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***New England Journal to Publish Study Results!***

We are very pleased to announce that the results of the **OPALS Cardiac Arrest Study** will be published in an upcoming issue of the **New England Journal of Medicine**. We don't yet have a date, but we will let you know as soon as it is available. Publication in this very highly respected journal represents the culmination of 10 years of relentless persistence and plain hard work by Paramedics, Research Staff, the Steering Committee, Base Hospital Medical Directors, Base Hospital Staff and many others. Congratulations to each of you for this truly ground-breaking accomplishment.

And it's not over – there is still important work to do! While the cardiac arrest portion of the study is complete, OPALS work continues in the OPALS Cardiac Arrest Database (OCAD) and the OPALS Pediatric Study, a 3 year study to determine the outcomes of children transported to hospital by ambulance for cardiac arrest, major trauma, respiratory distress and seizure. We will also keep you posted as the OPALS Prehospital Research Group takes shape in the coming months. The abstract of the article to appear in the New England Journal follows.

***Advanced Cardiac Life Support in Out-of-Hospital Cardiac Arrest***

Ian G Stiell, MD, MSc, FRCPC, George A Wells, PhD, Brian Field, ACP, MBA, Daniel W Spaite, MD, Lisa P Nesbitt, MHA, Valerie J De Maio, MD, MSc, Graham Nichol, MD, MPH, FRCPC, Donna Cousineau, BScN, Josee Blackburn, BSc, Doug Munkley, MD, Lorraine Luinstra Toohey, BScN, MHA, Tony Campeau, MAEd, Eugene Dagnone MD, Marion Lyver MD, for the OPALS Study Group

**BACKGROUND:** The Ontario Prehospital Advanced Life Support (OPALS) Study tested the incremental impact on out-of-hospital cardiac arrest survival of adding an Advanced Life Support program to a basic life support-defibrillation emergency medical services system that had previously optimized defibrillation response (Rapid Defibrillation).

**METHODS:** This multicenter, before-after, controlled clinical trial was conducted in 17 cities and enrolled adult out-of-hospital cardiac arrest patients during Rapid Defibrillation and subsequent Advanced Life Support phases. Paramedics were trained to Advanced Life Support standards including endotracheal intubation and administration of intravenous drugs.

**RESULTS:** There were 5,638 patients enrolled. From the Rapid Defibrillation (N=1,391) to the Advanced Life Support (N=4,247) phase, the admission rate increased (10.9 percent vs. 14.6 percent, P<0.001) but survival to discharge did not (5.0 percent vs. 5.1 percent, P=0.82). The multivariate odds ratios for survival were: Advanced Life Support 1.1 (95 percent confidence interval 0.8 to 1.5), witnessed status 4.4 (3.1 to 6.4),

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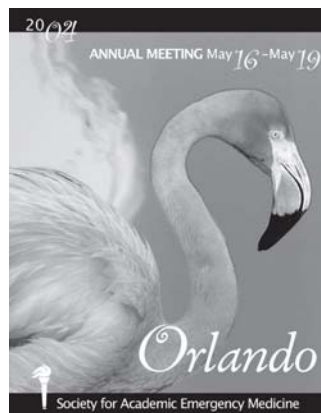
Bystander CPR 3.7 (2.5 to 5.4), and Rapid Defibrillation 3.4 (1.4 to 8.4). There was no survival improvement with Advanced Life Support for any subgroup.

**CONCLUSIONS:** The addition of Advanced Life Support interventions did not improve out-of-hospital cardiac arrest survival in a previously optimized Rapid Defibrillation emergency medical services system. The second (bystander CPR) and third (Rapid Defibrillation) links are far more important than the fourth link in the chain of survival. In order to save lives, health planners should make citizen CPR and Rapid Defibrillation response a major priority for emergency medical services system resource allocation.

**Key words:** prehospital, cardiac arrest, advanced life support, survival, defibrillation, cardiopulmonary resuscitation, emergency medical services

## OPALS STUDY RESULTS HEADLINE ORLANDO MEETING

The OPALS Prehospital Research Group has once again been busy taking its research on the road. Presentations were made at the conference for the Canadian Association of Emergency Physicians (CAEP) in Montreal in April, and at the Society for Academic Emergency Medicine (SAEM) meeting in Orlando, Florida in May. These meetings provide an important opportunity to inform the emergency medicine community of our research results and to receive feedback on the work prior to publication and for future studies. This was another very productive year with 8 abstracts accepted for presentation. We are reprinting a portion of these below and in the next issue. As well all abstracts can be found online at [www.ohri.ca/programs/clinicalepidemiology/opals](http://www.ohri.ca/programs/clinicalepidemiology/opals).



