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Original Research Article

Comparison of pain control between lidocaine and prilocaine spray (TEMPE) versus lidocaine gel in the treatment of premature ejaculation: a prospective randomized controlled trial in a tertiary care centre

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ABSTRACT

Background: Premature ejaculation is the most common cause of sexual dysfunction. There is no consensus on the treatment protocol due to poor understanding of the underlying mechanisms. Therefore, the present pilot study was conducted to compare the efficacy of topical eutectic mixture for premature ejaculation (TEMPE) spray with lidocaine gel for the treatment of premature ejaculation.
Methods: After obtaining ethics approval and written informed consent, 100 patients meeting the inclusion and exclusion criteria were included. Baseline values of intravaginal ejaculation time (IELT) and international index of erectile function (IIEF) were recorded. Patients were randomly assigned into group A (lidocaine plus prilocaine spray) and group B (lidocaine gel). After 4 weeks of treatment IELT and IIEF score were recorded. The findings were noted and analysed.
Results: Both the groups were similar in terms of demographic and baseline characteristics. There was a significantly higher improvement in IELT and IIEF score following treatment in group A as compared to group B. The incidence of side effects was lower in group A as compared to group B.
Conclusions: We recommend that the use of TEMPE spray for the treatment of premature ejaculation as it is better than lidocaine gel.

Keywords: Lidocaine and prilocaine spray, Lidocaine gel, Premature ejaculation, Local anesthetics, Topical treatment, TEMPE

INTRODUCTION

Premature ejaculation is one of the commonly reported sexual dysfunction amongst males.[1,2] The treatment protocols are still under debate as the pathophysiology is not completely understood. There are several diagnostic criteria for the diagnosis of premature ejaculation. The most widely used is the criteria laid down by the International society for sexual medicine (ISSM) defining premature ejaculation as: ejaculation that always, or nearly always, occurs before, or within, about one minute of vaginal penetration or a clinically significant and bothersome reduction in latency time, often to about three minutes or less; the inability to delay ejaculation on all or nearly all vaginal penetrations; and this condition determines negative personal consequences, such as distress, bother, frustration, and/or the avoidance of sexual intimacy.[3,4]

Previously, premature ejaculation was thought to be a psychogenic condition. But with a greater understanding of the underlying pathophysiologic mechanisms, several organic, neurological, iatrogenic causes have been identified.[5,6] Consequently, many treatment strategies have been developed. Nevertheless, penile hypersensitivity and shorter latency periods are the hypothesized underlying mechanisms.[7,8]

Traditionally, selective serotonin reuptake inhibitors (SSRIs) have been used in the treatment of premature ejaculation. But they are associated with significant adverse effects which limits their usage and patient compliance, leading to high rates of discontinuation.[9,10] Therefore, there has been search for an effective drug with lower side effects. Recently, topical anesthetics are being used for treatment. They have faster absorption rates as compared to oral agents, are devoid of any systemic side effects. However, they may be associated with local side effects like irritation and numbness.

Therefore, in this pilot study we compared the efficacy of topical eutectic mixture for premature ejaculation (TEMPE) spray with lidocaine gel for the treatment of premature ejaculation.

METHODS

This prospective randomized controlled trial was conducted in the department of urology, M.S. Ramaiah Medical College, Bengaluru from January 2020 to January 2023. Patients consenting to participate in the study and who met the inclusion and exclusion criteria as below, were included in the study.

Inclusion criteria

Male patients aged 18 to 65 years, patients having regular sexual life, patients diagnosed with premature ejaculation, and patients giving consent to participate in the study were included.

Exclusion criteria

Patients aged less than 18 years or above 65 years, patients allergic to any of the study drugs, patients having organic cause of premature ejaculation like anatomical abnormality, neurological or psychological causes, genital infections, patients having erectile dysfunction (ED) or any of the risk factors for ED like substance abuse, patients with uncontrolled hypertension or cardiovascular disease, and patients not giving consent to participate in the study were excluded.

All the patients attending OPD during the study period and diagnosed with premature ejaculation were considered for inclusion in the study. Premature ejaculation was defined by the ISSM criteria as ejaculation occurring within one minute of vaginal penetration.[11]

After taking approval of the institutional ethics committee and voluntary written informed consent from all the patients, they were included in the study. A total of 100 cases meeting the inclusion and exclusion criteria, were included in the study.

Baseline demographic characteristics were noted for all patients. Detailed past and personal histories were recorded. Baseline IELT was recorded using the stopwatch. Baseline international index of erectile function (IIEF) score was also recorded.[12]

The patients were randomly divided into two groups: group A (lidocaine plus prilocaine spray) and group B (lidocaine gel). The randomization was done according to the consolidated standards of reporting trials (CONSORT) 2010.

