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Tramadol/Paracetamol Combination have Better Safety Profile in Ambulatory Hand Surgery Pain Management

Tramadol/paracetamol combination is a better choice for pain manegment after ambulatory hand surgery. A randomized, double-blind, double-dummy, multicentre trial was conducted in Europe regarding the use of Tramadol/paracetamol combination in ambulatory hand surgery. The aim of this study was to compared the efficacy and safety of tramadol HCL 37.5 mg/paracetamol 325 mg combination tablet with tramadol HCL 50 mg capsule in the treatment of postoperative pain following ambulatory hand surgery. This trial was conducted from April to October 2003 according to the Declaration of Helsinki and Good Clinical Practice at 24 trial centres in 9 European countries. Two hundred and sixty one Patients aged 18-75 were enrolled in the study. Among the 261, 132 received tramadol/paracetamol combination treatment, and 129 took tramadol. The majority completed the trial (83.5%); reasons for premature withdrawal were lack of efficacy, adverse events (AEs), or protocol violations. Prior to hand surgery, patients were randomly assigned in a 1:1 ratio to receive either tramadol/paracetamol tablets or tramadol capsules. Efficacy was analyzed using the full analysis set (FAS) which included all randomized patients who received at least 1 dose of trial medication and provided information with respect to the primary efficacy variable. A per-protocol (PP) analysis including all FAS patients without major protocol violations was used for sensitivity analysis. The primary efficacy variable was the rate of patients responding to treatment based on treatment satisfaction as recorded on the evening of the first postoperative day using a 4-point verbal rating scale (0 = poor, 1 = fair, 2 = good, 3 = excellent). A patient was defined as a responder with a rating of 2 or 3 and no intake of rescue medication or other concomitant analgesia before midnight of the first Postoperative day. Secondary efficacy variables included the assessment of the patient's average pain intensity over the last 24 hours for surgery and first postoperative day on an 11-point numerical rating scale (NRS) from 0 = no pain to 10 = worst imaginable pain. Safety evaluations by the investigator included adverse events (AEs) documentation and sedation assessment after surgery and before discharge. A larger proportion of FAS patients in the tramadol/paracetamol group (78.1% *vs* 71.9% in the tramadol group) were considered treatment responders at the end of the first postoperative day (primary efficacy variable). The PP analysis confirmed the finding (83.6% *vs* 75.7%), with an estimated difference of 7.94% (tramadol/paracetamol *vs* tramadol; 95% CI [−2.7, 18.6]; *P*= 0.13). Treatment satisfaction was also recorded as at least good in more patients on combination therapy (77.3% *vs* 71.9% on tramadol treatment). A total of 71.9% of tramadol/paracetamol and 64.1% of tramadol patients rated pain intensity with a score of ≤3 on the 11-point NRS on the evening of surgery day. The proportion of patients with this score increased to 83.6% of tramadol/paracetamol and 81.3% of tramadol patients in the evening of the first postoperative day which corresponded to mean scores of 1.7 ± 2.0 for both groups (*P*= 0.61). The proportion of patients experiencing no pain (score = 0) on the evening of the first postoperative day had markedly increased from surgery day: 16.4% to 35.9% for tramadol/paracetamol, 18% to 36.7% for tramadol treatment. There were no differences between treatments regarding vital signs and sedation assessment. Ten minutes after deflation of the tourniquet, the majority of patients in both groups were awake and spontaneous communication was possible (93.8% for tramadol/paracetamol, 91.4% for tramadol). In this study tramadol/paracetamol combination tablets have provided comparable analgesic efficacy with a better safety profile to tramadol capsules in patients experiencing postoperative pain following ambulatory hand surgery.

ARTICLES INSIDE

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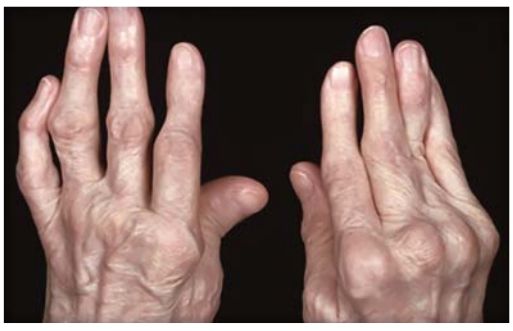
Men with Migraines have Higher Prevalence of Generalized Anxiety Disorder

