



PATIENT SAFETY June 2004

1: Am J Cardiol. 2004 May 1;93(9):1086-91.

Usefulness and safety of percutaneous myocardial laser revascularization for refractory angina pectoris.

Salem M, Rotevatn S, Stavnes S, Brekke M, Vollset SE, Nordrehaug JE.

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This prospective, double-blind, randomized, sham-controlled trial was designed to control for patient and investigator bias in assessing symptomatic improvement after percutaneous myocardial laser revascularization (PMLR) therapy. Eighty-two patients with stable angina pectoris (class III or IV) not amenable to conventional revascularization and with evidence of reversible ischemia, ejection fraction $\geq 25\%$, and myocardial wall thickness ≥ 8 mm were randomized to either PMLR with optimal medical therapy (n = 40) or to a sham procedure with optimal medical therapy (n = 42). With the exception of 1 laser technician, all patients, investigators, and assessors were blinded to treatment through the 12-month follow-up. The primary end point was restricted to Canadian Cardiovascular Society angina class improvement to limit the number of patients exposed to a sham procedure. Secondary assessments included medication usage, quality of life, exercise testing, ejection fraction, and hospitalizations. The incidence of serious adverse events, as determined by cardiac event-free survival at 12 months, was similar between groups. At 12 months, Canadian Cardiovascular Society angina scores improved by ≥ 2 classes in significantly more PMLR-treated patients than sham control patients (35% vs 14%, p = 0.04). Angina-specific quality-of-life measures were significantly higher in the PMLR group at each follow-up (p < 0.05). Exercise and medication usage was similar between groups at 12 months. We conclude that PMLR therapy is reasonably safe and effective as symptomatic improvement in patients refractory to medical therapy, and that the clinical benefit is not attributable to placebo effect or investigator bias.

Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

PMID: 15110197 [PubMed - indexed for MEDLINE]

2: Am J Med. 2004 May 15;116(10):693-706.

Comment in:

Am J Med. 2004 May 15;116(10):714-6.

Exercise training for patients with heart failure: a systematic review of factors that improve mortality and morbidity.

Smart N, Marwick TH.

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PURPOSE: To determine the efficacy of exercise training and its effects on outcomes in patients with heart failure. **METHODS:** MEDLINE, Medscape, and the Cochrane Controlled Trials Registry were searched for trials of exercise training in heart failure patients. Data relating to training protocol, exercise capacity, and outcome measures were extracted and reviewed. **RESULTS:** A total of 81 studies were identified: 30 randomized controlled trials, five nonrandomized controlled trials, nine randomized crossover trials, and 37 longitudinal cohort studies. Exercise training was performed in 2387 patients. The average increment in peak oxygen consumption was 17% in 57 studies that measured oxygen consumption directly, 17% in 40 studies of aerobic training, 9% in three studies that only used strength training, 15% in 13 studies of combined aerobic and strength training, and 16% in the one study on inspiratory training. There were no reports of deaths that were directly related to exercise during more than 60,000 patient-hours of exercise training. During the training and follow-up periods of the randomized controlled trials, there were 56 combined (deaths or adverse events) events in the exercise groups and 75 combined events in the control groups (odds ratio [OR] = 0.98; 95% confidence interval [CI]: 0.61 to 1.32; P = 0.60). During this same period, 26 exercising and 41 nonexercising subjects died (OR = 0.71; 95% CI: 0.37 to 1.02; P = 0.06). **CONCLUSION:** Exercise training is safe and effective in patients with heart failure. The risk of adverse events may be reduced, but further studies are required to determine whether there is any mortality benefit.

Publication Types:

Review

Review, Academic

PMID: 15121496 [PubMed - indexed for MEDLINE]

3: Am J Ophthalmol. 2004 May;137(5):806-11.

Topographically supported customized ablation for the management of decentered laser in situ keratomileusis.

