limited palliation with no long-term survivors, and reirradiation in most cases is unfeasible because of local toxicity. Experience is accumulating using laser-induced thermal therapy (LITT) for treatment of recurrent, unresectable head and neck cancers leading to favorable results and apparent long-term efficacy in some cases. In this study, we review our results on 104 patients with recurrent head and neck cancer who were treated by LITT. Best results were seen in oral cavity tumors where average survival was 20.3 months (10.7–30 months; 95% CI) compared to neck (average = 14.4 months, 7.5–20.7 months; 95% CI) and other tumor sites (average = 18 months, 13.8–22.3 months; 95% CI). Tumor regrowth was not seen after treatment for an average of 47 days, with significant palliation of symptoms observed in most of these patients. Therapy response was inversely related to initial tumor volume and was dependent on both histology and growth rate. Smaller slow-growing tumors and more differentiated tumors were palliated successfully with a better local therapy response rate than poorly differentiated and rapidly dividing malignancies. The results of LITT in recurrent head and neck cancer and the prognostic factors predicting outcome in this patient population are also reviewed.

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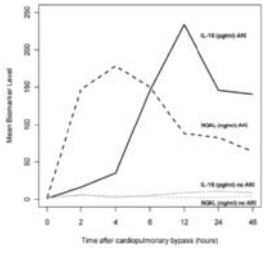
NEUTROPHIL GELATINASE–ASSOCIATED LIPOCALIN AND INTERLEUKIN-18: EARLY, SEQUENTIAL, PREDICTIVE BIOMARKERS OF ACUTE KIDNEY INJURY AFTER CARDIAC SURGERY. C. Parikh, J. Mishra,* Q. Ma,* C. Kelly,* C. Dent,* P. Devarajan,* C. Edelstein,** Yale University, New Haven, CT; *Cincinnati Children's Medical Center, Cincinnati, OH; **University of Colorado Health Sciences Center, Denver, CO.

Purpose: Acute kidney injury (AKI) is a frequent complication of cardiopulmonary bypass (CPB). The lack of early biomarkers for AKI has impaired our ability to intervene in a timely manner. In the present study, we tested whether urinary neutrophil gelatinase–associated lipocalin (NGAL) and interleukin-18 (IL-18) can be combined as predictive biomarkers for diagnosis and prognosis of AKI following CPB. **Methods:** Serial urine samples were analyzed by ELISA for IL-18 and NGAL in 20 patients who developed AKI (defined as a 50% or greater increase in serum creatinine after CPB) and 35 controls (age-, race-, and gender-matched patients who did not develop AKI after CPB). Exclusion criteria included preexisting renal insufficiency and nephrotoxin use. **Results:** Using serum creatinine, AKI was detected only 48–72 hours after CPB. In contrast, NGAL increased 25-fold within 2 hours and declined after 6 hours of CPB (Lancet, 2005). Urine IL-18 increased at 4–6 hours after CPB, peaked at over 25-fold at 12 hours, and remained markedly elevated up to 48 hours after CPB. Also, on multivariate analysis, both IL-18 and NGAL were independently associated with number of days in AKI. **Conclusions:** Our results indicate that urinary NGAL and IL-18 are increased in tandem after CPB. The combination of these biomarkers may allow for the reliable early diagnosis and prognosis of AKI at all times after CPB, much prior to the rise in serum creatinine.



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A SINGLE-DOSE PHARMACOKINETIC STUDY OF MYFORTIC (MYCOPHENOLATE SODIUM) IN LIVER TRANSPLANT RECIPIENTS: PRELIMINARY FINDINGS. T.W. Perry, J.F. Trotter, U. Christians, J. Bendrick-Peart, University of Colorado Health Sciences Center, Denver, CO.

