

# Evaluation of an Oral Patient-Controlled Analgesia Device for Pain Management in Oncology Inpatients

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Currently available patient-controlled analgesia (PCA) devices deliver medication via intravenous (IV), epidural, intrathecal, transdermal, and subcutaneous routes.<sup>1,2</sup> Several clinical studies documented better pain control when patients had direct access to their own pain medication.<sup>3,4</sup> Hospitalized patients usually are transitioned from PCA management to oral analgesics given on an as-needed basis before they are discharged; however, such medications still primarily are delivered one dose at a time by nursing staff. Currently, no secure, controlled oral PCA device is available to deliver opioid tablets/capsules to hospitalized patients or to outpatients in need of supervised access to oral pain medications on an as-needed basis.

An oral PCA device that allows patients access to their pain medications directly at the bedside should increase patient satisfaction in a way similar to that of the IV PCA modality. One proposed solution to prevent a delay in as-needed delivery of oral analgesics is to schedule doses around the clock, with patients retaining the right to refuse

**Abstract** An oral, patient-controlled analgesia (PCA) device uses radio-frequency identification technology to allow patients direct, controlled access to medication at the bedside. Twenty oncology inpatients participated in a pilot study to evaluate the device's design function and patient, nursing, and pharmacy satisfaction. The referring oncology physicians ordered oral pain tablets or capsules on an as-needed basis; the drugs were dispensed by the device with a specified lockout time interval and with a provision for administration of an immediate dose, if desired. In all, 95% of the patients reported that use of the device provided better pain control, since it allowed them to receive medication directly without delay. Further, 100% of the patients preferred using the device to calling a nurse for each dose of as-needed medication. All patients desired to use the device again during future hospitalizations if they required oral breakthrough pain medications. More than 80% of nurses surveyed stated that the device was reliable and easy both to program and to query about medication-dispensing data. In addition, more than 90% of nurses reported that patients' pain appeared to be better controlled when the device was used; they also indicated that the device saved them nursing time. Pharmacy staff agreed that the device's disposable medication tray was easy to fill; however, it did not save them time. The results of a Cronbach's-alpha statistic calculated for patient and nursing questionnaires showed these surveys to be reliable tools that featured consistent responses. The overall conclusion from this pilot study was that the oral PCA device was a useful, functional device that should improve pain management in selected patients in the acute care setting.

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medication.<sup>5</sup> Although this approach reportedly allows patients better pain control, it is a labor-intensive task for the nursing staff.

A modified Baxter IV PCA system previously was used for patient-controlled oral delivery of liquid morphine, but its use was not widely adopted.<sup>6</sup> Additionally, a Velcro wrist pouch containing two doses of tablets or capsules was used as an oral PCA drug delivery system in one facility.<sup>7</sup>

A recent Canadian study<sup>8</sup> reported on an oral

PCA program using one dose of medication stored in a child-resistant medication vial kept at the patient's bedside. Patients documented the time of medication use on a flow sheet and then requested another single dose in advance so that it was available when needed. This approach, although better than the traditional routine of waiting to ask for each as-needed dose, still required each dose to be delivered to the bedside by nursing staff.

A secure, oral PCA device that uses radiofrequency identification (RFID) technology to identify patients and to dispense medication has been developed to deliver pain tablets or capsules as needed.<sup>9</sup> A pilot clinical study evaluated the usability and acceptance of the device to manage pain in an oncology inpatient population.

## Methods

### STUDY DESIGN

An institutional review board (IRB)-approved protocol was used to enroll 20 oncology inpatients being treated in a community-hospital oncology unit. All patients met eligibility criteria of the study and signed informed consent documentation. Oncology patients entered in the study could have any pain syndrome that required oral pain medication as needed as ordered by the treating physician.

The patient eligibility criteria included the following: age of at least 21 years; no history of drug abuse; a physician order for an oral as-needed pain medication; ability to sign an informed consent form for volunteer participation, to understand instructions for using the device, and to demonstrate how the device should be used; anticipation that the device would be used for at least 48 hours; and agreement to use the device exclusively for themselves, to maintain the security of the device as part of the informed-consent process, and to complete a questionnaire when use of the device ended. Patients were ineligible if they were pregnant.

An investigational device exemption was granted by the hospital IRB, because the device had a low-risk status. Hospital-based medical oncologists were the referring physicians for study enrollment. A standard order sheet for using the device was developed with a limited formulary; the ordering physician could select one medication (ie, hydrocodone, hydro-morphine, morphine, oxycodone, or propoxyphene) from the order sheet. The drug, the dose of the drug, and the lockout time interval between doses were specified on the order sheet by the treating physician. In addition, if desired by the physician, an immediate time when patients should first receive the drug from the device was noted.