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PURPOSE: To evaluate the efficacy, predictability, and safety of topographically supported customized ablations (TOSCA) for decentered ablations following laser in situ keratomileusis (LASIK). **DESIGN:** Prospective nonrandomized clinical trial. **METHODS:** Nine patients (11 eyes) with LASIK-induced decentered ablations underwent TOSCA following flap lifting. Topographically supported customized ablation was performed using a corneal topographer to obtain a customized ablation profile, combined with a flying spot laser. **RESULTS:** Mean follow-up was 9.22 +/- 2.82 months (range 6-12 months). No intra- or postoperative complications were observed. Manifest refraction (spherical equivalent) did not change significantly (pre-TOSCA: -0.14 +/- 1.58 diopters [range, -1.75 to +3.00 diopters] to +0.46 +/- 1.02 diopters [range, -1.00 to +1.75 diopters]; P = .76), whereas there was a statistically significant reduction in the refractive astigmatism (pre-TOSCA: -1.55 +/- 0.60 diopters [range, -3.00 to -0.75 diopters] to -0.70 +/- 0.56 diopters [range, -2.00 to -0.25 diopters]; P = .003). Mean uncorrected visual acuity improved significantly (P < .001) from 0.45 +/- 0.16 (range, 0.2-0.7) to 0.76 +/- 0.29 (range, 0.2-1.2) at last follow-up. Mean best-corrected visual acuity improved from 0.74 +/- 0.22 (range, 0.4-1.0) to 0.95 +/- 0.20 (range, 0.6-1.2; P = .002). Eccentricity showed a statistically significant reduction after TOSCA treatment (pre-TOSCA: 1.59 +/- 0.46 mm [range, 0.88-2.23 mm]; post-TOSCA: 0.29 +/- 0.09 mm [range, 0.18-0.44 mm]; P < .001). **CONCLUSION:** In our small sample, enhancement LASIK procedures with TOSCA appear

to improve uncorrected and best-corrected visual acuity as well as eccentricity in patients with LASIK-induced decentered ablation.

Publication Types:

Clinical Trial

PMID: 15126143 [PubMed - indexed for MEDLINE]

4: Am J Surg. 2004 May; 187(5):630-4.

Full-thickness intraperitoneal excision by transanal endoscopic microsurgery does not increase short-term complications.

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PURPOSE: Transanal endoscopic microsurgery (TEM) is a minimally invasive technique for full-thickness excision of benign and malignant rectal neoplasms located 4 to 24 cm above the anal verge. Entrance into the peritoneal cavity during TEM has been regarded as a complication that mandates conversion to open laparotomy for adequate repair of the defect. This study compares the rate of complications arising from TEM with and without intraperitoneal entry. **METHODS:** Patients undergoing peritoneal entry were compared to those who did not.

RESULTS: No perioperative deaths occurred. There was no significant difference in the incidence of postoperative complications. No major complications occurred with peritoneal entry, and all peritoneal entries were closed transanally via endoscope. **CONCLUSIONS:** Entry into the peritoneum during TEM is not associated with an increased incidence of complication. Entry into the peritoneum during TEM excision does not mandate conversion to open laparotomy but may be safely repaired endoscopically. Lesions likely to be above the peritoneal reflection and within reach of the endoscope (4 to 24 cm) should be considered for TEM excision.

PMID: 15135680 [PubMed - indexed for MEDLINE]

5: Am Surg. 2004 May; 70(5):467-71.

Reducing medication errors in a surgical residency training program.

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Medication errors contribute to in-hospital morbidity and mortality. Teaching hospitals and the surgical residency training programs they support should take proactive steps to reduce error frequency. In order to accomplish meaningful error reduction, we must first define the scope and nature of the problem. Pharmacists at the Monmouth Medical Center prospectively recorded medication prescribing errors made by surgical residents during 2 years. These data were reviewed to determine the types of medication errors made most frequently by surgical house officers. Seventy-five medication-prescribing errors were made by surgical house staff in the years 2001 and 2002. Thirty-three of these errors involved orders for antibiotic therapy. Errors that could not be directly attributed to knowledge deficits were responsible for 36 of the 75 errors (48%), whereas specific knowledge deficits were responsible for 39 of the 75 errors (52%). Twentyeight of the 36 errors not directly attributable to knowledge deficits (78%) were made at the postgraduate year one level, whereas only 15 of the 39 knowledge deficit errors (38%) were made at the postgraduate year one level. Though targeted education to address specific knowledge deficits may substantially reduce the occurrence of "knowledge deficit" medication errors within surgical residency training programs, more costly measures such as the implementation of physician computerized order entry will likely be needed to reduce maximally the frequency of medication ordering errors. Many prescribing

errors cannot be attributed to specific knowledge deficits.
PMID: 15156958 [PubMed - indexed for MEDLINE]

6: Am Surg. 2004 May;70(5):425-32.

Skin-sparing and nipple-sparing mastectomy: preoperative, intraoperative, and postoperative considerations.

