

## Avancen Abstracts of Publications in Peer Reviewed Journals

Note that a quoted p value in these publications < 0.05 means that the data is statistically significant.

**Rosati J., Gallagher, M., Shook, B., Luwisch, E., Favis, G., Deveras, R., Sorathia, A. & Conley, S. (2007) Evaluation of an Oral Patient-Controlled Analgesia Device for Pain Management in Oncology Inpatients. Journal of Supportive Oncology, 5(9), 443-448.**

Evaluation of the Medication On Demand (MOD<sup>®</sup>) device prototypes in a pilot study at Halifax Medical Center, Daytona Beach, Florida supported by a Small Business Innovation Research (SBIR) Phase I NIH grant to Avancen. The device used Radiofrequency Identification (RFID) technology in patient wristbands to evaluate the first oral PCA device concept in twenty oncology inpatients. Ninety five percent of the patients reported better pain control using the device as compared to the manual delivery of as needed oral pain medication, and 100% of the patients preferred using the device compared to the need to call the nurse for each dose of medication. More than 80% of the nurses surveyed stated that the device was reliable to use, easy to program and query for data. More than 90% of nurses reported the patients' pain appeared to be better controlled when the device was used. The study conclusion was that the oral PCA device was a useful, functional device that should improve pain management in selected patients in the acute care setting.

**Lambert, T.L., Cata, D.M. (2014) The Traditional Method of Oral As-Needed Pain Medication Delivery Compared to an Oral Patient-Controlled Analgesia Device Following Total Knee Arthroplasty, Orthopedic Nursing, 33(4), 217-223.**

An Avancen MOD<sup>®</sup> Corporation sponsored study at Flagler Hospital, St. Augustine, FL. Post-operative pain control was compared using either the manual delivery of as needed oral opioid pain medication by nursing staff versus the MOD<sup>®</sup> patient controlled delivery of the same medications. Each group enrolled 30 patients after total knee replacement. Fifty-five percent of the device group compared to 75% of the control group reported numeric pain scores  $\geq 5$  on post-operative day two (p value .0007) and 63% of the device group as compared to 87% of the control group reported pain scores  $\geq 5$  the last twenty-four hours prior to discharge (p = 0.04). The device group reported statistically significant less pain interference with general activity, mood, physical therapy, sleep and appetite as compared to the control group.

**Pizzi, L.J., Chelly, J.E., Marlin, V. (2014) Nursing Time Study for the Administration of a PRN Oral Analgesic on an Orthopedic Postoperative Unit. Pain Management Nursing, 15(3), 603-608.**

An Avancen MOD<sup>®</sup> Corporation sponsored study at the University of Pittsburgh Medical Center, Shadyside Hospital, Pittsburgh, PA. The study aim was to measure the time necessary for a nurse to manually deliver a single dose of oral pain medication in an orthopedic post-operative unit. Each task to deliver the medication and return for reassessment of pain with chart documentation was measured in specific steps using an electronic PDA device that measured each step. Nurses across 28 shifts participated in the time measurements to arrive at a meaningful database acknowledging that each nurse and patient encounter had expected variations. The mean time in minutes for a single delivery of an oral pain tab was 10.9 minutes.

**Pizzi, L.J., Bates, M., Chelly, J.E. & Goodrich, C.J., A Prospective Randomized Trial of an Oral Patient-Controlled Analgesia (PCA) Device Versus Usual Care Following Total Hip Arthroplasty  
Poster presentation from the University of Pittsburgh Medical Center (UPMC) Shadyside Hospital at the American Society of Pain Management Nursing Meeting, 2017. Manuscript is now in press at Orthopedic Nursing Journal.**

An Avancen MOD<sup>®</sup> Corporation sponsored study to evaluate pain control after total hip arthroplasty in a prospective randomized population of either a control group or a MOD<sup>®</sup> group of patients. On post-op day 1 the mean pain score of the device group was 4.7 as compared to the control group at 6.0 ( $p < 0.0001$ ) whereas the average oxycodone dose for the device group was 5 mg as compared to 8 mg for the control group ( $p < .0001$ ). The nursing survey responses were more than 90% favorable for the overall device use and the agreement that the device saved nursing time. This study proves that MOD<sup>®</sup> patients had significantly less pain than those getting the same medication from nursing staff and that the pain was better controlled with lower doses of drug allowed more frequently using the MOD<sup>®</sup> PCA technology.

**Collins, L., Cata, D. & Conley, S. A Comparison Timing Study – An Oral PCA Versus Traditional Delivery. This study has been completed. A poster was presented at the National Magnet Nursing meeting in 2018, the manuscript is in preparation for submission to Orthopedic Nursing.**

An Avancen MOD<sup>®</sup> Corporation sponsored study at Flagler Hospital, St. Augustine, Florida. The goal of the study was to measure the time necessary for the manual delivery of an oral pain medication in an orthopedic inpatient surgical unit as a baseline time to compare with the nursing time needed for the delivery of a single dose of pain medication from the MOD<sup>®</sup> device. The completed manual delivery time is 12.7 minutes in this unit as compared to the 10.9 minutes in the UPMC orthopedic inpatient unit. The

Wi-fi MOD® time measurements revealed that the nursing time required for a single delivery of oral pain medication from the device required 2.1 minutes. This included the nursing time to acquire the medication tray and patient wristband, program the device, teach the patient how to use the device and the discharge time needed once the patient was removed from the device. After an eight-dose tray from the device had been used and replaced with another tray, the nursing time to continue to deliver a single dose of medication from the device from then on was 40 seconds per dose until the time the patient is removed from the device. This study validates the time savings for nursing when the device is adopted for the as needed delivery of oral pain medication compared to the manual delivery by nursing staff. A manuscript is now in preparation for submission for publication.