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Research Article

ROLE OF PLACEBO AND PSYCHOLOGICAL COUNSELING IN THE MANAGEMENT OF *SHUKRAGAT VATA* W.S.R. TO PREMATURE EJACULATION

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ABSTARCT

Premature Ejaculation is very common male sexual disorder. Anxiety, Stress, Fear etc. are the main etiological factor of premature ejaculation. In *Ayurveda*, this condition can be correlated with *Shukragat Vata*. In this clinical trial management is done by Placebo with psychological counseling. Placebo (starch powder) is given 6 gm. two times a day with *Koshna jal* (warm water) as a *Anupana* in 20 patients. Placebo with psychological counseling was found to be effective to a certain extent in the management of *Shukragat Vata* (premature ejaculation). This study was conducted on 23 patients with statistically highly significant result ($p<0.001$) on the chief complaints of Premature Ejaculation.

KEY WORDS: Premature Ejaculation, *Shukragat Vata*, Placebo, Psychological counseling.

INTRODUCTION

Premature Ejaculation is the very common male sexual disorder, affecting on an average 40% of men worldwide(1). The World Health Organization (WHO) 2nd International Consultation on Sexual Health defined it as "... persistent or recurrent ejaculation with minimal stimulation before, on or shortly after penetration and before the person wishes it, over which the sufferer has little or no voluntary control which causes the sufferer and / or his partner bother or distress..."[2]. Kinsey's observed that Asian men have shorter times to ejaculation than Caucasians, who in turn have shorter times to ejaculation than Afro-Caribbean's, has been interpreted to suggest that some races are more "sexually restrained" than others[3]. An increased susceptibility to premature ejaculation in men from the Indian subcontinent has been reported[4].

Vajikarana (Aphrodisiac) is one of the branches of *Ayurved* which deals with the preservation and amplification of sexual potency of a healthy man and conception of healthy progeny as well as management of defective semen, disturbed sexual potency and spermatogenesis along with treatment of seminal related disorders in man[5]. *Vajikarana* promotes the sexual capacity and performance as well as improves the physical, psychological and social health of individual[6]. In *Ayurved* there is concept of *Shukragat vata* which can be correlated with premature ejaculation[7].

Shukragata vata is a distinct pathological entity characterized by a group of clinical presentations related either with the impairment of ejaculation or with the impairment of seminal properties. The clinical presentations of *Shukragata vata* are as

1. Early ejaculation
2. Delayed ejaculation
3. Seminal abnormalities
4. Affliction of fetus/premature birth/delayed birth.

The different clinical presentations of a same pathological process occur according to the affliction of the vitiated *Vata* on the various structural and functional attributes of *Shukra*. In delayed ejaculation although the intra-vaginal ejaculation eventually occurs, it requires a long time and strenuous efforts at coital stimulation, and sexual arousal may be sluggish. It may be caused when the vitiated *Vata* loses its *Drutatva or Chalatva* after the enlodgement which leads to lack of sufficient stimulation for ejaculation. It may also

happen when the vitiated *Vata* causes the diminution of *Shukra dhatu by Shoshana svabhava*, and quantitatively less amount of *Shukra* is ejaculate after long effort[8]. Seminal parameters are impaired when the vitiated *Vata* afflict the functional characteristics of *Shukra* as semen or spermatozoa. When *Vata* affects these characteristics, *Shukra dushti is* explained as *Phenila, Tanu, Rooksha*[9], *Grathita, Vivarnadi yukt*[10], *Vatika shukra, Grandhishukra (Vatakaphaja), Ksheena (vata paittika)*[11], *Alpa retas, Ksheena retas and Vishushka retas*[12] occurs. These are seminal abnormalities lacking in the qualities like count (azoospermia or oligospermia), motility (asthenospermia) and morphology (teratospermia). The physical properties of semen like volume viscosity, appearance, transparency etc. may also be impaired due to *Vata* vitiation.

Aims and Objectives

To evaluate role of Placebo and Psychological Counseling in the treatment of Premature Ejaculation.

