
Selected published abstracts of Baylor researchers

AMERICAN JOURNAL OF CARDIOLOGY

Relation of weights of intraaneurysmal thrombi to maximal right-to-left diameters of abdominal aortic aneurysms

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Am J Cardiol 2006;98(11):1519–1524. Copyright 2006. Reprinted with permission from Elsevier.

We determined the weight of operatively excised thrombi within abdominal aortic aneurysms (AAAs) in 42 patients aged 52 to 92 years (mean 73 ± 9). The thrombi in the 32 men ranged in weight from 12 to 586 g (mean 162 ± 135) and in the 10 women, from 12 to 351 g (mean 94 ± 102). The maximal right-to-left diameter of the AAA by computed tomography immediately preoperatively in the 32 men ranged from 5.0 to 11.0 cm (mean 7.6 ± 1.7), and in the 10 women from 4.0 to 10.5 cm (mean 6.7 ± 1.9). The relation of the weight of the intraaneurysmal thrombus to the maximal right-to-left diameter of the AAA preoperatively was highly significant in both men ($r = 0.72$, $P < 0.001$) and women ($r = 0.88$, $P < 0.001$). The intraaneurysmal thrombi consisted virtually entirely of fibrin, indicating no evidence of organization.

AMERICAN JOURNAL OF SURGERY

Pregnancy outcomes after gastric-bypass surgery

Dao T, Kuhn J, Ehmer D, Fisher T, McCarty T

Am J Surg 2006;192(6):762–766. Copyright 2006. Reprinted with permission from Excerpta Medica, Inc.

Background: The purpose of this study is to compare outcomes of patients who become pregnant within the first year after surgery and those who delayed pregnancy until after 1 year after surgery.

Methods: A retrospective review was performed to identify patients who became pregnant after their gastric-bypass surgery from 2001 to 2004. Endpoints included pregnancy complications, fetal birth weight and outcome, delivery method, weight change during pregnancy, and nutrition.

Results: Of 2,423 patients who had undergone bariatric surgery from 2001 to 2004, 21 patients became pregnant within the first year after surgery and 13 became pregnant after 1 year. Similar outcomes were seen between the 2 groups regarding fetal weight, term pregnancy, and complications.

Conclusions: Pregnancy outcomes within the first year after weight-loss surgery revealed no significant episodes of malnutrition, adverse fetal outcomes, or pregnancy complications. Anxiety over poor outcomes of pregnancy during the first year after bariatric surgery can be allayed.

CLINICAL CHEMISTRY

Factitious diarrhea induced by stimulant laxatives: accuracy of diagnosis by a clinical reference laboratory using thin layer chromatography

Shelton JH, Santa Ana CA, Thompson DR, Emmett M, Fordtran JS

Clin Chem 2007;53(1):85–90. Reprinted with permission from the American Association for Clinical Chemistry.

Proc (Baylor Univ Med Cent) 2007;20:209–211

Background: Surreptitious ingestion of laxatives can lead to serious factitious diseases that are difficult to diagnose. Most cases involve ingestion of bisacodyl or senna. Thin layer chromatography (TLC) of urine or stool is the only commercially available test for these laxatives. Such testing is considered highly reliable, but its accuracy in clinical practice is unknown. Our aim was to evaluate the reliability of TLC laxative testing by a clinical reference laboratory in the United States.

Methods: Diarrhea was induced in healthy volunteers by ingestion of bisacodyl, senna, or a control laxative ($n = 11$ for each laxative group). Samples of urine and diarrheal stool were sent in blinded fashion to the clinical reference laboratory for bisacodyl and senna analysis.

Results: TLC testing for bisacodyl-induced diarrhea revealed a sensitivity of 73% and specificity of 91% when urine was tested and sensitivity and specificity of 91% and 96%, respectively, when stool was analyzed. When diarrhea was induced by senna, the TLC assay for senna failed to identify even a single urine or stool specimen as positive (0% sensitivity).

Conclusions: Considering the expected prevalence of surreptitious laxative abuse in patients with chronic idiopathic diarrhea (2.4%–25%, depending on the clinical setting), TLC of urine or stool for bisacodyl by this reference laboratory would often produce misleading results, and testing for senna would have no clinical value. The major problems are false-positive tests for bisacodyl and false-negative tests for senna.

