruffolo [1], Arianna Casiraghi [1], Rebecca S. Degliuomini [1], Matteo Frigerio [2], Andrea Braga [3], Maurizio Serati [4,†], Marco Torella [5], Massimo Candiani [1] and Stefano Salvatore [1,*]

OBIETTIVO

- → miglioramento dei *sintomi*
- → ripristino *funzione* urogenitale
- → evitare la comparsa di *complicanze*

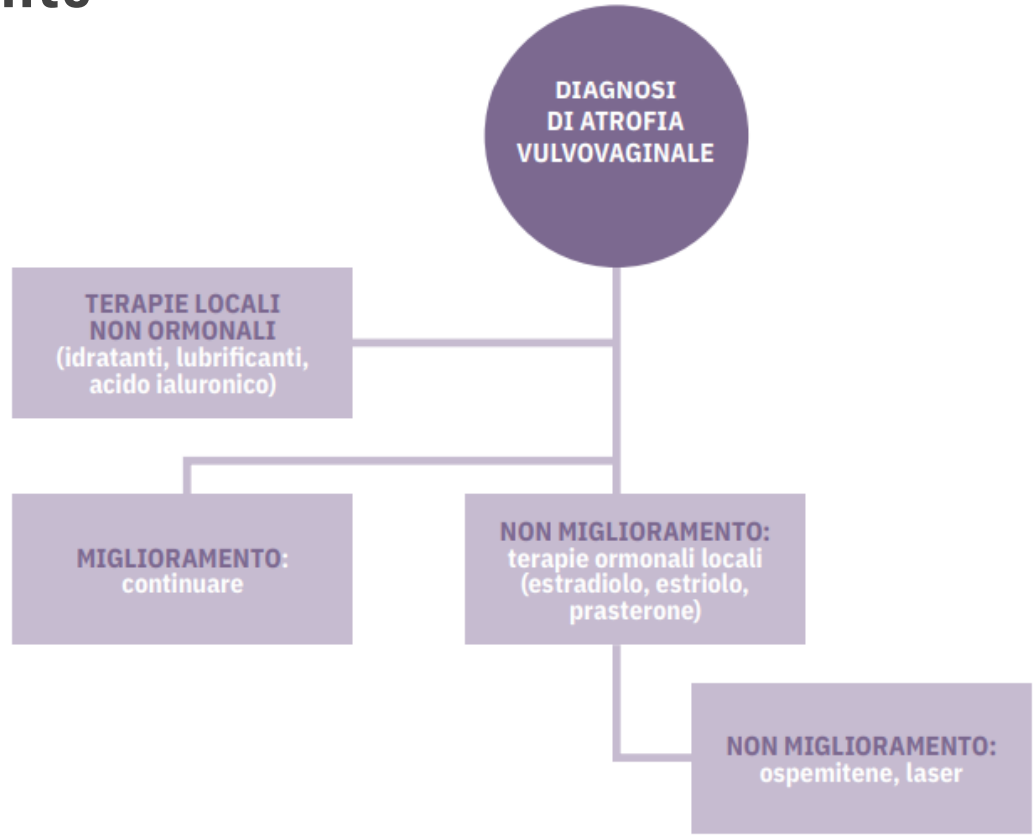
COUNSELLING

- → condizione *cronica e progressiva*
- → peggiora alla sospensione della terapia specifica

STILE DI VITA

- → perdita di *peso*
- → *attività sessuale*
- → astensione dal *fumo*

Trattamento



For symptoms such as vaginal dryness, dyspareunia or other symptoms associated with this syndrome, the first line of treatment is **moisturizers (Evidence IA)**

If they do not provide adequate improvement of symptoms or if moderate to severe symptoms continue, **estrogens** are used

S. Palacios et al., Climateric 2015

In case of vaginal atrophy, the choise is **local estrogen therapy (Evidence IA)**. In cases coexistent with vasomotor symptoms affecting quality of life, the choice is systemic hormonal therapy (Evidence IA).

Local estrogenic or systemic treatments can be combined with moisturizers and lubrificants.

