Autologous Platelet - Rich Plasma versus Phytoestrogen Gel in Management of Menopausal Women with Stress Urinary Incontinence

Original Article

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ABSTRACT

Objectives: The aim of this study was to conduct a comparison between the efficacy of autologous platelet-rich plasma (PRP) and phytoestrogen vaginal gel in the treatment of stress urinary incontinence (SUI) in postmenopausal women.

Patients and Methods: This prospective randomized clinical study was carried out on 40 post- menopausal women with mild to moderate SUI, positive cough leakage test result, absence of infection and no surgery related to SUI. Two equal sets of cases were formed.: Group I (PRP group): injected with platelet-rich plasma (PRP) at the mid-urethral site on the anterior vaginal wall close to external urethral sphincter and group II (Phytoestrogen gel group): received phytoestrogen gel as intravaginal gel.

Results: International consultation on incontinence questionnaire- short form (ICIQ-SF) and incontinence outcome questionnaire (IOQ) were significantly improved after 6 months compared to baseline and in group I (P <0.05). ICIQ-SF, incontinence impact questionnaire (IIQ-7), IOQ, urinary distress inventory (UDI-6) and Overactive Bladder Symptom Scores (OABSS) were significantly lower after 6 months compared to baseline in group I and II (P <0.001). ICIQ-SF, UDI-6 and IIQ-7 were significantly lower after 6 m in Group I than in Group II (P<0.05). The success rate was significantly higher in group I than in group II (P =0.027).

Conclusions: In menopausal women with SUI, the repeated PRP injection was more effective and safer in alleviating SUI than phytoestrogen gel.

Key Words: Menopausal women, phytoestrogen gel, platelet- rich plasma, stress urinary incontinence.

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INTRODUCTION

With an estimated frequency of 40% among adult women, stress urinary incontinence (SUI) is an unpleasant gynaecology condition prevalent globally. Popular risk factors include traumatic birth, advanced maternal age, obesity, and a lack of oestrogen in the body[1].

Suffering from depression and social isolation are two outcomes of urinary incontinence, which can have negative effects on a woman's physical, mental, social, and sexual health. The spontaneous loss of urine that happens with physical activity, such as sneezing, coughing, or exercise, is known as Sudden Urinary Incontinence (SUI). The urethra's support muscles, which are located on the pelvic floor and attach to the front vaginal wall become weak. after pregnancy and childbirth is a major cause of this condition[2].

Mild SUI, leakage during vigorous actions such as exercise, sneezing, laugh, cough, or lifting something heavy; moderate or severe SUI, leakage during less strenuous activities such as standing or bending[3].

During the menopausal transition, women go through a lot of changes, both emotionally and physically. Genitourinary symptoms, sleep disturbances, mood disorders, vasomotor symptoms, and irregular menstruation are all possible in women[4].

Mid-urethral tapes and Colpo suspension are long-lasting and effective anti-incontinence operations[5].

Severe urine incontinence results from a low oestrogen level. Because oestrogen, a naturally occurring hormone, maintains a healthy level of muscular strength. Muscles throughout the body, especially those in the anterior

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vaginal region, relax when oestrogen levels drop, and bladder prolapse occurs in women after menopause[6]. As estrogen receptors are in the anal sphincter, pelvic floor, bladder, and vagina, estrogen therapy has been studied as a potential therapy for symptoms related to the pelvic floor, including urine incontinence[7].

As oestrogen receptors are in the anal sphincter, pelvic floor, bladder, and vagina, oestrogen therapy has been studied as a potential treatment for symptoms related to the pelvic floor, including urine incontinence[7].

Phytoestrogens may be useful in treating or avoiding pelvic floor symptoms and disorders since they are biochemically similar to oral estragon replacements currently available (oestradiol, estriol, and conjugated estragon)[8].

Platelet-derived therapies are becoming increasingly popular in a wide range of surgical and medical fields. There are proteins that have biological activity, including transforming growth factor-β, platelet-derived growth factor, insulin-like growth factor, vascular endothelial growth factor, and platelet-derived epithelial growth factor. Because of their critical role in these processes, platelets are an appealing candidate for therapies that are designed to improve the natural healing process[9].

