

CLINICAL PRACTICE

Conceptualizing breakthrough pain

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ABSTRACT

The concept of breakthrough pain (BTP) is examined through the development of a conceptual model with a long-term goal of positively impacting the management of chronic pain patients who experience BTP when hospitalized. The model is based on a 2008 Health Economic Model of Breakthrough Pain developed by Abernethy, Wheeler, and Fortner, which will be referred to as the parent model. The conceptual model of BTP, titled, Novel Conceptual Model of Breakthrough Pain (NCMBP) shares a similar structure in regards to the relationships of major constructs. Like the parent model, the NCMBP is based on three major constructs which are analyzed and explained further with associated concepts. The NCMBP is primarily concerned with the importance of a pain management plan and the endpoint result of patient-perceived analgesia. The NCMBP is viewed as a necessary foundation for continuing safe and effective pain management in the setting of a current opioid overdose epidemic in the United States. The structure and conceptual relationships of the NCMBP are preliminary and will continue to undergo revision as conduction of research is attempted to test the model.

Key Words: Breakthrough, Opioids, Conceptual model, Chronic pain, Hospitalized, Overdose epidemic, Analgesia

1. INTRODUCTION

The development of a conceptual model to explain breakthrough pain (BTP) within the context of hospitalized patients that also experience a baseline level of chronic pain is strenuous. Pain is complex when it is combined with comorbidities and other innumerable factors, creating a challenging pain situation that requires complex treatment plans.^[1] One significant factor contributing to the complexity of BTP control is the public awareness of increasing opioid misuse. Published in November 2019, the National Survey on Drug Use and Health (NSDUH) found data to support prescription opioid misuse as a leading cause of death or unintentional injury in young adults and adolescents.^[2] Opioid-involved death rates from an overdose increased by 45.2% from the year 2016 to 2017.^[3] Opioid misuse alone causes BTP man-

agement to become difficult as providers must now exercise considerable caution as they demonstrate opioid stewardship not only to treat legitimate patients, but also to help reduce societal harm caused by opioids. This direct cause and effect relationship is currently unbalanced and serves as the inspiration of the NCMBP. When complete, the long-term goals for this model will include empowering providers with confidence in their treatment plans, with less scrutiny from medical professional peers and the public, and to reassure providers that BTP is a legitimate symptom experienced by patients.

Pain control plans and interventions are later discussed as a moderator within the model. Because of appropriate treatment plans in place, patients will directly benefit through alleviation of their BTP symptoms. Already demonstrated

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by the parent model, hospital systems can incur a financial benefit as patient satisfaction increases, and readmissions for pain control are reduced. However, the parent model, developed in 2008 may no longer be completely relevant given the rapidly changing culture of pain control and opioid use. Currently published on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) website as a “news alert”, communication about pain items have been removed from surveys given to patients, effective on patient discharges after September 30, 2019. The Centers for Medicare & Medicaid Services (CMS) might now be viewed as an entity that has alleviated hospital systems and providers of any financial consequence from patients that perceive their pain management as suboptimal. To debate the positive or negative consequences of these changes are not the intention of this writing but are necessary to illustrate significant government changes currently active within the specialty of pain management and opioid use. Dynamic hospital reimbursement policy is only one of many factors that further supports the ongoing development and analysis of the NCMBP.

1.1 Background

Current conceptual models regarding pain in any context were searched in CINAHL and PubMed, with the search terms: pain, conceptual, and model. The oldest result including all search terms was published recently in 1978, “Pain in Labor: A Conceptual Model for Intervention.” The literature results suggested that acute pain was first researched rather than chronic pain. Results pertaining to chronic pain involved specific types of chronic pain, such as cancer pain, or a specific patient classification, such as Hispanic patients. There was no single conceptual model that provided an overview for the management of BTP. This further inspired thought about how currently published models could be specific to a single diagnosis, but not have a bigger “all encompassing” model as influence. Researchers at the American Academy of Pain Medicine agreed that current literature about noncancer pain is limited when they described their model development about clinician communication and pain.^[4] Henry and Matthias used health communication models as the primary influence for their model regarding pain communication, suggesting that their model be used as a framework to coordinate future research. Alarming, since this framework was only introduced into publication in 2018, emphasizing limited available literature on conceptual models with pain as the primary concept. Knowing that some of the oldest public hospitals in the United States were founded in the mid-1700s, such as Pennsylvania Hospital, founded in 1751, shows that conceptual focus on pain has taken centuries to gain attention and for researchers to invest resources to understand this symptom. In the 1900s, pain management was viewed as

“taking the terror out” and reducing the associated symptoms of severe diseases. However, now these same analgesics are used for chronic pain with arguably low understanding of long-term consequences. The NCMBP is needed to contribute to a knowledge deficit in the appropriate management of BTP. Once the research is conducted utilizing this model, it may be possible to track trends in analgesic plans, either supporting current practices, or suggesting strategies for improvement. Other possibilities include the ability to track specific analgesics to particular endpoints, and will be explained later through the use of thought experiments.