## Are Any ALS Treatments Associated with Better Survival in Out-of-Hospital Cardiac Arrest?

Stiell IG, Nesbitt L, Wells GA, Nichol G, Cousineau D, De Maio V, Brisson D, Beaudoin T, Vaillancourt C, Spaite D, Lyver M, Field B, Munkley D, Luinstra L, Campeau T, Dagnone E, Maloney J, Blackburn J, Huszti E, for the OPALS Study Group

**OBJECTIVES:** In the Ontario Prehospital Advanced Life Support (OPALS) Study Phase III, we demonstrated that an ALS program did not improve cardiac arrest survival in a rapid defibrillation EMS system. In this study, we sought to determine if specific ALS treatments are associated with better survival.

**METHODS:** This multicenter clinical trial was conducted in 17 communities and enrolled all adult out-of-hospital cardiac arrest patients during the 12-month BLS-D rapid defibrillation and the 36-month ALS phases. Paramedics were trained to ALS standards including endotracheal intubation and IV drug use. The primary outcome was survival to discharge. Chi-square and stepwise logistic regression analyses were performed.

**RESULTS:** The 5,637 patients enrolled had these characteristics: mean age 69.2 (range 16-102), male 66.7%, witnessed 51.7%, bystander CPR 14.7%, initial rhythm VF/VT 32.3%, defibrillator <8 minutes 93.3%; survival 5.1%. During the ALS phase, success rates were intubation 93.7% and IV insertion 89.0%. This table compares survivors (N=286) and non-survivors (N=5,351), giving adjusted odds ratios and 95% CIs for factors associated with survival:

FACTOR	SURV	NON-S	O.R.	95%CI
Bystander Witnessed	57.3%	41.5%	3.8	2.6,5.6
RMS Witnessed	29.4%	8.3%	13.1	8.3,20.7
Bystander CPR	30.8%	13.9%	2.8	1.9,4.0
Defibrillator <8 min	97.5%	93.2%	3.9	1.5,10.1
Age <75 Years	75.3%	60.8%	1.7	1.2,2.2
Atropine I.V.	5.5%	34.4%	0.2	0.1,0.4
Epinephrine I.V.	12.9%	37.2%	0.2	0.1,0.3
Lidocaine I.V.	29.2%	8.2%	20.9	12.6,34.8
Intubation	56.5%	69.0%	0.7	0.6,0.99

Hosmer\_Lemeshow goodness-of-fit  $p=0.10$ .

**CONCLUSIONS:** This study further confirms the importance of bystander CPR and early defibrillation. Among ALS interventions, intubation, atropine and epinephrine had a negative association and only lidocaine had a positive association with survival. Randomized trials are required to further evaluate the value of ALS interventions.

**Predictors of Survival for Out-of-Hospital Chest Pain Patients in the OPALS Study** Stiell IG, Ong M, Nesbitt L, Jaffey J, Wells GA, Beaudoin T, for the OPALS Study Group

**OBJECTIVES:** We previously demonstrated the addition of an ALS EMS program led to a reduction in mortality and improvement for chest pain patients. In this study, we sought to determine which specific factors were associated with better survival.

**METHODS:** This multicenter before-after controlled clinical trial was part of the Ontario Prehospital Advanced Life Support (OPALS) Study, looking specifically at chest pain patients. During the before phase, care was provided at the BLS-D level. During the after phase, ALS providers performed endotracheal intubation and administered IV drugs. We performed a stepwise logistic regression analysis to identify independent predictors of survival, regardless of phase.

**RESULTS:** 10,089 patients were enrolled during two 9-month BLS and ALS phases. The table shows the predictors with % of survivors (N=9,742) and non-survivors (N=345), odds ratios for survival with 95% CIs:

PREDICTOR	SURV	NON-S	O.R.	95%CI
Age in years	67	78	0.9	0.9 0.9
Systolic BP (mean)	144	130	1.0**	1.0 1.0
EMS 'life-threatening'	9.6%	22.9%	0.7**	0.5 1.0
Myocardial infarction	11.6%	42.6%	0.2**	0.1 0.2
Unstable angina	7.8%	3.7%	1.4	0.8 2.6
Intubation	0.04%	1.7%	0.2**	0.0 0.8
Fluid bolus IV	1.8%	5.2%	0.9	0.4 1.7
Nitroglycerin SL	37.5%	29.0%	1.4**	1.0 1.9
ASA PO	32.0%	30.1%	1.0	0.7 1.3
Morphine IV	2.2%	3.8%	0.6	0.3 1.1
Furosemide IV	0.9%	2.6%	0.1**	0.2 0.9