This study aimed to compare the effect of autologous platelet-rich plasma and phytoestrogen vaginal gel in management of SUI in menopausal women.

PATIENTS AND METHODS

This prospective randomized clinical study carried out on 40 post- menopausal women with mild to moderate SUI, positive cough leakage test result, absence of infection and no surgery related to SUI. After receiving approval from the Ethical Committee Tanta University Hospitals, Tanta, Egypt, the study was conducted from October 2022 to October 2023. Obtaining patients informed written consent was a standard procedure.

Exclusion criteria were patients with mixed urge-predominant incontinence, incontinence caused by a neurogenic factor. grade 3 cystocele, body mass index (BMI) > 30, genitourinary fistulas, cancer of the urinary tract, anticoagulation therapy other than aspirin, thrombocytopenia (Platelet less than 50000), infections of the genital tract and immunological diseases.

Randomization and blindness

Patients who meet the requirements were included in the research. Cases were enrolled in each group utilizing computer-generated random numbers in closed sealed, opaque envelopes that were opened by chief nurse, who did not involve in the research or data collection and determined the group of each patient. Two equal groups of cases were formed: Group I (PRP group): received a PRP injection at the anterior vaginal wall, where the mid-urethra is situated close to external urethral sphincter and group II (Phytoestrogen gel group): received phytoestrogen gel as intravaginal gel.

A detailed history, clinical examination, and laboratory investigation were administered to all patients [complete blood count (CBC), tests of liver and kidney function and analysis of urine included urine culture and sensitivity].

Group I (platelets rich plasma group): BY using 20 cc syringe, 1.5 cm of anticoagulant was withdrawn. From the patient's peripheral vein, a blood sample measuring 14 cm was taken using the same syringe. A gentle shaking motion was used to combine the sample with the anticoagulant. In PRP tube, by opening the tube and holding it at a 45 ° angle, the blood was poured into the narrow section of the tube and turning it at a 90° angle, completing the blood to the second line, and then closing the tube. Red and white cells were separated from the blood using a computerized apparatus that spun the sample at 4000 RPM for 10 minutes or 3500 RPM for 5 minutes. After the separation, the white part is raised through the control in the tube until it remains above the line in the narrow part of the tube. In a syringe 3 cm the needle was changed with 10 cm or 20 cm syringe needle, the tube was opened from the second opening and needle was inserted completely to tube bottom, 2 cm PRP was withdrawn. Following positioning the patients in a dorsal lithotomy posture, the injection sites were disinfected using betadine. Five to ten minutes before the procedure, a topical anaesthetic was administered to the paraurethral, sub-urethral, and lateral urethrovaginal regions, as well as the anterior vaginal wall encompassing the urethral meatuses. Inject 8 mm of PRP into the anterior vaginal wall, three sites on each side, near the external urethral sphincter, using a 30-G needle and a 5-cc syringe, this should be done after isolation. The injection is administered into the paraurethral region, extending for 10 mm between the external urethra and the lateral vaginal wall. Patients were evaluated for pain severity using a numerical rating scale both during and 24 hours after the completion of the procedures. The injection repeated after one month.

Group II (Phytoestrogen gel group): Patients included in this group received phytoestrogen intravaginal gel were instructed to apply 5 ml dose two - three times weekly for two months at bedtime by: Screwing applicator onto tube replacing tube top. Slightly pressing the extreme end of tube allows cream to penetrate. Applicator, patients should the piston be resistant, delicately pull. The application should be filled in. Remove applicator from tube, which must immediately be closed with its top. In lying position, knees up and wide, delicately introduce applicator in the vagina as deep as possible. Completely push the piston.

Then withdraw the applicator without touching the piston and dispose of it.

Success rate of the treatment was determined as it is the fraction or percentage of success among several attempts to perform a procedure. Failure rate of the treatment was determined.