1.2 Purpose

Model development

The parent model used for the development of the NCMBP is the health economic model of breakthrough pain illustrated in Figure 1. The authors of the parent model described BTP as an abrupt onset of pain occurring in the context of managed chronic pain.^[5] The authors supported a need for this economic model due to their claim that undertreatment of BTP is a common phenomenon. They argue that despite various guidelines available, one significant problem is that patients are suboptimally dosed medications. Highly regarded entities have made recommendations about the maximum recommend use of opioids such as the Centers for Disease Control, one of many influences that may lead to underdosing.^[6]

The authors present a model with three major domains to help clinicians with their decision-making for patient care. The domains mentioned in the parent model include: (a) participants, (b) nature of impact, and (c) end point. After a “participant” has an “impact” the model argues that the participant reaches an “end point”. The end point domain is intended for providers to attempt to balance the costs of care against the benefits, while achieving a favorable outcome for all participants involved. An area of criticism involves the assignment of values to the various endpoints. Value to the endpoint, such as cost, is arbitrarily assigned and can vary based on the perception of the type of participant. A concise example to demonstrate this involves the cost of a prescription analgesic, where the patient assigns high “value” or importance to cost (cost over outcome), and in unintentional opposition, the provider assigns the lowest importance to cost. Neither the patient nor the provider is wrong. Perhaps the provider implements a plan due to knowledge deficit of prescription costs or for prioritizing immediate BTP control (outcome over cost). Patient and provider preferences are varying, which legitimately defends arbitrary value assignments to endpoints, but the inability to objectively and consistently assign values demonstrates a model weakness, seemingly irreparable as currently designed.

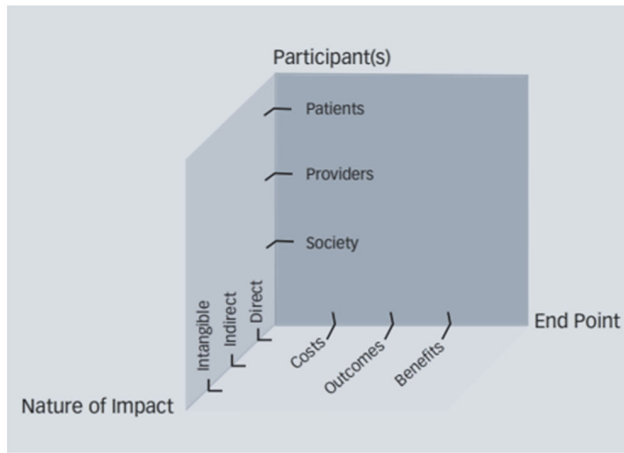


Figure 1. Health economic model of BTP

2. CONCEPTUAL MODEL & DEFINITIONS

The NCMBP illustrated in Figure 2 also shows three major domains or constructs, but the model is directly focused on patient and provider interaction and less on an overall health system or society. This does not mean that the health system or society is directly excluded. The authors argue that if patients and providers are reaching agreements on BTP plans, the health system and society will indirectly benefit. For example, if the patient has a better attendance record at work due to improved BTP control, the employer (society) will benefit.

The first construct is a pain control plan which attempts to detail the possible types of interventions a provider can initiate. It attempts to be inclusive of most traditional interventions by describing three types of interventions: (a) pharmacologic analgesics, (b) non-pharmacologic analgesics, and (c) disease management. Analgesics aim to immediately and directly address the pain a patient is experiencing, but it is important to remember that pain is a symptom of an underlying process and is not an independent phenomenon. Therefore, addressing the underlying process, if possible, is an important component of a successful plan. Non-pharmacologic interventions are also well supported by current literature and can include spinal cord stimulation, superficial application of heat or cold, physical therapy, and clinical psychology.^[7]

