

Abstract

Randomised Control Trial: Oestrogen-Soaked Vaginal Packing for Decubitus Ulcer in Advanced Pelvic Organ Prolapse (OPOP trial)

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Objective: To determine if the use of oestrogen cream when compared with aqueous cream soaked vaginal packing in the management of decubitus ulcers associated with POP, improves its healing time. Secondly, the effect on endometrial safety by looking at the presence of hyperplasia via histological assessment of hysterectomy specimens or endometrial tissue sampling is assessed. Patients' tolerability at initial packing (VNRS 0 to 10), overall patient satisfaction at the point of ulcer resolution and perioperative outcomes including surgeon's satisfaction toward the tissue's condition during operation (VNRS 0 to 10), operating time, intraoperative blood loss, complications, post-surgical resumption of urination and duration of hospital stay are the secondary outcomes.

Methods: This is a single-centered, double blinded randomized control trial. Women with advanced POP and intact uterus complicated with decubitus ulcer planned for surgery are invited to participate. These women are randomized into two groups using either oestrogen or aqueous cream vaginal packing twice weekly as a preoperative regimen till the ulcer healed followed by hysterectomy and vaginal repair. Those women who are deemed unfit for surgery undergo endometrial assessment via transvaginal scan and endometrial sampling once the ulcer has healed.

Results: So far, 31 out of 50 women have been recruited, with the mean age of 67 years old, into oestrogen (n=15) and aqueous cream (n=16) arms. No significant demographic differences have been noted between the two groups. Time for ulcer to heal for oestrogen ranges from 14 days to 89 days, with mean healing time of 41 days. As for aqueous cream, time taken varies from 19 days to 70 days with mean of 36 days. When looking at endometrial safety in women with oestrogen cream, there were 28% (n=4) who had hyperplasia, 14% (n=2) complex atypical hyperplasia, 14% (n=2) simple hyperplasia. No hyperplasia has been detected in the aqueous cream arm.

Conclusion: So far, aqueous cream has been shown to be just as effective as oestrogen soaked vaginal cream for treatment of decubitus ulcers. Worryingly, some women in the oestrogen cream arm have shown significant endometrial changes. The interim data suggests that aqueous cream should be used preferably to oestrogen cream.