



PATIENT SAFETY August 2004

1: Am J Cardiol. 2004 Jul 15;94(2):193-5.

Evaluation of a high-dose dexamethasone-eluting stent.

Hoffmann R, Langenberg R, Radke P, Franke A, Blindt R, Ortlepp J, Popma JJ, Weber C, Hanrath P.

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This study evaluated the safety and efficacy of a dexamethasone-eluting stent with a special high dexamethasone-loading dose for treatment of de novo coronary lesions in 30 patients. Eight patients had in-stent restenosis (restenosis rate 31%) at 6-month follow-up, and the in-stent late lumen loss was 0.96 +/- 0.63 mm due to an average intimal hyperplasia area obstruction of 32 +/- 21%, indicating that high-dose dexamethasone-loaded stents do not significantly reduce neointimal proliferation.

PMID: 15246899 [PubMed - indexed for MEDLINE]

2: Am J Gastroenterol. 2004 Jun;99(6):1099-104.

Amantadine therapy for chronic hepatitis C: a dose escalation study.

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OBJECTIVES: Amantadine reduces liver transaminase levels in some patients with chronic hepatitis C at doses of 200 mg daily and may improve the sustained virological response (SVR) when given with interferon and ribavirin. The primary purpose of the present investigation was to study the safety and toxicity of higher doses of amantadine in subjects who previously failed or were intolerant to interferon. The secondary aim was to test the efficacy of higher dose of amantadine against hepatitis C. **METHODS:** An open-labeled prospective study was conducted starting with amantadine 200 mg daily and increasing to 500 mg daily while monitoring for safety, toxicity, and efficacy. An amantadine blood level exceeding 1,600 ng/ml was considered toxic requiring dose reduction. The patient's symptoms, laboratory tests, and quality of life were monitored.

RESULTS: One hundred patients enrolled in the study. Normalization of alanine aminotransferase (ALT) for each dose was as follows: 200 mg (35%), 300 mg (49%),

400 mg (53%), and 500 mg (56%). The incidence of toxic amantadine plasma levels increased with dose, i.e., 200 mg (0%), 300 mg (6%), 400 mg (27%), and 500 mg (49%). The frequency and severity of arthralgias and fatigue improved at all dosages administered. No changes in the occurrence or severity of headache, insomnia, or depression were reported. Serious adverse events included myocardial infarction and suicide attempt. Other side effects included

impotence, confusion, alopecia, and hoarseness. CONCLUSIONS: Amantadine given at a dose of 300 mg daily is safe, and significantly lowers ALT blood levels more than 200 mg daily. The enzyme response rate does not significantly improve above 300 mg, but toxicity increases.

PMID: 15180732 [PubMed - indexed for MEDLINE]

3: Am J Hum Genet. 2004 Jul;75(1):65-74. Epub 2004 May 20.

Long-term safety and efficacy of enzyme replacement therapy for Fabry disease.

Wilcox WR, Banikazemi M, Guffon N, Waldek S, Lee P, Linthorst GE, Desnick RJ, Germain DP; International Fabry Disease Study Group.

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Elsewhere, we reported the safety and efficacy results of a multicenter phase 3 trial of recombinant human alpha -galactosidase A (rh-alpha GalA) replacement in patients with Fabry disease. All 58 patients who were enrolled in the 20-wk phase 3 double-blind, randomized, and placebo-controlled study received subsequently 1 mg/kg of rh-alpha GalA (agalsidase beta, Fabrazyme, Genzyme Corporation) biweekly in an ongoing open-label extension study. Evidence of long-term efficacy, even in patients who developed IgG antibodies against rh-alpha GalA, included the continuously normal mean plasma globotriaosylceramide (GL-3) levels during 30 mo of the extension study and the sustained capillary endothelial GL-3 clearance in 98% (39/40) of patients who had a skin biopsy taken after treatment for 30 mo (original placebo group) or 36 mo (original enzyme-treated group). The mean serum creatinine level and estimated glomerular filtration rate also remained stable after 30-36 mo of treatment.

Infusion-associated reactions decreased over time, as did anti-rh- alpha GalA IgG antibody titers. Among seroconverted patients, after 30-36 mo of treatment, seven patients tolerized (no detectable IgG antibody), and 59% had > or =4-fold reductions in antibody titers. As of 30 mo into the extension trial, three patients were withdrawn from the study because of positive serum IgE or skin tests; however, all have been rechallenged successfully at the time of this report. Thus, enzyme replacement therapy for 30-36 mo with agalsidase beta resulted in continuously decreased plasma GL-3 levels, sustained endothelial GL-3 clearance, stable kidney function, and a favorable safety profile.

Publication Types:

Clinical Trial

Clinical Trial, Phase III

Randomized Controlled Trial

PMID: 15154115 [PubMed - indexed for MEDLINE]

4: Am J Nurs. 2004 Jul;104(7):89-93.

Perineural local anesthetic infusion.

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Publication Types:

Review

Review, Tutorial

PMID: 15243269 [PubMed - indexed for MEDLINE]

5: Ann Rheum Dis. 2004 Aug;63(8):923-30.

Comment in:

Ann Rheum Dis. 2004 Aug;63(8):897-900.

Paracetamol in osteoarthritis of the knee.

