The MOD® Oral PCA Safety Experience After 4,000 Patients

Sharon Conley MD PhD CPE, Chief Medical Officer, Avancen MOD Corporation

Summary

This paper reports the results of a survey from four hospitals and a skilled nursing facility regarding their experiences with patients using the oral patient-controlled analgesia device called the Medication on Demand, i.e., MOD® device. These facilities have had these devices in continuous use for a total of 4,000 patients. All patients included were taking oral opioid tablets from their devices with the ability to self-administer each dose within the prescribed lockout interval in hours programmed to their device. No patient required rescue for respiratory suppression. This data validates the safety and efficacy of this technology for the delivery of as-needed PRN pain medication.

Introduction

The Medication on Demand, i.e., MOD® device is an electronic oral patient-controlled analgesia device that is locked onto an IV pole at the patient bedside within easy reach of the patient. The patient wears a Radio Frequency Identification (RFID) wristband that is registered to their device during the device programming steps.

Wireless devices are programmed by the nursing staff on each unit by accessing the MOD® program platform located on the facility computer network.

To program each device, one registers the RFID wristband of the patient and enters the identification of the patient user, the drug name and dose, when the first dose is allowed, and the lockout interval in hours between doses. A sealed tray of eight doses of medication is loaded into the device and locked for patient use.

When the patient sees a green light on the device, the lockout interval has passed to allow access to a dose of medication. The patient obtains a dose of medication for self-administration by registering their numeric level of pain by pushing the appropriate numeric button on the pain scale, followed by holding their RFID wristband in front of the device. If the device recognizes the wristband, the dispenser wheel will turn and expose a single dose of medication for the patient to self-administer.

The MOD® enables qualified patients to manage their pain by putting them in control of their medication access within the required lockout time intervals between doses. Each facility adopts a policy and procedure for the device use outlining strict patient selection criteria to assist in maintaining device safety and patient compliance.

In general, patients must be awake with no evidence of confusion or dementia, no difficulty swallowing medications, no physical disability that would prevent them from removing medication from the device, and caution or exclusion for any patient with a previous or ongoing history of controlled substance abuse. All patients are required, either orally or by signature, to agree to the protection of the device and its contents and to use the medication only for themselves with each dose promptly removed and self-administered.

Survey Data

The total number of patients who have used MOD® devices by April 2018 in these facilities was determined from the number of disposable Radio Frequency Identification (RFID) wristbands used by each facility. Each patient wears one RFID wristband registered to their device exclusively for their MOD® use. When the patient is discharged from the device, their disposable RFID wristband is removed and not reused. Taking into account the numbers purchased and used, and correcting for any waste or wristband use during evaluation periods prior to purchase, an estimated minimum total number of 4000 to 4200 patients have used devices at these facilities for opioid tabs. This data did not take into account those wristbands used for devices that dispensed nonsteroidal antiinflammatory medications.

All facilities use wireless devices with two having achieved direct integration of device data into their electronic health record, another facility has to date an integration in progress and the other two are using data from their standalone databases collected from the device use. Updated experience with the device use from the time of adoption in each facility was collected by submitting a survey to the unit nurse manager, a pain team member, or a facility administrator most familiar with the device use in their facility. Numbers of patients to date having used devices are: Facility A (460), B (800), C (1627), D (863), and E (250).

Table 1 reports the summary of the survey data received from all facilities.

Table 1 - MOD® Safety Data

Patient Data from Each Facility	A Total of 4,000 Patients	%	Comments
Patients who needed naloxone rescue for respiratory depression from oral opioids taken from MOD® devices	All facilities reported none	0%	NO facility has ever needed to use naloxone for rescue for respiratory depression and NO facility has ever needed to fill out an incident report related to MOD® use.
Patients removed from MOD® devices and why	Facility A – 1	0.03% ----------	Patient was removed for saving pills on the bedside table, i.e. hoarding meds early on during the MOD® experience; patient had not been adequately screened for a history of opioid abuse – was removed from the device. ---------- "Less than 10 usually elderly unable or unwilling to deal with 'technology.'" "A few removed for medication changes not available in MOD trays."
	Facility B		"Two patients had a poor initial assessment, could not reliably use the device, and one patient needed more constant nursing attention."
	Facility C	--------	"A few removed that could not understand how to use the device."
	Facility D		"5-10 removed for medication changes not available in MOD trays or needed higher doses of medication."
	Facility E		None reported
Number of incidents of nursing staff diversion from MOD® devices	All facilities reported none	0%	None reported
Percentage of patients using an extended release (ER) scheduled opioid combined with an immediate release (IR) opioid from the MOD®	Facility A – less than 10% Facility B, C & D – none		At Facility A, less than 10% of patients after total knee arthroplasty or total hip receive both ER and IR opioids if additional meds are needed for optimal pain control. Facilities B-E do not report using ER opioids in addition to MOD® use.