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The last several decades have witnessed significant advances in the surgical management of breast cancer. Although many have embraced breast conservation as

the procedure of choice, some patients will still opt for mastectomy for a variety of reasons. Recently, the concept of skin sparing mastectomy and immediate breast reconstruction has emerged as an option that provides excellent cosmetic results while being oncologically safe. However, this surgical approach must be considered within a multidisciplinary context, and there are a number of perioperative issues that need to be considered. In addition, newer techniques, which spare the nipple and/or areola, warrant further examination.

Publication Types:

Review

Review, Tutorial

PMID: 15156951 [PubMed - indexed for MEDLINE]

7: Am Surg. 2004 May;70(5):420-4.

Update on the NSABP and ACOSOG breast cancer sentinel node trials.

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Sentinel lymph node biopsy in women with breast cancer has become routine in many surgical practices; yet basic questions regarding the procedure remain unanswered. The National Surgical Adjuvant Bowel and Breast Project (NSABP) and the American College of Surgeons Oncology Group (ACOSOG) trials address the issues of morbidity, efficacy, safety, and the significance of low-volume disease. NSABP B-32 randomizes women to sentinel lymph node biopsy followed by a

standard level I and II axillary dissection or sentinel lymph node biopsy without dissection unless metastatic disease is noted by H&E examination.

Overall survival, disease-free survival, and morbidity serve as end points.

Further pathologic evaluation of the lymph nodes with immunohistochemistry will be performed by the study center. This study is nearing its anticipated accrual goal. Patients enrolled in the now-closed ACOSOG Z0010 trial underwent bone marrow aspiration just prior to sentinel node biopsy. Immunocytochemical analysis of the marrow will be compared to sentinel lymph node (SLN) biopsy to determine prognostic accuracy. ACOSOG Z0011 randomizes women undergoing breast-conserving therapy with low-volume axillary disease to completion axillary dissection or observation. Overall survival, disease-free survival, local regional control, and morbidity serve as end points. This trial is currently enrolling patients.

Publication Types:

Review

Review, Tutorial

PMID: 15156950 [PubMed - indexed for MEDLINE]

8: Anesthesiology. 2004 May;100(5):1146-50.

Unanticipated difficult airway in anesthetized patients: prospective validation

of a management algorithm.

Combes X, Le Roux B, Suen P, Dumerat M, Motamed C, Sauvat S, Duvaldestin P, Dhonneur G.

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BACKGROUND: Management strategies conceived to improve patient safety in anesthesia have rarely been assessed prospectively. The authors undertook a prospective evaluation of a predefined algorithm for unanticipated difficult airway management. **METHODS:** After a 2-month period of training in airway management, 41 anesthesiologists were asked to follow a predefined algorithm for management in the case of an unanticipated difficult airway. Two different scenarios were distinguished: "cannot intubate" and "cannot ventilate." The gum elastic bougie and the Intubating Laryngeal Mask Airway (ILMA) were proposed as the first and second steps in the case of impossible laryngoscope-assisted tracheal intubation, respectively. In the case of impossible ventilation or difficult ventilation, the IMLA was recommended, followed by percutaneous transtracheal jet ventilation. The patient's details, adherence rate to the algorithm, efficacy, and complications of airway management processes were recorded. **RESULTS:** Impossible ventilation never occurred during the 18-month study. One hundred cases of unexpected difficult airway were recorded (0.9%) among 11,257 intubations. Deviation from the algorithm was recorded in three cases, and two patients were awakened before any alternative intubation technique attempt. All remaining patients were successfully ventilated with either the facemask (89 of 95) or the ILMA (6 of 95). Six difficult-ventilation patients required the ILMA before completion of the first intubation step. Eighty patients were intubated with the gum elastic bougie, and 13 required a blind intubation through the ILMA. Two patients ventilated with the ILMA were never intubated. **CONCLUSION:** When applied in accordance with a predefined algorithm, the gum elastic bougie and the ILMA are effective to solve most problems occurring during unexpected difficult airway management.

Publication Types:

Validation Studies

PMID: 15114211 [PubMed - indexed for MEDLINE]

9: Anesthesiology. 2004 May;100(5):1076-80.

Molecular genetic testing for malignant hyperthermia susceptibility.