The second major construct is BTP, which attempts to provide a visual representation of the active occurrence of BTP. The presence of BTP is confirmed by a subjective provider evaluation of the patient. Given concerns for opioid abuse, patient reports are now increasingly less reliable because of the consequences to providers and patients if the patient is not truthful. Currently, BTP remains subjective, but there have been studies to support the presentation of the symptom which increases the likelihood of capturing a legitimate case

of BTP. The presenting characteristics of BTP can include a decline in psychological health such as depression, anxiety, or a decline in daily activities such as reduced productivity at work.^[7] Tolerance to current treatment, such as taking prescribed analgesics without relief in the setting of worsening disease is another reason to explain BTP, where analgesics are not able to compete with the rapid progression or changes in a disease process.

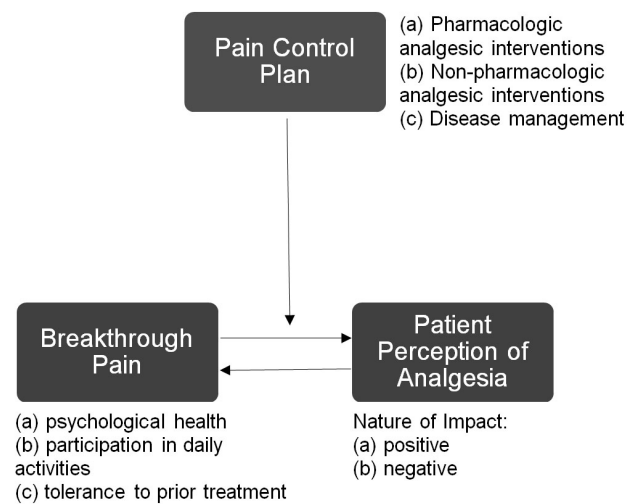


Figure 2. The NCMBP model

The third major construct is the occurrence of analgesia from the patient perspective. This conceptual model incorporates patient empowerment to report if their pain control plan has achieved a positive or negative impact. A positive impact indicates that a tolerable level of pain control has been achieved and a negative impact indicates that the BTP is unchanged or worsened. The issue of abuse and diversion is not adequately addressed within this model, as this major component relies on patient reports of adequate analgesia. An evaluation tool for pain is also under consideration to help providers and patients understand the severity of pain, such as an observational pain assessment tool. However, it is important not to forget that patients must be involved in their care, and this model is based on the premise that patients should have at least a minimal level of trust when they are seeking care. Providers must be cautious not to prematurely label their patients with negative attributes, as the resulting patient medical record can follow the patient, impacting their care indefinitely. The American Medical Association (AMA) has adopted the 4D model to describe providers who abuse or disregard their prescribing privileges as dated, duped, dishonest, or disabled.^[8] In the complex environment of pain management, providers must also be wary that they are not accused of misprescribing. In this model, the provider is empowered by having varying approaches to the treatment

plan, where the provider is not obligated to prescribe opioids. However, to keep the model balanced, it is intentional for the patient to also have empowerment by having the ability to give feedback on whether the endpoint is positive or negative.

3. ANALYSIS OF CONCEPTUAL MODEL

The conceptual model shown in Figure 2 demonstrates four relationships between three major constructs.

- The pain control plan moderates BTP.
- The pain control plan moderates the patient's perception of analgesia.
- BTP directly affects the patient's perception of analgesia.
- The patient's perception of pain can have a direct impact on BTP.

The pain control plan is intended to be the moderator variable between BTP and the patient perception of analgesia. In attempts to be straightforward, there is a reduction in BTP and the patient will have an increased perception of analgesia if the plan is effective. BTP is also an independent variable as by the very nature of the concept, it often occurs in the setting of pain that is chronic and is often unpredictable. The patient perception of pain is dependent upon the resolution of BTP which is expected to occur due to a modification to the pain control plan. Even if the plan is changed, if the patient does not perceive a tolerable level of pain control, BTP is then expected to still be present. As demonstrated in the model, BTP will persist or worsen until there is a positive nature of impact as determined by the patient.

