

The Effectiveness of Management Protocol for Acute Diabetic Complications in a Thai Hospital

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Background: DKA and HHS are the most serious diabetic emergencies. The treatment usually begins by primary physician at the emergency room. Even when the approved guideline is used in the hospital, the outcomes of treatments vary widely due to human errors. The authors developed a protocol for this condition and prepared pre-printed order to insure that every patient will get the best treatment. Very low dose insulin was used in our protocol based on scientific evidence of good efficacy. It is safer than current regimen.

Objective: To demonstrate the effectiveness of Lerdsin DKA/HHS Hospital Protocol to treat diabetic emergency patients.

Material and Method: After protocol development, a retrospective cohort study was performed to compare 34 DKA/HHS patients treated with conventional ADA's guideline to 34 patients treated with Lerdsin DKA/HHS Hospital Protocol.

Results: The groups of patients had comparable demographic data, and severity of illness including vital signs, serum osmolality, anion gap, serum glucose, serum BUN/Cr, serum Na, K, Cl, HCO₃, blood pH, and urine ketone. However, the hypoglycemia, rebound hyperglycemia, time to switching from intravenous insulin to intermediate acting insulin subcutaneously, total insulin doses, and total house staff called were significantly lower in Lerdsin DKA/HHS Hospital Protocol group compare to the conventional ADA's guideline group. After plotting the graph from serum glucose and insulin used, the physician can estimate the 24-hour insulin requirement and switch insulin from intravenous to subcutaneous route immediately after the metabolic abnormality is resolved.

Conclusion: The very low dose insulin regimen plus pre-printed order of laboratory investigation, fluid and electrolyte treatment, and precipitating causes treatment following the Lerdsin DKA/HHS Hospital Protocol can improve the outcome of treatment in our hospital.

Keywords: Diabetes ketoacidosis (DKA), Hyperosmolar hyperglycemic state (HHS), Effectiveness and management protocol

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Diabetes ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS) are acute and serious diabetic complications⁽¹⁾, which are commonly handled by general practitioners at the emergency department using conventional clinical guideline. However, pitfalls and complications from conventional management method do exist. In one teaching hospital in Spain, 70% of cases had delayed initiation of intravenous fluid therapy⁽²⁾. The mortality rate is 18.83% in Taiwan⁽³⁾. To overcome these obstacles and reduce mortality, many teaching hospitals have developed pre-printed

management protocols and the results of their implementation are very impressive, especially in pediatric DKA⁽⁴⁾.

A pre-printed management protocol is a set of treatment orders written to capture treatment domain from general clinical guidelines⁽⁴⁻⁷⁾. The main objective of the protocol is to prevent delay and inappropriate treatment with insulin and intravenous fluid replacement. The pre-printed protocol ensures that all important treatments are delivered properly to the patients and human errors avoided as much as possible. Since very low dose insulin therapy was effective with fewer complications, the concept of very low dose insulin was integrated into the Lerdsin DKA/HHS Hospital Protocol. The present retrospective cohort study was conducted to verify the effectiveness and safety of Lerdsin DKA/HHS Hospital Protocol for

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the management of DKA and HHS in a tertiary care hospital.

Material and Method
Protocol development

Lerdsin DKA/HHS Hospital Protocol for the management of DKA and HHS was developed to cover four major treatment domains of DKA and HHS management. These four treatment domains are selected from general clinical guidelines, then re-written into easy-to-follow order set using check boxes. The four domains are fluid resuscitation, insulin

delivery, acid/base treatment, and precipitating cause treatment (Fig. 1).

The insulin infusion regimen selected to use in the Lerdsin DKA/HHS Hospital Protocol for the management of DKA and HHS is the University of Nebraska Medical Center regimen. The insulin concentration rate is 0.2 to 8 units per hour, with maximum at eight units per hour, supported by Kitabchi insulin clamp study⁽⁸⁾. Because insulin is a high alert drug, the authors chose 1:5 as standard insulin, saline solution and controlled by an infusion pump. The rationale behind this concentration is its

Lerdsin Protocol for DKA/HHS
Intravenous continuous insulin infusion
using very low insulin regimen

Investigation Section

<input type="checkbox"/> CBC	<input type="checkbox"/> BS, BUN, Cr, Na, K, Cl, HCO3	<input type="checkbox"/>
<input type="checkbox"/> Arterial blood gas	<input type="checkbox"/> Urine exam	<input type="checkbox"/>
<input type="checkbox"/> EKG 12 leads	<input type="checkbox"/> Portable CXR	<input type="checkbox"/>

Fluid/electrolyte

No. 1 bottle for resuscitation NSS1000cc via IV rate...../hr.
..... via IV rate...../hr.
 call the doctor after it run out.