Background: Enteric coated mycophenolate sodium (EC-MPS) is the sodium salt formulation of the active immunosuppressive compound mycophenolic acid (MPA). This drug was recently approved for use in renal transplantation. The pharmacokinetic profile for MPS has been well studied in renal transplant recipients but has not been described in the liver transplant population. **Methods:** This study is designed to determine the pharmacokinetic profile of MPS in liver transplant recipients. Patients enrolled in this study must be ≥ 12 months post-transplant and on a stable dose of tacrolimus or cyclosporine for 3 months. Exclusion criteria included ALT ≥ 235 IU/l, serum creatinine ≥ 2.5 mg/dL, current use of sirolimus, mycophenolate mofetil, or azathioprine, or acute cellular rejection within 3 months of enrolment. Each patient was orally administered one dose EC-MPS 720 mg followed by measurement of blood levels of MPA at the following intervals (hours) t = 0, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 8.0, and 12.0. Previous renal transplant studies have defined the MPA pharmacokinetics with EC-MPS as tmax mean (range) = 2 h (0.8–8), Cmax mean ± SD = 26.1 ± 12.0 µg/mL, AUC_{0-12} mean ± SD = 66.5 ± 22.6 µg-hr/mL. **Results:** From August to November 2005, eight patients were enrolled in this study. Demographics include 4 male/4 female, mean age = 53.4 years, mean weight = 81.2 kg. Etiology of underlying liver disease: four hepatitis C, two PBC, one hepatitis B, one hemangioma. Mean time post-transplant = 4.73 years. Results from this study showed the following pharmacokinetic parameters: tmax mean (range) = 2.9 h (1.5–5), Cmax mean ± SD = 33.9 ± 21.9 µg/mL, AUC_{0-12} mean ± SD = 52.9 ± 25.2 µg-hr/mL.

TABLE 1 MPA Pharmacokinetic Parameter Comparison for Renal and Liver Transplantation

Patient Population	*tmax (h)*	*Cmax (µg/mL)*	*AUC0–12 (µg-hr/mL)*
Renal transplantation recipients	2.0 (0.8–8.0)	26.1 ± 12.0	66.5 ± 22.6
Liver transplantation recipients	2.9 (1.5–5.0)	33.9 ± 21.9	52.9 ± 25.2

Conclusion: (1) These preliminary findings show that in liver transplant recipients, the pharmacokinetic parameters of MPA appear similar to renal transplant patients. (2) Further study is required to better understand the pharmacokinetic profile of MPA in liver transplant patients and determine if any significant differences will be noted due to underlying liver disease or coadministered immunosuppressants.

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MAGNETIC RESONANCE SPECTROSCOPY, DIFFUSION TENSOR IMAGING, AND MAGNETIC RESONANCE PERFUSION IN THE EVALUATION OF FIBROMYALGIA PATIENTS: A PROSPECTIVE STUDY. M. Petrou, B. Foerster, S. McLean, R. Harris, D.J. Clauw, P.C. Sundgren, University of Michigan, Ann Arbor, MI.

Purpose: To determine if there are significant differences between fibromyalgia (FM) patients and healthy controls using three different functional brain imaging techniques to assess for differences in a number of brain areas that have been considered to play a role in pain processing. **Materials and Methods:** All subjects (20 FM patients and 20 age-matched controls) underwent a conventional pre- and postcontrast MRI as well as completing extensive baseline clinical work-up including the McGill Pain Questionnaire and pain/pressure sensitivity testing. For 2D-CSI proton spectroscopy (TE/TR = 144/1500 ms), 18 1 × 1 × 1 cm voxels were placed in areas implicated in pain processing. Metabolite ratios were calculated for each voxel. DTI was performed using a single-shot spin-echo EPI technique along nine different directions with a b value of 1,000 s/mm^2 and standardized 50 mm^2 regions of interests (ROIs) were placed in a number of potential pain processing regions. For MR perfusion, 20 50 mm^2 circular ROIs were placed in selected gray and white matter structures to allow calculation of relative quantitative data for mean time to enhance (MTE) and negative enhancement integral (NEI). Student's *t*-test was used for statistical analysis. **Results:** Analysis of the 2D-CSI data showed mean Cho/Cr ratios to be significantly higher in FM patients compared to normal controls in the right prefrontal subcortical white matter (p = .02) and the left parietal white matter (p = .04). Nonsignificant similar trends were seen in the left thalamus (p = .07) and the left internal capsule (p = .09). No significant differences were found in apparent diffusion coefficient (ADC) and fractional anisotropy (FA) values between fibromyalgia patients and normal controls in most of the different regions examined. A tendency for lower FA values was found in the parietal white matter in patients with fibromyalgia compared to the normal healthy controls, 0.256 ± 0.026 (mean ± SD) vs 0.273 ± 0.034, respectively (p = .06). Regarding MR perfusion, relative MTE values were significantly lower in FM patients compared to healthy controls in the following areas: bilateral insula, thalami, prefrontal dorsolateral gray matter, corona radiata, frontal white matter, parietal white matter, and right internal capsule. **Conclusion:** Our data suggest that there are differences between FM patients and healthy controls in brain regions that have been implicated in pain processing. Larger studies are needed to better understand the determinants and consequences of CNS changes in FM, correlate with clinical symptoms, and evaluate the potential of functional imaging in disease monitoring and therapy response.