Table 2 Level of evidence of treatments for genitourinary syndrome of menopause

Treatments	*Level of evidence*
Lifestyle	
Sexual activity	II-2B
Obesity	III-C
Exercise	III-C
Smoking	II-3B
Vaginal moisturizers 2–3 times/week for improvement of symptoms	I-A
Vaginal lubricants for sexual activity	II-2B
Other treatments	
Homeopathy	III-D
Phytotherapy	III-D
Phytoestrogens	II-3D
Systemic and local hormonal therapy	
Improvement of symptoms	I-A
Tropism	I-A
Vaginal laser for improvement of symptoms and tropism	I-A

Società internazionale della menopausa

International IMS Menopause Society

Menopause: The Journal of The North American Menopause Society
Vol. 27, No. 9, pp. 976-992
DOI: 10.1097/GME.0000000000001609

NAMS Position Statement

The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society

CONCLUSIONS AND RECOMMENDATIONS

- Education about and screening for GSM is recommended for perimenopausal and postmenopausal women. [Level C]
- First-line therapies for women with GSM include non-hormone lubricants with sexual activity and regular use of long-acting vaginal moisturizers. [Level A]
- For women with moderate to severe GSM and those who do not respond to lubricants and moisturizers, several safe and effective options are available:
  - Low-dose vaginal ET [Level A]
  - Vaginal DHEA [Level A]
  - Ospemifene [Level A]
  - Systemic ET (when VMS are also present) [Level A]

World J Clin Oncol. 2022 Feb 24; 13(2): 71–100.
Published online 2022 Feb 24. doi: 10.5306/wjco.v13.i2.71
PMCID: PMC8894268
PMID: 35316932

Management of genitourinary syndrome of menopause in breast cancer survivors: An update

Daniel María Lubián López

According to international guidelines, nonhormonal therapies are the first-line treatment for mild-moderate VVA. Therefore, survivorship guidelines from the American Society of Clinical Oncology (ASCO)/American Cancer Society (ACS)[81] and the North American Menopause Society[82] recommend the use of nonhormonal therapies, specifically water-or silicone-based lubricants and vaginal moisturizers, as first-line therapy for dyspareunia and vaginal dryness in BCSs. Severe signs or symptoms usually require pharmacological management (local hormonal therapy)[83].

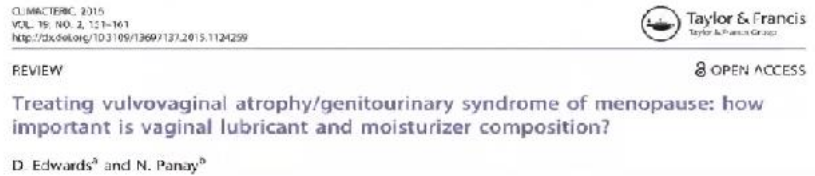
Terapia locale non ormonale

VAGINAL LUBRICANTS	VAGINAL MOISTURIZERS (LONG-ACTING)
For use with sexual activity (reduce friction); Applied before sexual activity; Formulations: Water-based Oil-based Silicone-based	For use on a regular basis; Applied at bedtime 2-3 times weekly. 

Menopause practice: a Clinician's guide (North american Menopause society)

Raccomandazione **WHO:** Preferire lubrificanti e idratanti con osmolalità < 380 mOsm/kg

Valore accettabile nella pratica clinica: **< 1200 mOsm/kg**



CLIMACTERIC, 2015
VOL. 19, NO. 2, 151–161
http://dx.doi.org/10.3109/13697137.2015.1124259

Taylor & Francis

REVIEW

OPEN ACCESS

Treating vulvovaginal atrophy/genitourinary syndrome of menopause: how important is vaginal lubricant and moisturizer composition?

D. Edwards[a] and N. Panay[b]

Vaginal dryness and dyspareunia improved more in the pH-balanced gel group than in the placebo group (baseline mean 8.20 compared with end-point mean 4.23 [*P*=.001] and 8.23 compared with 5.48 [*P*=.040], respectively). Vaginal pH-balanced gel reduced the vaginal pH (gel: baseline mean 6.49 compared with end-point mean 5.00; placebo: 6.22 compared with 5.69 [*P*<.001]), and enhanced vaginal maturation index (gel: 45.5 compared with 51.2; placebo: 46.4 compared with 47.9 [*P*<.001]) and vaginal health index (gel: 15.8 compared with 21.1; placebo 14.3 compared with 16.98 [*P*=.002]). There was no significant difference in adverse effects between the two groups except for mild irritation at the early time of pH-balanced gel administration.