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BACKGROUND: For more than 30 yr, the in vitro contracture test (IVCT) was the only appropriate diagnostic tool for malignant hyperthermia (MH). After the introduction of molecular genetics into MH research, guidelines for molecular genetic diagnosis of MH susceptibility were published. The aim of this study was to establish applicability of the guidelines, sensitivity, and specificity of genetic testing in MH and advantages for studied patients. **METHODS:** The IVCT was performed following the guidelines of the European MH Group. Mutation analyses were performed by amplification of genomic DNA by polymerase chain reaction and restriction enzyme digestion. **RESULTS:** Two hundred eight individuals underwent MH testing between January 2001 and April 2003. In 32 of 67 initially genetic-tested patients, the familial mutation was identified, and they were diagnosed as MH susceptible. The IVCT followed negative genetic test results in 20 patients, and all but one had negative IVCT results. Three patients were scheduled to undergo elective surgery, and IVCT and genetic testing were performed simultaneously. All three had positive IVCT results and were carriers of their familial mutation. **CONCLUSIONS:** In families with known MH mutations,

there is a 50% chance of reliably confirming MH susceptibility by noninvasive testing. The authors found the negative predictive value of genetic testing to be 0.95 (95% confidence interval, 0.75-0.99), but for patient safety, they still recommend following the guidelines for genetic testing in MH and therefore performing an IVCT in case of negative genetic results.
PMID: 15114203 [PubMed - indexed for MEDLINE]

10: Ann Intern Med. 2004 Jun 1;140(11):932; author reply 933.
Comment on:

Ann Intern Med. 2003 Aug 19;139(4):267-73.
Patient safety and medical malpractice.
Gale HL.

Publication Types:
Comment
Letter

PMID: 15172913 [PubMed - indexed for MEDLINE]

11: Br J Ophthalmol. 2004 May;88(5):643-6.

Comment in:

Br J Ophthalmol. 2004 May;88(5):601-2.
The relation of volume with outcome in phacoemulsification surgery.
Haib M, Mandal K, Bunce CV, Fraser SG.
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BACKGROUND/AIMS: High case volume has been associated with better health outcomes for a variety of procedures and conditions including coronary angioplasty, carotid endarterectomy, colorectal surgery, and various types of cancer surgery. The association of volume and outcome has important implications for patient safety and healthcare delivery planning. The relation between surgical volume and outcome has not, as far as is known, been looked at for phacoemulsification alone. METHODS: All cataract surgery performed from 1996 to 2001 by six consultant surgeons was reviewed. Using theatre logbooks and cross checking with the hospital database, the total number of phacoemulsification procedures performed per surgeon per year was calculated. The total number of operations in which it was judged that significant intraoperative complications occurred was also counted. RESULTS: When the data were pooled for all the surgeons there was evidence that complication rate decreased over time (Spearman's rho = -0.319, p = 0.058). If the data were pooled from all the years and all the surgeons then there was strong evidence of a decrease in complication rate with an increase in the number of cases (Spearman's rho = -0.63, p<0.01). CONCLUSIONS: This study is the first to describe a possible relation between volume of surgery and the outcome (as measured by complication rates) for phacoemulsification. There are however some caveats in that the issue of case mix was not addressed and that the results are from a single unit and may not necessarily be generalisable
PMID: 15090416 [PubMed - indexed for MEDLINE]

12: Cancer. 2004 May 15;100(10):2201-7.

Safety and efficacy of high-dose chemotherapy with autologous stem cell transplantation for patients with malignant astrocytomas.
Chen B, Ahmed T, Mannancheril A, Gruber M, Benzil DL.
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BACKGROUND: Malignant astrocytomas are among the most resistant tumors to curative treatments. Mean survival without treatment is measured in weeks, and even with maximal surgery and radiation, the mean reported survival is < 1 year. The advent of supportive treatments and newer agents has resulted in benefits

for many patients with cancer. The authors investigated the safety and effect on survival of a high-dose thiotepa and carboplatin regimen with autologous stem cell transplantation (ASCT) in patients with malignant astrocytomas who were enrolled in a prospective trial approved by an institutional review board (IRB). METHODS: Twenty-one patients were enrolled in an IRB-approved, prospective trial. After baseline testing was completed, patients underwent peripheral stem cell mobilization with cyclophosphamide (4 g/m²) and etoposide (450 mg/m²) followed by granulocyte-colony-stimulating factor (10 microg/kg). Peripheral stem cells were harvested when leukocyte counts recovered. Patients received 2 cycles of thiotepa (750 mg/m²) and carboplatin (1600 mg/m²) followed by infusion of the preserved stem cells. The cycles were administered 6-10 weeks apart. Primary outcome measures were patient survival (Kaplan-Meier analysis) and treatment toxicity (using National Cancer Institute common toxicity criteria). RESULTS: Autologous stem cells were harvested effectively and transfused in all patients. Kaplan-Meier survival analysis demonstrated a survival time of 34.3 +/- 5.5 months (range, 9-94 months). Despite significant myelosuppression, only three patients experienced Grade 4 complications and eight experienced Grade 3 complications. CONCLUSIONS: High-dose chemotherapy with thiotepa and carboplatin