The inpatient pharmacy used a manual packaging procedure to fill the disposable medication trays of the device. Each tray contained eight doses of medication. The filled trays had clear adhesive covers that were attached using a simple roll-on procedure. Each tray was labeled with the appropriate prescription information and was delivered to the inpatient unit for use in a device. The nursing and pharmacy staffs used a narcotic tracking form to document medications dispensed from the de-

VICES. When the trays were empty, narcotic tracking forms were returned to the pharmacy so that nurses could receive other loaded trays; nurses then loaded one tray into each device and programmed the devices using a user-friendly software program loaded into a laptop computer attached to the devices.

Before the clinical study began, the nursing staff received in-service training regarding the operational details of the device. The sponsor's support staff was available to answer questions or to help solve problems. Nursing manuals and quick-reminder cards were provided for easy reference resources. A pharmacy user guide, tray support, and supplies were provided for the manual packaging of the drug trays.

Each patient received an RFID identification wristband containing an RFID tag<sup>9</sup> that allowed wireless communication between the tag in the wristband and a reader contained within the device itself. The RFID tag was composed of a silicon microchip and antenna; the RFID reader contained within the device was programmed to recognize tags within the patients' wristbands and tags contained within nursing cards as part of the initial programming of the device for each prescription. This procedure provided exclusive access to the device by patients wearing the wristbands and to their nurses.

Participating patients had to demonstrate their ability to activate the device and to remove the drug from the device tray one dose at a time. At the end of each timed lockout interval, a green "ready" light on the device signaled that the medication was available for dispensing. The green light remained on until patients decided that they needed another dose of medication. To receive the drug, patients pushed a button on the device to activate the RFID reader; they then swiped their wristbands over the RFID reader site to activate the device, to turn the medication tray, and to expose one dose of medication that they then could remove. After receiving a dose, patients could activate the device again only after the programmed lockout interval passed.

The nursing RFID card was programmed into the device so that nurses would have access to both the device and its software programs. The nursing RFID card enabled nurses to override the lockout time and to make an immediate dose of medication available for patients at the bedside, if necessary. The card also was used if nurses needed to open the device top and access the medication tray. The devices retained in memory each time that patients received a dose or that nurses made any override doses available or loaded any new tray into the device. The nurses could use a laptop computer at any time to query the device memory about dispensing data for entry into the electronic medication record.

The programmed device with a loaded medication tray was disconnected from the computer laptop, delivered to the patient's bedside, and locked onto an IV pole for easy patient access. After being instructed on use of the device, each patient verbally agreed to use the device in a responsible manner. Patients were informed that their participation in the study would be terminated if they did not adhere to the usage rules with which they agreed.

At regularly spaced intervals throughout the day, depending upon the device's lockout interval, the nursing staff questioned patients about their levels of pain on a scale of 0–10. Patients' pain was reassessed between dosing intervals. These data were collected as part of the routine hospital pain policy and were not recorded as part of this clinical study.

RFID technology maintained the device security. Entry to the device was possible only by patients wearing the RFID wristbands and nurses carrying the RFID cards. In addition, an RFID wristband antenna ran the entire length of each wristband; if a wristband was cut from a patient's wrist or damaged, the wristband became disabled. This design discouraged the unauthorized use of the wristband by another party. Additional security was provided by the device's memory, which documented each operation of the device and the time of the operation.

Patient surveys were obtained after patients used the device for 48 hours or when the study ended, whichever occurred first. Nurses completed written questionnaires after each device was used at 24 and 48 hours. Pharmacy staff completed questionnaires for each study device used.

### STATISTICAL ANALYSIS

Survey results are reported as the numbers of responses and the percentages of responses to each question. Questions required an answer of either “highly disagree,” “disagree,” “agree,” or “highly agree.” In several cases, nurses responded that the questions were “not applicable,” since they may not have performed the programming operation involved.

A Cronbach's-alpha statistic was computed to assess the reliability of each of the different survey tools. For these calculations, each question response was assigned a number that corresponded with the response (highly disagree = 1, disagree = 2, agree = 3, highly agree = 4). The calculation considered any missing values in the database as noted in the tables. A value of 0.7 or higher indicated good reliability<sup>10</sup>; a reliable survey would permit the calculation of a summary score consisting of the sum of the values of individual responses. Surveys containing missing responses would have their summary score inflated by the reciprocal of the proportion of non-missing responses. The mean response for each individual question and the mean summary score were calculated. Further, 95% confidence intervals (CI) were presented for all means. All analyses were carried out using SAS Version 9.1 (SAS Institute, Cary, North Carolina).

