Optimum usage of prilocaine-lidocaine cream in premature ejaculation

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Key words. Premature ejaculation–prilocaine—lidocaine cream

Summary. Premature ejaculation is a common male sexual disorder in which orgasm and ejaculation occur before the desired moment. The primary therapeutic approach to premature ejaculation has been behavioural and pharmacotherapy. In this study, we evaluated the efficacy and optimum usage of lidocaine-prilocaine cream 5% in preventing premature ejaculation. Forty patients were examined in the study group and randomized into four groups, each comprising 10 patients. Patients in group 1 applied lidocaine-prilocaine cream 5% for 20 min, the patients in group 2 applied it for 30 min, and the patients in group 3 applied the cream for 45 min before sexual contact, with all patients covering the penis with a condom. Patients in the fourth group applied a base cream as placebo. In group 1, the pre-ejaculation period increased to 6.71 ± 2.54 min without any adverse effects. In group 2, although the pre-ejaculation period increased in four patients up to $8.70 \pm$ 1.70 min, six patients in this group and all patients in group 3 had erection loss because of numbness. In the placebo group, there was no change in their pre-ejaculation period. Therefore, lidocaine-prilocaine cream 5% is effective in premature ejaculation and 20 min of application time before sexual contact is the optimum period.

Introduction

Premature ejaculation is the most prevalent form of male sexual dysfunction and can be defined as a habitual form of rapid ejaculation in the first minute after penetration before the person wishes to achieve orgasm. There are also some other

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definitions such as an absence of voluntary control over the ejaculatory reflex (Kaplan, 1974) or an inability to control the ejaculatory reflex (Berkovitch *et al.*, 1995). The cause of premature ejaculation was believed to be psychological in most patients, except in some rare organic conditions such as urinary tract infections, prostatitis, diabetes mellitus, atherosclerosis and alcoholism (Godpodinoff, 1989). For the majority of patients with primary premature ejaculation treated with various drugs, especially antidepressants, alpha blockers and sympatholytic agents, the cause is believed to be psychological (Murphy & Lipshultz, 1987; Hsieh *et al.*, 1999).

Lidocaine 2.5% and prilocaine 2.5% cream is a eutectic mixture of local anaesthetics (EMLA) which can penetrate intact skin and provide reliable local analgesia. EMLA Cream has been found to be efficient for local anaesthesia in extracorporeal shock wave lithotripsy (ESWL), ulcer debridement, cryotherapy of wards and minor urological surgical procedures such as frenulotomy, meatoplasty, removal of smegma (Honnens de Lichtenberg et al., 1992; Hoebeke et al., 1997; Gupta et al., 1998; Vanscheidt et al., 2001) and also in premature ejaculation (Berkovitch et al., 1995). The aim of this study was to investigate the optimum usage time of EMLA Cream in the treatment of premature ejaculation.

Patients and methods

Our study comprised 40 patients with primary premature ejaculation (mean age 29.4 years, range 20–40) who presented to the Department of Urology at Firat University Medical Faculty. In the medical history, all patients revealed an ejaculation within the first minute after penetration and were married or had a constant sexual partner

for more than 2 years. Patients with organic factors for sexual dysfunction such as genitourinary tract infection, diabetes mellitus, hypertension, neurological disorders or obvious psychological problems requiring psychiatric drug use were not included in the study. Patients were randomly divided into four groups, each consisting of 10 patients. Thirty patients applied one tube of 2.5-g EMLA Cream on the penis and a condom was used for covering the penis. In group 1, the patients removed the condom after 20 min, in group 2, after 30 min, and in group 3, after 45 min. All patients were warned to wipe the cream from the penis before penetration because of the rapid effect of the cream to vaginal mucosa. In the control group, the patients were not aware of the fact that they were using a placebo cream, and were instructed to apply a 2.5-g cream, which was prepared without any additives, and to wait 20 min before penetration.

In all groups, the pretreatment ejaculation periods were accepted as 1 min in all patients. In the statistical analyses, Student's t-test and, after application, one-way anova with the Tukey test were used. A P < 0.05 value was considered to indicate statistical significance.

Results

In group 1, every patient applied the EMLA cream at least five times (range 5–9), and all reported normal erections. In one patient, there was no change in his pre-ejaculation period and he ejaculated in the first minute after vaginal penetration, as before treatment. In another patient, the pre-ejaculation time only increased to 3–5 min, but in eight patients of this group the pre-ejaculatory period prolonged 5–11 min (mean: 6.71 ± 2.54) after vaginal penetration. This increase was found to be statistically significant (P < 0.05) according to the before-application pre-ejaculation periods.

In group 2, every patient applied the EMLA cream at least five times (range 5–8), and in four patients in this group the pre-ejaculation period prolonged to 7–13 min (mean: 8.70 ± 1.70). Also, this increase was found to be statistically significant

(P < 0.05) according to the before-application preejaculation periods. The other six patients in this group were not satisfied with the cream and complained of erection loss as a result of numbness of the penis and delayed ejaculation.