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BACKGROUND: Paracetamol is a recommended symptomatic treatment of osteoarthritis

(OA), but in clinical trials sample sizes have been relatively small and variable daily doses of paracetamol have been used. **OBJECTIVES:** To determine the therapeutic efficacy of paracetamol in OA of the knee and identify predictive factors of clinical response to treatment. **METHODS:** A double blind, parallel group, placebo controlled trial of analgesic efficacy and safety of paracetamol versus placebo including 779 patients with OA of the knee. Patients were randomly assigned to receive paracetamol 4 g/day (n = 405) or placebo (n = 374) for 6 weeks. Symptomatic OA of the knee was required at inclusion with global pain intensity of the knee during physical activities for the past 24 hours of ≥ 30 mm on a 100 mm visual analogue scale. The primary end point was a 30% decrease of global pain intensity of the knee. Intention to treat analyses were performed. **RESULTS:** The percentage of responders did not differ significantly between groups: 52.6% and 51.9% in paracetamol and placebo groups, respectively (p = 0.840). In a subgroup of patients with chronic mechanical knee pain without signs of inflammation (n = 123), the mean change in pain intensity from baseline was 25.2 mm v 15.2 mm, in the paracetamol (n = 63) and placebo (n = 60) groups, respectively-mean difference 10.0 mm; 95% CI 1.0 to 19.0; p = 0.0294. No serious adverse events were attributable to treatment. **CONCLUSION:** A statistically significant symptomatic effect of oral paracetamol 4 g/day over placebo was not found, suggesting that paracetamol use in symptomatic OA of the knee should be further explored. The tolerability and safety of paracetamol, at the recommended maximum dose of 4 g/day, was confirmed over 6 weeks.

Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

PMID: 15249319 [PubMed - indexed for MEDLINE]

6: Arch Ophthalmol. 2004 Jul;122(7):997-1001.

Treatment of epithelial ingrowth after laser in situ keratomileusis with mechanical debridement and flap suturing.

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OBJECTIVE: To evaluate the efficacy and safety of mechanical debridement and suturing of the laser in situ keratomileusis (LASIK) flap in the treatment of clinically significant epithelial ingrowth after LASIK. **METHODS:** In a retrospective study, 20 eyes (n = 19 patients) in which clinically significant epithelial ingrowth developed after LASIK were treated with lifting of the flap, scraping of the epithelial ingrowth, and flap suturing. Primary outcome measurements including recurrence of ingrowth, uncorrected visual acuity (VA), manifest refraction, best spectacle-corrected VA, and complications were evaluated at the last postoperative examination. **RESULTS:** At the last postoperative examination (mean +/- SD, 10.5 +/- 14.3 months; range, 1.5-64 months), 100% of eyes had no recurrence of clinically significant epithelial ingrowth. The uncorrected VA changed from 20/20 or better in 7 eyes (35%) and

20/40 or better in 15 eyes (75%) preoperatively to 20/20 or better in 9 eyes (45%) and 20/40 or better in 16 eyes (80%) at the last follow-up examination. There was no significant change in the mean logarithm of the minimum angle of resolution (logMAR) uncorrected VA before (mean +/- SD, 0.3 +/- 0.5; range, -0.1 to 1.7) and after surgery (mean +/- SD, 0.2 +/- 0.4; range, -0.1 to 1.7) (P =.40). Mean +/- SD spherical equivalent changed from -0.21 +/- 0.82 diopters (D) (range, -1.25 to 1.00 D) preoperatively to -0.53 +/- 0.89 D (range, -2.50 to 0.38 D) at last follow-up (P =.30). No eyes lost 2 or more lines of best spectacle-corrected VA, and there were no complications associated with the treatment. CONCLUSIONS: Suturing the LASIK flap in addition to mechanical debridement of epithelial ingrowth is a safe and effective treatment for clinically significant epithelial ingrowth after LASIK.

PMID: 15249364 [PubMed - indexed for MEDLINE]

7: Arch Ophthalmol. 2004 Jul;122(7):957-65.

A 5-year, multicenter, open-label, safety study of adjunctive latanoprost therapy for glaucoma.

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OBJECTIVE: To evaluate the 5-year safety and efficacy of adjunctive 0.005% latanoprost once daily. METHODS: Patients with primary open-angle or exfoliation glaucoma who completed a 3-year, open-label, uncontrolled, prospective trial could enter a 2-year extension phase. High-resolution color photographs of irides were taken at baseline and at 14 subsequent visits. Photographs were assessed for change in iris pigmentation compared with baseline. Intraocular pressures and adverse events were recorded. MAIN OUTCOME MEASURE:

Development

and progression of increased iris pigmentation over 5 years. RESULTS: Of the 519 original patients, 380 enrolled in the extension phase with approximately 89% having an eye color known to be susceptible to color change. After 5 years, most patients had no increase in iris pigmentation, but certain colored irides exhibited notably greater susceptibility than others. For those whose irides did change, onset occurred during the first 8 months in 74% and during the first 24 months in 94%. No patient developed an increase in pigmentation after month 36; the rate of progression decreased over time. Adverse event profiles were similar for patients with and without increased pigmentation. The overall mean intraocular pressure reduction from baseline of 25% was sustained with no need for change in intraocular pressure-lowering treatment in 70% of the eyes.

CONCLUSION: Latanoprost therapy is safe and well tolerated for long-term treatment of open-angle glaucoma.

Publication Types:

Clinical Trial

Multicenter Study

PMID: 15249358 [PubMed - indexed for MEDLINE]

8: Arch Surg. 2004 Jul;139(7):766-74.

Sequential preoperative arterial and portal venous embolizations in patients with hepatocellular carcinoma.

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HYPOTHESIS: Hepatic resection is the only curative treatment for large hepatocellular carcinoma (HCC). Sequential, preoperative, selective transcatheter arterial chemoembolization (TACE) and portal vein embolization (PVE) allow feasible and safe major hepatic resections to be performed in HCC patients with chronic liver disease. **DESIGN:** Retrospective cohort study. **SETTING:** University hospital. **PATIENTS:** Seventeen HCC patients who underwent preoperative PVE following selective TACE for planned major hepatic resections were enrolled. The indications for PVE were determined using the volumetric ratio of the future remnant liver parenchyma and the indocyanine green retention ratio at 15 minutes. **INTERVENTION:** Preoperative TACE and PVE. **MAIN OUTCOME MEASURES:** Tumor characteristics and blood test results before and after TACE and PVE, changes in the volumes of the liver segments after PVE, the feasibility of major hepatic resections, and short- and long-term patient prognoses. **RESULTS:** The liver function test results transiently worsened after TACE and PVE but returned to baseline levels within 1 (after TACE) or 2 (after PVE) weeks. Within 2 weeks after PVE, 22% +/- 4% hypertrophy of the nonembolized segments was obtained; subsequent major hepatic resections were feasible in 16 patients. Four minor complications (25%) were experienced postoperatively; however, liver failure did not occur. The 5-year overall and disease-free survival rates after curative resection were 55.6% and 46.7%, respectively. **CONCLUSIONS:** Sequential TACE and PVE contribute to both the broadening of surgical indications and the safety of major hepatic resections performed in HCC patients with damaged livers. The long-term outcome of this treatment strategy is satisfactory.