Incontinence Outcome Questionnaire (IOQ), four symptoms are associated with the condition: discomfort, postoperative symptoms, preoperative overactive bladder (OAB), and any preoperative or postoperative changes in OAB symptoms. Four complications that are of concern include residual urine, hospital readmission, urinary or other infections, and other complications. Seven characteristics pertaining to quality of life (QoL): fatigue, depletion of energy, irritability, snappiness, depression, tearfulness, overall health assessment, restrictions on daily activities, alterations in sexual behavior, and changes in body perception. Five regarding satisfaction factors were considered, including changes in symptoms before and after the operation, recovery time, information satisfaction, increase in well-being, and recommendation of the procedure. One aspect pertained to pre-operative urine incontinence issues. The severity of SUI was mostly evaluated using the ICIQ-SF at baseline and after 6 months. Responses to the questionnaire yielded total points that were used to classify the condition as minor, moderate, severe, or extremely severe. The value cutoffs were[10]: Slight 1-5, moderate 6-12, severe 13-18 and very severe 19-21.

Urinary Distress Inventory, Short Form (UDI-6) is a condensed form of a condition-specific QoL instrument that is used much more often than its extended counterpart owing to its practicality. An increased UDI-6 score is indicative of a more severe impairment. The whole-score scale is 0 to 100[11]. Which composed of: Continual urination, leakage associated with a sense of urgency, activity-associated leakage, sneezing or coughing up trace quantities of leaking (drops), inability to empty the bladder and anxiety or pain in the genital or lower abdomen region.

Incontinence Impact Questionnaire (IIQ-7) is a psychometric questionnaire pertinent to urinary incontinence. This survey evaluates the psychological and social consequences of UI in female women. ICI grades provide an A level of validation for the IIQ-7; the total score ranges from 0 to 100 which composed of: Physical activity, mental health (anxiety, depression), social life, traveling more than 30 minutes from home, entertainment, housework, and depression, sense of frustration, which are further divided into 4 categories: PA physical activity (items 1 and2), TR travel (items 3 and 4), SA social activities (item 5), and Emotional health (items 6 and 7).

Overactive Bladder Symptom Scores (OABSS) are intended to quantify OAB symptoms into a single score. Greater severity of symptoms is denoted by greater total scores, ranging from zero to fifteen points. The OABSS comprises four questions: two to five daylight frequencies (2 points), three night-time frequencies points, five urgency points, and five UUI points.

The primary was the efficacy of autologous PRP versus phytoestrogen as a treatment. The secondary outcome was the degree of SUI relief and assesses sexual function.

Sample Size Calculation

Applying G*Power 3.1.9.2 (Germany, Universität Kiel). The following factors were taken into account when determining the sample size: Prior research indicates that following therapy, the UDI-6 should have a mean difference of 3, with a SD of 2.5[12]: 5 cases were added to each cohort in order to overcome dropout, as well as a 95% confidence limit and 95% power of the study. As a result, we recruited 20 patients for each cohort.

Statistical analysis

Statistical analysis was conducted using SPSS v26. (IBM Inc., Chicago, IL, USA). We used an unpaired Student's t-test to compare the two groups' quantitative variables, which were given as means and standard deviations (SD). Qualitative variables were analyzed using the Chi-square or Fisher's exact test when appropriate and were presented as frequency and percentage (%). Statistical significance was determined by a two-tailed *P value* of less than 0.05.

RESULTS

Fifty-two patients were evaluated for eligibility; seven patients did not meet the criteria, and five patients decline to participate in the study. Twenty cases each were divided randomly among the remaining patients. The statistical analysis was performed on all assigned patients after they were followed up (Figure 1).

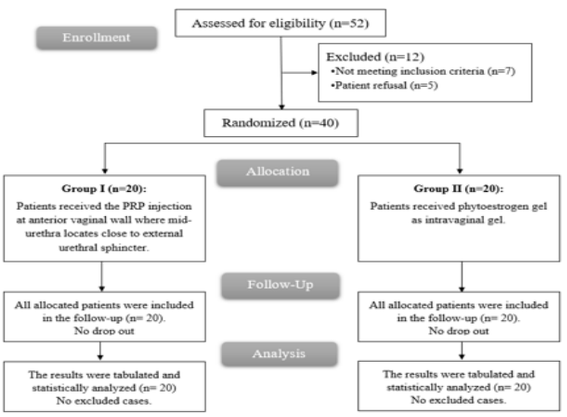

Fig. 1: CONSORT flowchart of the enrolled patients

Both groups showed no statistically significant differences in demographic or urodynamic data (Table1).

