PROTOCOL C-87-010-01

The Clinical Use and Safety of TTS (Fentanyl) in the Management of Pain in Patients with Cancer

SYNOPSIS

STUDY OBJECTIVE

The objective of this study was to establish the clinical utility and safety of TTS (fentanyl) in the treatment of pain in patients with cancer.

METHODS

This multi-center trial was conducted open label. Patients requiring narcotics for pain management were converted from other conventional analgesics to oral morphine and titrated to a stable dose prior to the initiation of TTS (fentanyl). The stabilized morphine dose provided the basis for calculation of the equianalgesic dose of TTS (fentanyl) based on established analgesic potency ratios. Patients reapplied TTS (fentanyl) systems every 3 days. Immediate release morphine was available for breakthrough pain.

The adequacy of analgesia, use of morphine supplements, and routine safety evaluations were obtained at scheduled intervals throughout the trial.

RESULTS

Data are reported for thirty-one patients who received TTS (fentanyl). Duration of wearing ranged from 12 hours to 150 days. Eight patients have discontinued the trial; 23 remain as active participants. Reasons for withdrawal include death (5 patients), non-compliance (1 patient), caretaker decision (1 patient), and inadequate pain control (1 patient).

Patients were successfully converted from conventional analgesics to TTS (fentanyl) using standard analgesic potency ratios. Most patients initiated treatment in the dose range of 25 to 75 mcg/hr. Approximately 1/3 of these patients required a dose increase at the end of the first week of treatment. Morphine was used successfully to supplement analgesia during the onset period following the first application of TTS (fentanyl) and for breakthrough pain thereafter.

After 1 month of TTS (fentanyl) therapy, pain control as judged by the patient was improved over both the pre-study and the baseline (oral morphine) narcotic regimens. Patient compliance and acceptance of the transdermal route of administration was excellent.

No patient terminated the study due to an adverse experience other than death. In no case was death attributed to TTS (fentanyl) or associated with TTS dose or duration of therapy.

Eight concomitant events with possible or unknown relationship to TTS (fentanyl) were reported. In 6 cases investigators reported other suspected causes, but were not able to rule out TTS (fentanyl). These included mental confusion (3 patients), agitation, sedation, and unsteady gait. Minor topical effects were reported for 2 patients.

SUMMARY AND CONCLUSIONS

The clinical utility and safety of TTS (fentanyl) has been demonstrated in this group of patients with pain due to cancer. An appropriate algorithm for converting patients from conventional narcotics to TTS (fentanyl) has been presented. The management of patients receiving TTS (fentanyl) for nearly 5 months has been described. TTS (fentanyl) use in patients with acute and/or chronic pain due to cancer has been shown to be safe. No unanticipated effects were observed. The transdermal delivery of fentanyl proved a convenient and more acceptable route of continuous narcotic administration that achieves better and more acceptable pain control than conventional routes of narcotic administration.

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