## Results

### PATIENT DATA

Of the 20 patients enrolled in the study, 12 were male, and 8 were female; 19 patients were Caucasian, and 1 was African-American. These demographics approximated a random sampling of the community population.

It was anticipated that each patient would be on the study for 48 hours and then have the option of continuing use of the device. All patients requested that they remain on the study

**Table 1**  
Drug Usage

IMMEDIATE-RELEASE ORAL PAIN MEDICATIONS	ORDER OF STUDY ENTRY (DOSES)	LOCKOUT TIME (h)	TOTAL DOSES
Hydrocodone (5 mg) + acetaminophen (500 mg)	16 (1)	4	1
Hydrocodone (7.5 mg) + acetaminophen (500 mg)	2 (22)	4	27
	13 (5)	3	
Hydromorphone (2 mg)	17 (42)	2	49
	18 (7)	3	
Hydromorphone (4 mg)	8 (56)	2	75
	19 (19)	3	
Morphine (15 mg)	1 (12)	2	126
	3 (8)	3	
	4 (8)	3	
	7 (32)	3	
	9 (60)	3	
	20 (6)	3	
Oxycodone (5 mg)	3 (14)	3	190
	4 (23)	3	
	5 (8)	4	
	6 (55)	2	
	7 (21)	3	
	10 (6)	4	
	11 (8)	2	
	12 (31)	2	
	14 (16)	3	
	15 (8)	3	
<b>Total</b>			<b>468</b>

until they were discharged or experienced a change in status that prevented their use of the device. Total patient days on study were more than anticipated (92 days); a total of 468 doses were delivered from the study devices.

Table 1 provides the entire drug usage data for the 20 patients using the devices. No patients were dismissed from the study because of noncompliance or any breach in the device security. The patient mix represented a wide range of admission diagnoses, from elective admissions for chemotherapy to emergency admissions for pain management and preterminal care. The physician-ordered lockout intervals between doses ranged from a minimum of 2 hours to a maximum of 4 hours. Three patients were sequentially changed from one pain medication to another by physician orders during the hospitalization.

Patients were asked to complete a patient survey after using the device for 48 hours. Table 2 reports the patient survey questions and responses. Each “agree” or “highly agree” response reflected a positive experience with the device. Responses to eight of the nine questions were positive in 95% or more cases; the exception was the response to question 3 (“The button was easy to push and allowed the device to identify my coded wristband;” 80% positive).

**Table 2**

**Patient Survey**

QUESTIONS	n (%)			
	HIGHLY DISAGREE	DISAGREE	AGREE	HIGHLY AGREE
1. The written instructions to use the device were easy to understand.*	—	—	10 (53)	9 (47)
2. The instructions from my nurse to use the device were easy to understand.	—	—	7 (35)	13 (65)
3. The button was easy to push and allowed the device to identify my coded wristband.	2 (10)	2 (10)	7 (35)	9 (45)
4. It was easy to tell by the green light on the device when the medication was available to be taken.*	—	1 (5)	6 (32)	12 (63)
5. The pill was easy to remove from the device.	—	1 (5)	9 (45)	10 (50)
6. My pain has been better controlled, because I could get my pain medication directly by using the device.	—	1 (5)	9 (45)	10 (50)
7. I prefer using this device rather than calling a nurse for each dose of pain medication.*	—	—	6 (32)	13 (68)
8. I would like to continue to use this device if I remain in the hospital.*	—	—	7 (37)	12 (63)
9. If I return to the hospital in the future, I would like to have this device for my pain tablets.	—	—	7 (35)	13 (65)

\*Question 1 was not answered by one patient, who wrote that she did not need to read the instructions, since the device was so easy to understand. Question 4 was not answered by one patient; no reason was given. Questions 7 and 8 were not answered by one patient, who recorded that they were not applicable.

The value for the Cronbach’s-alpha reliability measure was 0.83, indicating that the patient survey is a reliable tool. The mean calculated summary score was 31.2 (95% CI, 29.6–32.8).

**NURSING DATA**

Each patient’s nurse at the 24- and 48-hour intervals of device use was asked to complete a survey (Tables 3a and 3b). The rationale for using two nursing surveys was to collect as much nursing data as possible.

For the 24-hour survey, the value for the Cronbach’s-alpha reliability measure was 0.79, indicating that the nursing survey is a reliable tool; the mean calculated summary score was 22.2 (95% CI, 20.3–24.1). For the 48-hour survey, the value for the Cronbach’s-alpha reliability measure was 0.99, indicating that the nursing survey is a highly reliable tool; the calculated mean summary score was 27.9 (95% CI, 26.0–29.9).