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PRONOUNCED INFLAMMATORY RESPONSE FOLLOWING CARDIOPULMONARY BYPASS ASSOCIATED WITH CENTRAL NERVOUS SYSTEM INJURY. B. Ramlawi, J.L. Rudolph, S. Mieno, J. Feng, E.R. Marcantonio, F.W. Sellke, Cardiothoracic Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA.

Introduction: Neurocognitive decline (NCD) is a common complication in cardiac surgical patients. Its pathophysiology remains unknown, leading to significant morbidity particularly in the elderly. We studied the inflammatory response and CRP in relation to NCD following cardiopulmonary bypass and correlated this to a marker of axonal central nervous system (CNS) injury. **Methods:** Prospective cohort of 43 low-risk patients undergoing CABG and/or valve procedures using cardiopulmonary bypass were administered a neurocognitive battery preoperatively, postoperatively at day 4, and at 3 months. Battery consisted of eight validated assessments covering memory, executive function, naming, attention, fluency, and premorbid intelligence. Following published STS Consensus Statement, NCD was defined as 1 SD from baseline on ≥ 25% of tasks. CRP, interleukin (IL)-1β, IL-6, and IL-10 were quantified from serum with high sensitivity immunoassay and fold change (FC) calculated between preoperative/postoperative samples at 6 hours. Increase of serum tau protein after surgery (dichotomous) was used as marker of axonal CNS damage. **Results:** Cohort had an NCD rate of 45% (mean age 72 ± 3.6 years). Baseline characteristics and known predictors of NCD such as age, education level, and perioperative temperature were not significantly different between patients with/without NCD. Patients with NCD had significantly higher increase of CRP, IL-1β, and IL-10 compared to those without NCD as described in the table below. Serum tau protein increase was significantly correlated to NCD. **Conclusions:** Increased CRP and inflammatory response perioperatively is associated with NCD in patients following cardiopulmonary bypass. Inflammation plays a key role in NCD pathophysiology, likely via axonal CNS injury, and could become a target for prevention.

Marker	*NCD Group (55%) Pre vs 6 Hours-Mean Fold diff 6 SEM)*	*No NCD Group (45%) Pre vs 6 Hours-Mean Fold Diff 6 SEM*	*p Value*	*Statistical Test*
CRP	18.60 ± 5.9	4.89 ± 2.2	.019	Mann-Whitney
IL-1β	7.14 ± 4.3	1.64 ± 0.2	.002	Mann-Whitney
IL-10	236.6 ± 102.4	30.19 ± 11.6	.01	Mann-Whitney
IL-6	5.54 ± 0.7	4.22 ± 0.6	NS	Mann-Whitney
Tau protein	78% increased	27% Increased	.024	Spearman

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APOPTOSIS GENE EXPRESSION AND ACTIVATION DURING CARDIOPULMONARY BYPASS. B. Ramlawi, J. Feng, C. Bianchi, S. Mieno, F.W. Sellke, Division of Cardiothoracic Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA.

Objective: Cold blood cardioplegia (CBC) has been advocated as an advancement in myocardial protection during cardiopulmonary bypass (CPB) and cardioplegic arrest (CA) leading to decreased postoperative morbidity. Bcl-2, Bad, and caspase 3 are intermediates within the apoptosis cascade, which is activated following ischemia-reperfusion (IR)-induced myocardial injury. We studied the expression and modification of these apoptosis intermediates due to cardioplegia and CPB in humans within cardiac and skeletal muscle. **Methods:** Right atrial and skeletal muscle was harvested from cardiac surgical patients (N = 6) before and after CPB, CBC, and mild hypothermia. Total and modified (cleaved/phosphorylated) caspase 3, Bcl-2, and Bad were measured by quantitative immunoblotting using specific antibodies. Microarray gene expression analysis was carried out using Affymetrix U95 GeneChip following RNA isolation. Activity of terminal caspase 3 was