Vaginal pH-Balanced Gel for the Control of Atrophic Vaginitis Among Breast Cancer Survivors

A Randomized Controlled Trial

Lee, Yoo-Kyung; Chung, Hyun Hoon; Kim, Jae Weon; Park, Noh-Hyun; Song, Yong-Sang; Kang, Soon-Beom

Author Information

Obstetrics & Gynecology 117(4):p 922-927, April 2011. | **DOI:** 10.1097/AOG.0b013e3182118790

Idratanti vaginali all'acido ialuronico

- Polimero indispensabile per **trofismo** e **turgore** di derma e mucose
- Maggiore **idratante naturale** (1g di HA può legare fino a 6 lt di H20)
- Azione diretta sul **processo di riparazione** tissutale

Peso molecolare > 200 kDa

J Sex Med. 2021 Jan;18(1):156-166. doi: 10.1016/j.jsxm.2020.10.016. Epub 2020 Dec 5.

Hyaluronic Acid in Postmenopause Vaginal Atrophy: A Systematic Review

Carlos Campagnaro M Dos Santos [1], Maria Laura R Uggioni [1], Tamy Colonetti [1], Laura Colonetti [1], Antonio José Grande [2], Maria Inês Da Rosa [3]

The results presented suggest that treatment with hyaluronic acid, when compared with the use of estrogens, does not present a significant difference in the results obtained for the outcomes: epithelial atrophy, vaginal pH, dyspareunia, and cell maturation.

Terapia ormonale locale

COMPOSITION	FDA-APPROVED DOSAGE
Vaginal creams 17β-estradiol	Initial: 2-4 g/d for 1-2 wk Maintenance: 1 g/1-3 times/wk (0.1 mg active ingredient/g)
Conjugated estrogens	For VVA: 0.5-2 g/d for 21d then off 7d For dyspareunia: 0.5 g/d for 21d then off 7d, or twice per week (0.625 mg active Ingredient/g)
Estrone	2-4 g/d (1 mg active Ingredient/g) intended for short-term use; progestogen recommended)
Vaginal rings 17β-estradiol	Device containing 2 mg releases approximately 7.5 µg/d for 90 d (for VVA)
Estradiol acetate	Device containing 12.4 or 24.8 mg estradiol acetate releases 0.05 or 0.10 mg/d estradiol for 90 d (both doses release systemic levels for treatment of VVA and vasomotor symptoms)
Vaginal suppository , DHEA	1 suppository nightly (containing 6.5 mg prasterone)
Ospemifene	60 mg daily oral

Menopause practice: a Clinician’s guide (North american Menopause society)

Terapia ormonale locale

Review > Cochrane Database Syst Rev. 2016 Aug 31;2016(8):CD001500.
doi: 10.1002/14651858.CD001500.pub3.

Local oestrogen for vaginal atrophy in postmenopausal women

Anne Lethaby [1], Reuben Olugbenga Ayeleke, Helen Roberts

- indicazione: dispareunia e AVV
- miglioramento dei sintomi:
  - riduzione ph
  - aumento lattobacilli
  - miglioramento citologia vaginale e uretrale
- tutte le formulazioni sembrano avere stessa efficacia –> *terapia personalizzata*

Controindicazione: sanguinamenti uterini non diagnosticati, neoplasie estrogeno-dipendenti

Warning EMA-PRAC

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 gennaio 2020
EMA/20248/2020

Informazioni per gli operatori sanitari

- Le creme ad alto dosaggio di estradiolo non devono essere prescritte per un periodo più lungo di un unico ciclo di trattamento della durata massima di 4 settimane per i rischi associati all'esposizione sistemica all'estradiolo.
- I dati di farmacocinetica sulle creme ad alto dosaggio di estradiolo (100 microgrammi/grammo) per uso intravaginale mostrano un'esposizione sistemica all'estradiolo, con livelli superiori a quelli previstinell'intervallo di valori normale nel post-menopausa (fino a cinque volte al di sopra del limite superiore dei livelli di riferimento sierici per l'estradiolo pos tmenopausale pari a 10-20 pg/ml).
- L'esposizione sistemica ad estradiolo potrebbe essere associata ad effetti indesiderati simili a quelli della terapia ormonale sostitutiva orale e transdermica come: iperplasia/carcinoma endometriale, cancro del seno e dell'ovaio ed eventi tromboembolici.
- Le creme ad alto dosaggio di estradiolo non devono essere prescritte con altri medicinali che rientrano nella terapia ormonale sostitutiva.