The groupings of questions in the nursing surveys addressed issues regarding use of the device. Questions 1 and 2 on both surveys asked nurses about their impression of their patients’ experiences with the device; the responses were positive, with 89% or more agreeing and/or highly agreeing on the easy use of the device. Question 7 on both surveys reported that 95% (24 hours) or 84% (48 hours) of the nurses agreed that their patients’ pain appeared to be better controlled since they were able to self-medicate directly using the device.

Questions 3–6 of the nursing surveys asked about the reliability of the device and the ease of setting it up, programming it, and obtaining data from it. The minimum positive response to these questions was 87%; on day 2, all the nurses agreed and/or highly agreed with the questions.

Questions 8 and 9 appeared on the 48-hour nursing survey only. In all, 84% of the nurses surveyed thought the device

**Table 3a**

**Nursing Survey at 24 Hours**

QUESTIONS	n (%)			
	HIGHLY DISAGREE	DISAGREE	AGREE	HIGHLY AGREE
1. The patient understands how to use the device.	—	1 (5)	8 (40)	11 (55)
2. The patient can easily use the device.	—	2 (10)	8 (40)	10 (50)
3. The device was easy to set up and program.*	—	2 (12)	13 (76)	2 (12)
4. The device was easy to program for the time interval required between medication doses.*	—	2 (13)	12 (74)	2 (13)
5. The device was easy to query to obtain charting data.	1 (5)	1 (5)	13 (65)	5 (25)
6. The device functions reliably.	1 (5)	1 (5)	12 (60)	6 (30)
7. The patient’s pain appears to be better controlled since he/she is able to self-medicate with the device.*	—	1 (5)	8 (42)	10 (53)

Questions 3 and 4 lacked responses from nurses who did not program the device when the patient began using it and gave the answer “not applicable.” Data were compiled on the number of responses recorded. Question 7 lacked a response from a nurse, who stated that her assessment was difficult, because the patient appeared confused.

**Table 3b****Nursing Survey at 48 Hours\***

QUESTIONS	n (%)			
	HIGHLY DISAGREE	DISAGREE	AGREE	HIGHLY AGREE
1. The patient understands how to use the device.	—	—	14 (74)	5 (26)
2. The patient can easily use the device.	—	2 (11)	12 (63)	5 (26)
3. The device was easy to set up and program. <sup>†</sup>	—	—	9 (69)	4 (31)
4. The device was easy to program for the time interval required between medication doses. <sup>†</sup>	—	—	8 (73)	3 (27)
5. The device was easy to query to obtain charting data. <sup>†</sup>	—	—	14 (87)	2 (13)
6. The device functions reliably.	—	—	15 (79)	4 (21)
7. The patient's pain appears to be better controlled since he/she is able to self-medicate with the device. <sup>†</sup>	—	3 (17)	12 (67)	3 (17)
8. The device saves nursing time, since I do not have to take each dose of pain medication to the patient directly. <sup>†</sup>	1 (6)	2 (11)	12 (67)	3 (17)
9. I would like to use the MOD device <sup>‡</sup> for my patients who are capable of using the device.	1 (5)	1 (5)	14 (74)	3 (16)

\*Data is based on 19 patients because one patient was discharged prior to 48 hours of the device use.

<sup>†</sup>Questions 3, 4, and 5 were related to an interaction with the device software. Nurses who did not need to use these features during their time with the patient answered these questions as "not applicable." Data were compiled on the number of responses recorded. Question 7 was not answered by one nurse, who stated that she could not determine whether her patient's pain was better controlled. Question 8 was not answered by one nurse, who stated that her patient only used one dose of medication, so she could not determine whether the device saved her time.

<sup>‡</sup>Medication On Demand (MOD) device refers to the oral patient-controlled analgesia device.

saved time (question 8), and 90% desired that patients meet its criteria use the device in the future (question 9).

**PHARMACY DATA**

A pharmacy survey (Table 4) was completed for each patient who completed use of the device. There were insufficient data from Table 4 to calculate a Cronbach's-alpha reliability measure. In all, 75% of the pharmacy staff gave positive responses to questions concerning simplicity of loading the clear plastic drug tray. However, the pharmacy staff's responses to questions 2 and 3 indicated that use of the drug trays did not ease medication inventory or save a significant amount of pharmacy time.

**Discussion**

The two goals of the clinical study were to evaluate the device for its mechanical and software reliability and to measure the satisfaction of the patients, nurses, and pharmacists after using the device.