CLINICAL TRANSPLANTATION

Radiofrequency thermal ablation of hepatocellular carcinoma before liver transplantation—a clinical and histological examination

Martin AP, Goldstein RM, Dempster J, Netto GJ, Katabi N, Derrick HC, Altrabulsi B, Jennings LW, Ueno T, Chinnakotla S, Dawson S III, Randall HB, Levy MF, Onaca N, Sanchez EQ, Orr D, Klintmalm GB

Clin Transplant 2006;20(6):695–705. Reprinted with permission from Blackwell Publishing.

Background: Radiofrequency ablation (RFA) of hepatocellular carcinoma (HCC) is an optional treatment for patients awaiting liver transplantation (LTX). The study evaluates the efficacy of RFA in the explanted liver and its effect on patient outcome.

Material and method: Forty-seven patients underwent RFA and were listed for transplant between January 1998 and May 2003. The patients were divided into two groups: transplanted and non-transplanted. Both groups were evaluated in terms of tumor characteristics, recurrence, mortality rate, and time on the waiting list. The ablation sites in the explanted livers were examined for percentage of necrosis by hematoxylin & eosin (H&E) stain and by TUNEL stain.

Results: Transplantation was carried out in 35 patients (74.5%). Ten patients (21.3%) died before transplant or were removed from the wait list, while two patients (4.2%) are still listed. Mortality and tumor-related mortality were significantly higher in the non-transplanted group. The time spent on the waiting list was longer in the non-transplanted patients (350 vs. 186 d average, $P = 0.0345$). Thirty-eight ablation sites were examined in the explanted livers. The percentage of tumor necrosis by TUNEL staining

was 19.6% higher than that reported by H&E staining. After TUNEL staining, 28 sites (73.7%) had more than 90% necrosis, eight sites (21.0%) had 50–90%, and two sites (5.3%) had less than 50% necrosis.

Conclusions: RFA and LTX can be used successfully in HCC patients, and in most cases, tumor necrosis can be achieved with ultrasound-guided RFA. H&E stain tends to under-represent the amount of tumor necrosis on the ablation sites. Survival of RFA patients after LTX is excellent.

JOURNAL OF THE AMERICAN ACADEMY OF DERMATOLOGY

A randomized comparison of continuous vs. intermittent infliximab maintenance regimens over 1 year in the treatment of moderate-to-severe plaque psoriasis

Menter A, Feldman SR, Weinstein GD, Papp K, Evans R, Guzzo C, Li S, Dooley LT, Arnold C, Gottlieb AB

J Am Acad Dermatol 2007;56(1):31.e1–31.e15. Copyright © 2007. Reprinted with permission from American Academy of Dermatology, Inc.

Background: Previous studies of infliximab in psoriasis have demonstrated rapid improvement with induction therapy and sustained response with regularly administered maintenance therapy.

Objective: The efficacy and safety of continuous (every-8-week) and intermittent (as-needed) maintenance regimens were compared.

Methods: Patients with moderate-to-severe psoriasis (n = 835) were randomized to induction therapy (weeks 0, 2, and 6) with infliximab 3 mg/kg or 5 mg/kg or placebo. Infliximab-treated patients were randomized again at week 14 to continuous or intermittent maintenance regimens at their induction dose.

Results: At week 10, 75.5% and 70.3% of patients in the infliximab 5 mg/kg and 3 mg/kg groups, respectively, achieved PASI 75; 45.2% and 37.1% achieved PASI 90 (vs 1.9% [PASI 75] and 0.5% [PASI 90] for placebo; $P < .001$). Through week 50, PASI responses were better maintained with continuous compared with intermittent therapy within each dose, and with 5 mg/kg compared with 3 mg/kg continuous therapy.

Limitations: Longer term (>1 year) maintenance therapy and further study of infliximab serum concentrations over this period, in both PASI 75 responders and non-responders, would be preferable.

Conclusions: Through week 50, response was best maintained with continuous infliximab therapy. Infliximab was generally well-tolerated in most patients.

JOURNAL OF HEAD TRAUMA REHABILITATION

Deep venous thrombosis management following traumatic brain injury: a practice survey of the traumatic brain injury model systems

Carlile MC, Yablon SA, Mysiw WJ, Frol AB, Lo D, Diaz-Arrastia R

J Head Trauma Rehabil 2006;21(6):483–490. Reprinted with permission from Lippincott Williams & Wilkins.

Objective: To determine national patterns of screening, prophylaxis, and treatment of deep venous thrombosis (DVT) following traumatic brain injury (TBI) within the Traumatic Brain Injury Model Systems (TBIMS).