Creme ad alto dosaggio di estradiolo

(100 µgE2 per grammo: 0, 01%)

La posizione di SIM e SIGITE

La dichiarazione EMA:

- ➔ fa riferimento ad un prodotto che non è in commercio in Italia
- ➔ potenzialmente molto pericolosa se erroneamente estesa a tutti i prodotti ormonali a basso dosaggio presenti sul mercato nazionale.
- ➔ rischia di indurre le donne a evitare un trattamento dimostratosi sicuro e efficace in moltissimi trial clinici e studi osservazionali di lunga durata.

There was no evidence of a difference in the proportions of women with breast disorders between the two treatment groups (OR 0.12, 95% CI 0.01 to 1.13, one RCT, n = 192).


Review > Cochrane Database Syst Rev. 2016 Aug 31;2016(8):CD001500.
doi: 10.1002/14651858.CD001500.pub3.

Local oestrogen for vaginal atrophy in postmenopausal women

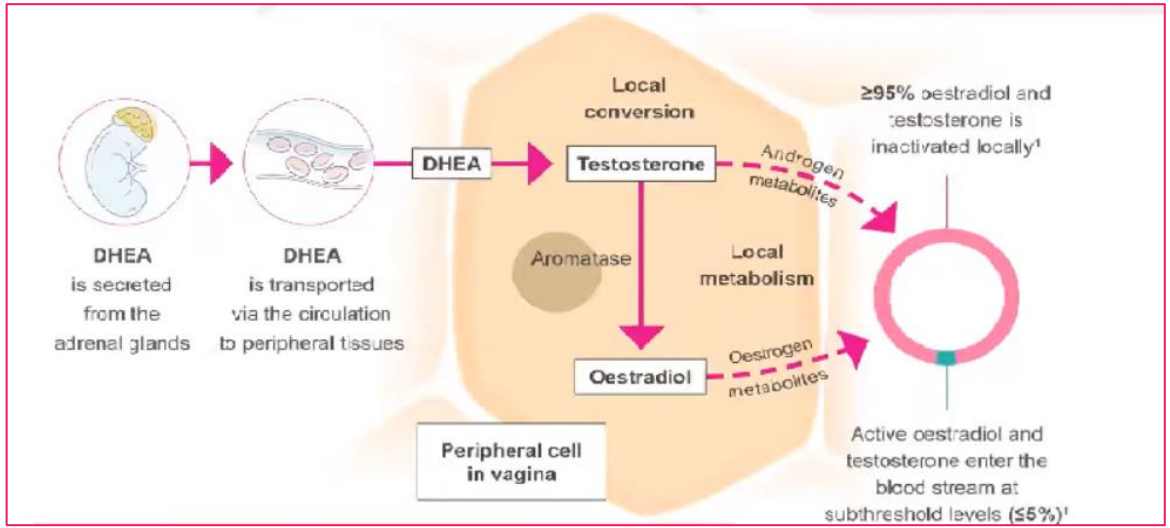
Anne Lethaby [1], Reuben Olugbenga Ayeleke, Helen Roberts

La posizione di SIM e SIGITE

- ➔ Farmaco EFFICACE e SICURO:
  - livelli di estrogeno sierici mantenuti nei range di normalità postmenopausali
  - sicurezza endometriale: non necessaria terapia progestinica
  - Non dimostrati effetti riferibili a altre complicanze sistemiche come eventi tromboembolici o carcinoma mammario
- ➔ L'importanza di **rimuovere la black box** dai foglietti illustrativi dei prodotti contenenti estrogeni vaginali per terapie locali

Terapia con DHEA

- precursore trasformato dalle cellule della mucosa vaginale in estrogeni e testosterone