MATERIALS AND METHODS

Patients attending in the *Vajeekarana* O.P.D. of Department of Kayachikitsa, I.P.G.T. & R.A., Gujarat Ayurved University, Jamnagar having genuine complaints of premature ejaculation fulfilling the criteria for inclusion was selected irrespective of race, caste and religion, between the age group of 21-50 years. Pre entry examination was simple and brief and tried to include an interview of the wife wherever it was possible.

Psychological treatments often involve counseling or sexual therapy that can include talking about relationships and experiences with a mental health professional and/or learning practical tools. By investigating relationships and individual issues that may be causing or compounding PE, mental health professionals can help find effective ways of coping with and solving problems that may be causing PE. This therapy also includes - Distraction techniques: distracting mental exercises during sex (such as thinking of mundane things like baseball, work, etc.). These techniques are probably most useful for men with occasional PE or men who experience PE in the initial stages of a new sexual relationship. For men with long-standing PE, the consistent use of these techniques usually interferes with spontaneity and satisfaction.

Eligibility Criteria

Considering the different definitions put forth by various scientist for premature ejaculation, the inclusion criteria for the present study was kept as following.

1. Ejaculation prior to ten penile thrusts.
2. Ejaculation before, on or within one minute of sexual act after penetration.
3. Unable to satisfy partner in at least 50% of the coital incidences.
4. Unable to delay ejaculation till the person wishes it.
5. The problem should be persistent or recurrent and cause marked distress or Interpersonal difficulties.

Exclusion Criteria

1. Factors that affect the duration of the excitement phase of sexual act such as novelty of the partner or situation and recent frequency of sexual act will be taken into account.
2. The problem should not be a due exclusively to the direct effect of a substance (E.g. Withdrawal of opioids).
3. Persons having very short post ejaculatory refractory period will be excluded.
4. Major psychiatric illness.
5. Routine pathological and biochemical investigations will be done to exclude any other major pathology.

Drug and Dose

The selected patients were given Placebo (Starch Powder) 6gms two times day before lunch & supper with *Koshna jal* as *Anupana* for the duration of 2 months. Along with Placebo, Psychological Counseling was also given. *Haritaki churna* is given, 6 gm at bed time for *Koshta shudhi* for 3 days before starting the medication. All the patients were directed to keep the frequency of sexual act and duration of foreplay as usually they are adopting so that a change in them will not make error in the evaluation of therapy. A generalized moderate *Pathyapathya* were advised to all patients.

Investigation

- Complete Blood Count
- Urine – Routine
- Semen Analysis (BT&AT)

Criteria of assessment

The improvement in the patient was assessed mainly on the basis of relief in the sign and symptoms of the disease. To assess the effect of therapy objectively, all the sign and symptoms were given scoring depending upon their severity.

Related sign & symptoms were recorded from 1st day - starting day of treatment then weekly or daily observation was done during the course of the treatment. Gradation of the symptoms was made depending on the severity and specific symptom score prior to treatment and after completion of the treatment were taken and their difference was assessed.

1. Intra-vaginal Ejaculatory Latency Time (IELT) less than one minute

a	Mere thought, sight or voice of partner	5
b	Immediately after penetration	4
c	Within 30 seconds of penetration	3
d	Within 2 minutes	2
e	Within 2-5 minutes	1
f	More than 5 minutes	0

2. Voluntary control over ejaculation

a	Never	5
b	Lack of control on most occasions	4
c	Less than 25% encounter	3
d	Less than 50% encounters	2
e	Less than 75 % encounters	1
f	Full control over ejaculation	0

3. Patient satisfaction

a	No orgasm at all	5
b	Lack of enjoyment	4
c	Satisfaction during 25% sexual acts	3
d	Satisfaction during 50% sexual acts	2
e	Satisfaction during 75% sexual acts	1
f	Satisfaction during every sexual act	0

4. Partner's satisfaction

a	No orgasm at all	5
b	Lack of enjoyment	4
c	Satisfaction during 25% sexual acts	3
d	Satisfaction during 50%	2
e	Satisfaction during 75%	1
f	Satisfaction during every sexual act	0