Table 1: Demographic and urodynamic data of the studied groups

		Group I(n=20)	Group II(n=20)	*P*
Age(years)		55.75±5.38	52.8±4.79	0.075
Weight(kg)		70.65±7.18	72.6±7.66	0.411
Height(m)		1.68±0.07	1.67±0.07	0.583
BMI (kg/m^2)		25.21±2.98	26.22±2.67	0.268
Parity		2.9±1.07	2.8±1.01	0.762
Mode of delivery	CS	16(80.0%)	15(75.0%)	0.705
	NVD	4(20.0%)	5(25.0%)	
Pad test		6.75±2.84	5.55±1.93	0.127
Menopause		5(25.0%)	4(20.0%)	0.705
Urodynamic				
CBC (ml)		366.65±195.32	288.95±169.44	0.187
Q max (mL/sec)		12.15±6.09	10.4±6.18	0.373
Urine volume (ml)		233.75±52.24	222.95±41.46	0.473
ALPP (cm H_2O)		95.75±30.29	104.4±27.24	0.348

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, CS: Cesarean section, NVD: normal vaginal delivery, CBC: Complete Blood Count, Q max: Maximum Urine Flow Rate, ALPP: Abdominal Leak Point Pressure.

ICIQ-SF and IOQ were significantly improved after 6 months compared to baseline and in group I (P <0.05). ICIQ-SF and IOQ were insignificantly different after six months in comparison to baseline and in group II (Table 2).

Table 2: International Consultation on ICIQ-SF and IOQ at baseline and after 6 months in group I and II

		Group I(n=20)	Group II
ICIQ-SF			
Baseline	Mild	3(15.0%)	5(25.0%)
	Moderate	11(55.0%)	9(45.0%)
	Severe	6(30.0%)	6(30.0%)
After 6 months	Cure	8(40.0%)	2(10.0%)
	Mild	6(30.0%)	5(25.0%)
	Moderate	4(20.0%)	10(50.0%)
	Severe	2(10.0%)	3(15.0%)
	P	0.002*	0.383
IOQ			
Baseline	Mild	2(10.0%)	2(10.0%)
	Moderate	10(50.0%)	9(45.0%)
	Severe	8(40.0%)	9(45.0%)
After 6 months	Cure	9(45.0%)	4(20.0%)
	Mild	5(25.0%)	3(15.0%)
	Moderate	4(20.0%)	10(50.0%)
	Severe	2(10.0%)	3(15.0%)
	P	<0.001*	0.064

Data are presented as mean ± SD or frequency (%). * Significant *p value* <0.05. ICIQ-SF: International Consultation on Incontinence Questionnaire- short Form, IOQ: Incontinence Outcome Questionnaire, IIQ-7: Incontinence Impact Questionnaire, UDI-6: Urinary Distress Inventory, OABSS: Overactive Bladder Symptom Scores.

ICIQ-SF and IIQ-7 were significantly lower after 6 months compared to baseline in group I (P <0.001). IOQ, UDI-6 and OABSS were significantly lower after 6 months compared to baseline in group I and II (P <0.05). ICIQ-SF and IIQ-7 were insignificantly different between baseline and after 6 months in group II (Table 3)

Table 3: Questionnaires that evaluate the severity of their urinary incontinence at baseline and after 6 months in group I and II

	Group I(n=20)	Group II(n=20)
Baseline	10.45±4.88	9.8±5.81
After 6 months	4.95±4.64	8.45±5.47
P	<0.001*	0.062
Baseline	2.3±0.66	2.35±0.67
After 6 months	1.1±1.07	1.55±1
P	<0.001*	<0.001*
Baseline	39.85±15	41.4±15.4
After 6 months	22.2±14.49	31.5±10.84
P	<0.001*	0.012*
Baseline	29.6±19.76	31.45±18.48
After 6 months	13.2±9.38	27.1±19.88
P	<0.001*	0.475
Baseline	6.45±2.46	6.4±4.19
After 6 months	3.85±2.83	4.15±3.7
P	0.001*	0.024*

Data are presented as mean ± SD or frequency (%). * Significant *p value* <0.05. ICIQ-SF: International Consultation on Incontinence Questionnaire- short Form, IOQ: Incontinence Outcome Questionnaire, IIQ-7: Incontinence Impact Questionnaire, UDI-6: Urinary Distress Inventory, OABSS: Overactive Bladder Symptom Scores.

