Computer Decision Support Software (EndoTool™) Safely Improves Glycemic Control in the Burn Intensive Care Unit

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The use of Army medical and/or other Army records in the preparation of this material is acknowledged, but is not to be construed as implying official Department of the Army approval of the conclusions presented.

Introduction

The stress response associated with severe burn incites a hyperglycemic state linked with negative outcomes for the burned patient. We previously showed the widespread adoption of intensive insulin therapy[1] among American Burn Association Burn centers [2] yet no published reports describe an efficacious method to consistently achieve tight glycemic control in the critically burned. Extremes in glycemic variability are difficult to manage in these patients and achieving consistent time in target glucose range without increasing hypoglycemic risk is a challenge.

The advent of computer decision support software (CDSS)[3] offers the possibility of improved control and standardization of insulin therapy within the burn unit. CDSS systems provide the ability to predict insulin requirements based on patient-specific response to previous doses as a function of their unique insulin resistance pattern, while minimizing hypoglycemic events. No data support safety or efficacy of any computerized dosing software specifically for the burn population.

Objectives

The purpose of this study was to compare our current paper-based nomogram for insulin titration to the EndoTool™ computer decision support system to establish the safest and most effective method of managing intensive insulin therapy in the burn ICU.

Methods

- Randomized crossover clinical study
- Single center burn ICU
- 18 civilian/military burn patients
- Patients receiving continuous insulin infusion were randomized to receive glucose management using a traditional paper-based protocol (PP) or computer protocol (CP) for 72 hours then crossed over to the alternate method for an additional 72 hours
- Primary endpoint: time in target glucose range of 80-110 mg/dl
- Statistical analysis: Student's paired t-test, Wilcoxon signed-ranks test, Mann-Whitney U-test, chi square
- Significance accepted for two-tailed $p \leq 0.05$

Grant Support

- The National Institutes of Health (1 R01 GM063120-04)
- The Technologies for Metabolic Monitoring (TMM)/Julia Weaver Fund, a Congressionally directed program jointly managed by the USA MRMC, NIH, NASA and the Juvenile Diabetes Research Foundation
- Combat Casualty Care Division US Army Medical Research and Materiel Command

Results

	Total	Civilian	Military	*p* value
	n = 18	n = 7	n = 11	
	mean ± sd	mean ± sd	mean ± sd	
age (years)	32 ± 16.6	48 ± 16.7	22 ± 3	**0.01**
% TBSA Burn	43 ± 19.1	38 ± 11.4	46 ± 22.8	0.41
% TBSA Full Thickness	25 ± 20.2	18 ± 15.2	30 ± 22.4	0.23
No. Subj. Pos. Inhalation Injury	8 (44.4%)	2 (28.6%)	6 (54.5%)	0.37
Injury Severity Score	25 ± 9.1	19 ± 5.1	28 ± 9.6	**0.04**
Body Mass Index	26 ± 3.2	30 ± 3	25 ± 2.9	0.09
ICU days	64 ± 50	51 ± 34.6	73 ± 57.4	0.53
Admission Hemoglobin A1c	5.6 ± 0.4	5.7 ± 0.5	5.6 ± 0.4	0.59
No. Subj. Acute Adrenal Insufficiency in ICU	6 (33.3%)	4 (57.1%)	2 (18.2%)	0.09
No. Subj. In-hospital Death	4 (22.2%)	3 (42.9%)	1 (9.1%)	0.09
No. Subj. History IDDM/NIDDM	0	0	0	n/a

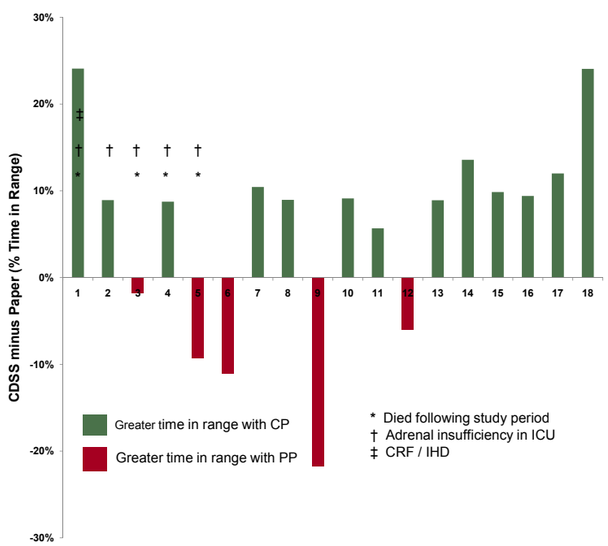

Figure 1: Time each subject spent in target range (80-110 mg/dl) expressed as time in CP minus time in PP
(CRF = chronic renal failure; IHD = intermittent hemodialysis)