PMID: 15249411 [PubMed - indexed for MEDLINE]

9: Br J Cancer. 2004 Jul 5;91(1):45-9.

Multicenter randomized phase III trial of epirubicin plus paclitaxel vs epirubicin followed by paclitaxel in metastatic breast cancer patients: focus on cardiac safety.

Baldini E, Prochilo T, Salvadori B, Bolognesi A, Aldrighetti D, Venturini M, Rosso R, Carnino F, Gallo L, Giannessi P, Conte PF, Orlandini C, Bruzzi P. Medical Oncology Department, S. Chiara University-Hospital, Via Roma 67, 56132 Pisa, Italy. e.baldini@do.med.unipi.it

The aim of the study was to evaluate cardiac safety of two different schedules of Epirubicin and Paclitaxel in advanced breast cancer patients enrolled into a multicenter randomized phase III trial. Patients received Epirubicin 90 mg m⁻² plus Paclitaxel 200 mg m⁻² (3-h infusion) on day 1 every 3 weeks for eight courses (arm A), or Epirubicin 120 mg m⁻² on day 1 every 3 weeks for four courses followed by four courses of Paclitaxel 250 mg m⁻² on day 1 every 3 weeks (arm B). Left ventricular ejection fraction was evaluated by bidimensional echocardiography at baseline, after four and eight courses of chemotherapy and every 4 months during follow-up. Baseline median left ventricular ejection fraction was 60% in arm A and 65% in arm B; after four courses, figures were 57 and 60%, respectively. After eight courses, the median left ventricular ejection fraction in arm A declined to 50% while no further reduction was detected in arm B by adding four courses of high-dose Paclitaxel. Seven episodes of congestive heart failure were observed during treatment in arm A. Present monitoring demonstrated that the risk of congestive heart failure or impairment in the cardiac function correlated only with the cumulative dose of Epirubicin; no impact on cardiotoxicity can be attributed to high-dose Paclitaxel.

Publication Types:

Clinical Trial
Clinical Trial, Phase III
Multicenter Study
Randomized Controlled Trial

PMID: 15173858 [PubMed - indexed for MEDLINE]

10: Br JOphthalmol. 2004 Jul;88(7):877-83.

A comparison of the fixed combination of latanoprost and timolol with the unfixed combination of brimonidine and timolol in patients with elevated intraocular pressure. A six month, evaluator masked, multicentre study in Europe.

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PURPOSE: To compare the intraocular pressure (IOP) reducing effect and safety of fixed combination (FC) latanoprost/timolol with unfixed combination (UFC) brimonidine/timolol in patients with increased IOP. **METHODS:** In this 6 month, randomised, evaluator masked, parallel group European study, patients with glaucoma or ocular hypertension and IOP > or =21 mm Hg on monotherapy or >16 mm

Hg on dual therapy received either FC latanoprost/timolol at 8:00AM or UFC brimonidine/timolol at 8:00AM and 8:00PM. The primary outcome was the difference from baseline to month 6 in mean diurnal IOP reduction. **RESULTS:** 325 of 334 randomised patients were included in intent to treat analyses (FC latanoprost/timolol, 163; UFC brimonidine/timolol, 162). Baseline diurnal IOP levels were similar: FC latanoprost/timolol, 26.4 (SD 2.7) mm Hg; UFC brimonidine/timolol, 26.5 (SD 2.8) mm Hg ($p = 0.851$). At month 6, levels were 16.9 (SD 2.8) mm Hg in FC latanoprost/timolol patients and 18.2 (SD 3.1) mm Hg in UFC brimonidine/timolol patients ($p < 0.001$). No adverse events were reported by 76.4% and 75.5% of patients receiving FC latanoprost/timolol versus UFC brimonidine/timolol, respectively. Larger proportions of brimonidine/timolol treated patients reported study medication related adverse events (18.6% v 7.3%) and discontinued study participation because of this (10.8% v 1.8%). **CONCLUSION:** Fixed combination latanoprost/timolol administered once daily is both more effective and better tolerated than twice daily dosing with UFC brimonidine/timolol.

Publication Types:

Clinical Trial
Multicenter Study
Randomized Controlled Trial

PMID: 15205229 [PubMed - indexed for MEDLINE]

11: Br J Surg. 2004 Jul;91(7):842-7.

Randomized clinical trial of low molecular weight heparin with thigh-length or knee-length antiembolism stockings for patients undergoing surgery.

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BACKGROUND: This was a randomized clinical trial to determine the efficacy and safety of a 'blanket' protocol of low molecular weight heparin (LMWH) and the best length of antiembolism stocking, for every patient requiring surgery under general anaesthesia. **METHODS:** Of 426 patients interviewed, 376 agreed to be randomized to receive one of three types of stocking: thigh-length Medi thrombexin climax (Medi UK, Hereford, UK), knee-length thrombexin climax and thigh-length Kendall T.E.D. (Tyco Healthcare UK, Redruth, UK). All patients received LMWH thromboprophylaxis. Duplex ultrasonography was used to assess the incidence of postoperative deep vein thrombosis (DVT). **RESULTS:** No postoperative DVT occurred in 85 patients at low or moderate risk. Nineteen DVTs occurred, all in the 291 high-risk patients: two with the Medi thigh-length stockings, 11 with the Medi knee-length stockings (odds ratio 0.18 (95 per cent confidence interval 0.04 to 0.82); $P = 0.026$) and six with the Kendall T.E.D. thigh-length place of work, where blinding injuries most often occur.