Respiratory Depression from Oral Opioids

Respiratory depression is a frequent concern when patients are given intravenous (IV) or other systemic routes of opioid administration either into the intrathecal (spinal) or epidural space. The American Society of Anesthesiology task force review of the literature reported no significant differences between these approaches for the incidence of severe respiratory depression as reported by Horlocker, et al. (2009). Sumida, Lesley, Hanna, Murphy and Kumar (2009) found

an increased risk of respiratory depression when extended release morphine is given by an epidural route as compared to IV Patient Controlled Analgesia (PCA).

The incidence of severe respiratory depression requiring naloxone rescue for IV PCA has been cited in numerous publications. However, there are no standardized criteria for administration of naloxone other than “severe respiratory depression” without a rigid definition. Cashman and Dolan (2004) reviewed 165 studies of parenteral opioid use. Ten studies reported the total frequency of naloxone rescue for IV PCA in 1.9% of patients 95% CI 1.9-2.0%. In an effort to improve patient safety, Rosenfeld, et al. (2015), from the Mayo Clinic Arizona Hospital, Phoenix, observed that 1.2% of patients receiving IV-PCA required naloxone rescue.

The Joint Commission (TJC) Sentinel Event Alert (2012) called attention to the need for ongoing safety improvements regarding the use of parenteral opioids in hospitalized patients. The alert referred to the continued opioid related adverse drug events including deaths reported yearly to TJC Sentinel Event Database from medication errors, improper monitoring, excessive dosing, medication interactions, and adverse drug reactions. A similar alert was issued by the Institute for Safe Medication Practices (2013).

A retrospective analysis of 21,276,691 adult patient discharges from inpatient data from the Premier database (Premier Inc., Charlotte, NC) from 2008-2012 explored the morbidity of opioid use with and without sedatives in different patient populations in different locations inside the hospital (Overdyk, et al., 2016). No distinction was made between the administration of parenteral opioids and oral opioids. Using the appropriate ICD-9 codes for procedures and diagnoses, outcomes were classified as cardiopulmonary arrest, cardiopulmonary resuscitation or respiratory arrest classed together as CPRA. The overall incidence of CPRA of those patients receiving opioids only (62,995) was 0.31% or 3 in 1000 patients. Only 42% of those patients with CPRA survived to discharge. Twenty-five percent of those who experienced CPRA were located on general care floors i.e. non-critical care locations. Among general care floor patients .0775% or 0.78 per 1000 were classed as CPRA. When opioids were combined with sedatives the risk of CPRA was significantly increased.

There is no definitive published data on the risk of respiratory depression from immediate release oral opioids or immediate release oral opioids combined with extended release oral opioids in the acute care setting. This observation was acknowledged in an extensive reporting of opioid risk factors and guidelines for monitoring respiratory depression by the American Society for Pain Management Nursing (Jarzyna, et al. 2011). Avancen’s additional extensive search of the literature since 2010 including Medline®/PubMed® searching and the Cochran Database did not locate any studies with data on the incidence of rescue for respiratory depression from oral opioids in the acute care setting.

The MOD® data as shown in Table 1 reported no episodes of respiratory depression that would require naloxone rescue in 4000 patients using oral opioids. Using the data from the Premier

database, one might estimate a minimum of 3 and a maximum of 12 patients among the 4000 that could be at risk for CPRA from opioid use with an expected increase if sedatives are combined with opioids. However, the data reported here confirms the safety of those patients using MOD® devices for the administration of oral opioids regarding the risk of significant respiratory depression. The fact that the patient must be alert to request and self-administer a dose of oral medication almost assures that any sedation would preclude this step. Nevertheless, this finding does not remove the need for scheduled routine sedation and respiratory assessments for patients receiving opioids either oral or intravenous with or without sedatives.

