EFFICACY OF TTS (FENTANYL) IN THE MANAGEMENT OF PAIN IN PATIENTS WITH MALIGNANCY

PILOT STUDY

SYNOPSIS

STUDY OBJECTIVE

The objective of this open-label pilot study was to evaluate the safety and adequacy of the continuous use of TTS (fentanyl) reapplied every three days for the treatment of chronic cancer pain.

METHODS

Seven patients at the University of Pittsburgh Cancer Institute were entered into the trial. The initial TTS (fentanyl) dose was calculated based upon the the equianalgesic potency ratio of the narcotic used prior to study entry. Four TTS (fentanyl) dosage strengths were available with a nominal delivery rate of 100, 75, 50, and 25 mcg/hr fentanyl (40 cm^2, 30 cm^2, 20 cm^2, 10 cm^2, respectively). Multiple systems were worn when higher doses were required. Systems were reapplied every 72 hours.

After initial application, TTS (fentanyl) dose was titrated for each patient within a hospital setting over the course of three days, or as long as was necessary. Change in dose during titration occurred no more frequently than every 24 hours. After an appropriate dose was reached, new TTS (fentanyl) systems were applied to a fresh skin site every 72 hours. When discharged, patients entered a 3-week program of twice weekly nursing visits to monitor patient progress. After completion of the 3-week program, patients were given the opportunity to remain on long-term TTS (fentanyl) administration.

Morphine sulfate was administered as needed for supplemental analgesia. Patients were evaluated at designated time intervals for pain intensity, vital signs and serum fentanyl concentration. Records were kept of all concomitant medications administered during the study and any adverse events.

RESULTS

Seven patients entered the study. Two patients chose to terminate TTS (fentanyl) use: one due to nausea, vomiting and visual hallucinations and one because of feelings of euphoria. Four patients died during the study, as a result of their malignancies. As of February 1, 1988, one patient remained on long-term, TTS (fentanyl) use.

Six of the 7 patients achieved adequate analgesia with TTS (fentanyl) systems reapplied every 3 days. One patient was changed to a 2 day dosing schedule after 108 days of treatment.

The most commonly reported adverse experience was nausea and vomiting (6 of 7 patients). Various neurological side effects were reported second in frequency (thick speech, lethargy, anxiety, ataxia/ataxic gait). Two patients reported sedation.

Vital signs remained within clinically acceptable ranges throughout the study. Within patient pain scores remained relatively stable throughout the study.

SUMMARY AND CONCLUSIONS

The data from this study indicate that TTS (fentanyl) systems reapplied every 72 hours were well-tolerated by patients with pain due to metastatic cancer and was chosen for chronic treatment by 5 of the seven patients. Adverse experiences noted were those associated with narcotic administration.

On the basis of the data from this pilot study, an expanded multi-center trial of the use and safety of TTS (fentanyl) was warranted.

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