



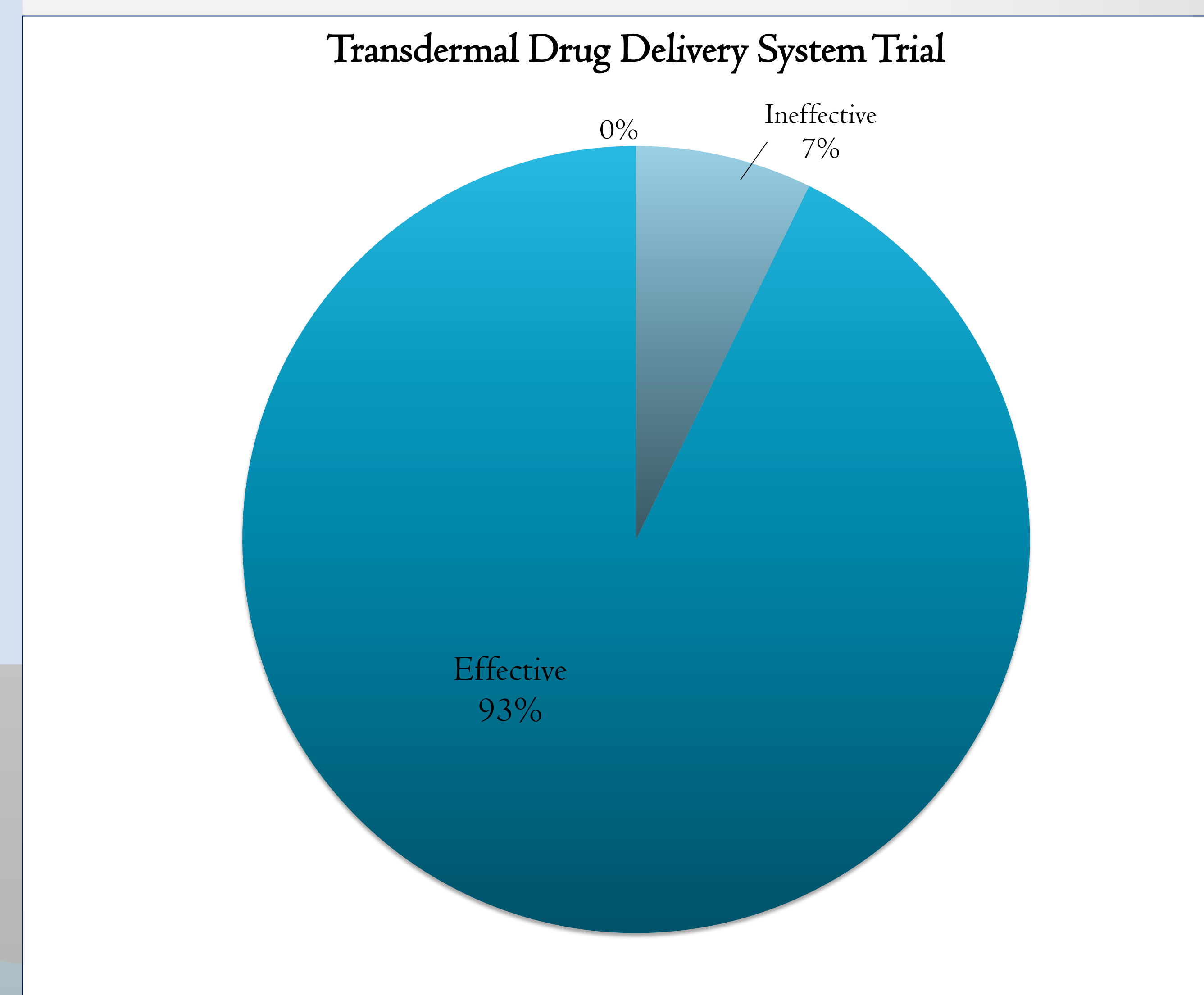
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The purpose of this trial was to evaluate the transdermal approach in effectively managing post-operative acute pain in the first 24 hours after total knee replacement without additional IV narcotics by placing patients in control of their own pain management. In addition the trial also focused on mobility beginning on the same day of surgery, and improvement of pain scores monitored by a third party vendor. The system consists of a credit card sized patch that is applied to the patient's chest or upper outer arm. The "on Demand" button is pressed to deliver a controlled amount of medication transdermally over 10 minutes. Over a 24 hour period, a maximum amount of 80 doses is allowed, however only 6 doses are allotted per hour. The system gives the patient control of delivering their own pain medication as needed. The system is discontinued prior to discharge from the hospital.

207 patients were included in the transdermal drug delivery system trial. 192 patients reported the patch to be effective while 15 reported it being ineffective. A Welch modified two-sample t-test was conducted to compare the pain levels, on a scale from 0-10, reported by patients in two groups. The mean pain reported by patients in the effective group is statistically lower than the mean pain reported by patients in the ineffective group. Eight patients were excluded based on adverse effects reported and/or requests by the patient for removal of the system.



The trial results revealed a 95% decrease in IV narcotic use post-operatively with all patients ambulating within the same day of surgery. 44% improvement in overall pain scores was noted in this group of patients.

Overall the Transdermal drug delivery system has compelling opportunities for improved pain control and improved patient satisfaction.