6.5 mg di prasterone intravaginale

- efficaci nei sintomi della VVA/GSM
- migliorano i parametri fisici
- migliorano la sessualità

Re Nappi, 2019

Terapia con DHEA

approved for treatment moderate to severe dyspareunia associated with VVA/GSM

- Inserted intravaginally once daily at bedtime
- Phase 3 trials reveal improvements compared to baseline over placebo of 4 coprimary objectives
  - Decreased percentage of parabasal cells
  - Decreased vaginal pH
  - Decreased pain with sexual activity
  - Improvement in moderate to severe vaginal dryness
- Serum steroid levels remained well within normal postmenopausal range

ISSWSH
International Society for the Study of Women's Sexual Health, Inc.

- Livelli di steroidi sierici in linea con i normali livelli postmenopausali (Martel et al, J.Ster. Biochem. Mol. Biol. 159, 142-153, 2016
- Nessun effetto di DHEA sull'endometrio (Labrie et al., 2015)
- Approvato senza black box in US
- No limiti di tempo per il trattamento

Table 1 Efficacy of intravaginal prasterone in postmenopausal women with vulvovaginal atrophy in 12-week phase III trials

Trials	Tx (mg)	No. of women[a]	Mean change from BL at week 12 [BL]			
			Parabasal cells (%)[b]	Superficial cells (%)[b]	Vaginal pH[b]	Dyspareunia[b,c]
ERC-231 [19, 22]	PRA 3.25	79	−37.3 [65.7]***	+4.8 [0.7]***	−0.8 [6.5]***	−1.0 [2.6]
	PRA 6.5	81	−47.4 [65.1]***	+5.6 [0.7]***	−1.0 [6.5]***	−1.3 [2.6]*
	PL	77	−1.6 [68.5]	+0.9 [0.7]	−0.2 [6.5]	−0.9 [2.6]
ERC-238 [20]	PRA 6.5	325	−41.6 [54.3]***	+10.2 [1.0]***	−1.0 [6.3]***	−1.4 [2.5]**
	PL	157	−12.0 [51.7]	+1.7 [1.0]	−0.3 [6.3]	−1.1 [2.6]
Pooled analysis of ERC-231, -238 and -210[d] [24]	PRA 6.5	436	−42.7 [56.2]***	+9.0 [0.9]***	−1.0 [6.4]***	−1.4 [2.6]***
	PL	260	−7.6 [56.2]	+1.3 [0.9]	−0.3 [6.4]	−0.9 [2.6]

PRA and PL were administered intravaginally once daily at bedtime

BL baseline, *PL* placebo, *PRA* prasterone, *Tx* treatment

*$p = 0.013$, **$p = 0.0002$, *** $p < 0.0001$ vs. PL

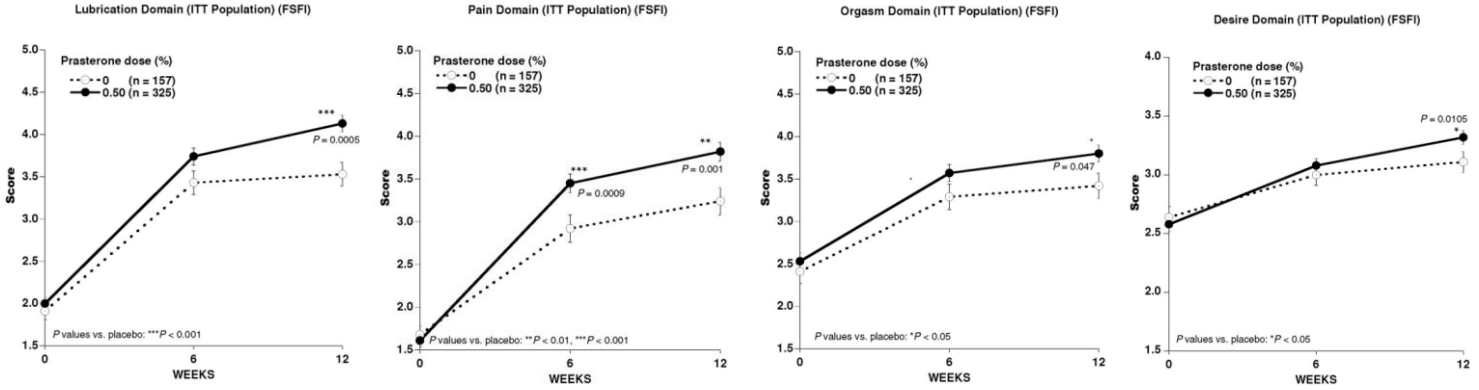
[a]All randomized patients who received ≥ 1 study drug and met the study entry criteria at BL evaluation