Hosmer-Lemeshow goodness-of-fit p=0.12

**CONCLUSIONS:** This largest controlled trial of out-of-hospital chest pain patients shows that blood pressure, EMS code 'life threatening', and myocardial infarction impact survival. Regarding interventions and survival, only nitroglycerin was positively associated while both furosemide and intubation were negatively associated. Randomized trials are needed to further assess the value of specific EMS treatments for chest pain.

**What is the Etiology of Out-of-Hospital Pediatric Cardiopulmonary Arrest?** Gerein R, Osmond M, Stiell IG, Nesbitt L, Campbell S, for the OPALS Study Group

**OBJECTIVES:** Pediatric cardiopulmonary arrest (CPA) outside hospital has a very high mortality rate. In hopes of developing strategies to improve pre-hospital resuscitation we evaluated the etiology and initial compromise of pediatric CPA.

**METHODS:** The Ontario Prehospital Advanced Life Support (OPALS) Study is a large multicenter initiative to evaluate the impact of EMS programs on 17 communities with 40,000 critically ill and injured patients. As part of this study we conducted a prospective cohort study that included all children < 19 years with prehospital CPA in a 10-year period from 1992-2002. Data were collected from ambulance reports and centralized dispatch data. We performed descriptive statistics with 95% CIs.

**RESULTS:** There were 308 children with CPA with these characteristics: Mean age 4.1 (range 0-18); Male 55.2%; Unwitnessed arrest 68.5%; CPR first started by: bystander 19.2%, First Responder (Fire/Police) 27.9%, BLS crew 22.4%, ALS (paramedics) 9.4%. Initial rhythm: asystole 83.1%, PEA 13.9%, VF 2.4%, VT 0.6%; overall survival to discharge was 2.1% CPA witnessed in 27.9% of cases; bystander 77.9%, EMS 22.1%. Initial compromise of witnessed arrests was judged to be: respiratory 47.7%, trauma 23.3%, sudden collapse (presumed electrical) 14.0%, and progressive shock 2.3%. Presumed etiology was SIDS 27.3%, trauma 13.0%, drowning 10.7%, respiratory disease 9.0%, chronic disease 8.4%, strangulation 4.9%, asphyxia 4.2%, fire 4.2%, neonatal asphyxia 3.6%, and cardiac disease 3.2%.

**CONCLUSIONS:** This is the largest prospective cohort of pediatric CPA reported to date and reveals that most pediatric arrests are unwitnessed and receive no bystander CPR. Those witnessed are most often due to respiratory arrests or trauma. SIDS, trauma and drowning are the most common etiologies. These data are vital to planning large resuscitation trials and highlights the need for better strategies for prevention, early recognition, and increasing the frequency of bystander CPR for children.

**What are the Most Important Unanswered Questions for Pediatric Cardiac Arrest?** Stiell IG, Nesbitt L, Wells GA, Campbell S, Nadkarni V, Berg R, Osmond M, Donoghue A, De Maio V, Mechem C, Richmond N, Tunik M, Hatley T, Clark L, Spaite D, Mears G, Valenzuela T, for the NIH Pediatric Cardiac Arrest Study Group (Presented at CAEP only)

**OBJECTIVES:** Pediatric cardiac arrest survival is very poor and resuscitation efforts are hampered by a paucity of evidence from robust clinical trials evaluating therapeutic options. We surveyed experts to determine research priorities for planning such trials in pediatric cardiac arrest.

**METHODS:** Our international, NIH-funded, resuscitation group conducted this prospective mail survey using a modified version of Dillman's Total Design Method. We selected 241 experts from professional organizations in 15 countries. Recipients rated the research priority, using a 5-point Likert scale, for each of 47 potential study questions presented in 4 domains (EMS Systems, Gas Exchange, Circulation, Post Resuscitation). We distributed the survey 4 times, twice each by email and by regular mail. The results were tabulated with simple descriptive statistics.

