Prolonged-release hyaluronic acid derivative vaginal gel for BRCA-mutation carriers in surgical menopause

Fabio Barra, Maria Grazia Centurioni, Umberto Perrone, Marco Paratore, Paolo Sala, Simone Ferrero, Franco Alessandri and Claudio Gustavino

Unit of Obstetrics and Gynecology, IRCCS Ospedale Policlinico San Martino, Genoa, Italy

CONTEXT

Women with **BRCA mutation** undergoing **premature surgical menopause** following **risk-reducing bilateral salpingo-oophorectomy** (RRSO) experience early **loss** of **estrogens**.

This causes, mainly in the first months after surgical procedure, a relevant worsening of **global sexual health**.

OBJECTIVE

This study aims to assess the efficacy of non-hormonal, **prolonged-release hyaluronic acid derivative vaginal gel** [1] in improving **vulvovaginal estrogen-deprivation symptoms** in **postmenopausal women** with **BRCA mutation after RRSO**.

MATERIALS AND METHODS

This was a **single-arm**, **prospective**, **longitudinal pilot study** enrolling **postmenopausal** women with **BRCA 1** and **2** mutations, who had undergone **RRSO** in the previous six months.

Patients applied prolonged-release **Hydeal-D 0.2% vaginal gel** (Fidia Farmaceutici, Abano Terme, Italy) every three days for 12 consecutive weeks and underwent visits at three study times: baseline [**V0**]; 4 weeks [**V1**]; 12 weeks [**V2].**

At each visit, **sexual function** was evaluated by *Female Sexual Function Index* (**FSFI**) and by investigating the presence and intensity of **superficial** and **deep dyspareunia** at *Visual Analogue Scale* (**VAS**); **vaginal status** was assessed by *Vaginal Health Index* (**VHI**) and by evaluating **local pH** using a vaginal dipstick.

RESULTS

Thirty-seven patients were enrolled in this study; the mean (±SD) age of the study population was 43 years (range, 35-57); 83.8% (n=31) of women were partnered and 75.7% (n=28) were sexually active.

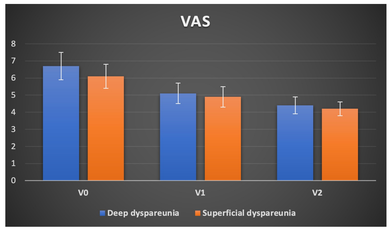
The **VHI** total score significantly **increased** at both follow-up visits (+5.6 ± 2.1 between V0 and V1; +3.5 ± 1.9, between V1 and V2; $p < 0.001$ and $p = 0.023$, respectively).

At V2, there was a significantly **higher** mean **FSFI** total score in comparison to V0 (29.4 ± 5.3 vs 23.4 ± 5.9 points, $p < 0.001$); among FSFI sub-domains, the highest improvement was observed for **lubrification** ($p < 0.001$).

Additionally **vaginal pH** significantly **decreased between V0 and V1** (-1.4 ± 0.5; $p < 0.001$) and remained stable between V1 and V2 (-0.3 ± 0.2; p=0.13). Both **superficial** and **deep dyspareunia improved** at VAS during the study time ($p = 0.010$ and $p < 0.001$, **Table**).

Only one woman reported **mild vaginal burning sensation** (2.7%) related to local vaginal gel use; nevertheless, **no** patient **discontinued** the **treatment**.

Table. *VAS for deep (BLU) and superficial (ORANGE) dyspareunia at V0 (baseline), V1 and V2.*



CONCLUSIONS

The results of this pilot study demonstrated that hyaluronic acid derivative vaginal gel (**Hydeal-D**) application can **improve** the **sexual function** of **postmenopausal BRCA** mutated **women** after **RRSO**.

1 Gustavino C, et al. **Efficacy and safety of prolonged-release hyaluronic acid derivative vaginal application in the postpartum period: a prospective randomised clinical trial.** Ann Med. 2021 Dec;53(1):1589-1597.