PMID: 15185423 [PubMed - indexed for MEDLINE]

12: Drug Saf. 2004;27(6):393-410.

Prevention of anaphylactic reactions to anaesthetic drugs.

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Although screening tests to prevent anaphylaxis during anaesthesia have been advocated, such tests are unlikely to have significant impact on reducing the incidence of anaphylaxis during anaesthesia. This is due to the low prevalence of the disease, the diversity of drugs used in anaesthesia and the incidence of false positive and negative tests. The suggested risk factors of allergy, i.e. atopy, asthma, family history, female sex, previous exposure, vasectomy, use of zinc protamine sulfate insulin and allergy to cosmetics, eggs, fish and non-anaesthetic drugs are not valid. Although all have theoretical or real associations with anaphylaxis during anaesthesia the majority of patients with such a history undergo uneventful anaesthesia. Fruit allergy, anaphylaxis to cephalosporins and penicillin, barbiturate allergy, gelatin allergy and allergy to metabisulphite and eggs require consideration in avoiding particular drugs. The incidence of anaesthetic anaphylaxis can be reduced by avoiding latex exposure in patients with spina bifida or latex allergy, and preventing second reactions in patients with a history of anaphylaxis, or major undiagnosed or undocumented adverse events during anaesthesia. Determining the cause of an adverse event and the drug responsible, and adequately communicating those findings can reduce second reactions. Avoiding neuromuscular blocking drugs (NMBDs) in patients who have reacted to an NMBD, and use of non-intravenous techniques should also reduce the incidence of second reactions. Desensitisation, and blocking with monovalent quaternary ammonium compounds may allow improved safety of NMBDs and pretreatment with antihistamines and corticosteroids may block or ameliorate the severity of reactions, but there is currently little evidence to support their routine use.

Publication Types:

Review

Review, Tutorial

PMID: 15144233 [PubMed - indexed for MEDLINE]

13: Exp Neurol. 2004 Aug;188(2):491-4.

Pilot trial of high dosages of coenzyme Q10 in patients with Parkinson's disease.

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The safety and tolerability of high dosages of coenzyme Q10 were studied in 17 patients with Parkinson's disease (PD) in an open label study. The subjects received an escalating dosage of coenzyme Q10--1200, 1800, 2400, and 3000 mg/day

with a stable dosage of vitamin E (alpha-tocopherol) 1200 IU/day. The plasma level of coenzyme Q10 was measured at each dosage. Thirteen of the subjects achieved the maximal dosage, and adverse events were typically considered to be unrelated to coenzyme Q10. The plasma level reached a plateau at the 2400 mg/day dosage and did not increase further at the 3000 mg/day dosage. Our data suggest that in future studies of coenzyme Q10 in PD, a dosage of 2400 mg/day (with vitamin E/alpha-tocopherol 1200 IU/day) is an appropriate highest dosage to be studied.

Publication Types:

Clinical Trial

Clinical Trial, Phase II

PMID: 15246848 [PubMed - indexed for MEDLINE]

14: Gastroenterol Clin North Am. 2004 Jun;33(2):407-20, xi.

Methotrexate in inflammatory bowel disease.

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Over the past decade methotrexate has emerged as a new treatment for chronically active Crohn's disease. Although controlled trials to compare the relative efficacy and safety of azathioprine and methotrexate in therapy-resistant patients are desirable, these studies will be difficult, if not impossible, to conduct because of the relatively small differences in potency and tolerability between these agents. A more productive area for future investigations is to explore the use of these drugs in combination with infliximab and other biologic treatments.

Publication Types:

Review

Review, Tutorial

PMID: 15177546 [PubMed - indexed for MEDLINE]

15: Health Care Manage Rev. 2004 Apr-Jun;29(2):90-7.

Factors that impact the transfer and retention of best practices for reducing error in hospitals.

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Recent research and theory in organizational learning literature advances seven propositions that illuminate the nature and complexities of transferring and retaining best practices for reducing error and increasing patient safety in U.S. and Canadian hospitals.

Publication Types:

Review
Review, Tutorial

PMID: 15192981 [PubMed - indexed for MEDLINE]

16: Healthc Inform. 2004 Jun;21(6):80.

Point-of-care protection. Hospitals move to enhance patient safety in common but high-vulnerability situations.

17: Healthc Q. 2004;7(3):76-80.

Lessons to be learned from England about the potential of GP computer systems to improve patient safety.

Protti D.

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PMID: 15230172 [PubMed - indexed for MEDLINE]

18: Hepatology. 2004 Jul;40(1):6-9.

Comment in:

Hepatology. 2004 Jul;40(1):23-6.

Acetaminophen and the U.S. Acute Liver Failure Study Group: lowering the risks of hepatic failure.

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Acetaminophen overdose is the leading cause for calls to Poison Control Centers (>100,000/year) and accounts for more than 56,000 emergency room visits, 2,600 hospitalizations, and an estimated 458 deaths due to acute liver failure each year. Data from the U.S. Acute Liver Failure Study Group registry of more than 700 patients with acute liver failure across the United States implicates acetaminophen poisoning in nearly 50% of all acute liver failure in this country. Available in many single or combination products, acetaminophen produces more than 1 billion US dollars in annual sales for Tylenol products alone. It is heavily marketed for its safety compared to nonsteroidal analgesics. By enabling self-diagnosis and treatment of minor aches and pains, its benefits are said by the Food and Drug Administration to outweigh its risks. It still must be asked: Is this amount of injury and death really acceptable for an over-the-counter pain reliever?

Publication Types:

Review

Review, Tutorial

PMID: 15239078 [PubMed - indexed for MEDLINE]

19: Hosp Case Manag. 2004 Jul;12(7):suppl 1-2.

Patient safety alert. Finding root causes without blame helps eliminate errors.