In group 3, every patient applied EMLA Cream at least five times (range 5–7) and all of them complained of erection loss because of numbness of the penis and delayed ejaculation.

In the placebo group, all patients applied the placebo cream at least five times (range 5–8). Although they all had a normal erection, nine of them reported no change in their pre-ejaculatory period after vaginal penetration and ejaculated in the first minute, as before treatment. Only one patient had 2–3 min of prolonged ejaculation time and a total mean ejaculation time of 1.01 ± 0.07 in this group, which was not statistically significant (P > 0.05) according to the before-application periods (Table 1).

Discussion

Premature ejaculation is the most common form of male sexual dysfunction, affecting 30% of men and defined as an inability to exert voluntary control over the ejaculatory reflex with the result of rapid orgasm (Berkovitch et al., 1995; Xin et al., 1996). For many authors the diagnostic criterion is the time between penetration and ejaculation and this time is agreed to be 1 min (Kaplan, 1974). Patients with premature ejaculation can be subdivided into primary premature ejaculators, those who have suffered from premature ejaculation since the beginning of their sexual lives, and secondary premature ejaculators, those who have suffered from premature ejaculation after years of normal sexual functioning (Godpodinoff, 1989). Although the cause of premature ejaculation is unknown in most cases, some authors suggest that it is a psychological problem of performance anxiety and have accordingly tried to treat patients by sex therapy or various drugs (Murphy & Lipshultz, 1987; Lechtenberg & Ohl, 1994). Sex therapy is defined as squeezing the glans penis to increase the

| Groups | Patients | | | | | | | | | | Mean time (min) |
|------------------|----------|-----|-----|-----|-----|-----|------|------|-----|-----|-----------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| Placebo | 2.4 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1.01 |
| Group 1 (20 min) | 1 | 4.2 | 6.6 | 7.5 | 7.0 | 7.7 | 8.5 | 6.6 | 8.1 | 7.8 | 6.71 |
| Group 2 (30 min) | _ | _ | _ | _ | _ | _ | 8.33 | 8.67 | 10 | 8 | 8.71 |
| Group 3 (45 min) | _ | _ | _ | _ | _ | _ | _ | _ | _ | _ | 0.0 |

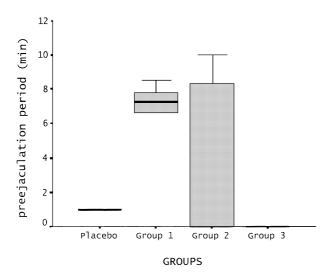


Figure 1. Pre-ejaculation periods of patients before and after treatment.

pre-ejaculatory period and includes the drugs sertraline (Kim & Seo, 1998), lorazepam (Segraves, 1987), clomipramine (Haensel *et al.*, 1996) and paroxetine hydrochloride (McMahon & Touma, 1999). Some investigators have evaluated these patients by penile biothesiometry and have concluded that patients with primary premature ejaculation have penile hypersensitivity and can be treated by desensitizing preparations (Xin *et al.*, 1996). For this purpose, topical agents such as lidocaine (Atan *et al.*, 2000) and SS Cream (Choi *et al.*, 2000) have been used and to reportedly different degrees of success.

EMLA Cream has also been used for premature ejaculation 30 min before sexual contact in 11 patients, and although the results were excellent in five patients, one patient did not enjoy the sexual activity because of numbness and delayed ejaculation (Berkovitch et al., 1995). Local anaesthetics have long been applied topically to provide anaesthesia of the mucous membranes. Providing anaesthesia to intact skin has, however, been far more difficult to overcome, as penetrating the skin requires a high water content and a high concentration of the base form of the anaesthetic is required. The high water content of EMLA Cream enables it to penetrate intact skin. When EMLA Cream was applied for 15 min, both the sensory and the pain thresholds increased further and dermal analgesia persisted for 1–2 h after removal of the cream (Arendt-Nielsen & Bjerring, 1985).

In this study, we investigated the optimum usage of EMLA Cream by patients applying it 20, 30 and 45 min before penetration. Before application the pre-ejaculation period of all patients was accepted to be 1 min. In group 1, eight patients had improvement in their pre-ejaculatory period (mean

time: 6.71 ± 2.54) and the increase was statistically significant (P < 0.01) according to the before-application period and also in comparison with the placebo group. In group 2, although four patients had a statistically significant (P < 0.01) improvement in their pre-ejaculatory period (mean time: 8.70 ± 1.70), the increase was not statistically significant compared with group 1 (P = 0.05). The other six patients of group 2 and also all patients of group 3 complained of numbness and erection loss without ejaculation, and so were not included in the statistical analysis (Figure 1).

In conclusion, application of EMLA Cream for 20 min has been determined as the optimum period in the treatment of premature ejaculation.

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