Each construct also includes several associated concepts to assist with an understanding of the major constructs. The pain control plan is a construct that includes pharmacologic analgesic interventions, non-pharmacologic interventions, and disease management. Breakthrough pain includes psychological health, participation in daily activities, and tolerance to prior treatment. The patient perception of analgesia after the pain control plan is modified is either positive or negative. There are 15 different possible interactions within all the concepts which demonstrates the variability in managing pain. The number of possible scenarios further increases infinitely when attempting to define each concept. Consider a patient who is admitted to the hospital for further pain management after being unable to perform any weight-bearing activities to her bilateral lower extremities due to extensive osteoarthritis. The provider chooses to increase her opioid medication (pharmacologic analgesic intervention) to increase her tolerance for ambulation (participation in daily activities) and the patient is successfully discharged home (positive impact) instead of a rehab facility. Now expand this scenario to infinite possibilities, consider if the provider attempts to change the patient to a newer opioid with a dif-

ferent pharmacokinetic profile. This demonstrates the same interaction between the concepts as the previous scenario but is completely different considering that the plan involves a different analgesic. Modifications within the concepts allow for infinite possibilities which is a feature of this model to allow the patient and provider to customize the pain control plan as needed for a positive response to BTP.

Heuristics

The use of simple case studies such as those used in the analysis allows readers to understand the complexities of pain management and to illustrate that a "cookie cutter" approach to pain management will be unsuccessful given varying factors, circumstances, and preferences. Using case studies allows the model to be hypothetically tested with extreme cases, or cases that are not encountered frequently in typical practice.

Making the opposite assumption is also utilized during the development of this model. The model assumes that the patient who reports BTP is being truthful, but the opposite assumption is appropriate for realizing weaknesses of the model, and for situations where the model cannot be appropriately used. An example is in the scenario of a deceptive patient, but because the provider attempts to be empathetic, the provider is not able to recognize that they are being "duped." Evidence supports that empathy from emotionally intelligent providers may impair their ability to discern between real patients and actors.^[8] Obviously, as humans, providers do not make the correct decisions 100 percent of the time. However, this model does not currently have a solution for when the opposite occurs, and the provider is wrong. Or even worse, the provider realizes that they are wrong after several plan modifications to the plan occur.

A third heuristic is influenced by thought experiments, and arguably the most beneficial in the development of this model. Thought experiments are used to explain a hypothetical scenario using assumptions from literature to make predictions if the model were used in real-world cases. This is most important because if thought experiments are tested with real data, these data can uncover new findings in the management of chronic pain. For this reason, two thought experiments are explained in a separate section below.

4. THOUGHT EXPERIMENTS

The first thought experiment attempts to illustrate that non-pharmacologic interventions are effective at controlling BTP. The specific type of intervention for the thought experiment is physical activity. Figure 3 suggests that lower physical activity decreases patients' psychological health as participation in daily activities decreases. Specifically, symptoms

of BTP such as depression and the ability to ambulate become more severe as physical activity decreases. Physical therapy is a useful and common measure in the hospital setting because of the availability of physical and occupational therapists to work with patients. The therapists are trained on measuring mobility impairments and can keep track of progression or regression of physical activity of patients during their hospitalization. In 2018, a randomized controlled trial concluded that physical therapy was effective at reducing chronic lower back pain when patients were evaluated for pain and disability at three and six months.^[9] There is also evidence to support that physical therapy is also effective for neuropathic pain, further supporting the thought experiment.^[10] One counterargument to this thought experiment could include age limitations where physical activity is not a realistic intervention for an older adult, but the Department of Physical Therapy at California State University has found that benefits from physical therapy do not decrease with age.^[11] Participants reviewed ranged from age 80 to 100 and were even found to have improvements in their symptoms of anxiety and depression stemming from chronic back pain.

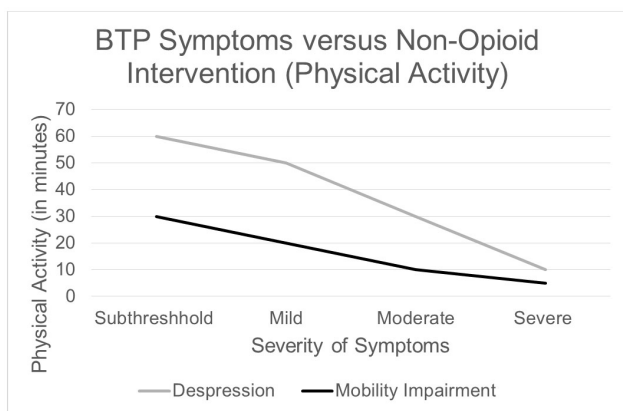


Figure 3. Thought experiment one

The second thought experiment illustrated in Figure 4, shows the relationship between opioid use and the severity of pain expressed by the patient. Increases in opioid use, expressed as a morphine milligram equivalent (MME), decreases the severity of pain only to a certain point. After this point (MME x 4) the experiment shows that further increases in opioid use do not lead to further decreases in pain. This thought experiment is critical in providing education to patients who may not understand that there are maximum levels of recommended opioid use. It is generally accepted in practice that providers need to balance the risks versus the benefits when increasing opioids. Data collected by the CDC suggests that with daily MMEs > 200, about 1 in 32 patients will experience an opioid overdose related death.^[6] The same data