No. 2 bottle for K replacement
 please write down K value here..... and check urine out put before order K
NSS 1000 cc. + K..... mEq 5%D/NSS/2 1000 cc. + K.....mEq
 via IV rate.....cc/hr

No. 3 bottle for IV insulin delivery DTX q 1 hr.
 Regular insulin 100 unit in NSS 500 cc. (1 unit/5cc) IV drip

DTX	Insuliuin infusion (u/hr)
<60	OFF
61-80	0.3 = 2 microdrop/min
81-100	0.5 = 3 "
101-120	0.8 = 4 "
121-140	1.0 = 5 "
141-170	2.0 = 10 "
171-200	3.0 = 15 "
201-250	4.0 = 20 "
251-300	5.0 = 25 "
301-350	6.0 = 30 "
351-400	7.0 = 35 "
>400	8.0 = 40 "

Call the doctor when

DTX < 60 to adjust insulin down 1 to 2 steps
 Systolic BP < 100 mmHg.
 Serum K < 3 mEq/dl

Other Retain urethral catheter and record urine output q 1 hr. q 8 hr.
 Repeat electrolyte at.....

Addendum If K 3.3-5.3 start IV insulin as Lerdsin infusion protocol and add Kcl 20-30 mEq/L in each 1000 cc. fluid for maintenance K at 4.5. (another line, not resuscitating fluid)
 If K > 5.3 start IV insulin as Lerdsin infusion protocol, recheck K q 2 hr.
 If K < 3.3 replace K 20-30 mEq /hr, use **infusion pump, start insulin protocol when K > 3.3**

Signature.....

Fig. 1 Lerdsin DKA/HHS Hospital Protocol for management of DKA and HHS

simplicity and most physiologic. The insulin IV drip/ hour will be manually increased/decreased according to blood sugar results from finger stick test (Fig. 1). If the serum glucose decreases below 60 mg/dl, one should stop the insulin infusion for one hour then lower the rate of insulin 1 or 2 steps. In cases that have poor response with the serum glucose decrease at a rate less than 50 to 75 mg/dl per hour, one should increase the insulin rate 1 or 2 steps. Minor change of insulin rate can be easily made in the order set according to blood sugar results. This very low dose insulin regimen plus fine adjustment of insulin infusion rate is a new concept. It imitates the glucose-pancreas auto regulation, resulting in less hypoglycemia and slowly re-equilibrates the metabolic derangement in the body to prevent cerebral edema⁽⁹⁾.

The Lerdsin DKA/HHS Hospital Protocol for management of DKA and HHS is pre-printed and ready to use as shown in Fig. 1. This protocol has been implemented as routine medical care for DKA/HHS patients at Lerdsin Hospital since July 2009.

A retrospective cohort study was conducted. Medical records of patients treated before and after protocol implementation were reviewed. To have a power of 80%, type II error of 5% and probability for any treatment complication about 30% in the old method and 2% in the new method, the sample size was 32 in each group. To cover some medical records that might have missing important variables, the number of each group was increased to 34. The DKA/HHS patients treated by usual clinical guideline regimen before protocol implementation were cases reviewed retrospectively from July 2009 until reaching the target of 34 cases. These 34 cases then were compared to the 34 cases treated with the new protocol since July 2009.

Patient selection

Males and females, 14 to 75 years with the diagnosis of DKA, HHS, or both, who were admitted into internal medicine department, or in other departments, but under the care of internal medicine were included in this study.

Diabetic ketoacidosis is defined as serum blood sugar ≥ 300 mg/dl, blood pH ≤ 7.2 , serum $\text{HCO}_3 \leq 15$, serum anion gap ≥ 12 , and positive serum ketone or ketone amount in urine is ≥ 2 .

Hyperosmolar hyperglycemic state is defined as serum blood sugar ≥ 300 mg/dl serum osmolarity ≥ 320 .