Design: E-mail survey instrument.

Setting: Multicenter regional TBIMS.

Results: Fifteen of the 16 rehabilitation centers within the TBIMS responded to the survey (94% response rate). Approximately half of these centers routinely screen to detect subclinical DVTs (56% venous duplex ultrasonography, 12% plasma D-dimer) on admission to inpatient rehabilitation. Fifty-six percent of respondents use anticoagulation prophylactically, while 69% use mechanical means for DVT prophylaxis. Eighty fatal pulmonary emboli were reported for TBI patients in 189 practice-years, corresponding to 0.42 fatalities per year of practice.

Conclusions: No consensus exists regarding the optimal methods for screening, prevention, or treatment of DVT in TBI patients in the acute rehabilitation setting of the TBIMS. The number of fatal pulmonary emboli reported among these centers emphasizes the need to develop evidence-based clinical practice guidelines for the prevention and treatment of venous thromboembolism in this patient population.

JOURNAL OF VASCULAR SURGERY

Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease

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J Vasc Surg 2007;45(1):10–16. Copyright 2007. Reprinted with permission from The Society for Vascular Surgery.

Objective: This randomized prospective study was designed to compare the effectiveness of treating superficial femoral artery occlusive disease percutaneously with expanded polytetrafluoroethylene (ePTFE)/nitinol self-expanding stent grafts vs surgical femoral-to-above knee (AK) popliteal artery bypass with synthetic graft material.

Methods: From March 2004 to May 2005, 100 limbs in 86 patients with femoral-popliteal arterial occlusive disease were identified. Patients had symptoms ranging from claudication to rest pain, with or without tissue loss, and were prospectively randomized for treatment into one of two groups. The limbs were treated percutaneously with angioplasty and one or more self-expanding stent grafts (n = 50) or surgically with femoral-to-AK popliteal artery bypass using synthetic Dacron or ePTFE grafts (n = 50). The mean \pm SD total length of artery stented was 25.6 \pm 15 cm. Follow-up evaluation with ankle-brachial indices and color flow duplex sonography imaging were performed at 3, 6, 9, and 12 months after treatment.

Results: Patients were monitored for a median of 18 months. No statistical difference was found in the primary patency ($P = .895$) or secondary patency ($P = .861$) between the two treatment groups. Primary patency at 3, 6, 9, and 12 months of follow-up was 84%, 82%, 75.6%, and 73.5% for the stent graft group and 90%, 81.8%, 79.7%, and 74.2% for the femoral-popliteal surgical group. Thirteen patients in the stent graft group had 14 reinterventions, and 12 reinterventions occurred in the surgical group. This resulted in secondary patency rates of 83.9% for the stent graft group and 83.7% for the surgical group at the 12-month follow-up.

Conclusions: Management of femoral-popliteal arterial occlusive disease using percutaneous treatment with a stent graft is comparable with surgical revascularization with conventional femoral-to-AK popliteal artery bypass using synthetic material up to 12 months. Longer-term follow-up would be helpful in determining ongoing efficacy.

LIVER TRANSPLANTATION

Acute graft-versus-host disease after liver transplantation: role of withdrawal of immunosuppression in therapeutic management

Chinnakotla S, Smith DM, Domiati-Saad R, Agura ED, Watkins DL, Netto G, Uemura T, Sanchez EQ, Levy MF, Klintmalm GB

Liver Transpl 2007;13(1):157–161. Reprinted with permission from the American Association for the Study of Liver Diseases.

Graft-versus-host disease (GVHD) after liver transplantation is rare but associated with a very high mortality (over 85%). Most treatments focus on increasing immunosuppression, addition of antibody preparations such as OKT3 and antithymocyte globulin to eliminate the donor lymphocytes, and supporting myelopoiesis by use of cytokines. However, the results are very poor. We reasoned that a better therapeutic approach would be to reduce the immunosuppression and allow the patient's immune system an opportunity to reject the allograft donor T cells. We tested this novel therapeutic approach in 3 patients diagnosed with GVHD. Two patients had rapid loss of donor T cell chimerism and resolution of their symptoms. The other patient continued to progress to severe GVHD and died. The patients who responded to withdrawal of immunosuppression had a later onset of symptoms and a lower level of donor CD3⁺ T cells at the start of treatment. We conclude that larger studies are needed to further evaluate these results and to determine what factors may affect the likelihood that a patient may respond to this approach.