with concomitant ASCT was used safely to treat patients with malignant astrocytomas and may provide a survival advantage. Copyright 2004 American Cancer Society.

PMID: 15139065 [PubMed - indexed for MEDLINE]

13: Cancer. 2004 May 15;100(10):2052-63.

Cardiac profiles of liposomal anthracyclines: greater cardiac safety versus conventional doxorubicin?

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Although conventional doxorubicin is associated with favorable clinical outcomes in patients with a variety of tumor types, it long has been associated with the risk of development of cardiotoxicity. Therefore, researchers have focused their efforts on the development of new formulations to improve efficacy while minimizing associated toxicities. The most successful strategy reported to date has been liposomal encapsulation, which alters the pharmacokinetics of the drug, with the goal of maintaining efficacy and improving the therapeutic index. The cardiac profiles of three liposomal anthracyclines, liposomal daunorubicin, nonpegylated liposomal doxorubicin, and pegylated liposomal doxorubicin, were reviewed. More studies will be needed to determine the cardiac safety of liposomal daunorubicin. Although nonpegylated liposomal doxorubicin demonstrated more favorable cardiac safety compared with conventional doxorubicin, its cardiac safety appeared to be mitigated when high bolus doses were administered. Of the liposomal formulations, the strongest evidence of cardiac safety was observed with pegylated liposomal doxorubicin. Compared with conventional doxorubicin, pegylated liposomal doxorubicin was associated with a significantly lower risk of development of cardiac events ($P < 0.001$). Moreover, the risk of cardiotoxicity was not increased in patients who were treated with pegylated liposomal doxorubicin at cumulative doses > 450 mg/m² or in patients at increased risk for cardiotoxicity, such as those with prior adjuvant doxorubicin use. Liposomal doxorubicin formulations provided a favorable advantage over conventional doxorubicin in terms of cardiac safety. Recent evidence also suggests that the improved cardiac safety of liposomal doxorubicin formulations is reflected by their successful use in combination with trastuzumab and other chemotherapy agents. Copyright 2004 American Cancer Society.

Publication Types:

Review
Review, Tutorial
PMID: 15139046 [PubMed - indexed for MEDLINE]

14: Cornea. 2004 May;23(4):377-9.

Cataract extraction following penetrating keratoplasty.

Nagra PK, Rapuano CJ, Laibson PL, Kunimoto DY, Kay M, Cohen EJ.

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OBJECTIVE: To assess the safety of cataract extraction following penetrating keratoplasty for corneal graft survival and to evaluate visual and refractive outcomes in corneal graft patients undergoing cataract extraction. METHODS: Retrospective chart review of 29 eyes of 24 patients with corneal grafts who underwent cataract extraction from January 1, 1993 to December 31, 2002, followed on the Cornea Service at Wills Eye Hospital. RESULTS: The mean time from penetrating keratoplasty to cataract extraction was 8.4 years (range 2 months to 36 years). Following cataract extraction, the corneal grafts remained clear in all but 1 eye (3%), during an average follow-up time of 44.5 months (range 3-118 months). All of the remaining patients benefited from improved visual acuity, with 15 of 28 patients having a postoperative best-corrected visual acuity of 20/30 or better. Patients also benefited from decreased absolute spherical refractive error, with a preoperative mean value of 6.6 +/- 3.4 D compared with 2.4 +/- 1.6 D postoperatively, while cylindrical refractive error remained relatively stable at 3.2 +/- 2.9 D preoperatively and 2.8 +/- 2.4 postoperatively. The patient who developed graft failure had 3 episodes of preoperative endothelial rejection and a clear corneal graft at the time of cataract surgery. CONCLUSIONS: Cataract surgery following penetrating keratoplasty is a safe and effective procedure, with a low but definite risk of corneal graft failure. In patients with clear grafts and visually significant cataracts, cataract extraction alone is preferred over repeat penetrating keratoplasty and cataract extraction.