**RESULTS:** The 109 returns (45.2% completion) were from U.S.A. 50.5%, Canada 38.5%, Europe 2.7%, Australasia 4.6%. Respondents were 14.6% EMS professionals and 85.4% physicians: emergency medicine 45.0%, pediatrics 42.2%, internal medicine 4.6%, anesthesia 3.7%, cardiology 1.8%. The following had the 10 highest proportions of priority 1 and 2 responses regarding pediatric cardiac arrest survival:

75.0% What is the incremental value of prehospital CPR, defibrillation, and ALS?

73.9% What is the effectiveness of bag-valve-mask vs. intubation?

73.4% Does epinephrine improve outcome?

69.4% Does post resuscitation hypothermia improve outcome?

65.8% Does chest compression before defibrillation improve outcome?

65.2% Does vasopressin improve outcome?

61.7% What is the efficacy of CPR-only for the 1<sup>st</sup> 3 minutes?

59.6% Do AEDs improve outcomes?

58.5% Is end-tidal CO<sub>2</sub> effective for ETT tube placement?

58.3% Is compression-only CPR as effective?

**CONCLUSIONS:** This is the first international survey of research priorities for this under-studied area and the results will considerably assist the planning of large, multi-center clinical trials for pediatric cardiac arrest.

**What are the Characteristics and Outcomes of Non-Transported Pediatric Patients?** Kahalé J, Osmond M, Stiell IG, Nesbitt L, Maloney J, Trickett J

**OBJECTIVES:** We recently showed that 28% of children attended by paramedics are not transported to hospital by ambulance. This study aims to determine the characteristics of this non-transported population.

**METHODS:** This was a prospective cohort study in a single city with a 2-tiered EMS system. Enrolled were all children <16 years seen but not transported by paramedics to hospital over a 5 month period. We collected data from Ambulance Call Reports (ACRs), phone interviews and hospital charts. We used descriptive statistics.

**RESULTS:** Over 5 months there were 345 non-transported pediatric patients. Mean age=6 (range=0-15); 58.3% male; Dispatch priority urgent 68.1%, prompt 30.4%; Pick-up location: residence 58.6%, street 21.7%, public place 10.4%; Primary problem: trauma 50.7% (normal exam 36.6%, laceration 22.9%, contusion 13.7%) medical 45.2% (respiratory 30.7%, GI/vomiting 10.9, seizure 9.0%) Procedures performed: BLS 15.1%, ALS 3.5% Reason stated by paramedics for not transporting patient: parent will take child to MD 27.8%, parent will monitor child's condition 25.8% Phone interview: 106 parents (30.7%) participated. 76.4% believed there was a true emergency at the time of the 911 call. 75.5% stated that paramedics did not recommend that the child be brought to the hospital by ambulance. Hospital Charts: We confirmed that 51 of the 345 children were seen at an ED within 48 hours of the 911 call. Triage at the ED: Semi-urgent 47.8%, Urgent 39.1% and Emergent 6.5%; Outcomes: 68.6% discharged without follow-up, 15.8% discharged with follow-up, 7.8% admitted to the hospital. Average length of stay for those admitted was 2 days. No deaths were reported.

**CONCLUSIONS:** This is the largest study of non-transported children following EMS attendance. The majority of patients did not require immediate or urgent medical care and had good short-term outcomes. We recommend that EMS services review their handling of non-transported children to ensure good outcomes.

## STEERING COMMITTEE SUMMARY APRIL 6, 2004

Funding for Prehospital Research, including the OPALS Cardiac Arrest Database (OCAD), was discussed and four sources were identified: 1) 3 year unrestricted grant from Medtronic Physio-Control; 2) Ministry of Health funding, ending June 30, 2004; 3) CIHR grant for the OPALS Pediatric Study and; 4) the NIH Pediatric Cardiopulmonary Arrest planning grant.

The results of the OPALS Cardiac Arrest Study will be published in an upcoming issue of the New England Journal of Medicine. This publication is the culmination of 10 years of dedication and perseverance by all involved including paramedics, base hospital medical directors and staff, the study steering committee and many others.

Progress was discussed for all Prehospital Studies (please see the specific newsletter section for details). There remain a number of missing ambulance call reports for the Chest Pain Study and we are working with Tony Campeau to see if the Cooksville warehouse could serve as a source for this data. As well, Lorie Luinstra Toohey is checking the base hospital database to see if the prehospital information available in it could serve as a substitute for missing ACRs. Overall, 200 outcomes are outstanding from hospital health records and these are being followed up with the respective Hospital Health Records Departments. Outcomes of a further 900 cases were not identified in hospital records, and are being pursued via the Ontario Death Register with the assistance of Cancer Care Ontario. The few remaining missing outcomes in the Respiratory Distress Study are also being accessed via the Death Register.