Generalized anxiety disorder (GAD) is much more common among adults who have migraines than those without migraine (6% *vs*. 2%), according to a new study from researchers at the University of Toronto. This study was published in the journal *Headache*, March 2017 issue. The aims of this study were to investigate the prevalence and unadjusted and adjusted odds of 12-month GAD among adults with migraine in comparison to those without migraine. This study pinpointed a number of possible factors linking migraine and GAD. First author, professor Esme Fuller Thomson, explained, "This link between migraine and GAD in the past year was partially explained by the disturbingly high prevalence of debilitating chronic pain (30%) and problems in managing household responsibilities (28%) among those with migraine." Co-author Janany Jayanthikumar added, "we were not surprised that chronic pain played a strong role in the link between migraines and GAD. The unpredictable and uncontrollable nature of migraine pain can be extremely anxiety producing as it often interferes with family and work responsibilities with little or no warning." Interestingly, the study found that men with migraine had almost double the odds of GAD compared with women with migraine. The first subsample of this study was included those with (n=2232) and without migraine (n=19,270), and the second subsample was restricted to those with migraine (n=2232). Generalized anxiety disorder was based on the World Health Organization (WHO) Composite International Diagnostic Interview (CIDI) scale. Fully, 6% of those with migraines had past year GAD in comparison of 2.1% of those without migraine ($P<.001$). The socio-demographically adjusted odds of past year GAD were two and a half times higher among those with migraine than those without (Odd ratio= 2.46; 95% Confidence Interval= 2.00-3.02). A path analysis indicated that debilitating pain and limitations in Instrumental activities of daily living (IADLs) were mediators in the relationship between migraine and GAD. In the sample restricted to migraines, the factors associated with higher odds of 12-month GAD included having a university degree, having low income, being without a confidant, and being male. This was a surprising finding because in the general population, women are more likely than men to develop GAD. But this new study showed men are more sufferer. This may be due to the fact that men are less likely than women to take medication to treat their migraine and therefore the disorder may be more painful and less controllable, which could result in anxiety. Migraines who did not have a confidant had five times the odds of GAD compared to those with at least one person to confide in; with social support being shown to play an important protective role in the mental health consequences of other chronic pain disorders. "It is important for health professionals to be monitoring for the presence of mental health problems, including anxiety disorders, in their patients with migraine. Of particular concern are men with migraines, those who experience chronic and debilitating pain, those who are struggling to cope with their daily responsibilities and those who are socially isolated" suggested Fuller Thomson.

New Tool for Prognosis and Choice of Therapy for Rheumatoid Arthritis



Rheumatoid arthritis (RA) is an inflammatory disease where the joints become stiff and swollen, and is associated with future joint destruction. This destruction is caused by immune cells, which normally attack foreign organisms, instead react against the tissues in the joints, resulting in inflammation. In RA, antibodies are formed that affect the inflammation in the joints. In an article published in the journal *Annals of the Rheumatic Diseases*, researchers at Uppsala University show that antibodies against the cartilage protein collagen II are associated with a good prognosis. Professor Johan Rönnelid who has led the study said, "Analysing these antibodies, in combination with other relevant antibodies, could be used for predicting prognosis and choosing therapy for rheumatoid arthritis patients." In some RA patients antibodies are formed that target collagen II, an important protein in joint cartilage. These antibodies drive the inflammation early in the disease and the highest amounts of collagen antibodies have been detected at the time of diagnosis, after which the levels decrease during the first year. In the present paper researchers have followed a large group of RA patients during five years to see if there is a correlation between the collagen antibodies and disease development. First author of the study said "We found that patients with collagen antibodies showed increased signs of inflammation during the first six months after diagnosis, after this there was no difference compared to patients without any collagen antibodies. We also discovered that the presence of collagen antibodies at the time of diagnosis was associated with a better prognosis." For patients with RA it is common to examine the presence of antibodies against proteins called citrullinated peptides. In the studied patient group it was found that the presence of such antibodies showed an opposite association to inflammation as compared to collagen antibodies. The presence of antibodies against citrullinated peptides was associated with increased inflammation late in the follow-uptime and patients with these antibodies had a more severe disease course during the follow-up. "In all, our findings suggest that a combined analysis of antibodies against collagen and antibodies against citrullinated peptides could be a new tool for predicting the disease course and perhaps also for choosing therapy in newly diagnosed RA patients," said professor Johan Rönnelid.