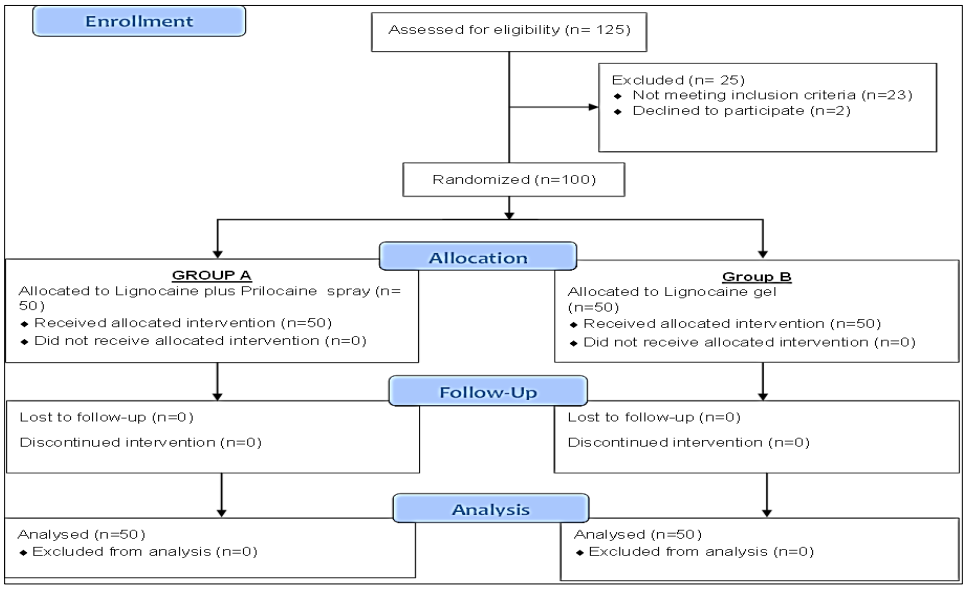

Figure 1: CONSORT 2010 flow diagram.

Group A patients were instructed to apply TEMPE spray delivering 7.5 mg lidocaine base plus 2.5 mg prilocaine base per actuation. Patients were instructed to apply it on the glans penis and body shaft 10 minutes before sexual activity (a total of 3 actuations). Group B patients were instructed to apply lidocaine gel (1.5 grams) on the glans penis and body shaft 10 minutes before sexual activity.

Patients were followed up 1 month after the initiation of treatment. Post-treatment IELT and IIEF were recorded. Complications, if any, were noted.

The data was analysed using the statistical package for the social sciences (SPSS) software version 22.0. All the qualitative data was expressed as percentages. The p values were assessed by Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). All the quantitative data was expressed as mean±standard deviation. P values were assessed by the unpaired and paired t tests. P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the tables.

RESULTS

The two groups were comparable in terms of demographic characteristics (Table 1).

Table 1: Distribution of demographic and baseline characteristics in the study population.

Parameter	Group A	Group B	P value
Age (in years)	32.41±5.20	33.10±4.32	0.801

The two groups were similar in terms of baseline IELT and IIEF scores (Table 2).

The post-treatment IELT and IIEF scores were significantly higher in group A than in group B; p values: less than 0.001 (Table 3).

Table 2: Distribution of baseline findings in the study population.

Parameters	Group A	Group B	P value
IELT (in seconds)	32.40±1.23	33.11±2.12	0.621
IIEF	15.41±2.34	15.34±1.67	0.942

Table 3: Distribution of post-treatment findings in the study population.

Parameters	Group A	Group B	P value
IELT (in seconds)	620±20.12	432±18.12	<0.001*
IIEF	28±1.2	22±1.4	<0.001*

*statistically significant.

There was only one reported local irritation in group A as compared to 6 patients experiencing local irritation and 2 patients experiencing significant penile numbness in group B (Table 4).

Table 4: Distribution of side effects in the study population.

Parameters	Group A	Group B	P value
Side effects	2 (4%)	8 (16%)	0.045*

*statistically significant.

DISCUSSION

In the present study, we observed that there was a significant increase in IELT time following treatment in both the groups. However, on comparison of the two groups, it was observed that the IELT was much longer in the cases treated with TEMPE spray as compared to lidocaine gel. There was also a significant improvement in the IIEF score after treatment following TEMPE spray than lidocaine gel.

There are studies, including phase 2 and 3 trials, that have demonstrated the efficacy of TEMPE spray and Lidocaine gel in the prolongation of IELT.[13-15] But these studies have either compared the topical anesthetic with placebo or oral agents. Therefore, ours is a pilot study comparing the efficacy profile of different formulations of local anesthetics. The mechanism of action of local anesthetics is either by desensitization of the penis or by delay of the ejaculatory reflex.

Hypersensitivity is hypothesized to be the underlying cause of premature ejaculation.[16] It has been shown that in patients with premature ejaculation, they have shorter latency period and greater amplitudes of somatosensory evoked potentials from the glans penis suggesting existence of abnormal reflex pathways and possibly, greater cortical representation of sensory stimuli from the glans penis.[17-19] Therefore, various desensitization techniques have been tried for the treatment and management of premature ejaculation. There is no consensus in the type of anesthetic to be used or the duration of exposure.

Most of the anesthetic agents are used off-label in the treatment of premature ejaculation. Studies have shown duration of application up to 30 minutes before sexual intercourse.[16,20] However, using an aerosolized form reduces this duration to less than half.[16]

In our study, we found lower incidence of side effects with TEMPE spray as compared to the lidocaine gel. In both the groups only local side effects were reported and none of the patients reported any systemic side effects. TEMPE is alcohol-free mixture leading to less incidence of stinging and local irritation. Lidocaine gel is oil-based, stays longer and is absorbed in the female genital tract leading to vaginal or clitoral anesthesia in addition to causing penile numbness. TEMPE, being oil-free, is devoid of these side-effects and does not require the application of condom.[21]

Limitations

This pilot single center study is limited by the OPD attendance of the patients undergoing circumcision. Therefore, the results may not be generalized.

CONCLUSION

Premature ejaculation is a common cause of sexual dysfunction with a variety of treatment regimens. Though there is no recommended treatment protocol, however local anesthetics are preferred due to their favorable side effect profile. In the present study, we compared the TEMPE spray and lidocaine gel and concluded that TEMPE spray is more effective than lidocaine gel in the treatment of premature ejaculation.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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