[No authors listed]

PMID: 15211766 [PubMed - indexed for MEDLINE]

20: Hosp Case Manag. 2004 Jul;12(7):97-8, 100-1.
Clinical practice guidelines improve patient care at Connecticut hospital.
[No authors listed]

PMID: 15211758 [PubMed - indexed for MEDLINE]

21: Int J Cancer. 2004 Aug 10;111(1):138-46.
mTHPC-mediated photodynamic therapy for early oral squamous cell carcinoma.
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Surgery and radiotherapy are standard treatments for early oral squamous cell carcinoma, both resulting in good tumour control. However, neither of these modalities is without consequent functional or cosmetic impairment, and there are patients in whom both are contraindicated. Furthermore, there is a significant risk of metachronous tumours developing in the oral cavity, and salvage or retreatment with either surgery or radiotherapy poses difficulties. Photodynamic therapy (PDT) offers the potential for improved functional and cosmetic outcomes, while achieving comparable tumour control. We conducted an open-label, multicentre study to assess the efficacy and safety of meta-tetrahydroxyphenylchlorin (mTHPC) in patients with early oral cancer. One hundred twenty-one patients received intravenously administered mTHPC, followed 96 hr later by illumination of the tumour surface with 652 nm laser light. Of these patients, 114 were protocol compliant. A complete tumour response was achieved in 85% of protocol-compliant patients (97 of 114 patients). A complete response was maintained in 85% of responders at 1 year and in 77% at 2 years. One- and 2-year actuarial survival rates were 89% and 75%, respectively. In the opinion of the investigators, tumour clearance was accompanied by excellent cosmetic and functional results, without impact on the patients' performance status. Mild-to-moderate pain at the treatment site, a recognised side effect of PDT in the oral cavity, was reported by 82% of patients but was manageable with appropriate analgesia. Mild-to-moderate skin photosensitivity reactions were reported for 13% of patients. mTHPC offers an effective alternative treatment for early oral squamous cell carcinoma. It is associated with excellent functional and cosmetic results and can be used in conjunction with other standard therapies. Copyright 2004 Wiley-Liss, Inc.

Publication Types:

- Clinical Trial
- Clinical Trial, Phase II
- Multicenter Study

PMID: 15185355 [PubMed - indexed for MEDLINE]

22: J Am Coll Surg. 2004 Jul;199(1):39-47; discussion 47-50.
Patient safety: effect of institutional protocols on adverse events related to feeding tube placement in the critically ill.
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BACKGROUND: Inadvertent passage of a nasogastric feeding tube into the tracheobronchial tree can result in pneumothorax. Measures requiring feeding tube passage to 35 cm only followed by a radiograph to verify intraesophageal

placement and creation of a specialized placement team were implemented to decrease the incidence of procedure-related pneumothorax. This study evaluates the effectiveness of our safety measures. STUDY DESIGN: Radiology reports from January 2000 through July 2003 were searched by computer with an algorithm designed to detect feeding tube placements possibly associated with the complication of intrabronchial placement or pneumothorax. Results were manually examined to eliminate false positives and verify causality. RESULTS: Feeding tubes were placed in 4,190 unique patients during the study period; 87 patients had an intrabronchial malposition, and 9 experienced a pneumothorax caused by their feeding tube. The safety measures resulted in a significant decrease in procedure-related pneumothorax (0.09% versus 0.38%, $p < 0.05$), and a decrease in pneumothorax among patients with an intrabronchial placement (3% versus 27%, $p < 0.05$). More than two-thirds of patients with a misplaced tube had an endotracheal tube or tracheostomy, illustrating that such patients are not protected. Repeated malposition in the same patient was surprisingly common; 32% of patients with one intrabronchial misplacement ultimately had multiple misplacements. The risk of pneumothorax increased with misplacement at night ($p < 0.05$) and increased exponentially with each additional misplacement ($p < 0.05$). CONCLUSIONS: Creating a specialized placement team, and initiating the safety measure of limiting feeding tube placement to 35 cm and obtaining a radiograph before full advancement reduced the incidence of procedure-related pneumothorax.

PMID: 15217627 [PubMed - indexed for MEDLINE]

23: J Am Coll Surg. 2004 Jul; 199(1):8-20; discussion 20-2.

A prospective, longitudinal study of nonconventional stricturoplasty in Crohn's disease.

Sampietro GM, Cristaldi M, Maconi G, Parente F, Sartani A, Ardizzone S, Danelli P, Porro GB, Taschieri AM.

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BACKGROUND: Bowel-sparing techniques have been proposed to avoid extended or repeated resections in patients with Crohn's disease (CD), but without precise indications, prospective evaluation, and with a technically limited repertoire. STUDY DESIGN: A prospective longitudinal study of new nonconventional stricturoplasties (NCSP) in order to evaluate the safety, type and site of recurrence, and longterm clinical and surgical efficacy. RESULTS: Between January 1993 and December 2002, 102 among 305 consecutive patients underwent at least one NCSP for complicated CD. Patients were treated following precise indications and then included in a prospective database with scheduled followup. Factors claimed to influence postoperative and longterm outcomes and type and site of recurrence were analyzed. We performed 48 ileoileal side-to-side isoperistaltic stricturoplasty (SP), 41 widening ileocolic SP, 32 ileocolic side-to-side isoperistaltic SP, associated with Heineke-Mikulicz SP (in 80 procedures) or with minimal bowel resections or both (in 47 procedures). Postoperative mortality was nil; complication rate was 5.7%. Ten years clinical and surgical recurrence rates were 43% and 27%, respectively. Recurrence rate on an NCSP site was 0.8%. No specific factor was identified as related to postoperative or longterm outcomes. CONCLUSIONS: Perioperative and longterm results of NCSP are comparable to or even better than both conservative and resective surgery as reported in the literature, with a low recurrence rate on

the NCSP site. Considering the unpredictability of the clinical course of CD and the lifetime need for surgical procedures, NCSP, together with minimal resection and classic SP repertoire, should be considered first-line treatment in complicated CD.