assessed by fluorometric assay. TUNEL assay was performed on atrial sections to identify cells undergoing apoptosis. Two-tailed paired *t*-test was used for statistical analysis. **Results:** In response to CPB, skeletal muscle samples did not show changes in total or modified apoptosis protein levels in response to CPB. In myocardial tissue, CBC significantly increased phosphorylation or cleavage of Bcl-2, Bad, or caspase 3, while there was no significant change in total protein levels. Bcl-2 (Ser70) and Bad (Ser112) phosphorylation were increased by 2.35 ± 0.40 fold and 1.64 ± 0.25 fold, respectively ($p < .05$), while caspase 3 activity was increased 1.50 ± 0.14 fold ($p < .05$) after cardioplegic IR. The number of apoptotic cells in atrial tissue using TUNEL staining was increased following CBC/CA. Microarray analysis did not reveal any significant differential gene expression for the genes studied. **Conclusion:** Cold blood cardioplegic arrest triggers the modification/activation balance of both proapoptotic (caspase 3) and antiapoptotic (phospho-Bad and phospho-Bcl-2) proteins. This change is specific to myocardium as apoptosis cascade is not significantly altered following CPB in peripheral skeletal muscle. Moreover, protein activation rather than total protein levels may be the primary indicator of apoptosis induction in myocardium.

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GENE EXPRESSION PROFILES FOLLOWING CARDIAC SURGERY IN DIABETIC PATIENTS AND THEIR CLINICAL CORRELATION. B. Ramlawi, T.A. Khan, M. Ruel, P. Voisine, C. Bianchi, M. Boodhwani, F.W. Sellke, Division of Cardiothoracic Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA.
Background: Diabetes mellitus (DM) is an independent risk factor for complications following cardiac surgery. We examined peripheral gene expression and clinical responses to cardiopulmonary bypass (CPB) in patients with and without DM. **Methods:** Skeletal muscle was harvested from non-DM ($n = 5$) and insulin-treated DM ($n = 5$) patients before and after CPB. Oligonucleotide microarrays of 12,625 genes were performed on matched samples. Postoperative weight gain, systemic vascular resistance (SVR), temperature, and vasopressor requirements were determined. Nonparametric correlation analyses were used to examine clinical and gene expression relationships. **Results:** Mean CPB duration was 77.5 ± 4.0 minutes. Compared to pre-CPB, peripheral tissue post-CPB revealed 626 up-regulated and 348 down-regulated genes in non-DM vs 420 up-regulated and 473 down-regulated genes in DM patients ($p < .001$). Mean percent weight gain was 4.5 ± 1.4%. Expression of TR3, a nuclear receptor that mediates vascular endothelial cell function, was shown to negatively correlate with percent weight gain. When compared to non-DM, patients with DM had greater weight gain (1.8% ± 0.56 vs 7.3 ± 2.0%, non-DM vs DM, $p = .03$), which correlated with lower levels of TR3 expression (post/pre-CPB ratio 7.6 ± 3.3 vs 1.7 ± 0.3, non-DM vs DM; Spearman's rank correlation $r = -.68$, $p = .03$). SVR, temperature, and vasopressor requirements were not significantly different in non-DM and DM. **Conclusions:** The gene expression profile following CPB is quantitatively and qualitatively different in diabetic patients. Clinical correlation suggests that differential TR3 expression is associated with postoperative weight gain, likely due to vascular endothelial dysfunction and tissue edema. These results have possible implications for the design of tailored operative strategies for diabetic patients undergoing CPB.