None of the design features or software interfered with the study. The only problematic design feature noted by patients

was the push-button needed to activate the RFID reader; after 20% of patients indicated that the button was difficult to push, investigators changed the design of the RFID activator from a button to a touch pad.

Participants otherwise were uniformly positive about their experience with the device. Many oncology patients experience multiple hospitalizations during their course of treatment; they are familiar with the hospital routine and understand that multiple demands upon nursing staff often lead to slow delivery of as-needed oral analgesics. The patients' past hospital experience with obtaining oral as-needed pain medication may have caused them to express a positive bias.

The nursing surveys also provided a positive view of the patients' and nurses' ability to use the device. Interestingly, the nurses thought that the device saved them time. The overall cost and time-savings data gathered for this new method when compared with the usual route of as-needed oral pain medication delivery will be evaluated by future studies.

The pharmacy staff agreed that manual filling of the trays was easy. However, pharmacy workers did not agree that the

**Table 4****Pharmacy Data**

QUESTIONS	n (%)			
	HIGHLY DISAGREE	DISAGREE	AGREE	HIGHLY AGREE
1. The clear plastic drug tray was simple to load with medications.	—	5 (25)	10 (50)	5 (25)
2. The inventory of this medication using the delivery tray method is easier than the usual inventory of this medication.	3 (15)	13 (65)	3 (15)	1 (5)
3. The delivery of the medication using a tray device that fits into the MOD* saved pharmacy time compared with the usual delivery of the medication.	3 (15)	12 (60)	4 (20)	1 (5)

\*Medication On Demand (MOD) refers to the oral patient-controlled analgesia device.

system simplified inventory or accountability of oral pain medications or that use of the device tray saved them time. This was a clinical trial testing a new device, so it is not surprising that pharmacy workers did not report time savings—any new approach to dispensing medication from the pharmacy would require new protocols to simplify drug inventory and delivery in a new container. Pharmacy-written comments indicated that drugs needed to be removed from unit-dose packages to load trays; there were no provisions for use of bulk bottles, which would have saved the time of pharmacy staff. Pharmacists suggested that prepackaged trays would be a workable solution to save more time; thus, prepackaged disposable trays for the device are being manufactured to contain any of four oral pain medications most commonly used by oncology patients.

The drug ordered most frequently in this study was oxycodone (Table 1). This finding agrees with that of our recent survey on the most frequently used oral breakthrough pain medications in oncology inpatients,<sup>11</sup> which revealed a limited formulary of breakthrough pain medications used in oncology inpatients. Thus, the use of prepackaged trays is feasible.

Studies using PCA modalities primarily focused on managing postoperative pain. The oral PCA device used in this study was for breakthrough pain in oncology inpatients; however, it may have multiple applications in other hospitalized patients who would benefit from oral PCA pain management (eg, those who have undergone surgery, who are in chronic pain, who are being treated for obstetric or gynecologic indications, or who have selected general medical conditions). Additional future studies with larger patient populations are needed to further define the device's role in the acute care setting.

The most common approach for PCA management has involved IV administration of drugs. Some surgical studies indicated a trend toward an earlier conversion to oral pain medi-

cations after IV PCA than was practiced previously. These studies reported similar or better pain control with oral pain medications than with IV PCA devices.<sup>12,13</sup>

The logical step-down from current PCA modalities would be an oral PCA device to prepare patients for use of oral medications at home. Switching postoperative patients to oral analgesics on an as-needed basis frequently is delayed, because no controlled, secure oral PCA modality has been available. The availability of an oral PCA device may transition inpatients to oral as-needed pain medications earlier, which would allow adequate time for adjusting oral pain medication dosages before patients are discharged.

Strategies for reinventing healthcare in the future focus on safety and more efficient, cost-effective service and patient-centered, equitable care.<sup>14</sup> A controlled, secure oral PCA device meets these requirements; in the future, it should facilitate better pain management for multiple patient groups treated in the acute care setting.

## Conclusion

A new oral PCA device that uses RFID technology is a useful tool for pain management in oncology inpatients. The data from this study have been used to refine a final design for a market-ready oral PCA device.

## CONFLICT-OF-INTEREST STATEMENT

Ms. Rosati is an educational consultant for AVANCEN LLC. She was responsible for nursing and staff education and technical support for the study. Dr. Conley is the President and CEO of AVANCEN LLC. The clinical trial document was authored by Dr. Conley, who served as the principal investigator for the study. Mr. Luwisch is an AVANCEN, LLC investor and an employee of Halifax Medical Center.

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