PMID: 15097133 [PubMed - indexed for MEDLINE]

15: Environ Health Perspect. 2004 May;112(6):A332-3.

Chemical process safety at a crossroads.

Merritt CW.

Publication Types:

Editorial

PMID: 15121524 [PubMed - indexed for MEDLINE]

16: Health Phys. 2004 May;86(5 Suppl):S120-3.

Radiation safety considerations in GliSite 125I brain implant procedures.

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The traditional approach to treatment of certain malignant brain tumors involves permanent implantation of I seeds sequential to tumor's resection. This approach has recently been changed for patients with unifocal recurrent gliomas. What began during the 1990's as a large clinical trial utilizing GliSite Radiotherapy System, is currently becoming standard of care. This radiotherapy system consists of an inflatable balloon catheter, 2, 3, or 4 cm diameter, which is surgically placed in the tumor resection cavity; its positioning and the level of conformity within the cavity are verified via MRI imaging with contrast. The balloon is then filled with appropriate volume of I in the liquid form. Radiation treatment prescription dose ranges from 40 to 60 Gy (4,000 to 6,000 rads). This is accomplished by allowing 2.77 to 16.6 GBq (75 to 450 mCi)

of I to remain in the balloon for 3-5 d. Numerous technical, dosimetric, and logistical considerations arise when handling large quantities of iodine necessary to perform GliSite procedures. They require coordination of efforts of several hospital departments and the institution's RSO-in our case, two RSOs, at the University of Colorado Hospital and University of Colorado Health Sciences Center hold separate radioactive materials licenses. Based on our experiences and those of others, we conclude that, with appropriate guidance and care, these procedures can be performed safely without excessive restrictions. PMID: 15069303 [PubMed - indexed for MEDLINE]

17: Issue Brief Cent Stud Health Syst Change. 2004 May;(82):1-4.

Paying for quality: health plans try carrots instead of sticks.

Strunk BC, Hurley RE.

Growing national attention to improving quality and patient safety is spurring development of quality-based financial incentives for physicians and hospitals. Health plans in particular are driving these pay-for-performance initiatives, according to findings from the Center for Studying Health System Change's (HSC) 2002-03 site visits to 12 nationally representative communities. For now, there is little standardization across plans in how quality improvement is measured, and incentive payments typically are modest in comparison with providers' total revenue. Nevertheless, today's nascent efforts can provide a foundation on which to build. Support from major plans and public and private purchasers, sufficiently large financial incentives properly aligned with base provider payment systems, and improvements in quality measurement can all help foster widespread provider acceptance and, ultimately, improvements in health care quality.

PMID: 15151134 [PubMed - indexed for MEDLINE]

18: J Am Diet Assoc. 2004 May;104(5):779-86.

An evidence-based approach for dietitian prescription of multiple vitamins with minerals.

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Dietitians working in hospitals are routinely involved in assessing energy and macronutrient (ie, protein, fat, carbohydrate) requirements of patients. However, complete nutritional therapy requires a comprehensive review of vitamin and mineral requirements. Scientific evidence for vitamin and mineral supplementation is primarily based on healthy, free-living people. This raises clinical challenges for dietitians working with patients whose vitamin and mineral requirements are impacted by various diseases, conditions, and medical treatment. Dietitians are the best-positioned health professionals to lead an evidence-based approach toward recommending vitamin and mineral supplements. The

dietitians at the Toronto Rehabilitation Institute were authorized through a medical directive to prescribe multiple vitamins with minerals and to discontinue orders for unnecessary vitamin supplements. This is an ongoing, advanced practice initiative that focuses on the clinical efficacy for and safety of supplementation with multiple vitamins with minerals. It involves assessing the strength of evidence as it emerges in the literature, determining its relevance to specific patient populations in the practice setting and re-evaluating clinical practices for potential applications. When dietitians assume advanced practice initiatives, they are better equipped to deliver high-quality patient care. Simultaneously, state-of-the-art dietetic practice heightens dietitian recognition as a valuable member of the health care team.

PMID: 15127064 [PubMed - indexed for MEDLINE]

19: J Am Geriatr Soc. 2004 May;52(5):666-74.

Efficacy and safety of rofecoxib 12.5 mg versus nabumetone 1,000 mg in patients with osteoarthritis of the knee: a randomized controlled trial.