NEW ENGLAND JOURNAL OF MEDICINE

Sorafenib in advanced clear-cell renal-cell carcinoma

Escudier B, Eisen T, Stadler WM, Szczylik C, Oudard S, Siebels M, Negrier S, Chevreau C, Solska E, Desai AA, Rolland F, Demkow T, Hutson TE, Gore M, Freeman S, Schwartz B, Shan M, Simantov R, Bukowski RM; TARGET Study Group

N Engl J Med 2007;356(2):125–134. Copyright © 2007 Massachusetts Medical Society. All rights reserved. Reprinted with permission.

Background: We conducted a phase 3, randomized, double-blind, placebo-controlled trial of sorafenib, a multikinase inhibitor of tumor-cell proliferation and angiogenesis, in patients with advanced clear-cell renal-cell carcinoma.

Methods: From November 2003 to March 2005, we randomly assigned 903 patients with renal-cell carcinoma that was resistant to standard therapy to receive either continuous treatment with oral sorafenib (at a dose of 400 mg twice daily) or placebo; 451 patients received sorafenib and 452 received placebo. The primary end point was overall survival. A single planned analysis of progression-free survival in January 2005 showed a statistically significant benefit of sorafenib over placebo. Consequently, crossover was permitted from placebo to sorafenib, beginning in May 2005.

Results: At the January 2005 cutoff, the median progression-free survival was 5.5 months in the sorafenib group and 2.8 months in the placebo

group (hazard ratio for disease progression in the sorafenib group, 0.44; 95% confidence interval [CI], 0.35 to 0.55; $P < 0.01$). The first interim analysis of overall survival in May 2005 showed that sorafenib reduced the risk of death, as compared with placebo (hazard ratio, 0.72; 95% CI, 0.54 to 0.94; $P = 0.02$), although this benefit was not statistically significant according to the O'Brien-Fleming threshold. Partial responses were reported as the best response in 10% of patients receiving sorafenib and in 2% of those receiving placebo ($P < 0.001$). Diarrhea, rash, fatigue, and hand-foot skin reactions were the most common adverse events associated with sorafenib. Hypertension and cardiac ischemia were rare serious adverse events that were more common in patients receiving sorafenib than in those receiving placebo.

Conclusions: As compared with placebo, treatment with sorafenib prolongs progression-free survival in patients with advanced clear-cell renal-cell carcinoma in whom previous therapy has failed; however, treatment is associated with increased toxic effects.

Sunitinib versus interferon alfa in metastatic renal-cell carcinoma

Motzer RJ, Hutson TE, Tomczak P, Michaelson MD, Bukowski RM, Rixe O, Oudard S, Negrier S, Szczylik C, Kim ST, Chen I, Bycott PW, Baum CM, Figlin RA

N Engl J Med 2007;356(2):115–124. Copyright © 2007 Massachusetts Medical Society. All rights reserved. Reprinted with permission.

Background: Since sunitinib malate has shown activity in two uncontrolled studies in patients with metastatic renal-cell carcinoma, a comparison of the drug with interferon alfa in a phase 3 trial is warranted.

Methods: We enrolled 750 patients with previously untreated, metastatic renal-cell carcinoma in a multicenter, randomized, phase 3 trial to receive either repeated 6-week cycles of sunitinib (at a dose of 50 mg given orally once daily for 4 weeks, followed by 2 weeks without treatment) or interferon alfa (at a dose of 9 MU given subcutaneously three times weekly). The primary end point was progression-free survival. Secondary end points included the objective response rate, overall survival, patient-reported outcomes, and safety.

Results: The median progression-free survival was significantly longer in the sunitinib group (11 months) than in the interferon alfa group (5 months), corresponding to a hazard ratio of 0.42 (95% confidence interval, 0.32 to 0.54; $P < 0.001$). Sunitinib was also associated with a higher objective response rate than was interferon alfa (31% vs. 6%, $P < 0.001$). The proportion of patients with grade 3 or 4 treatment-related fatigue was significantly higher in the group treated with interferon alfa, whereas diarrhea was more frequent in the sunitinib group ($P < 0.05$). Patients in the sunitinib group reported a significantly better quality of life than did patients in the interferon alfa group ($P < 0.001$).

Conclusions: Progression-free survival was longer and response rates were higher in patients with metastatic renal-cell cancer who received sunitinib than in those receiving interferon alfa.

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