

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Koike K, Yamamoto Y, Suzuki N, et al. Efficacy of porcine placental extract on shoulder stiffness in climacteric women. *Climacteric* 2013; 16: 447-52. (in Japanese with English abstract) CENTRAL ID: CN-00920084, Pubmed ID: 23113540

1. Objectives

To verify the clinical efficacy of porcine placental extract on shoulder stiffness in postmenopausal women taking hormone replacement therapy.

2. Design

Randomized controlled trial (RCT).

3. Setting

Kanazawa University Hospital and Sugita Clinic (2 institutions), Japan.

4. Participants

Fifty-four postmenopausal women with shoulder stiffness taking hormone replacement therapy.

5. Intervention

Arm 1: Hormone replacement therapy (product unknown) for 3 months, followed by hormone replacement therapy + 3 capsules/day of porcine placenta extract (350 mg/capsule) p.o. for 12 weeks (n=27).

Arm 2: Hormone replacement therapy (product unknown) for 3 months, followed by hormone replacement therapy + TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules p.o. for 12 weeks (n=27).

6. Main outcome measures

Degree of shoulder stiffness on a visual analogue scale (VAS).

7. Main results

Four of 54 patients were withdrawn. The VAS score was significantly lower (at the end of the study: 64.8% reduction from baseline, $P<0.01$) in arm 1 than in arm 2.

8. Conclusions

In postmenopausal women taking hormone replacement therapy, oral administration of porcine placenta extract is effective in improving prolonged or treatment-refractory shoulder stiffness.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

During the study period, administration of porcine placenta extract did not affect serum chemistry values, BMI, cardiovascular function, estradiol levels, or thyroid hormone levels, and did not cause abnormal uterine bleeding.

11. Abstractor's comments

Placenta extract is currently used as a supplement and advertised as a product effective in relieving menopausal symptoms. The present study evaluated the clinical efficacy of porcine placenta extract, focusing on shoulder stiffness that is prolonged or refractory to treatment in climacteric women taking hormone replacement therapy. It deserves some appreciation. Placenta extract contains many bioactive substances, of which low molecular weight peptides, etc., are thought to enter the systemic circulation from the gastrointestinal tract and exert effects in target organs. Although the mechanism of action of porcine placenta extract remains unknown, its effectiveness in improving shoulder stiffness refractory to hormone replacement therapy suggests a mechanism that is not mediated by estrogen receptors. Prior treatment with tokishakuyakusan may also affect the results. It is hoped that the authors will also investigate the relationship and differences between biologics and Kampo.

12. Abstractor and date

Ushiroyama T, 6 June 2015, 5 October 2015.