Kivitz AJ, Greenwald MW, Cohen SB, Polis AB, Najarian DK, Dixon ME, Moidel RA, Green JA, Baraf HS, Petruschke RA, Matsumoto AK, Geba GP; Protocol 085 Study Investigators.

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OBJECTIVES: To evaluate the use of starting doses of rofecoxib and nabumetone in patients with osteoarthritis (OA) of the knee. DESIGN: A 6-week, randomized, parallel-group, double-blind, placebo-controlled study. SETTING: One hundred thirteen outpatient sites in the United States. PARTICIPANTS: A total of 1,042 male and female patients aged 40 and older with OA of the knee (>6 months).

INTERVENTIONS: Rofecoxib 12.5 mg once a day (n=424), nabumetone 1,000 mg once a

day (n=410), or placebo (n=208) for 6 weeks. MEASUREMENTS: The primary efficacy

endpoint was patient global assessment of response to therapy (PGART) over 6 weeks, which was also specifically evaluated over the first 6 days. The main

safety measure was adverse events during the 6 weeks of treatment. RESULTS: The percentage of patients with a good or excellent response to therapy as assessed using PGART at Week 6 was significantly higher with rofecoxib (55.4%) than nabumetone (47.5%; P=.018) or placebo (26.7%; P<.001 vs rofecoxib or nabumetone). Median time to first report of a good or excellent PGART response was significantly shorter in patients treated with rofecoxib (2 days) than with nabumetone (4 days, P=.002) and placebo (>5 days, P<.001) (nabumetone vs placebo; P=.007). The safety profiles of rofecoxib and nabumetone were generally similar, including gastrointestinal, hypertensive, and renal adverse events.

CONCLUSION: Rofecoxib 12.5 mg daily demonstrated better efficacy over 6 weeks of treatment and quicker onset of OA efficacy over the first 6 days than nabumetone 1,000 mg daily. Both therapies were generally well tolerated.

Publication Types:

Clinical Trial

Multicenter Study

Randomized Controlled Trial

PMID: 15086644 [PubMed - indexed for MEDLINE]

20: Lancet. 2004 May 15;363(9421):1566-8.

Dangerous pathogens in the laboratory: from smallpox to today's SARS setbacks and tomorrow's polio-free world.

Heymann DL, Aylward RB, Wolff C.

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PMID: 15145625 [PubMed - indexed for MEDLINE]

21: Mod Healthc. 2004 Apr 26;34(17):21.

Beyond safety. Patient trust and loyalty are byproducts of patients' overall experience.

Kolb M.

Kern Medical Center, Bakersfield, Calif., USA.

PMID: 15146598 [PubMed - indexed for MEDLINE]

22: Mod Healthc. 2004 Apr 19;34(16):14.

Changing the subject. Tenet names six new CMOs to reinforce patient safety.

Reilly P.

Publication Types:

News

PMID: 15124439 [PubMed - indexed for MEDLINE]

23: Ophthalmology. 2004 May; 111(5):960-5.

Pulse IV cyclophosphamide in ocular inflammatory disease: efficacy and short-term safety.

Durrani K, Papaliadis GN, Foster CS.

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PURPOSE: To assess the efficacy and short-term safety of appropriately monitored pulse IV cyclophosphamide therapy in the treatment of patients with severe or treatment-resistant autoimmune ocular inflammatory disease. DESIGN:

Retrospective noncomparative interventional case series. PARTICIPANTS:

Thirty-eight patients with severe or recalcitrant ocular inflammation of diverse etiologies. METHODS: Charts of patients seen on the Ocular Immunology & Uveitis Service at the Massachusetts Eye & Ear Infirmary were reviewed. Thirty-eight consecutive patients treated with pulse IV cyclophosphamide between January 1995 and March 2002 were analyzed. MAIN OUTCOME MEASURES: The control of inflammation, steroid-sparing effect, visual acuity, and adverse reactions.

RESULTS: A positive response to treatment occurred in 68% of patients during the study period, with 55% achieving complete quiescence. A steroid-sparing effect was achieved in all patients previously on systemic steroid, allowing successful discontinuation of the drug in 41%. Visual acuity was maintained in 66% and improved in 21% of involved eyes. The most common side effects observed were fatigue (63%), nausea (32%), and headache (22%). None required a permanent discontinuation of therapy. CONCLUSIONS: Pulse IV cyclophosphamide is an effective therapeutic modality in patients with severe or treatment-resistant ocular inflammatory disease.