New Arena of Pain

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Obese People have Lower Pain Threshold

An extra layer of fat won't provide a cushion against pain in fact, obese people are more sensitive to pressure pain than those who are not overweight, and they are equally susceptible to extremes of hot and cold, according to a new study. This study was carried out at Leeds Beckett University, highlights the differences in pain response between different groups of people. The aim of this study was to investigate the influence of body fat percentage and its distribution on sensory detection and pain sensitivity responses to experimentally induced noxious stimuli in otherwise pain-free individuals. The results could reinforce the argument for weight loss programmes being part of pain management plans for obese people suffering from chronic pain. This results was published in the European Journal of *Pain*. The team investigated 74 volunteers, categorised as obese, overweight or normal according to their body mass index (BMI) a standard way of measuring if a person is at a healthy weight for their height. Volunteers in each group had pressure, cold and heat applied to two different areas of the body. The first experiment tested the hand, at the base of the thumb, an area that has little body fat. The second measured responses near the waist, in an area where extra fat is stored. Volunteers were asked to report at what point the pressure, cold or heat first felt painful. Each volunteer was also asked to report their experience of cold pain by putting their hands into icy water. Again, they were asked to report the point at which they felt pain. In the obese group, volunteers reported feeling pain from pressures equivalent to around 4.3kg per square centimeter, while those in the group with normal BMI reported pain at about 8.6kg per square centimeter. Interestingly, the middle group, those classed as 'overweight', had a slightly higher pressure pain threshold than the 'normal' group, with pain being reported at 10kg per square centimeter. In terms of response to hot and cold temperatures, there was no significant difference across any of the groups, when tested at the waist. Only a small increase in sensitivity was reported in tests on the hand, suggesting that an extra layer of fat is no protection against extreme temperatures. "Obese people are more likely to experience pain from factors such as the mechanical impact of increased weight on joints than people with a normal BMI," explains Dr Osama Tashani, a senior research fellow of the study. But this study suggests that even in areas of the body which are not bearing weight, obese people are more susceptible to pressure pain. The overweight group had the highest pressure pain threshold, which might be because there were more people in this group taking part in physical activities, which could also affect how a person feels pain. The team plan to carry out further research into the factors that make people more susceptible to pain. This includes examining the chemicals secreted by fatty tissues in the body which could affect the response of pain receptors.

Proper Movements in Muslim Prayer Ritual can Reduce Lower Back Pain

Five times a day, roughly 1.6 billion Muslims worldwide, bow, kneel, and place their foreheads to the ground in the direction of the holy city of Mecca, Saudi Arabia, as part of the Islamic prayer ritual, the Salat. According to research at Binghamton University of New York, the complex physical movements of the ritual can reduce lower back pain if performed regularly and properly. This study was published in the latest issue of the *International Journal of Industrial and Systems Engineering*. Mohammad Khasawneh Author of this study said "One way to think about the movements is that they are similar to those of yoga or physical therapy intervention exercises used to treat low back pain." While the research focused specifically on Islamic prayer practices, similar movements are also found in Christian and Jewish prayer rituals along with yoga and physical therapy. Moreover, studies indicate that there is a strong association between prayer and vigilance about maintaining a physically healthy lifestyle. Author also said, "Prayer can eliminate physical stress and anxiety, while there is also research that indicates prayer rituals can be considered an effective clinical treatment of neuro-musculoskeletal dysfunction." Researchers analyzed statistics based on the movements of computergenerated digital human models of healthy Indian, Asian, and American men and women, and models with lower back pain. The group found that the bowing portion is the most stressful on the lower back, but for individuals with low back pain, using proper knee and back angles during the ritual can reduce pain. The angles are based on individual body shapes. Author added, "The maximum compression forces created during prayer postures is much lower than National Institute for Occupational Safety and Health (NIOSH) safety limits, and the movements can be safely considered a clinical treatment for low back pain, as it requires different movements of the human body on a regular basis." For those with back pain, maintaining exact prayer postures may not be possible. According to Islamic traditions and practices, if individuals cannot stand, they are allowed to pray seated or laying. If they are able to stand, they should maintain correct postures as much as they can. The kneeling posture (sujud) increases the elasticity of joints. It is recommended for these individuals to spend more time in the kneeling posture. According to the research team, using incorrect angles and movements can increase pain. The team also suggested that further study is needed for physically handicapped individuals, those with more extreme body types and women especially pregnant women to find the best movements for these groups.

Interesting Facts

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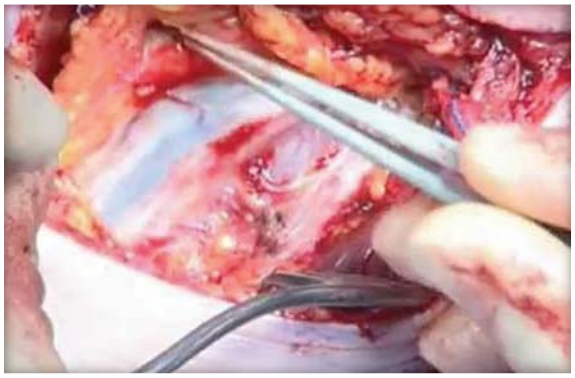
Postoperative Pain Management by Multimodal Analgesic

