PGE_1 with Gelucire®-based formulations was similar to that attained with intracavernous injections. This finding is consistent with the similar levels of change in the blood flow rate and RI value of both arteries after intracavernous injection and transurethral delivery of PGE_1. These findings imply that the transurethral delivery of PGE_1 at a dose of 500 μg in Gelucire® can achieve the same level of efficacy as that of intracavernous injections at a dose of 20 μg. Therefore, this method might become a promising alternative for delivering PGE_1 via the transurethral route.

The HLB value of formulation 1 was the highest among the 7 formulations tested, but its melting point is higher than 37 °C. This HLB value is favorable for mixing of the drug carrier with residual urine surrounding the application site, although the higher melting point might delay dissolution to some extent. This is probably the reason why it was effective in 1 case but failed to induce erection in another. Formulation 2 was composed of only Gelucire® 50/02, which melts at 50 °C and has a very low HLB value (2.68). Both properties are unfavorable for the transurethral delivery of PGE_1, for the reasons giving above, which explains why this formulation resulted in no response in 1 case and only tumescence in another. The same reasoning is applicable to formulation 6. Although formulation 3 consisted of Gelucire® 37/02, which melts at body temperature, the low HLB value (2.68) could have hindered wetting of the resulting liquid by residual urine. This is probably the reason that formulation 3 induced only tumescence in 1 case and a mild erection in another. Formulation 4 has a moderate HLB value (6.64) but a melting point higher than 37 °C. Thus this formulation was soluble in the urethra resulting in a satisfactory erection in 2 patients with venous leakage syndrome. Formulation 5 contained Gelucire® 44/14 and Gelucire® 37/02 in an equal ratio. This formulation has a moderate HLB value (6.64), which might be favorable for transurethral delivery. Furthermore, the melting point of this formulation is around body temperature, facilitating the distribution of the drug for absorption. This could explain the efficacy of formulation 5. Although the melting point of formulation 7 is higher than body temperature, its ability to induce erections was similar to that of formulation 5, possibly due to its moderate HLB value (5.32).

CONCLUSIONS

Although preliminary, our findings suggest that transurethral delivery of PGE_1 carried by a Gelucire®-based formulation results in improvements in erectile function similar to those achieved with intracavernous injections. This method appears to be a promising alternative to existing treatments of erectile dysfunction. Furthermore, the efficacy of transurethral delivery using this Gelucire® medication can possibly be optimized by altering the ratio of different grades of Gelucire® and with the addition of a liquifying agent to form a mixture with an appropriate HLB value and melting point.

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