5. Performance Anxiety

a	Anxiety that hampers all encounters	5
b	Anxiety that hampers sexual act in 75% encounter	4
c	Anxiety that hampers sexual act in 50% encounters	3
d	Anxiety that hampers sexual act in 25% encounter	2
e	Slight anxiety that does not disrupt the sexual act	1
f	No anxiety at all	0

6. Number of penile thrusts

a	None, discharge before penetration	5
b	Less than 5	4
c	Less than 10	3
d	Less than 15	2
e	Less than 20	1
f	More than 25	0

Improvised scoring scale for *Manasbhavas* on psychosexual parlance

A scoring scale was developed in the present study to evaluate the objectives of mind on psychosexual parlance. The interpretation of each characteristic was done according to the classical references and commentaries on them. Negative marks were also given wherever necessary.

1. *Raja* (Attachment)

a	Highly attached to partner and becomes highly agitated on rejection or denial in relation	2
b	More attached to partner, desperate on rejection, denial in relation	1
c	Normal attachment to partner and sensible approach on rejection or denial	0
d	No attachment with partner	-1

2. *Krodha* (Hatredness)

a	Always aggressive with partner on sexual and non sexual matters with occasional physical assaults	2
b	Often aggressive with partner on sexual and non sexual matters	1
c	Aggressive rarely in certain unavoidable conditions	0
d	Never aggressive even if needed to rise the occasion/instigated	-1

3. *Harsha* (Joy)

a	No entertainments or enjoyments in married life	2
b	Rarely involve in entertainments and enjoyments	1
c	Normally involve in entertainments and enjoyments	0
d	Over indulgence in entertainments and enjoyments	-1

4. *Preeti* (Satisfaction)

a	No satisfaction at all in marital life especially in sexual act	2
b	Poor satisfaction	1
c	Normal satisfaction	0
d	Abnormally joyful and easily satisfied in sexual activity without concern of partner satisfaction	-1

5. *Bhayam / Dhairyam* (Fear/Courage)

a	High level of performance anxiety disruptive in all most all sexual encounters	2
b	Moderate disruptive performance anxiety	1
c	Optimum level of performance anxiety	0
d	Careless about performance	-1

6. *Veeryam* (Will power/ Initiation)

a	Sexual act only on demand of partner	2
b	Occasionally go for sexual act on self interest	1
c	Positively involve in sexual act on self interest	0
d	Demanding sexual act even though the partner is not interested	-1

7. *Avasthanam* (Mental stability/Decisiveness)

a	Not decisive and make big mistakes on failure in sexual act which worsens the problem	2
b	Not trying to take corrective measure in failure of sexual act	1
c	Sensible analysis about the failure and take corrective measure	0

***8. Shraddha* (Desire)**

a	Never reveals self sexual desire and preferences to partner	2
b	Rarely reveals self sexual desire and preferences to partner	1
c	Reveals the self sexual desire and preferences to the partner	0
d	Demanding or insisting self sexual desire and preferences to the partner	-1

9. *Medha* (Intellect/Grasping power)

a	Very poor in grasping ideas during psychosexual counselling	2
b	Poor to grasp ideas	1
c	Normally grasping the ideas	0

10. *Dhriti* (Self restrain /Control)

a	Never unable to control sexual urge	2
b	Poor in self restraining in certain occasions where sexual urge to be controlled	1
c	Able to restrain self when needed	0
d	Forceful celibacy	1

Hamilton's Anxiety Rating Scale

To evaluate each patient's degree of anxiety and pathological conditions Hamilton's Anxiety Rating Scale was used.

GRISS Questionaire for sexual satisfaction

Golombok- Rust Inventory for sexual satisfaction (GRISS) (1983) is a short measure of sexual dysfunction which can be administered to heterosexual couples or individuals who have a current heterosexual relationship. It provides overall scores for men and women separately of the quality of sexual functioning with in a relationship. In addition subscales for premature ejaculation etc. can be obtained from this. The four itemed subscale for premature ejaculation was utilized in the present study.