from the CDC also recommends avoiding daily MME doses of >90 for chronic pain patients, and if doses are increased beyond this point, there must be thoughtful justification.^[6]

However, clinical practice in the hospital setting shows that daily MME dosages often exceed 90 in the patient with BTP. Despite current guidelines that are now several years old, this thought experiment aims to expose any potential benefits to safely increasing the recommended daily MME limit from 90 while also remaining under 200. There is a large range to be covered when discussing the values between 90 and 200, and currently available literature exploring increased use of opioids is vague. Current literature supports that patients and providers have different goals of care regarding pain management, leading to lower satisfaction scores from the visit.^[12]

With the previous thought experiment, providers can openly discuss their reasoning for the pain management plan they develop, hopefully encouraging patients to agree and feel optimistic about their care. Either the thought experiment will support patients who request more opioids, or the experiments will reveal clear dangers that patients must be informed about. Thought experiment two aims to be unbiased in specific findings but demonstrates a deficit that needs to be explored for patients and providers to undeniably have data about risks and benefits needed for developing an effective plan when opioid use starts to escalate. One significant fallacy must be exposed with the use of MME calculations for dosing opioids; MME conversions from one opioid to another are not exact. Opioids have unique properties and varying pharmacology which makes exact mathematical conversions inaccurate, not accounting for variables that can make some opioids stronger or weaker than others.^[13] Knowledge-based errors in clinical reasoning can be reduced if this thought experiment is applied to a patient population that is using the same analgesic, instead of performing MME conversions between various medications.

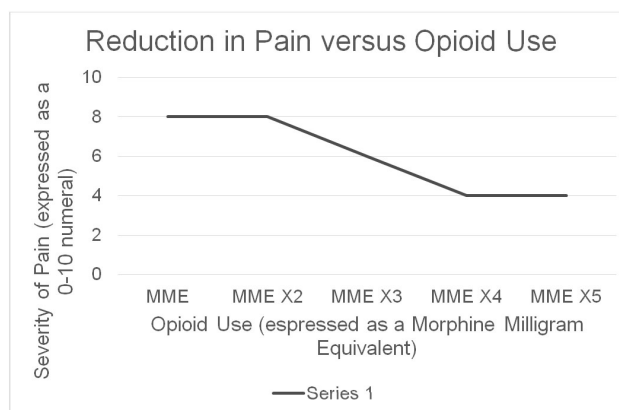


Figure 4. Thought experiment two

5. CONCLUSIONS AND FUTURE RESEARCH

This conceptual model is still in an entry level phase of development. Refinement of the model will continue until instruments are identified that can measure desired variables within the context of focused research interest. The current model purposefully does not identify a specific etiology of pain as a primary interest because of a desire to have the model utilized for all BTP sufferers. However, initial evidence to support the model may need to start with looking at etiologies separately to produce strong evidence of an accurate model. Having several ongoing studies each focusing on a specific etiology will help to create a control where the etiology of pain is the same for all patients in the research group. This is important so that data analysis will not have to consider variability in the etiology of pain as a weakness of the model.

The NCMBP is a straightforward approach that only superficially seems, simple. The patient needs a pain management plan that works. The provider also needs to agree that the

pain management plan is appropriate. Not simple is the development of an effective plan that the patient and provider both agree with, creating a knowledge deficit in BTP management. Further research is needed to determine the best methods that allow a patient to report their pain without fear of being doubted, while also making illegitimate reports of BTP easily identifiable by providers. Three components of this model that need to be addressed include:

- discussing initial BTP management plans and which components of the plan are modified first when undergoing revision;
- determining if an existing pain assessment tool is sufficient for patient perceived analgesia or if a new tool will need to be developed; and
- determining when and how to remove a patient from being classified as a BTP sufferer and transitioning to a diagnosis of opioid abuse.

CONFLICTS OF INTEREST DISCLOSURE

The authors declare that there is no conflict of interest.

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