[b]Co-primary endpoint

[c]Pain at sexual activity; self-assessed symptom rated 0 (none) to 3 (severe)

[d]Data from ERC-210 were limited to postmenopausal women who reported dyspareunia as their most bothersome symptom and those receiving PRA 6.5 ($n = 30$) or PL ($n = 26$)

Prasterone: A Review in Vulvovaginal Atrophy, Young-A Heo, 2019



Effect of Intravaginal Prasterone on Sexual Dysfunction in Postmenopausal Women with Vulvovaginal Atrophy, Labrie 2015

Terapia per OS: TOS

Menopause: The Journal of The North American Menopause Society
Vol. 29, No. 7, pp. 767-794
DOI: 10.1097/GME.0000000000002028

NAMS Position Statement

The 2022 hormone therapy position statement of The North American Menopause Society

Hormone therapy has been shown in RCTs to effectively treat symptoms of vulvovaginal atrophy (VVA).[45,46] Hormone therapy is FDA approved to treat moderate to severe symptoms of VVA and dyspareunia because of menopause but with the preference for low-dose vaginal therapy if solely prescribed for vulvar or vaginal symptoms.

Two vaginal therapies, vaginal ET and vaginal dehydroepiandrosterone (DHEA), have been FDA approved for treatment of moderate to severe dyspareunia, a symptom of VVA resulting from menopause. One oral therapy (a SERM) has FDA approval as well.

Key point

- Hormone therapy is FDA approved for four indications: moderate to severe VMS; prevention of osteoporosis in postmenopausal women; treatment of hypoestrogenism caused by hypogonadism, BO, or POI; and treatment of moderate to severe vulvovaginal symptoms. FDA guidance for treatment of genitourinary symptoms related to menopause in the absence of indications for systemic ET suggests the use of low-dose topical vaginal ET. (Level I)

Terapia per os: OSPEMIFENE

- SERM: modulatore selettivo del recettore degli estrogeni
- Unico prodotto orale approvato per trattamento di secchezza vaginale e dispareunia moderata/severa (NAMS)
- Miglioramento dimostrato su: pH vaginale, dispareunia, secchezza, obiettività genitale, UTI ricorrenti

Clinical Trial > Menopause. 2019 Jan 28;26(6):611-621. doi: 10.1097/GME.0000000000001292.

Efficacy and safety of ospemifene in postmenopausal women with moderate-to-severe vaginal dryness: a phase 3, randomized, double-blind, placebo-controlled, multicenter trial

David F Archer [1], Steven R Goldstein [2], James A Simon [3], Arthur S Waldbaum [4],

Terapia per os: OSPEMIFENE

- Profilo di sicurezza sulla mammella (attività antiestrogenica)
  - Ospemifene 60 mg associato a ridotto rischio di sviluppare carcinoma mammario e ridotto rischio di ricorrenza in studi preliminari
- Azione neutra sull'endometrio

Fitoestrogeni

- Fonti alimentari di fitoestrogeni: legumi (particolarmente la soia), molti tipi di frutta e altri vegetali (tra cui il trifoglio rosso), oltre ai cereali integrali.
- Dispersi in un gel e somministrati giornalmente possono essere efficaci sui sintomi e segni dell'AV (ruolo del veicolante?)
- Pochi studi clinici sulla loro efficacia e sicurezza

I fitoestrogeni possono esercitare dei benefici urogenitali (come gli isoflavoni della soia e del trifoglio rosso per via orale, Woods R et Al, 2004)**, ma la sicurezza non è stata dimostrata in donne con tumori estrogeno-sensibili.**

Fitoestrogeni

Fertil Steril. 2005 Jan;83(1):137-42.

Lack of effect of isoflavonoids on the vagina and endometrium in postmenopausal women.