IV PCA plays an important role in pain management in acute care albeit it has inherent significant risks and requires careful monitoring. With the MOD® device, patients can experience a safe seamless transition onto oral medication following the use of parenteral opioids allowing them to remain in charge of their pain medication delivery. Many surgical programs have discontinued the use of IV PCA on the day of surgery proceeding directly to oral pain medication as part of multimodality pain management in a patient centered environment.

Recent published guidelines for the management of acute pain in hospitalized patients recommend the use of oral pain medication including opioids instead of parenteral opioids for those patients that can take oral medications (Chou, et al., 2016; Herzig, et al., 2018). Enhanced recovery after surgery protocols primarily rely on multimodal pain management including oral pain medications beginning the day of surgery using scheduled acetaminophen and nonsteroidal antiinflammatory drugs along with other scheduled medications for pain and often prn oral opioids (Tan, Law and Gan, 2015).

Medication Diversion and Hoarding

A voiced concern with patient self-administration of oral opioids in a healthcare facility is the potential for the diversion of medication or the hoarding of medication by the MOD® user. No facilities reported any findings of patients diverting pain medications to others as shown in Table 1.

One facility reported a single incident of a patient saving medications from the device. The nurse manager comment regarding this patient was that the incident was early on in the facility experience. After being removed from the device use, the patient was ultimately found to have a history of opioid abuse that would have likely disqualified the patient from the use of the device if adequately screened. Of the 4,000 patients observed to date using MOD® devices, the incidence of hoarding medications may be calculated with a 95% confidence interval of between 0 and 0.025% in any facility. Due to the large sample size, additional data would not significantly change this number and validates the extremely low risk of patients hoarding medications. Careful patient selection and education including an agreement to accept

responsibility for the device and its contents has likely resulted in hoarding as an extremely rare event.

Disqualified Patients from Device Use

As shown in Table 1, cited reasons for removing other patients from the MOD® device use were an inability to fully understand how to use the device, a change in medication not available from the device, or patients requiring frequent assessment and changes of the pain care plan. These events are not unusual and point to the need for careful patient assessment and selection prior to the deployment of the device.

No Staff Diversion

No staff diversion of medication from MOD® devices has been reported from any of the facility surveys as shown in Table 1. New MOD® device databases called the Pain Data Query System (PDQS) system released in 2018 provides the pharmacy with additional tracking information of staff device use and medication inventories to detect any possible inconsistences in controlled substance use to identify any potential drug diversion.

Multimodal Pain Management

Multimodal pain management regimens are acknowledged as the standard for pain management in surgical patients as reviewed by the American Society of Anesthesiologists Task Force on Acute Pain Management (2012). Each institution defines the preferred combination of anesthesia techniques and medications to achieve multimodal pain management as there is no “gold standard” approach (Parvizi and Bloomfield, 2013). However, all of these regimens deploy oral as-needed opioids as part of multimodality pain management.

One MOD® facility reported occasionally combining a scheduled extended release (ER) opioid with an immediate release (IR) opioid supplied from the MOD® device for additional pain medication. The use of a scheduled ER opioid provides a higher dose of oral opioid combined with an IR opioid enabling the patient to titrate their pain medication according to their additional pain management needs from the device.

Hospitals contributing to this report initiate oral opioids either the day of surgery or the following day using MOD® devices. Pain management after total knee arthroplasty using MOD® devices has been compared to a control group receiving oral opioids from the nursing staff. MOD® patients had statistically significant lower pain scores and less interference from pain 24 hours prior to discharge with regards to mood, physical therapy, activity, sleep, and appetite compared to the control group (Lambert and Cata, 2014). In a recent study using devices after total hip

arthroplasty, lower pain scores were reported in the device group taking oxycodone PRN on day one postoperatively compared to a usual care group receiving the same medication from nursing staff given by the numeric pain scale. Patients using devices were using on average smaller doses of oxycodone compared to larger doses in the usual care group at each medication administration step (Pizzi, et al., 2018). The safety profile of these devices as reported here further validates their utility for better pain management using safe, effective technology.

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