pressed for 1 min. The penis was scanned, and the arterial and arteriolar circulation was examined.

Another 18 patients entered a study on the transurethral delivery of PGE_1. Five milligrams of a semisolid formulation containing 500 μg PGE_1 was placed at the tip of the plastic outfit of a syringe needle (25 gauge). Details of the formulations used are listed in Table 1. The piston of the plastic syringe was pulled down to a certain volume, and the same plastic outfit was replaced on the tip. Then the plastic outfit was inserted fully into the urethra. The piston of the syringe was pushed to expel enough air to force out the semisolid medication, and the syringe was then removed. Patients were encouraged to urinate immediately before application; residual urine facilitated the insertion of the plastic outfit and the dispersion of the drug.

The penile responses were evaluated based on the erection grade (1: tumescence only, erectile angle < 45°; 2: partial erection, erectile angle between 45° and 90°; 3: full erection, erectile angle > 90°), and the erection rigidity score was assessed by palpation (1: no rigidity; 2: poor rigidity; 3: moderate rigidity; 4: full rigidity). Grades and scores were assigned by patients and confirmed by the investigator. A computerized sonography system (SSA 260A Sonolayer, Toshiba, Tokyo, Japan) with an imaging frequency of 7.5 MHz and pulse Doppler with a frequency of 3.0 MHz were used to assess the blood flow pattern after either intracavernous or transurethral delivery of PGE_1. The peak flow of bilateral cavernosal arteries and the peak velocity were determined. After recording the Doppler arterial waves, the resistance index (RI) of the bilateral cavernosal arteries was also determined. Statistical analysis of the results was based on a two-factor ANOVA test using general linear model procedures of the SAS statistical system (SAS Institute, Cary, NC, USA). Data are presented as the mean and standard deviation (SD).

The grade of Gelucire® (Gattefosse, France) is designated by 2 numbers separated by a slash. The first number indicates its melting point, and the second number stands for its HLB value (hydrophilic and lipophilic balance). The melting points and HLB values of the 7 formulations tested are listed in Table 1. The melting point was higher than, lower than, or around 37 °C. The HLB value was calculated by summing the contribution of each component based on the weight fraction of individual components and their HLB values. A dipping bath comprising a blend of a mixture of various grades of Gelucire® at a certain weight ratio and lauroglycol (HLB 4) and sufficient PGE_1 to attain the desired concentration (500 ug/5 mg) in the blend was prepared and heated to 50 °C. While liquifying, an amount approximately equal to 5 mg was withdrawn into the needle outfit by pulling backwards on the piston of the syringe. The material was allowed to sit at room temperature until the blend solidified. According to Table 1, suppository formulations containing approximately 500 ug of PGE_1 in this form were prepared for transurethral delivery.

RESULTS

Fifty patients entered the preliminary study on the hemodynamic changes of the cavernosal artery after intracavernous injection of PGE_1. Their ages ranged from 26 to 80 years. Forty-three patients were diagnosed with vasculogenic impotence; etiologies were diabetes mellitus or hypertension in 4 patients, venous

Table 1. The Formulation Components of Drug Carrier Based on Gelucire®

No.	G 44/14	G 50/02	G 37/02	Lauroglycol	MP/HLB[a]
1	0.66	0.00	0.00	0.34	> /10.6[b]
2	0.00	0.66	0.00	0.34	> /2.68
3	0.00	0.00	0.66	0.34	< /2.68
4	0.33	0.33	0.00	0.34	> /6.64
5	0.33	0.00	0.33	0.34	= /6.64
6	0.00	0.33	0.33	0.34	> /2.68
7	0.22	0.22	0.22	0.34	> /5.32

[a]MP/HLB: melting point/hydrophilic lipophilic balance. [b] >: higher than 37 °C; <: lower than 37 °C; =: around 37 °C.