Nikander E[1], Rutanen EM, Nieminen P, Wahlström T, Ylikorkala O, Tiitinen A.

PATIENT(S): Sixty-four postmenopausal women with a history of breast cancer.

INTERVENTION(S): The women took (in a randomized order) 114 mg of isolated isoflavonoids or placebo in tablets daily for 3 months; the treatment regimens were crossed over after a 2-month washout period. The subjects were studied before and on the last day of each treatment period.

MAIN OUTCOME MEASURE(S): Vaginal dryness, maturation index (MI) of vaginal epithelium, endometrial thickness, histology, and expression of estrogen (E) and progesterone (P) receptors and the proliferation marker Ki-67 in the endometrium.

RESULT(S): Isolated isoflavones did not relieve vaginal dryness. Maturation index values remained unchanged during the isoflavone regimen, but decreased during the placebo regimen. No changes were found in any of the variables measured in the endometrium.

CONCLUSION(S): Daily administration of 114 mg of isolated isoflavones for 3 months had no effect on the subjective perception of vaginal dryness or on objective findings in the vagina or endometrium. This implies safety with regard to the endometrium.

Maturitas. 2006 May 20;54(2):135-40. Epub 2005 Nov 16.

The effect of a soy-rich diet on urogenital atrophy: a randomized, cross-over trial.

Manonai J[1], Songchitsomboon S, Chanda K, Hong JH, Komindr S.

Abstract

OBJECTIVE: To evaluate the effect of a soy-rich diet on urogenital symptoms, vaginal health index, and vaginal cytology in perimenopausal and postmenopausal women.

MATERIALS AND METHODS: Thirty-six perimenopausal and postmenopausal women (mean age 52.5+/-5.1 years) participated in a randomized, cross-over trial with two 12-week diet periods and two 4-week washout periods before and between treatments. The study diet consisted of a control diet (soy-free diet) and an isocaloric soy-rich diet (25 g soy protein in various forms of soy food containing more than 50 mg/day of isoflavones substituted for an equivalent amount of animal protein). Subjects were assessed for urogenital symptoms, vaginal health index, vaginal pH and vaginal cytology. The single physician and the single cytopathologist were blinded with regard to onset, period and randomization number. Statistical analyses were performed using paired t-test or Wilcoxon Signed Ranks Test, significance was set as $P<0.05$.

RESULTS: Good compliance to the diet was shown by the significant elevation of serum levels of daidzein and genistein during the soy-rich diet period. The symptoms of urge incontinence and vaginal dryness had significantly increased after 12-week of soy-free diet. All other urogenital symptoms did not change in both periods. The vaginal health index, the vaginal pH, the karyopyknotic index, and the maturation value were not significantly changed in both periods.

CONCLUSION: A soy-rich diet did not relieve the urogenital symptoms or restore the vaginal epithelium or improve the vaginal health in perimenopausal and postmenopausal Thai women.

Herbal products have not demonstrated any beneficial effect in clinical trials.
(NAMS, 2020)

Terapia fisica

- Razionale: aumento indice di salute vulvare e vaginale tramite **microtraumatismo** che induce formazione di nuovo collagene , angiogenesi e ispessimento dell'epitelio

MA

- Non approvate dall'FDA (2018: warning FDA sull'utilizzo per fini estetici, dati gli scarsi dati sulla sicurezza)
- Costi

Menopause: The Journal of The North American Menopause Society
Vol. 27, No. 9, pp. 976-992
DOI: 10.1097/GME.0000000000001609

NAMS Position Statement

The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society

Energy based therapy

- vulvovaginal energy based devices including lasers (fractional CO2 Erbium: YAG)
- radio-frequency devices

★ An effective non-hormon alternative
★ Option for women with a history of estrogen receptor positive breast cancer, an increased risk of thrombotic events

Take home

Diagnosi e trattamento precoce

Indagare la comparsa di sintomi genitourinari e sessuali fin dalla premenopausa

Counselling con la paziente sulle terapie disponibili

Terapia locale non ormonale

Terapia locale ormonale

Terapia per OS con Ospemifene, TOS

Terapia personalizzata sulle esigenze della paziente con *attenzione alla QoL*

Grazie **per l’attenzione**