PMID: 15217622 [PubMed - indexed for MEDLINE]

24: J Intern Med. 2004 Jul;256(1):63-9.

An open, randomized, controlled study of transdermal hormone replacement therapy on the rate of bone loss in primary biliary cirrhosis.

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OBJECTIVES: The prevalence of osteoporosis amongst patients with primary biliary cirrhosis (PBC) is high and may be a serious clinical problem. Hormone replacement therapy (HRT) is effective in preventing bone loss but has not been evaluated in randomized trials in PBC. The primary aim was to study the effect of transdermal HRT in combination with daily vitamin D and calcium supplementation on bone loss compared with vitamin D and calcium supplementation only in postmenopausal women with PBC. The secondary aim was to study the safety of transdermal HRT. **SUBJECTS/INTERVENTIONS:** Eighteen females with PBC were randomized to receive 2 years therapy with either (i) transdermal oestradiol 50 microg 24 h(-1) two times per week + medroxyprogesterone 2.5 mg day(-1) + alfacalcidol 0.25 microg day(-1) and calcium 1 g day(-1) or (ii) alfacalcidol 0.25 microg day(-1) and calcium 1 g day(-1). Dual-energy X-ray absorptiometry for measurement of bone mineral density (BMD) and sampling of blood and serum for measurements of biochemical markers of liver function was performed before, during and at the end of treatment. **RESULTS:** BMD increased significantly at the lumbar spine ($P < 0.05$) and the femoral neck ($P < 0.05$) in the HRT group whereas no significant change was found in the control group. One oestrogen-treated patient was excluded after 1 year because of deteriorating, but reversible, aminotransferases. Dropout frequency because of nonliver-related causes was higher in the HRT group. Otherwise, no difference with respect to adverse liver reactions was found between the groups. **CONCLUSION:** Transdermal HRT increases BMD in PBC patients with few severe side effects related to the liver.

Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

PMID: 15189367 [PubMed - indexed for MEDLINE]

25: J Oral Maxillofac Surg. 2004 Jul;62(7):806-15.

Analgesic safety and efficacy of diclofenac sodium softgels on postoperative third molar extraction pain.

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PURPOSE: The purpose of this single-blind, placebo-controlled, 3-arm parallel, randomized study was to compare the analgesic efficacy and tolerability of a single dose of 100 mg diclofenac potassium (Cataflam; Novartis, Stein, Switzerland), 100 mg diclofenac sodium softgel, and placebo in patients

experiencing moderate to severe postoperative pain after third molar extraction. PATIENTS AND METHODS: Seventy-five patients (67% female with a mean age of 23, age range 18 to 34.5 years) participated in the study following removal of at least 1 impacted mandibular third molar. Patients received a single dose of study medication when their postoperative pain reached a moderate or severe intensity. Analgesic efficacy measures included the time to meaningful pain relief measured using a stopwatch and time to rescue medication. Pain relief (PR) and Pain intensity (PI) ratings were recorded at 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, and 24 hours postdosing. Summary analgesic measures, including Summed Pain Relief Score (TOTPAR) and Summed Pain Intensity Differences (SPID), were calculated from the 0.25- to 6-hour responses. The time between pain relief and rescue and a global evaluation for the effectiveness of the study medications were recorded at the end of the study. Seven scheduled blood samples were collected from each patient for determining plasma concentrations of diclofenac anion. RESULTS: Both diclofenac sodium softgel and Cataflam were significantly more effective than placebo ($P < .0001$) for all summary analgesic measures. The average overall pain relief was substantially better from diclofenac sodium softgel than from Cataflam, but the difference was not statistically significant ($P = .14$). In patients taking diclofenac sodium softgel, 50% of the patients experienced a time to onset of analgesic activity within 18 minutes and the median analgesic duration was 5 hours (302 minutes). Fifty percent of the patients taking Cataflam had a time to onset of action within 38 minutes, and the median duration of analgesia was 4.5 hours (272 minutes). At the time of rescue drug administration or 6 hours, whichever was earlier, 72% of the patients given diclofenac sodium softgel rated the medication as a very good or excellent pain reliever, whereas only 45% of the patients taking Cataflam gave these ratings. No serious adverse events were observed in this study. The mean concentrations of diclofenac from the diclofenac sodium softgel formulation were significantly different from the Cataflam formulation. The mean C(max) for the softgel was almost twice that of Cataflam and C(max) was reached an hour earlier, on average. CONCLUSIONS: More diclofenac anion was absorbed at a quicker rate using the formulation diclofenac sodium softgel 100 mg than Cataflam. The softgel provided a very rapid onset of analgesic activity, a prolonged analgesic duration, and an acceptable side-effect profile in the postoperative third molar surgery pain model. In an acute pain situation, the rapid absorption of nonsteroidal anti-inflammatory drugs from a formulation like the Softgel may positively affect the time of onset and duration of inflammatory pain compared with other commercially available nonsteroidal anti-inflammatory drug formulations.

Publication Types:

Clinical Trial
Randomized Controlled Trial

PMID: 15218558 [PubMed - indexed for MEDLINE]

26: J Urol. 2004 Aug; 172(2): 533-6.

A prospective, randomized, placebo controlled, double-blind study of amitriptyline for the treatment of interstitial cystitis.