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THE RELATIONSHIP BETWEEN CAFFEINE AND BLOOD PRESSURE IN PREADOLESCENT AFRICAN AMERICAN GIRLS. J.G. Reddy,[a] J.O. Ebbert,[a] L.M. Klesges,[a] F.T.B. Enders,[a] R.C. Klesges,[a] J.Q. Lanctot,[b] B.S. McClanahan,[b] [a]Mayo Clinic College of Medicine, Mayo Clinic, Rochester, MN; [b]University of Memphis, Memphis, TN.
Purpose: While caffeine consumption has been shown to be associated with blood pressure (BP) elevation in controlled experiments, the relationship between caffeine consumption and higher BP levels in preadolescent (ages 6 to 11 years) and adolescent (ages 12 to 19 years) children consuming a regular diet has not been defined. The primary objective of this study was to assess the dose-response relationship between dietary caffeine intake and BP in 8- to 10-year-old African American girls consuming a regular diet. **Methods:** Demographic, three 24-hour dietary recalls, and BP data from 303 8- to 10-year-old African American girls in the Girls Health Enrichment Multisite Studies (GEMS) cohort were analyzed using linear and multiple regression models. **Results:** Dietary intake of caffeine was not associated with either systolic (SBP) or diastolic blood pressure (DBP) ($p = .33$ and .36, respectively). However, consistent with the literature, height and body mass index were positively associated with SBP ($p < .0001$ and $p < .0001$, respectively). Height and amount of sodium intake were positively associated with DBP ($p = .01$ and $p = .02$, respectively). **Conclusions:** Dietary intake of caffeine is not associated with elevated BP in 8- to 10-year-old African American girls consuming a regular diet.

	Univariate Analysis		*Multivariate Analysis*	
Variable	*Estimate**	p *Value*	*Estimate**	p *Value*
Caffeine (mg)	0.04	.33		
Age (yr)	2.52	.0004	−0.26	.74
Height (cm)	0.46	< .0001	0.32	.0002
BMI (kg/m²)	0.78	< .0001	0.57	< .0001
Sodium (mg)	−0.00014	.84		

*Univariate and multivariate estimates reflect the overall and adjusted difference in systolic blood pressure associated with a one-unit change in the variable of interest, respectively.

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PLASMA EXTRACELLULAR SUPEROXIDE DISMUTASE IS DECREASED IN HIGH-ALTITUDE MOUNTAINEERS WHO ARE ENDURANCE TRAINED. E.A. Regan, R.P. Bowler, J.D. Crapo, Department of Medicine, National Jewish Medical and Research Center, Denver, CO.
Purpose: To measure plasma concentrations of extracellular superoxide dismutase (EC-SOD) in healthy mature athletes. **Methods:** Subjects were identified at the annual meeting of the American Alpine Club who were over age 40 and active in mountaineering. They completed a questionnaire describing their aerobic training when not on expeditions and their general health, a health status survey (SF-36), and had pulmonary function tests performed. Blood samples were drawn and assayed for plasma EC-SOD using ELISA. A control group of similar-aged healthy subjects who were not selected for activity or interests was enrolled for comparison. Neither group reported a history of cardiovascular disease. **Summary:** The mean age of the mountaineer group was 52.7 years and the control group 55.7 years. Pulmonary function tests showed that the mountaineer group had a mean forced vital capacity as a percentage of predicted volume of 105 ± 3% (mean ± standard error of the mean) and forced expiratory volume in 1 second as a percentage of the predicted volume of 101 ± 3%. Plasma EC-SOD concentrations were 142.8 ± 17.4 ng/mL in the control group and 22.4 ± 2.56 ng/mL in the mountaineer group ($p < .001$). Looking at the mountaineer group alone and dividing them into an active (3 days per week of aerobic exercise) group and an extremely active (5 or more days per week of aerobic exercise) group the EC-SOD levels were 27.2 ± 3.4 and 17.6 ± 3.4 ($t = 1.99$, $p = .058$). **Conclusions:** EC-SOD is the primary catalytic antioxidant in the extracellular spaces and fluids. It scavenges superoxide and protects the vulnerable macromolecules of the extracellular matrix, such as collagen and proteoglycan, from oxidant damage. The majority of EC-SOD is bound to tissue and is in equilibrium with plasma levels. EC-SOD is highly expressed in the musculoskeletal tissues and exercise training has been shown to decrease plasma EC-SOD and raise tissue binding. Low EC-SOD plasma levels have been associated with a worse prognosis in cardiovascular disease but in the context of healthy, fit mountaineers may reflect the effect of increased tissue binding and better protection of the musculoskeletal system from oxidant injury. This is the first population study that has looked at plasma EC-SOD levels in relation to a group of individuals with a history of high-performance athletics and may provide insight into mechanisms of how exercise enhances function.

