request of a peer review group to omit the inactive control medication, and an attempt to evaluate the resulting data.

Method

Post partum patients with uterine pain following normal deliveries, with no language or intelligence barriers, participated in the study. They were questioned prior to the study and were informed about the medications and procedures to be used. All willingly signed informed consent forms. Patients were not given more than 1 experimental medication; if they experienced pain on more than 1 day of hospitalization, a 2nd dose of coded medication was not administered.

Each morning before breakfast, the subjects were questioned as to the intensity of uterine cramps. Equal numbers of patients were administered each of the experimental medications at each initial pain intensity level ('stratum') (table I). All of the experimental medications were identical in appearance. The dose was 2 capsules per subject, given on a double-blind basis, and each dose was individually identified by code number. Within each pain intensity stratum, the location of the patients on the ward determined the order in which they were interrogated and given medication. The interplay between the location of the patients and the rotation of the drugs determined the medication each patient received. For each initial pain intensity, successive groups of 10 medications included each dose. The order of medication in the groups was varied. Patients who awakened after 3.00 a.m. and requested medication for pain were asked to wait until 7.00 a.m. Those reporting pain earlier in the night were treated. The medications administered were prescribed by the patient care physician and were the same or similar to the drugs under study. All other analgesics were withheld for at least 4 h before the test drugs were given and for 8 h afterward, or until pain intensity had returned to pretreatment level for at least 2 interviews.

Observations were made before drug treatment and at 1, 2, 3, 4, 6, and 8 h after treatment. Before medication, the patients quantified the intensity of their pain from uterine cramping according to the empirical scale, 'a little', 'some', 'a lot', and 'terrible'. The pain intensity was stratified into these 4 levels, and the patients were assigned to the 'stratum' of their initial pain intensity. At each posttreatment observation, the subjects evaluated pain intensity and also estimated their relief (degree of pain alleviation), scored according to a similar scale which substituted the term 'complete' for 'terrible' as category 4. The pain intensity difference was calculated by subtracting the intensity at each subsequent point in time from the intensity reported at the time the medication was administered. The analgesia score is the sum of the pain intensity difference (SPID) and the relief score at each interval. The total analgesia score [GRUBER and BAPTISTI, 1963] for each patient was calculated by summing the analgesia scores for the 6 observations after treatment.

At the end of the 8th h of observation, the subjects were asked whether they had experienced any of the following symptoms: nausea, constipation, abdominal discomfort, headache, dizziness, drowsiness, nervousness, tremor, weakness, blurred vision, dry mouth, sweating, itching, or others. If any were reported, the patient