	Computer	Paper	*p value*
No. Septic Events / group	11	11	1.0
Insulin Rate / subject (u/hour; mean ± SD)	6.6 ± 6.7	6.2 ± 5.6	0.71
Unit Insulin Infused / subject (mean ± SD)	470 ± 484	437 ± 402	0.61
ml Feed / subject (mean ± SD)	7054 ± 3442	7303 ± 2759	0.70
Units Insulin : ml Feed / subject (mean ± SD)	0.08 ± 0.09	0.06 ± 0.04	0.29
No. Glucose Measurements/72 hrs / group (mean ± SD)	73 ± 3	67 ± 3.7	**<0.001**
Nursing compliance with recommendation (mean ± SD)	82 ± 17%	39 ± 15%	**<0.0001**

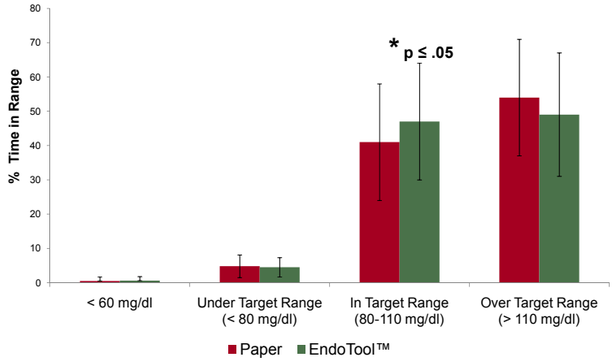

Figure 2: Time under, in and over target glucose range 80-110 mg/dl for each study arm for PP and CP

- More subjects (n=13) spent greater time in target (80-110 mg/dl) range using CP (Fig. 1)
- Time in target glucose range (80-110 mg/dl) was higher in the CP group (47 ± 17% versus 41 ± 16.6%; $p \leq 0.05$) (Fig.2)
- Time over target range was reduced in the CP group (49 ± 17.8% versus 54 ± 17.1; $p = 0.08$)
- No difference in time under target of 80 mg/dl (CP 4.5 ± 2.8%, PP 4.8 ± 3.3%; $p = 0.79$), under 60 mg/dl ($p = 0.65$), or under 40 mg/dl ($p = 1.0$)
- Mean glucose for CP arm was lower than PP arm (113 ± 10.2 mg/dl vs. 119 ± 14.0 mg/dl, $p = 0.02$)
- Amount of insulin infused and caloric intake were the same between groups
- More glucose measurements were performed in the CP group ($p < 0.001$)
- Nursing staff complied with CP recommendations twice as often compared to PP ($p < 0.0001$)

Discussion

The CP achieved significant improvement in maintaining serum glucose in the 80-110 mg/dl target range compared to our traditional PP. Subjects managed with PP spent more time over target range, yet there was no difference in time spent under target range (Fig 1). This demonstrates the CP is adept at controlling hyperglycemic excursion, without increasing hypoglycemic events. Groups proved to be comparable regarding caloric intake and insulin doses. Military and civilian patients were similar except for younger age and higher injury severity scores in the military cohort; when adjusted for age no outcome differences exist between these cohorts treated at our burn center [4]. Nursing staff were compliant with CP recommendations more often than with calculations from the PP and tested glucose more frequently in unstable patients. Thus, consistency in dosing is improved [5] for varied educational and experience levels among nurses with CDSS, and more frequent prompting by the CP may improve patient safety [6]. This trial was halted based on improved CP glycemic control without increased hypoglycemic events during a planned interim analysis; EndoTool™ became standard of care in our burn ICU in November 2008.

Conclusions

- CDSS improved glycemic control in burn ICU patients by achieving target glucose more often compared to a conservative paper-based nomogram.
- No increased risk of hypoglycemic events was associated with CDSS glycemic control.
- Nurses complied with CDSS recommendations more often than the calculated infusion rate from the paper protocol, increasing uniformity in delivery of insulin therapy.
- Consistent glycemic management will provide increased internal validity for multi-center clinical trials evaluating insulin therapy [5].

References

1. Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med.* 2001;345:1359-1367.
2. Mann EA, Pidcoke HF, Salinas J, et al. The impact of intensive insulin protocols and restrictive blood transfusion strategies on glucose measurement in American Burn Association (ABA) verified burn centers. *J Burn Care Res.* 2008;29:718-723.
3. Saager L, Collins GL, Burnside B, et al. A randomized study in diabetic patients undergoing cardiac surgery comparing computer-guided glucose management with a standard sliding scale protocol. *J Cardiothor Vascr Anesth.* 2008;22:377-382.
4. Wolf SE, Kauvar DS, Wade CE, et al. Comparison between civilian burns and combat burns from Operation Iraqi Freedom and Operation Enduring Freedom. *Ann Surg.* 2006;243:786-795.
5. Morris AH, Orme J, Truwit JD, et al. A replicable method for blood glucose control in critically ill patients. *Crit Care Med.* 2008;36:1787-1795.
6. Van Herpe T, De Brabanter J, Beullens M, et al. Glycemic penalty index for adequately assessing and comparing different blood glucose control algorithms. *Crit Care* 2008;12:R24.