The MOD® Experience after 1,000 Patients

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Summary

This paper reports the results of a survey from three 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 1,000 patients. All patients assigned to devices 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. 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 preloaded 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 patient selection criteria to assist in maintaining device safety and patient compliance.

In general, patients must have no evidence of confusion or dementia, no difficulty swallowing medications, no physical disability that would prevent them from removing medication from the device, and no 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 in these facilities by December 2014 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. 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 1,000 to 1,200 patients have used devices at these facilities.

Although one facility was converted onto wireless devices in 2014, other facilities are still undergoing the transition to wireless devices. With wireless device adoption, more precise databases of device use can be captured. Each survey was completed by the unit nurse manager, a pain team member, or a facility administrator.

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 1,000 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		Patient was removed for hoarding meds early on during the MOD® experience; patient had not been adequately screened for a history of narcotic abuse.
	Facility B – 3		Two patients had a poor initial assessment, could not reliably use the device, and one patient needed more constant nursing attention.
	Facility C – 2		Both patients removed for medication changes only
	Facility D – 0		None ever removed
Number of incidents of nursing staff diversion from MOD® devices	All facilities reported none	0%	
Percentage of patients using an extended release (ER) scheduled opioid combined with an immediate release (IR) opioid from the MOD®	Facility A – 80% Facility B, C & D – none		At facility A, approximately 80% of patients after total knee arthroplasty or total hip patients receive both ER and IR opioids. IR opioids are delivered using MOD® devices.

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).

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.

Current practice would indicate that, among a group of 1,000 patients receiving IV PCA, 12 to 19 would require naloxone for rescue from respiratory depression. The MOD® data as shown in Table 1 reported no episodes of respiratory depression from oral opioids that would require naloxone rescue. This data suggests that less than 0.1% of patients using MOD® devices for the administration of oral opioids would develop significant respiratory depression. The true number is not known because it is so rare. Nevertheless, this finding does not remove the need for scheduled routine sedation and respiratory assessments for patients receiving opioids either oral or intravenous.

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®, patients can experience a 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 proceeding directly to oral pain medication as part of multimodality pain management in a patient centered environment (Tan, Law and Gan, 2014).

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 hoarding, i.e., 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 narcotic abuse that would have likely disqualified the patient from the use of the device if adequately screened. Of the 1,000 patients observed to date using MOD®

devices, the incidence of hoarding medications may be calculated with a 95% confidence interval of between 0 and 0.295%. 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 a rare event.

Disqualified patients from device use

As shown in Table 1, cited reasons for removing five other patients from the MOD® device use were either an inability to fully understand how to use the device (2), a change in medication not available from the device (2), or more complex patients requiring frequent assessment and changes of the care plan (1). All of these events are not unusual and point to the need for careful patient assessment prior to the deployment of the device for each patient.

No staff diversion

No staff diversion of medication from MOD® devices was reported from any of the facility surveys as shown in Table 1.

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 facility often combines an extended release (ER) opioid with an immediate release (IR) opioid supplied from the MOD® device. 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). 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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