

patient education is required about drug uses and stricter regulatory activities will be needful to promote rational drug uses in this population.

1123835

**A Cross-sectional Study to Assess the Patients' Satisfaction and Effectiveness of Complementary and Alternative Medicine (CAM) in four chronic diseases in a tertiary referral centre in India**

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**Statement of Purpose, Innovation or Hypothesis:** The use of Complementary and Alternative Medicine (CAM) is increasing and becoming an important treatment option for patients with chronic diseases. The present study was conducted to assess the patients' satisfaction and extent of CAM use in four chronic diseases; Rheumatoid arthritis (RA), Diabetes mellitus (DM), Epilepsy and HIV.

**Description of Methods and Materials:** The study was approved by the IRB and conducted over a 16 week period in these diseases after written informed consent from participants. Key selection criteria were age more than 18 yrs and taking CAM along with established therapy. The Treatment Satisfaction Questionnaire for Medication (TSQM)™ was used to assess the satisfaction in domains like Effectiveness, no Side Effect, Convenience and Global Satisfaction. The domain scores ranged from 0 to 100 with higher scores representing greater satisfaction.

**Data and Results:** A total of 4664 patients were screened. Of these 1619 (34.71%) were found to be using CAM. Of these, 969/1619 (59.85%) declined to consent and thus only 650 were studied. The extent of use of CAM in DM was 63%, RA 42.73 %, HIV 26.19 % and Epilepsy 7.67%. Ayurveda was found to be most frequently used CAM 57.07 % (95% CI 53.27-60.89). Satisfaction in terms of effectiveness and global satisfaction was highest in HIV (69.43% and 69.24 % respectively) and least in RA (56.61 % and 54.13 % respectively). High scores were reported to "no side effect" domain in all four diseases indicating satisfaction with CAM.

**Interpretation, Conclusion or Significance:** The extent of use of CAM in four chronic diseases in a tertiary referral centre was found to be 34.71% .The users of CAM in DM, HIV and Epilepsy believed that CAM were safe, effective and convenient with high satisfaction. Given the potential interaction of CAM with conventional therapies, patients should be screened at least by history taking for use of CAM. Studies on the actual effectiveness may help physicians and patients in future management of these diseases.

1123838

**Evaluation of authenticity and rationality of promotional pharmaceutical drug literatures**

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**Statement of Purpose, Innovation or Hypothesis:** The promotional activities of pharmaceutical industry are governed by the World Health Organization, International Federation of Pharmaceutical Manufacturers and Associations, Organization of Pharmaceutical Producers of India, which are self regulatory codes.

Many studies showed that information disseminated through the advertisement is inconsistent with the code of ethics. Thus this study aims to evaluate the authenticity and rationality of the pharmaceutical promotional drug literatures.

**Description of Methods and Materials:** In this prospective observational study we collected 171 promotional pharmaceutical drugs literature from various departments such as Cardiology, Medicine, Nephrology, Oncology Orthopedics, and pediatrics at K.E.M. Hospital, Parel, Mumbai. The collected literatures were analyzed for rationality according to world health organization criteria (WHO) and authenticity of therapeutic claims made in promotional literature were verified by accessing standard literature through internet databases.

**Data and Results:** In this prospective observational study on pharmaceutical promotional drug literatures showed that 19.30% (33) were rational, 80.70% (138) were irrational, 49.12% (84) were authentic and 50.88% (87) were not authentic. Multinational companies showed 9.36% (16) rationale, 24.56% (42) irrational, 19.88% (34) authentic, 14.62% (25) not authentic and non multinational companies showed 9.36% (16) rationale, 56.72% (97) irrational, 29.83% (51) authentic and 35.67% (61) not authentic. Out of 171 promotional literatures 26.90% (46) were from diabetes blood pressure, 15.79% (27) from analgesics, 15.20% (26) from antibiotics and 31% (53) from other therapeutic area.

**Interpretation, Conclusion or Significance:** It was concluded from this study that pharmaceutical companies did not follow the WHO guidelines while promoting their drugs. They have only the commercial motive rather than the ethical educational aspect. Important information about contraindication, precautions, adverse drug reaction and drug interactions was usually missing. Non multinational pharmaceutical companies showed the more irrationality and non authenticity. There will be need of making stringent laws for ethical promotion of pharmaceutical drugs material.

1123960

**Plasma and CSF Levels of Arbaclofen Are Not Associated With Drowsiness**

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**Statement of Purpose, Innovation or Hypothesis:** Arbaclofen, the R-enantiomer of baclofen, is in development for spasticity due to multiple sclerosis. The primary dose limiting adverse event for racemic baclofen is drowsiness and sedation. We hypothesized that the S-enantiomer was the primary cause of these events.

**Description of Methods and Materials:** A 4-arm, parallel group, double-blind, dose-ranging PK study of arbaclofen and baclofen was conducted in healthy subjects to compare the plasma and CSF parameters. Twelve subjects in each group received arbaclofen doses of 5, 7.5, or 10mg, or baclofen doses of 20mg every six hours for four days after an up-titration period of nine days. Subjects completed a drowsiness scale every three hours while awake on Day 12. Scores ranged from zero "No Drowsiness" to 10 "Worst Possible Drowsiness". PK samples were taken on Day 14. AUC and Cmax values were analyzed by regression with the mean daily drowsiness scores.

**Data and Results:** No significant correlation was observed between drowsiness scores and arbaclofen or baclofen plasma PK parameters. No significant correlation was found for arbaclofen CSF parameters. However, baclofen CSF AUC and Cmax were significantly correlated to daily drowsiness scores with R2 values of 0.78 and 0.88 and p-values of 0.0016 and 0.0001, respectively.

**Interpretation, Conclusion or Significance:** These results suggest that drowsiness, the most common dosing-limiting adverse event for baclofen, is associated with CSF exposures of the S-enantiomer and not the R-enantiomer.