Subscale for P.E. can be designed on the basis of this scale. A four itemed subscale for PE was utilized in the present study. The items utilized were as follows:

1. Are you able to delay ejaculation during intercourse if you think you may be coming too quickly?

a	Never	4
b	Hardly ever	3
c	Occasional	2
d	Usually	1
e	Always	0

2. Can you avoid ejaculating too quickly during intercourse?

a	Never	4
b	Hardly ever	3
c	Occasional	2
d	Usually	1
e	Always	0

3. Do you ejaculate without wanting to almost as soon as your penis enters your partner's vagina?

a	Never	4
b	Hardly ever	3
c	Occasional	2
d	Usually	1
e	Always	0

4. Do you ejaculate by accident just before your penis is at least to enter your partner's vagina?

a	Never	4
b	Hardly ever	3
c	Occasional	2
d	Usually	1
e	Always	0

Total effect of therapy

Considering the relief of major symptoms and improvement in the quality of sexual functioning, the subjects were divided into the following groups to assess the total efficacy of each therapy.

1. Cured (100%) - achievement of certain reasonable voluntary control over ejaculation, sufficient length of sexual act according to wish with both partners satisfied.

2. Markedly improved (>75%) - sufficient length of sexual act according to wish with both partners satisfied, but no voluntary control over ejaculation.

3. Moderately improved (51 -75%) - improvement in duration of sexual act more than one minute or more than ten penile thrust with partner's satisfaction in at least 50% of incidents.

4. Unchanged (25-50 %) - duration of sexual act less than one minute or less than 10 penile thrust.

5. Worsened (<25%) - no change or worsening of duration of sexual act and or other sexual health parameters like erection, rigidity etc.

Observation and Results

Table1:

Type	**Placebo + Psychological Counseling**
Completed	20
Drop Out	3
Registered	23

In this clinical study, 23 patients of Premature Ejaculation were registered. 3 patients were LAMA, so 20 patients completed treatment.

Table 2: General Observation

Age(21-26yrs.)	43.62 %
Religion (Hindu)	92.65%
Occupation (Labour work)	55.10%
Married	85.71%
Vishamashan	84.69%
Koshta (Kroora)	53.06%
Sharir Prakruti (VP)	69.37%
Manisika (Rajas)	72.24%

Table 3: Effect of Placebo on the chief complaints of P.E. (n=20)

Symptoms	**Mean**	**%**	**S.D.**	**S.E.**	**t**	**p**
Intra-vaginal ejaculatory latency time	1.05	24.41	0.82	0.18	5.68	<0.001
Voluntary control over ejaculation	1.10	26.19	0.85	0.19	5.77	<0.001
Patient satisfaction	0.55	15.27	0.75	0.17	3.24	<0.01
Partner's satisfaction	0.55	18.64	0.60	0.13	4.06	<0.001
Performance anxiety	0.70	17.72	0.57	0.12	5.48	<0.001
Number of penile thrusts	0.25	5.88	0.44	0.09	2.51	<0.05

Table 4: Effect of Placebo on modified scale for P.E. based on GRISS Questionnaire (n=20)

Questions	**Mean**	**%**	**S.D.**	**S.E.**	**t**	**p**
Are you able to delay ejaculation during inter-course if you think you may be coming too quickly?	0.41	17.62	0.51	0.13	3.38	<0.01
Can you avoid ejaculation too quickly during intercourse	0.23	9.74	0.45	0.11	2.21	<0.05
Do you ejaculate without Wanting to almost as soon as your penis enter your partners Vagina?	0.50	19.04	0.52	0.13	3.88	<0.01
Do you ejaculate by accident just before your penis is at least to enter your partner vagina?	0.25	28.56	0.45	0.11	2.54	<0.05

Table 4: Effect of Placebo on the on *Manasbhavas* (n=20)