The Future of OPALS discussion centered around the OPALS Prehospital Research Group Proposal, which was sent to Michelle Welsford for distribution to UTM Directors. The executive of the OBHAG group also reviewed the proposal. Doug Munkley suggested using Base Hospital Medical Directors to sell the proposal to the UTMs. Ian Stiell will follow up with a letter requesting their assistance. John Trickett is chairing the OBHAG Data Subcommittee and will propose that the committee nominate two members at large to represent database providers, including one from the OPALS Group.

continued

The Prehospital C-Spine Rule Validation Study reported that Nova Scotia has received conditional ethics approval and the target date for active recruitment is scheduled for September 2004. New Brunswick has also generated interest in participating in the study, and work is underway to get them on board.

We expect to have the results of the NIH Resuscitation Trials Network grant competition by late May.

## ICD (MOCA) STUDY

The Medical Outcomes after Cardiac Arrest (MOCA) Study is looking at the incidence of implantation of Implantable Cardioverter Defibrillators (ICD) in survivors of cardiac arrest. It will also determine what the rate should be and the reasons for implantation or non-implantation. OPALS Prehospital Research Group Base Hospitals have been contributing survivor data to this important study. In March a draw was held to recognize those sites who submitted information in time for eligibility and **Julie Cummins, Research Paramedic** at the **Ottawa Base Hospital** won the \$200 prize. Congratulations Julie!

## OPALS CHEST PAIN STUDY UPDATE

The chest pain study is in the final stages of data collection. Final requests for patient outcomes have been sent out to the participating hospitals and hopefully this phase will be complete soon. As soon as the patient outcomes are complete we will resume data cleaning. We would like to send a sincere "THANK YOU!" to all the Base Hospital Staff and Health Records Staff who have worked extremely hard to complete this 13,000 case project.

## BIPHASIC I STUDY UPDATE

The BIPHASIC I Study Investigators' Meeting was held in Montreal on April 23, 2004 in conjunction with CAEP 2004. Almost 20 physicians, coordinators and industry representatives from across Canada and the United States met to review progress and discuss interim study results. This very successful pilot study has to date enrolled 148 patients from the following sites: Vancouver Fire; British Columbia Ambulance Service; Edmonton Fire; and Windsor Fire and Base Hospital. With approximately 50 patients to go to complete the 200 patient target, it is anticipated that results comparing an escalating biphasic energy regimen [200-300-360 joules] with fixed [150 joules] will be ready for presentation in 2005.

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**OPALS TRAUMA STUDY UPDATE**

A comprehensive review of all received ambulance call records has been done, and request lists have been sent out to all Base Hospitals. We are hoping to have the remaining call records located, and sent to us with a month. A hearty "THANK YOU!" GOES OUT TO ALL Base Hospital Staff who are working diligently to find these records.

**OPALS PEDIATRIC STUDY UPDATE**

This study will examine the outcomes of children taken to hospital by ambulance for respiratory distress, cardiac arrest, major trauma and seizure. Within the last few weeks all of the Base Hospitals were contacted to determine where they were within the data retrieval process. While Base Hospitals are retrieving their remaining ACRs to be submitted, here, at the Ottawa Coordinating Center we are currently reviewing the submitted ACRs to determine if they meet inclusion criteria. If eligible, they will then be entered in the new pediatric databases. Please keep in mind that although we have a file on site for a particular month for a base hospital, this does not mean that all of the ACRs for that month have been received. More up-to-date lists will follow within the upcoming weeks. We look forward to working closely with the Base Hospitals to complete this data collection process.

**CAN-AM PEDIATRIC CARDIAC ARREST STUDY**

In January 2004, the CanAm group held Workshop #2 in Tucson, Arizona where they reviewed the overall goals and timeline for the project, decisions from Workshop #1, and goals for the current workshop. A comprehensive review of the literature was presented as well as the interim results of the survey of 240 international experts regarding the most important unanswered issues in prehospital treatment of pediatric cardiac arrest patients. The 3 most important unanswered questions, that are the highest priority for research, were the focus of attention. In April, the group undertook a preliminary discussion of methodological issues regarding the #1 priority question. Currently, the group is researching the most important interventions to be evaluated.



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**Submissions**

(Before July 31, 2004)

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