Publication Types:

Clinical Trial

PMID: 15121375 [PubMed - indexed for MEDLINE]

24: Plast Reconstr Surg. 2004 May; 113(6):1760-70.

Analysis of outpatient surgery center safety using an internet-based quality improvement and peer review program.

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Assessing the quality of care delivered in office-based outpatient surgery centers is difficult because formerly there was no central data collection system. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), in its ongoing effort to assess and improve patient care, has developed an Internet-based quality improvement and peer review program to analyze outcomes for surgery centers it accredits. Reporting is mandatory for all surgeons operating in AAAASF-accredited facilities. Each surgeon must report all unanticipated sequelae and at least six random cases reviewed by an accepted peer review group biannually. A total of 411,670 procedures were analyzed during a 2-year period (from 2001 to 2002). There were 2597 sequelae reported during this period. The most common sequela was hematoma formation following breast augmentation. Infection occurred in 388 cases. Deep vein thrombosis, pulmonary embolism, and intraoperative cardiac arrhythmias were found to occur in a frequency consistent with previous reports. Significant complications (hematoma, hypertensive episode, wound infection, sepsis, and hypotension) were infrequent. A total of 1378 significant sequelae were reported for 411,670 procedures. This calculates to one unanticipated sequela in 299 procedures (an incidence of 0.33 percent). Seven deaths were reported. A death occurred in one in 58,810 procedures (0.0017 percent). The overall risk of death was comparable whether

the procedure was performed in an AAAASF-accredited office surgery facility or a hospital surgery facility. This study documents an excellent safety record for surgical procedures performed in accredited office surgery facilities by board-certified surgeons.

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25: Plast Reconstr Surg. 2004 Apr 15; 113(5):1478-90; discussion 1491-5.

Practice advisory on liposuction.

Iverson RE, Lynch DJ; American Society of Plastic Surgeons Committee on Patient Safety.

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COMMITTEE STATEMENT: At the 69th annual meeting of the American Society of Plastic Surgeons (ASPS) in October of 2000, the ASPS Board of Directors convened the Task Force on Patient Safety in Office-Based Surgery Facilities. The task force was assembled in the wake of several highly publicized patient deaths involving plastic surgery and increasing state legislative and regulatory activity of office-based surgery facilities. In response to the increased scrutiny of the office-based surgery setting, the task force produced two practice advisories: "Procedures in the Office-Based Surgery Setting" and "Patient Selection in the Office-Based Surgery Setting." Since the task force's inception, professional and public awareness of patient safety issues has continued to grow. This heightened interest resulted in an increased need for plastic surgeons to communicate their views on the topic. To meet this challenge, the task force evolved into the Committee on Patient Safety, allowing the committee to address topics affecting the safety and welfare of plastic surgery patients, regardless of the facility setting. The "Practice Advisory on Liposuction" is the first advisory developed since the committee was formed. It was a lengthy and painstaking process for the committee, which included representatives from related plastic surgery organizations as well as the American Society of Anesthesiologists (ASA). Committee members included Ronald E. Iverson, M.D., chair; Jeffery L. Apfelbaum, M.D., ASA representative; Bruce L. Cunningham, M.D., ASPS/Plastic Surgery Educational Foundation (PSEF) Joint Outcomes Task Force representative; Richard A. D'Amico, M.D., ASPS representative; Victor L. Lewis, Jr., M.D., ASPS Health Policy Analysis Committee representative; Dennis J. Lynch, M.D., ASPS representative; Noel B. McDevitt, M.D., ASPS Deep Vein Thrombosis Task Force representative; Michael F. McGuire, M.D., The American Society for Aesthetic Plastic Surgery (ASAPS) representative; Louis Morales, Jr., M.D., American Society of Maxillofacial Surgeons representative; Calvin R. Peters, M.D., Florida Ad Hoc Commission on Patient Safety representative; Robert Singer, M.D., American Association for Accreditation of Ambulatory Surgery Facilities representative; Thomas Ray Stevenson, M.D., American College of Surgeons representative; Rebecca S. Twersky, M.D., ASA representative; Ronald H. Wender, M.D., ASA representative; and James A. Yates, ASAPS representative. The authors thank members of the committee for the insights they brought to this process. The final document represents their significant contributions to these efforts. They would also like to recognize DeLaine Schmitz and Pat Farrell of the ASPS staff for their work on and support of this project.

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