Symptoms	Mean	%	S.D.	S.E.	t	p
Raja	0.20	36.36	0.41	0.09	2.17	<0.05
Krodha	0.05	11.11	0.23	0.65	1	>0.05
Harsha	0.5	47.61	0.60	0.13	3.68	<0.01
Preeti	0.7	50	0.5	0.13	5.38	<0.001
Bhayam	0.5	3.33	0.51	0.11	4.35	<0.01
Veeryam	0.6	60	0.50	0.12	5.33	<0.001
Avasthanam	0.50	40	0.55	0.13	3.85	<0.01
Shraddha	0.55	91.66	0.51	0.12	4.81	<0.001
Medha	0	41.33	0.48	0.12	2.5	<0.05
Dhriti	0.05	40.89	0.63	0.15	3.58	<0.01

Table 5: Effect of Therapy on Hamiltons Anxiety Rating Scale

GROUP	Mean	%	S.D.	S.E.	t	p
Placebo (n=20)	0.30	37.45	0.48	0.11	2.60	<0.05

Table 6: Effect of therapy on Post ejaculatory refractory period

GROUP	Mean	%	S.D.	S.E.	t	p
Placebo (n=20)	0.87	14.19	0.93	0.22	4.02	<0.01

Table7: Overall effect of therapy

GROUP	Cured	Markedly improved	Moderately improved	Unchanged
Placebo (n=20)	00 %	5.88 %	11.76 %	82.35 %

DISCUSSION

In this clinical study no patient got complete remission, 5.88 % patient got markedly improvement, 11.76 % got moderate improvement, while 82.35 % not improved.

The intra-vaginal ejaculatory latency time improved by 24.41%, voluntary control over ejaculation improved by 26.19%, subjects satisfaction improved by 15.27%, partner satisfaction improved by 18.64%, performance anxiety by 17.72%,number of penile thrusts improved by 5.88%. Improvement in partner's satisfaction and number of penile thrusts were statistically highly significant ($p<0.001$). In case of IELT, voluntary control over ejaculation and performance anxiety were also highly significant ($p<0.001$).

Highly significant results were seen with regards to *Harsha* ($p<0.001$), *Preeti* ($p<0.001$), *Veeryam* ($p<0.001$), *Shraddha* ($p<0.001$. Improved results were seen with regards to Raja ($p<0.05$), *Harsha* ($p<0.01$), Bhayam ($p<0.01$), *Medha* ($p<0.05$), *Dhriti* ($p<0.01$). Insignificant results were seen in *Krodha* ($p>0.05$).

The effect of Placebo on modified scale for premature ejaculation based on Griss questionnaire is as tabulated above. 17.62% subjects were able to delay ejaculation during intercourse even though they thought that they may be coming too quickly which was statistically highly significant. 9.74% subjects were able to avoid ejaculating too quickly during intercourse, which was statistically significant. 19.04% subjects were able to ejaculate without wanting to almost as soon as their penis entered their partner's vagina which was statistically highly significant. 28.57% subjects were able to avoid ejaculating by accident just before their penis was at least to enter their partner's vagina which was also statistically significant.

Probable Mode of Action

Placebo with psychological counseling was found to be effective to a certain extent in the management of PE. Simple Psychological counseling could impart confidence and self esteem in the subject and help him to think positively and to indulge in sexual act enthusiastically by reducing performance anxiety. The suggestions help to avoid spectator effect so that sexual functioning will not deteriorate. His misconceptions regarding the act of copulation

are solved thus he follows the right techniques where and when ever necessary. *Dhee, Dhairya Atmsadi Vinjanam* is suggested to be excellent *Oushadha* for *Manodosha*[13] which is supplied through *counseling*. Placebo act as a *Manosamvardhana Chikitsa.* The fact that he is taking medicine for his problem and satisfaction that his unanswered questions related to the act of copulation through counseling have been answered, this could make the patient feel that his problem is reduced.

CONCLUSION

Anxiety and Stress are the triggering factor for Premature Ejaculation. So while treating a patient of Premature Ejaculation psychological counseling is must. But alone Placebo with psychological counseling is not able to achieve voluntary control. Hence when *Vrushya* drug having *Balya*, *Medhya*, *Shukrastambhak* properties is used along with psychological counseling then it will provide encouraging result in the patient of Premature Ejaculation.

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