Critical research appraisal

Literature

Title and Abstract

The title “ A prospective, randomized trial of intravenous prochlorperazine versus subcutaneous sumatriptan in acute migraine therapy in the emergency department” succinctly describes the research that is conducted. The abstract is very brief and includes the study purpose, sample size, design description, and conclusion. The abstract would have been strengthened by clearly stating the problem. The problem is distinguishing the most efficacious treatment of the two medications as evidenced by the patient’s adequate relief of pain, nausea, and/or sedation. Also, the abstract lacked a background section stating previous research conclusions regarding one or both of these medications treatment of migraines.

The gap of knowledge is expressed in the introduction background section. There is only one previous study, published in abstract form that reports prochlorperazine superior in treatment of migraines, but does not compare both drugs. This previous study lends to the reader a weak premise based upon the small sample size and lack of published full research. The limited previous study does lend to a problem that is significant to generate knowledge for practice. Migraines are among the top three reasons to visit the emergency department(ED) constituting 2. 2% of all US ED visits (Kostic et al., 2010, p. 1). Studies of various medication treatments exist regarding effective migraine treatment, but not with a statistically significant sample to compare prochlorperazine and sumatriptan with a measure of improvement in pain.

Problem and Purpose The purpose clearly states that the goal of the study is to prove that IV prochlorperazine with diphenhydramine is superior to

subcutaneous sumatriptan in reducing or halting acute migraines among ED patients. The editor's capsule summary accurately describes that both drugs are used to treat migraines but little evidence exists to support one over the other.

This study addresses that prochlorperazine is superior to sumatriptan in pain relief with the same side effects of nausea and sedation (Kostic et al., 2010, p. 2). It is interjected in the background that diphenhydramine is often given with prochlorperazine to reduce akathisia (Kostic et al., 2010, p. 1). The variables, or the outcome measurement of the mean improvement in pain response as indicated by a 13mm or greater improvement on the visual analog scale (VAS) 80 minutes post treatment among 66 consecutive patients that have been identified with acute migraines in a double blind randomized clinical trial with placebo controls among a Department of Defense closed emergency department with phone call after discharge as follow up was identified in the purpose.

Literature Review

There are twenty five recent and current references with which the authors draw from a literary review. However, only one sentence is utilized precluding the hypothesis of the study that prochlorperazine is the most effective in acute migraine treatment. This statement refers to only one of the twenty five articles referenced in research as the limited knowledge about the comparison of the two particular medications is limited with this malady. A literature search did not reveal other studies not mentioned in this research article. Therefore, the studies that pertain to this particular

research problem are thorough, provide a rational and context for the study, and are referenced by the author. (Burns & Grove, 2011, p. 440).

Conceptual Framework

The research performed by Kostic et al. (2010) does provide a clear major strength of framework. Kostic and colleagues (2010) provide a explicitly expressed and appropriate double blinded, placebo-controlled, randomized clinical trial to determine specific drug versus drug effectiveness of acute migraine treatment of patients in the emergency department. The study design itself is a strength and is in accord with the Standards of the Committee of Human Experimentation (Kostic et al., 2010, p. 2).

The selection of participants being consecutive may be a weaker point of framework in that a larger more varied group over time could have been utilized. A list of modified International Headache Society criteria for migraine was used prior to enrollment in the study by the physician. Adequate exclusion criteria such as contraindication to proposed medication therapy such as hypersensitivity, coronary artery disease, hypertension, pregnancy, recent utilization of the same class of medication within 24 hours, hepatic insufficiency, history of nonmelanoma cancer, hyperthermia, or atypical headache. A map of the framework is provided in the form of a subject flow chart utilizing the International Headache Society criteria (Kostic et al., 2010, figure 2).

The major strength of this particular research is that the clinician was not aware which medication the patient received; the pharmacy utilized a computer randomized number program to mix the medication. The clinician

could not identify the placebo or medication. The study findings were linked back to the framework in that the patients reported greater pain relief as on the VAS of 13mm or greater with prochlorperazine.

Methods The study was approved of by the local institutional review board. The Department of Defense has a closed tertiary care ED with over 65, 000 patients per year. The study was deemed ethical in accord with the Standards of the Committee of Human Experimentation (Kostic et al., 2010, p. 2). The well designed study's strengths are that all involved were blinded to the treatment and controls and randomization. The sample size of 66 patients is small and weakens the study.

The visual analog scale (VAS) is reliable in that the researchers assess pain prior to treatment with research medication and in twenty minute increments for up to 80 minutes or until the patient was discharged from the ED. The patients received a discharge callback within 72 hours to assess headache recurrence prompting an unscheduled return to a healthcare provider or ED. The researchers determined that a 13mm difference in VAS scoring was based upon previous studies as a significant indicator for improvement or decline.

The measurements were analyzed statistically among both groups the ones that received IV prochlorperazine and sumatriptan. It is important to note that the patients that received the prochlorperazine received a placebo of subcutaneous sumatriptan; the patients that received sumatriptan received a placebo of IV prochlorperazine. A power analysis of 80% was used to determine that the research group required 62 patients to detect a 13mm difference in pain. It was also conceived that additional observations and

ratings would be needed to rate drowsiness and nausea; these were also assessed using the same reliable 100-mm VAS measured at baseline and 20 minute intervals for a total time of up to 80 minutes or until patient was discharged.

The VAS does provide an accurate instrument with which to detect small differences between subjects. Subjects were called within 72 hours post discharge to determine headache recurrence that resulted in an unscheduled return to ED or provider. Power Analysis and Sample Size, version 2000, Statistical Package for the Social Sciences, version 15 and Number Cruncher for the Social Sciences are reliable and valid for primary data analysis (Kostic et al., 2010, p. 3).

Results

During the time frame of the research study, 187 subjects presented to the ED with migraine headaches. 66 participants were finished the study, 35 in the sumatriptan group and 31 in the prochlorperazine group. The statistical techniques used to analyze data from the prochlorperazine and sumatriptan group are identifiable and appropriate. The clear and concise results are presented in narrative form, tables and graphs enhance knowledge.

The findings show no mean difference between an increase in sedation among both medications in question. The mean difference is 1mm. Prochlorperazine with diphenhydramine did have a provide greater relief with respect to nausea; however, it is not statistically different with a confidence interval of -24 to 0. 5mm (Kostic et al., 2010, p. 4). 61% of the subjects were contacted successfully by phone within 72 hours of discharge.

43% of the prochlorperazine group reported headache recurrence compared to 63% of the sumatriptan group; however, all subjects that were contacted did not precipitate an unscheduled return to a provider (Kostic et al., 2010, p. 4).

Statistical significance can be increased by noting that of the 26 patients that were unable to be contacted by phone, none returned to a provider of care; this is supported by the fact that the setting is a closed healthcare system (Kostic et al., 2010, p. 4). Therefore the significant findings are fully explained and the statistically significant findings are clinically significant with no biases or inconsistencies noted. Confidence may be strengthened with a larger study and thus limits generalizations. Despite the small sample size, the findings that prochlorperazine is superior to sumatriptan is related to the framework and does add to the current body of knowledge with respect to migraine treatment.

In conclusion, the findings were as expected, and the statistical and clinical significance are clearly addressed (Burns & Grove, 2011, p. 441). Future studies were indicated with a larger sample size. The researchers did identify limitations and provide future direction. The researchers did not make recommendations for nursing practice in particular; however did relate that prochlorperazine is more cost effective at $2. 78 versus sumatriptan at $34. 78. The additional costs of peripheral IV supplies of $12. 60 also lend to the cost effectiveness of prochlorperazine.