

Second Signatory: Hindrance to Effective Breakthrough Pain Management?

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Received: 11 June 2021; Accepted: 14 June 2021

Citation: Syed Qamar Abbas. Second Signatory: Hindrance to Effective Breakthrough Pain Management?. Nur Primary Care. 2021; 5(4): 1-3.

ABSTRACT

Background: Breakthrough cancer pain is defined as a transient exacerbation of pain that occurs either spontaneously, or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background pain. Fentanyl citrate sublingual Tablet (FST) is administered to control breakthrough pain (BTP) and a 'top-up' dose is administered in 15 minutes if the pain does not respond. However, Nursing & Midwifery council (UK) recommends that for administration of controlled drugs (CD), a secondary signatory is required within secondary care.

Aims: To establish that breakthrough analgesia is administered on an in-patient unit according to the guidance.

Methods: Retrospective data was collected on patients at an adult Palliative care unit, requiring second dose of FST.

Results and Analysis: Over a period of 3 months, 46 episodes of BTP requiring second dose of FST were recorded. Top-up dose was signed for at 15 minutes for only 13 (28.2%) episodes. Further 14 (30.4%) doses were signed for with 5 minutes delay (20 minutes in total from first dose). 19 (41.3%) doses were signed for after 20 minutes with a range of 25-50 minutes (10 – 35 minutes delay). Note that there will be a further delay in administering the dose.

Conclusion: Majority of patients have BTP for less than 45 minutes. After reporting, it takes time to get the medication to patient. Second dose may get further delayed causing pain prolongation. This delay is due to finding second nurse to check medication. There are various solutions which could be employed to prevent this delay and to achieve effective BTP management.

Keywords

Hindrance to breakthrough pain control, Sublingual Fentanyl tablets, Second signatory.

Introduction

For a long time, pain is well recognised as a common problem in cancer patients with 50% to 90% of cancer patients experiencing pain at some stage [1]. It is also termed as most feared symptom as its physical and psychological impact is found immense on patients. Worsening pain may cause patients concerns about disease progression as well as prognosis [2]. This is why timely assessment and management of cancer pain becomes very

important for these patients. Cancer pain can exhibit in many forms including uncontrolled background pain, end-of-dose pain, breakthrough pain etc.

Breakthrough cancer pain (BTCP) is defined as a transient exacerbation of pain that occurs either spontaneously, or in relation to a specific predictable or unpredictable trigger, despite relatively stable and adequately controlled background pain [3]. Research studies have shown evidence that the oral transmucosal and intranasal preparations were associated with better breakthrough pain outcomes than was placebo, and that oral transmucosal fentanyl was more effective than immediate-release oral morphine

[4-6]. EAPC guidelines suggest that in some cases the buccal or intranasal Fentanyl preparations are preferable to immediate-release oral opioids due to more-rapid onset of action and shorter duration of effect [7].

Fentanyl citrate sublingual Tablet (FST) is administered to control breakthrough pain. Its Summary for Product Characteristics (SPC) advises following method of administration:

‘All patients must start therapy with a single 100 microgram sublingual tablet. If adequate analgesia is not obtained within 15-30 minutes of administration of a single sublingual tablet, a supplemental (second) 100 microgram sublingual tablet may be administered. If adequate analgesia is not obtained within 15-30 minutes of the first dose an increase in dose to the next highest tablet strength should be considered for the next episode of breakthrough pain’ [8].

However, Nursing & Midwifery council (UK) recommends that for administration of controlled drugs (CD), a secondary signatory is recommended within secondary care (NMC 2007). In practice, it is observed that nurses identify breakthrough pain, find a colleague to help them as second signatory and repeat the same process for subsequent dose after 15-30 minutes. This data was collected to find out if second dose was administered after 15 minutes if needed. Data was collected from a hospice setting, where there are fewer nurses to patient ratio, which means that there is more likelihood of drug being administered in time than in acute hospitals.

Aims

To establish that breakthrough analgesia is administered on an in-patient unit according to the guidance

Methods

Retrospective data was collected on patients at an adult Palliative care unit, requiring second dose of FST. Information was collected from CD record book and patients’ notes. As this was a service evaluation audit, no formal ethical approval was obtained from a Research Ethics Committee. However, data was analysed with total anonymity.

Results and Analysis

Over a period of 3 months, 46 episodes of BTCP requiring second dose of FST were recorded. Top-up dose was signed for at 15 minutes for only 13 (28.2%) episodes. Further 14 (30.4%) doses were signed for with 5 minutes delay (20 minutes in total from first dose). 19 (41.3%) doses were signed for after 20 minutes with a range of 25 – 50 minutes (10 – 35 minutes delay). Note that there will be a further delay in administering the dose.

Discussion

BTCP is a challenging aspect of cancer. Despite its self-limiting nature, the presence of BTCP can have a significant, negative, impact on the quality of life of patients and caregivers. BTCP may result in a number of complications – physical (e.g., related to

reduced activity and movement), psychological (e.g., presence of anxiety and depression), social (e.g., decreased levels of working and social interaction), and economic (e.g., increased healthcare costs) [9]. BTCP is characterised by a fast onset of severe to excruciating pain (reaching a maximum severity within 5 minutes), with a short duration (subsiding within 30–60 minutes), and which occurs 3–4 times per day [10,11]. It is important that such pain is controlled within the time, when it has the worst impact. That will require healthcare professionals to respond to patients’ request in this short period of time.

Medicines Management procedures are written down to protect patients. These provide guidance for clinical, cost-effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm [12]. This guidance needs to be looked at closely and systems need to be put in place to establish effective patient care with safety in mind. This delay in patients’ BTCP management can be managed by various pathways. It is important that these strategies will require careful patient selection.

- Checking both doses out at same time and allow patients to self-administer after 15 minutes if necessary. Medication can be signed back in if not required. Allowing a single nurse check for second dose.
- Allowing patients with capacity to take control of their BTP analgesia whilst on an in-patient unit.
- Leaving a single dose with patients which they can take at pain onset and inform nurses soon after that, which can be documented at both events (signing the dose out to patient and then administering it).

While this study particularly looked at the issue of breakthrough pain, it was clear that even in hospice setting, this pain was not adequately managed. This question should not only be asked for breakthrough cancer pain and rapid onset opioids but also for normal release opioids e.g., Morphine, as its careful handling but prompt administration will give patients control and make them more confident in their pain management. There have been questions about double checking indicating various limitations to the process [13].

Conclusion

Majority of patients have BTP for less than 45 minutes. After reporting, it takes time to get the medication to patient. Second dose may get further delayed causing pain prolongation. Systems need to be put in place to prevent pain prolongation and harm to patients. This process can further be followed up in pain management with normal release opioids to empower patients further to manage their pain, which will lead to their sense of well-being.

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