ICIQ-SF, IOQ and OABSS were insignificantly different at baseline and after 6 months between both groups. ICIQ-SF and IOQ were significantly improved after Six months in comparison to baseline and in group I (P <0.05). ICIQ-SF and IOQ were not significantly different after 6 months compared to baseline and in group II. ICIQ-SF, UDI-6 and IIQ-7 were not significantly different at baseline between both groups and were significantly lower after 6 m in Group I than in Group II (P <0.05). ICIQ-SF, IIQ-7, IOQ, UDI-6 and OABSS were significantly lower after six months in baseline in group I and IOQ, UDI-6 and OABSS (P <0.001). ICIQ-SF and IIQ-7 were insignificantly different between baseline and after six months in group II (Table 4).

Table 4: ICIQ-SF, IOQ and questionnaires that evaluate the severity of their urinary incontinence at baseline and after 6 months of the studied groups

		Group I (n=20)	Group II(n=20)	*P*
		ICIQ-SF		
Baseline	Mild	3(15.0%)	5(25.0%)	0.704
	Moderate	11(55.0%)	9(45.0%)	
	Severe	6(30.0%)	6(30.0%)	
After 6 months	Cure	8(40.0%)	2(10.0%)	0.091
	Mild	6(30.0%)	5(25.0%)	
	Moderate	4(20.0%)	10(50.0%)	
	Severe	2(10.0%)	3(15.0%)	
	P	0.002*	0.383	
		IOQ		
Baseline	Mild	2(10.0%)	2(10.0%)	0.945
	Moderate	10(50.0%)	9(45.0%)	
	Severe	8(40.0%)	9(45.0%)	
After 6 months	Cure	9(45.0%)	4(20.0%)	0.158
	Mild	5(25.0%)	3(15.0%)	
	Moderate	4(20.0%)	10(50.0%)	
	Severe	2(10.0%)	3(15.0%)	
	P	<0.001*	0.064	
		Severity of urinary incontinence		
ICIQ-SF	Baseline	10.45±4.88	9.8±5.81	0.704
	After 6 months	4.95±4.64	8.45±5.47	0.035*
	P	<0.001*	0.062	--
IOQ	Baseline	2.3±0.66	2.35±0.67	0.813
	After 6 months	1.1±1.07	1.55±1	0.177
	P	<0.001*	<0.001*	--
UDI-6	Baseline	39.85±15	41.4±15.4	0.749
	After 6 months	22.2±14.49	31.5±10.84	0.027*
	P	<0.001*	0.012*	
IIQ-7	Baseline	29.6±19.76	31.45±18.48	0.761
	After 6 months	13.2±9.38	27.1±19.88	0.007*
	P	<0.001*	0.475	--
OABSS	Baseline	6.45±2.46	6.4±4.19	0.964
	After 6 months	3.85±2.83	4.15±3.7	0.775
	P	0.001*	0.024*	--

Data are presented as mean ± SD or frequency (%). * Significant *p value* <0.05. ICIQ-SF: International Consultation on Incontinence Questionnaire- short Form, IOQ: Incontinence Outcome Questionnaire, IIQ-7: Incontinence Impact Questionnaire, UDI-6: Urinary Distress Inventory, OABSS: Overactive Bladder Symptom Scores.

Success rate was significantly elevated in group I than in group II (P =0.027) (Table 5).

Table 5: Improvement of the studied groups

	Group I (n=20)	Group II(n=20)	*P*
Success rate	14(70.0%)	7(35.0%)	0.027*
Failure rate	6(30.0%)	13(65.0%)	

Data are presented as frequency (%). * Significant *p value* <0.05.

DISCUSSION

SUI, or the involuntary leakage of urine during effort or exertion, is a major health concern that affects over 40% of adult females and negatively influence their daily performance and everyday functioning. The prevalence of SUI is higher in older women[13].