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PURPOSE: We conducted a prospective study to examine the safety and efficacy of the tricyclic antidepressant amitriptyline in patients with interstitial

cystitis (IC). MATERIALS AND METHODS: The study comprised 44 women and 6 men who

all met the symptom criteria of the National Institute of Diabetes, Digestive and Kidney Diseases for IC. The patients were randomly assigned to amitriptyline or placebo. Patients were prospectively treated for 4 months with a self-titration protocol that allowed them to escalate drug dosage in 25 mg increments in 1 week-intervals (maximum dosage 100 mg). The change from baseline

in the O'Leary-Sant IC symptom and problem index was the primary outcome parameter. Changes in functional bladder capacity and frequency (48-hour voiding log), and intensity of pain and urgency (visual analog scales) were chosen as secondary outcome parameters. RESULTS: Two patients (1 on amitriptyline, 1 on placebo) dropped out of the study due to side effects. Thus, the data of 48 patients (24 patients in each group) were available for evaluation. Mean symptom score decreased from 26.9 to 18.5 in the amitriptyline group compared with 27.6 to 24.1 in the placebo group ($p = 0.005$). Pain and urgency intensity improved statistically significantly in the amitriptyline group compared with the placebo group ($p < 0.001$). The frequency and functional bladder capacity improved to a much greater degree in the amitriptyline group but the differences were not statistically significant ($p = 0.063$, $p = 0.083$). Anticholinergic side effects were reported by all except 2 patients in the amitriptyline group (92%) and by 5 patients in the placebo group (21%). Mouth dryness was the most frequent side effect reported in the amitriptyline group (79%). CONCLUSIONS: Amitriptyline therapy for 4 months is safe and effective for treating IC. A statistically significant change in the symptom score and statistically significant improvement of pain and urgency intensity compared with placebo were observed. Anticholinergic side effects constitute the major drawback of amitriptyline treatment for IC.

Publication Types:

Clinical Trial

Randomized Controlled Trial

PMID: 15247722 [PubMed - indexed for MEDLINE]

27: J Urol. 2004 Jul;172(1):240-3.

Intravesical resiniferatoxin versus botulinum-A toxin injections for neurogenic detrusor overactivity: a prospective randomized study.

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PURPOSE: We investigated the effectiveness and safety of intravesical resiniferatoxin (Sigma Chemical Co., St. Louis, Missouri) and botulinum-A toxin injections into the detrusor muscle in a group of spinal cord injured patients with neurogenic detrusor overactivity unresponsive to conventional anticholinergic therapy. MATERIALS AND METHODS: A total of 25 patients were randomly assigned to receive intravesically 0.6 microM resiniferatoxin in 50 ml of 0.9% NaCl or injections into the detrusor muscle of 300 units botulinum A-toxin diluted in 30 ml 0.9% NaCl. Clinical evaluation and urodynamics were performed at baseline, and at 6, 12 and 18 months after treatment. RESULTS: In both arms there was a significant decrease in catheterization and incontinent episodes, and a significant increase in first detrusor contraction and maximum bladder capacity at 6, 12 and 18-month followup. There were no local side effects with either treatment. Botulinum-A toxin induced a significant decrease in the frequency of daily incontinence episodes ($p < 0.05$), a significant increase in first uninhibited detrusor contraction ($p < 0.01$) in maximum bladder capacity ($p < 0.01$), and a significant decrease in maximum pressure of

uninhibited detrusor contractions ($p < 0.01$) compared to resiniferatoxin at 6, 12 and 18-month followup. CONCLUSIONS: In spinal cord injured patients with refractory neurogenic detrusor overactivity, intravesical resiniferatoxin and botulinum-A toxin injections into the detrusor muscle provided beneficial clinical and urodynamic results with decreases in detrusor overactivity and restoration of urinary continence in a large proportion of patients. Botulinum-A toxin injections provided superior clinical and urodynamic benefits compared to those of intravesical resiniferatoxin.

Publication Types:

Clinical Trial
Randomized Controlled Trial

PMID: 15201783 [PubMed - indexed for MEDLINE]

28: J Vasc Surg. 2004 Jul;40(1):204; author reply 204.

Comment on:

J Vasc Surg. 2003 Aug;38(2):313-8.

Regarding "Safety of gadolinium contrast angiography in patients with chronic renal insufficiency".

Nyman U, Golman K.

Publication Types:

Comment
Letter

PMID: 15218489 [PubMed - indexed for MEDLINE]

29: JAMA. 2004 Jul 14;292(2):191-201.

Comment in:

JAMA. 2004 Jul 14;292(2):266-8.

Efficacy and safety of tenofovir DF vs stavudine in combination therapy in antiretroviral-naive patients: a 3-year randomized trial.

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CONTEXT: Tenofovir disoproxil fumarate (DF) is a once-daily nucleotide analogue reverse transcriptase inhibitor. OBJECTIVE: To evaluate the efficacy and safety of tenofovir DF compared with stavudine in antiretroviral-naive patients.

DESIGN, SETTING, AND PARTICIPANTS: A prospective, randomized, double-blind study

conducted at 81 centers in the United States, South America, and Europe from June 9, 2000, to January 30, 2004. A total of 753 patients infected with HIV who were antiretroviral naive were screened and 602 patients entered the study.

INTERVENTION: Patients were randomized to receive either tenofovir DF ($n = 299$) or stavudine ($n = 303$), with placebo, in combination with lamivudine and efavirenz.

MAIN OUTCOME MEASURE: Proportion of patients with HIV RNA levels of less than 400 copies/mL at week 48. RESULTS: In the primary intent-to-treat analysis in which patients with missing data or who added or switched

antiretroviral medications before week 48 were considered as failures, the proportion of patients with HIV RNA of less than 400 copies/mL at week 48 was 239 (80%) of 299 in patients receiving tenofovir DF and 253 (84%) of 301 in

patients receiving stavudine (95% confidence interval, -10.4% to 1.5%), exceeding the predefined -10% limit for equivalence. However, equivalence was

demonstrated in the secondary analyses (HIV RNA <50 copies/mL) at week 48 and through 144 weeks. Virologic failure was associated most frequently with efavirenz and lamivudine resistance. Through 144 weeks, the K65R mutation emerged in 8 and 2 patients in the tenofovir DF and stavudine groups, respectively (P = .06). A more favorable mean change from baseline in fasting lipid profile was noted in the tenofovir DF group at week 144: for triglyceride levels (+1 mg/dL for tenofovir DF [n = 170] vs +134 mg/dL for stavudine [n = 162], P<.001), total cholesterol (+30 mg/dL [n = 170] vs +58 mg/dL [n = 162], P<.001), direct low-density lipoprotein cholesterol (+14 mg/dL [n = 169] vs +26 mg/dL [n = 161], P<.001), and high-density lipoprotein cholesterol (+9 mg/dL [n = 168] vs +6 mg/dL [n = 154], P = .003). Investigator-reported lipodystrophy was less common in the tenofovir DF group compared with the stavudine group (9 [3%] of 299 vs 58 [19%] of 301, P<.001). The number of bone fractures and the renal safety profile were similar between the 2 groups. CONCLUSIONS: Through 144 weeks, the combination of tenofovir DF, lamivudine, and efavirenz was highly effective and comparable with stavudine, lamivudine, and efavirenz in antiretroviral-naive patients. However, tenofovir DF appeared to be associated with better lipid profiles and less lipodystrophy.

Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

PMID: 15249568 [PubMed - indexed for MEDLINE]

30: JAMA. 2004 Jul 14;292(2):180-9.

Comment in:

JAMA. 2004 Jul 14;292(2):266-8.

Efficacy and safety of emtricitabine vs stavudine in combination therapy in antiretroviral-naive patients: a randomized trial.

Saag MS, Cahn P, Raffi F, Wolff M, Pearce D, Molina JM, Powderly W, Shaw AL, Mondou E, Hinkle J, Borroto-Esoda K, Quinn JB, Barry DW, Rousseau F; FTC-301A Study Team.

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CONTEXT: Emtricitabine is a new, once-daily nucleoside reverse transcriptase inhibitor (NRTI) with potent activity against human immunodeficiency virus (HIV). OBJECTIVE: To assess the efficacy and safety of emtricitabine as compared with stavudine when used with a background regimen of didanosine and efavirenz. DESIGN, SETTING, AND PATIENTS: Randomized, double-blind, double-dummy study conducted at 101 research clinics in North America, Latin America, and Europe. The first patient was enrolled on August 21, 2000; no investigator or patient was unblinded until the last patient randomized completed the week 48 visit on October 24, 2002. Analyses were based on data collected in a double-blind setting with a median follow-up of 60 weeks. Patients were 571 antiretroviral-naive, HIV-1-infected adults aged 18 years or older with viral load levels greater than or equal to 5000 copies/mL. INTERVENTIONS: Receipt of either 200 mg of emtricitabine once daily (plus stavudine placebo twice daily) (n = 286) or stavudine at standard doses twice daily (plus emtricitabine placebo once daily) (n = 285) plus open-label didanosine and efavirenz, once daily. MAIN OUTCOME MEASURE: Persistent virological response, defined as achieving and maintaining viral load at or below the limit of assay quantification (< or =400 or 50 copies/mL). RESULTS: At the interim analysis on June 14, 2002, when the last patient randomized completed 24 weeks of double-blind treatment (median follow-up time of 42 weeks), patients in the emtricitabine group had a higher probability of a persistent virological response < or =50 copies/mL vs the

stavudine group (85% vs 76%, $P = .005$). This was associated with a higher mean CD4 cell count change from baseline for the emtricitabine group (156 cells/microL vs 119 cells/microL, $P = .01$ [of note, there was no statistical difference at 48 weeks [$P = .15$], although a sensitivity analysis, using an intent-to-treat population with the last CD4 cell count observation carried forward to week 48 showed a difference [$P = .02$]]). The independent data and safety monitoring board recommended offering open-label emtricitabine based on the interim analysis. The probability of persistent virological response $< \text{or } = 50$ copies/mL through week 60 was 76% for the emtricitabine group vs 54% for the stavudine group ($P < .001$). The probability of virological failure through week 60 was 4% in the emtricitabine group and 12% in the stavudine group ($P < .001$). Patients in the stavudine group had a greater probability of an adverse event that led to study drug discontinuation through week 60 than did those in the emtricitabine group (15% vs 7%, $P = .005$). CONCLUSION: Once-daily emtricitabine appeared to demonstrate greater virological efficacy, durability of response, and tolerability compared with twice-daily stavudine when used with once-daily didanosine and efavirenz.

Publication Types:

- Clinical Trial
- Multicenter Study
- Randomized Controlled Trial

PMID: 15249567 [PubMed - indexed for MEDLINE]

31: Lancet. 2004 Jul 10;364(9429):183-92.

Stem cells and repair of the heart.

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Stem-cell therapy provides the prospect of an exciting and powerful treatment to repair the heart. Although research has been undertaken in animals to analyse the safety and efficacy of this new approach, results have been inconclusive. The mechanism by which stem cells could improve cardiac function remains unclear. We describe the background to the concept of natural repair and the work that has been done to establish the role of stem cells in cardiac repair. Controversies have arisen in interpretation of experimental data. The important issues surrounding the application of stem-cell therapy to man are discussed critically. We discuss the future of this pioneering work in the setting of growing concerns about clinical studies in man without understanding the biological mechanisms involved, with the difficulties in funding this type of research.

Publication Types:

- Review
- Review, Tutorial

PMID: 15246732 [PubMed - indexed for MEDLINE]

197: Nurs Manage. 2004 Jun;35(6):25-31; quiz 31-2.

Sharps injury prevention: select a safer needle.

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Explore the clinical benefits of passive safety needles, including reduced exposure risk, ease of use, and minimal training requirements.

Publication Types:

Review

Review, Tutorial

PMID: 15184743 [PubMed - indexed for MEDLINE]

198: Nurs Stand. 2004 Jun 9-15;18(39):33-8.

Assessing the safety and effectiveness of hip protectors.

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Hip protectors are used in the preventive management of older people who are at risk of fracturing their hip after a fall. However, nurses have little guidance about which type is the most appropriate for particular patients. This article highlights the different designs available and their mechanical performance was assessed by the authors using a purpose-built impact rig. Problems with compliance and issues about tissue viability are discussed and the article also contains a risk assessment tool to help nurses decide on which is the most suitable type of hip protector to use.

Publication Types:

Review

Review, Tutorial

PMID: 15214118 [PubMed - indexed for MEDLINE]