Pain is a subjective and multidimensional experience, which is most often ignored by health care providers. Studies have found that the prior identification of patients at risk of experiencing postoperative pain will allow early intervention and better pain management. The current practice of using postoperative analgesics with a focus on patients' demands may not be adequate. Drugs such as intravenous diclofenac, COX 2 inhibitors and opioids may not be meeting all the requirements of postsurgical patients. Adequate postoperative pain relief must be an integral part of administration of anesthesia. Untreated surgical pain may result in a decrease in alveolar ventilation and vital capacity and even pneumonic consolidation. It can cause tachycardia, hypertension, myocardial infarction, insomnia and poor wound healing, deep vein thrombosis. Importantly, postoperative pain management is included as one of the important discharge criteria in day care anesthesia. Inadequate postoperative pain relief may result in clinical and psychological changes that may increase the morbidity and mortality as well as the cost of treatment as a whole, in addition to decreasing the quality of life postoperatively. So choice of proper analgesic is very important for pain postoperative pain management. Hence the knowledge of the mechanism of both acute and long-term chronic pain has led to the concept of multimodal analgesia. The technological developments with regard to drugs and also the route of administration of these drugs have modified the way the healthcare providers were able to effectively treat and manage postsurgical pain.

Paracetamol IV is Effective for Postoperative Pain Management in Head-Neck Surgery



Effective pain control in the postoperative period is essential for optimal recovery. Adequate postsurgical pain control increases patient satisfaction, improves sleep, results in a more rapid recovery and shorter hospital stay, and lowers the risks of postoperative complications. Paracetamol; a cyclooxygenase inhibitor and a nonopioid analgesic which acts through the central nervous system and is effective for post-operative pain management.

A prospective, double-blinded, randomized controlled study was carried out to compare the efficacy of preoperative 1g intravenous (iv) paracetamol with placebo (100 mL of normal saline) in providing postoperative analgesia in head-neck cancer surgery. The aim of this randomized study was to compare the analgesic efficacy of iv fentanyl with placebo *versus* iv fentanyl plus paracetamol for postoperative pain relief after head-neck cancer surgery as well as its impact on duration of hospital stay, if any. From 2008 February to 2009 December, 80 patients for palliative head-neck cancer surgery were enrolled in the study. Patients aged 30-70 years and American Society of Anesthesiologists (ASA) physical statuses I, II, or III scheduled for head-neck cancer surgery, were included in the study. Both groups were similar in regard to age, weight, sex, ASA physical status, duration of anesthesia and surgery, and the duration of surgical intensive care unit (SICU) as well as hospital stay. Exclusion criteria included patient refusal, known allergy or hypersensitivity or contraindication to paracetamol, impaired liver function, renal dysfunction, cardiopulmonary abnormality, alcoholism, uncontrolled chronic diseases, pregnant lady or breastfeeding mother. Total 80 patients were randomly divided into (F) and (P) Group receiving iv placebo and iv paracetamol, respectively, 5 min before induction. After extubation, all patients were transferred to SICU. Postoperative pain was assessed using a visual analog scale (VAS; 0 = "no pain" and 10 = "worst pain imaginable"). Postoperative analgesia was provided routinely to all patients by intramuscular diclofenac at 8 h interval and iv fentanyl 1 µg/kg was administered as rescue analgesic when the VAS score exceeded 3. Sedation was determined according to a sedation score ranging from 0 to 2 (0 = alert, 1 = drowsy but arousable to voice, and 2 = very drowsy, but arousable to shaking). The VAS scores and sedation scores were assessed at 1, 2, 4, 6, 8, 12, and 24 h after surgery. Total and incremental fentanyl consumption at these times for both the groups was also recorded. The total use of fentanyl as rescue analgesic in SICU was significantly higher in Group F over Group P (291.5 ± 39.3 *vs.* 221.5 ± 41.41) µg, respectively and the time for the first dose of rescue analgesic in the SICU was significantly lower in Group F over Group P (85.38 ± 38.07 *vs.* 148 ± 46.7) min, respectively. However, the number of patients requiring rescue analgesic was similar in both the groups. There was significant difference in the length of stay in SICU as well as in hospital. Group P was discharged earlier from SICU (3.3 ± 2.8 *vs.* 5.3 ± 4.7) days and from hospital (17 ± 8.2 *vs.* 23 ± 12.2) days, respectively. Incidence of PONV (post operative nausea vomiting) and sedation were similar among the two groups. Sedation scores and nausea are similar among the groups. No other postoperative complications were reported from any of the groups.

The study demonstrates the effectiveness of iv paracetamol as preemptive analgesic in the postoperative pain control after head-neck cancer surgery and earlier discharge from hospital.