In our work, most of the patients (80% and 75) in both PRP group and phytoestrogen gel group have CS mode of delivery. In disagreement with our study Ibrahim *et al*.[14] Regarding the method of delivery in our 30 cases, 25 (or 83.3% of the total) required a normal vaginal birth, while 5 (or 16.7% of the total) required a caesarean section.

However, Rortveit *et al*.[15] report that vaginal delivery was associated with a maximum improvement in risk. Furthermore, the vaginal birth group was at a higher risk of mild or acute incontinence than the C-section group. A study by Fritel *et al*.[16] recorded that the style of birth (spontaneous, forceps, or caesarean) has slightly and statistically insignificant effect on the severity level of SUI).

In the present research, ICIQ-SF questionnaire and IOQ questionnaire in moderate and sever patients was lower after six months in comparison to the baseline in PRP category while cure and mild cases increased after 6 months compared to baseline. Supporting our results, Tahoon *et al*.[17] found that The treatment effectiveness is illustrated by Before and three months after PRP, there was a shift in the distribution of disease severity, with more people reporting milder or moderate symptoms. Similarly, long *et al*.[18] reported alterations in SUI grade after PRP injection therapy. ICIQ-SF questionnaire in moderate and sever patients was lower after a six-month comparison to the baseline in PRP group. while cure and mild cases increased after 6 months compared to baseline.

In our results, in PRP group, ICIQ-SF, IOQ, UDI-6, IIQ-7, and OABSS were lowered after 6 m compared to baseline. Nikolopoulos *et al*.[19] provided evidence for his concept by showing a variety experimental animals that showed the rejuvenating effects of A-PRP mixtures, such as VEFG, IGF-1, PGDF, HGF, TGF-β, and FGF. In agreement with our results, long *et al*.[18] showed that the outcome is supported by numerous self-reported questionnaires administered prior to, one month after,

and six months following the treatment. Significant and persistent efficacy was demonstrated by the ICIQ-SF, UDI-6, IIQ-7, and OABSS questions. However, the POPDI-6 demonstrated a trend of improved symptom scores, but this was not statistically significant. Supporting our results, Tahoon *et al*.[17] found that Results from the ICIQ-SF, IIQ-7, and OABSS, which assessed treatment efficacy, showed a considerable improvement in incontinence at one month and three months post-treatment.

In our results, in phytoestrogen gel group, ICIQ-SF, IOQ, UDI-6, IIQ-7, and OABSS were lowered after 6 m compared if Phytoestrogen Gel in Management of Menopausal Women o baseline. Numerous research has suggested that phytoestrogens may have a beneficial impact on incontinence symptoms. For example, in Moreira *et al*.[20] Research on lignan phytoestrogens indicated that they may offer postmenopausal women some protection against self-reported incontinence. Cody *et al*.[21] found that Potential improvements in urinary incontinence were achievable through local oestrogen therapy..

In the current study, ICIQ-SF, UDI-6 and IIQ-7 were significantly decreased after 6 m in PRP group than in phytoestrogen gel group. In agreement with our results, Grigoriadis *et al*.[22] carried out single-centre, double-blind, randomized sham-controlled trial. During follow-up, The PRP group showed a substantial drop in the mean score of question 11a of the ICIQ-FLUTS questionnaire when compared to the sham.

Results showed that the PRP group had a 70% success rate, which was significantly higher than the phytoestrogen gel group's 35% success rate. Our findings agreed with Ibrahim *et al*.[14] showed that PRP is an effective therapy for SUI with an 83% success rate, and that most patients reported a decrease in SUI severity shortly following their initial PRP injection. In agreement to our work, a study done by Long *et al*.[18] demonstrates APRP is effective in treating women with SUI.

The research had certain limitations, one of which was a small sample size. Experimentation was limited to one location. Only a brief time has been given for patient follow-up. There was broad variation in PRP preparation method, dosage, injection site, and therapy time. There is no control group. The effects of hypoestrogenism may be mild and treatable with local estrogen therapy immediately following menopause, but they may be difficult to reverse as time goes on.

CONCLUSIONS

In menopausal women with SUI, the repeated PRP injection was more effective and safer in alleviating SUI than phytoestrogen gel.

CONFLICT OF INTERESTS

There are no conflict of interests.

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