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EPIDEMIOLOGY OF PLAYGROUND INJURIES IN AN URBAN SCHOOL SYSTEM RESULTING IN EMERGENCY DEPARTMENT EVALUATION. L.M. Ryan, J.L. Wright, Children's National Medical Center, George Washington University School of Medicine and Health Sciences, Washington, DC.
Background: More than 200,000 children less than 15 years of age are treated per year in US emergency departments (ED) for playground-related injuries. The majority of such injuries occur on public playgrounds; most occur at schools. Most injuries occur when children fall from equipment onto the ground. Cost of care is estimated at $7.5 billion annually. **Objective:** To characterize the epidemiology of ED-evaluated playground injuries occurring in an urban public school system. **Design/Methods:** All 168 schools in the 65,000 pupil District of Columbia public school system are supported by an on-site registered nurse. Clinical practice policy mandates that school nurses prenotify the ED at Children's National Medical Center (CNMC) for all students requiring emergency referral. Since 2003, referrals and associated ED treatment records are incorporated into a database to facilitate illness and injury surveillance and tracking. Injury data were analyzed for school year 2003–2004 to identify cases of playground injury. Descriptive epidemiologic and bivariate analysis was conducted. **Results:** During this period, 161 students, ages 3–19, were referred by a school nurse and evaluated at CNMC ED. Seventy-nine (49.1%) referrals were due to injury. Of injured students, 13 (16.4%) were playground related. The most common mechanism of injury was a fall from playground equipment (69.2%). Fractures (46.1%) and lacerations (30.7%) were the most common types of injury. All playground-related fractures were due to falls from monkey bars. The rate of fracture for playground-injured students (556/1,000 student-years) was significantly higher than the rates of fracture for all injured patients in the same age range seen in the CNMC ED during calendar year 2003 (134/1,000 patient-years, RR = 4.15, 95% CI 3.51–4.90). **Conclusion:** Fractures are overrepresented as an outcome of school playground injuries and are predominantly the result of falls from equipment. Opportunities for intervention should include further evaluation of urban school playground safety, including playground maintenance and injury patterns.

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RELATIONSHIP BETWEEN PRIMARY CARE ACCESS AND PEDIATRIC INJURY AND POISONING: AN ANALYSIS OF THE 2003 NATIONAL HEALTH INTERVIEW SURVEY. L.M. Ryan,[1] R.J. Freishtat,[1] S.D. Simon,[2] V. Sharma,[2] J.L. Wright,[1] [1]Children's National Medical Center, George Washington University, Washington, DC; [2]The Children's Mercy Hospital, Kansas City, MO.
Background: Primary care access is associated with better health and lower costs of care; its effect on injury risk has not been evaluated. Although not consistently demonstrated, positive outcomes associated with primary care injury counseling have been shown. The American Academy of Pediatrics identifies preventive counseling as a priority during well-child visits. Despite this, injuries remain the leading cause of pediatric morbidity and mortality. Is this an effect of inadequate access to primary care services? **Design/Methods:** Data from the Child Health Care Access and Utilization section of the Sample Child Core of the 2003 National Health Interview Survey (NHIS) were analyzed to identify children with limited access to primary care services. Access patterns were determined based on survey responses to indicators of primary care access: usual place of routine/preventive care, usual place of health care, and presence of unmet health care needs. Responses were categorized as limited, partially limited, not limited, and unmet needs. Using multiple logistic regression comparisons, the impact of these limitations on medically attended injury/poisoning rates was evaluated. An adjusted odds ratio of injury as a function of limited primary care access was obtained after controlling for confounders and demographic differences. **Results:** With control for gender, age, minority status, poverty, and medical insurance, no significant effect of primary care access limitations or presence of unmet health care needs was shown on the proportion of medically attended pediatric injury/poisoning episodes (Table 1). **Conclusions:** Primary care access, as a single variable, is not associated with a significant effect on medically attended injury/poisoning episodes in the pediatric population. Injury risk likely reflects multifactorial contributory circumstances and events.

TABLE 1 Odds Ratio of Injury and/or Poisoning Episode for Access Categories

Access Category	*Odds Ratio*	p *Value*	*95% Confidence Interval*
Limited	0.39	> .16	0.10–1.46
Partially limited	0.96	> .91	0.51–1.82
Unmet needs	1.15	> .61	0.68–1.93