Demographic data of all patients were collected as follows, age, gender, diabetes duration, type of diabetes, diagnosis of diabetic emergency, diagnosis of precipitating disease, vital signs, serum sodium, serum potassium, serum bicarbonate, serum chloride, serum anion gap, serum BUN, serum creatinine, blood pH, and serum osmolarity.

Result of treatment included (1) hypoglycemia defined as serum glucose ≤ 60 mg/dl, (2) hypokalemia defined as serum potassium < 3.5 mg/dl, (3) time from first IV insulin drip to target blood sugar 250 mg/dl, (4) number of rebound hyperglycemia defined as the value of serum glucose rebound up to more than half of the first value at admission after being treated to target blood sugar (5) duration of time spent from first insulin administered continuously intravenously to switching to intermediate acting insulin administered subcutaneous, (6) the number of blood glucose tests, (7) total dose of insulin given, and (8) number of resident called to see patients.

Statistical analysis

Parametric variables were summarized in means \pm standard error of mean (SEM) and compared between two groups by student-t test. Non-parametric variables were summarized in frequency (%) or median and using non-parametric tests such as Mann-Whitney u-test or Chi-square test where appropriate to compare between two groups. P-value ≤ 0.05 is considered to be statistically significant.

Results

In Table 1, the demographic characters of both groups were comparable (before and after the protocol was implemented). The group of patients before the protocol was implemented will be named "control group". The group of patients after the protocol was implemented will be named "protocol group". The severity of DKA and HHS, which are reflected by body responses and biochemical values, were matched. Table 2 shows that many outcomes were improved after protocol implemented. Hypoglycemia was statistically significantly lower in the "protocol" group (0.03 vs. 0.20, $p = 0.047$). Hypokalemia was statistically significantly lower in the "protocol" group (0.38 vs. 0.82, $p = 0.037$). Average number of rebound hyperglycemia was also statistically significantly lower in the "protocol" group (0.29 vs. 2.09, $p < 0.001$). Time spent before switching from intravenous insulin to hypodermic route was significantly shorter in the "protocol" group (26.40 vs. 50.76, $p < 0.001$). A

Table 1. Demographic variables of patients in group before and after Lerdsin DKA/HHS Hospital Protocol

	Control group	Protocol group	p-value
No. of patient	34	34	
Male:female	17:17	17:17	1.0 ^a
Age (years)	51.22 ± 2.69	50.49 ± 3.38	0.862
Age onset (years)	43.08 ± 6.88	40.43 ± 3.34	0.590
DM year (years)	6.88 ± 2.38	7.11 ± 1.88	0.881
DM2:DM1	17:17	15:19	0.62 ^a
Serum glucose (mg/dl)	692.80 ± 41.85	641.06 ± 48.14	0.407
Serum osmolarity (mosmol/l)	322.54 ± 4.80	325.76 ± 5.53	0.653
Serum Na (mEq/l)	131.50 ± 1.76	132.60 ± 1.91	0.666
Serum K (mEq/l)	4.86 ± 0.20	4.80 ± 0.24	0.858
Serum HCO ₃ (mEq/l)	12.53 ± 1.29	11.71 ± 1.26	0.640
Serum Cl (mEq/l)	95.31 ± 1.72	97.00 ± 1.82	0.491
pH of blood	7.20 ± 0.03	7.19 ± 0.03	0.790
Anion gap	28.82 ± 2.34	30.16 ± 2.08	0.661
Systolic BP (mm/Hg)	125.38 ± 3.50	126.06 ± 3.81	0.894
Diastolic BP (mm/Hg)	71.88 ± 2.46	74.85 ± 2.72	0.441
Heart rate (/min)	104.73 ± 2.79	99.00 ± 3.29	0.184
Temperature (celcius)	37.38 ± 0.12	37.26 ± 0.23	0.641
Respiratory R (/min)	23.47 ± 1.10	24.92 ± 1.31	0.384
Serum BUN (mg/dl)	30.71 ± 3.23	42.94 ± 5.37	0.480
Serum Cr (mg/dl)	1.98 ± 0.21	2.38 ± 0.38	0.344
Urine ketone	1.91 ± 0.20	1.82 ± 0.21	0.752
DKA:HHS	23:18	25:22	0.78 ^a

Data presented as mean ± SEM, or number (n)

^a p-value using Chi-square test

Other variables p-value using student-t test

Table 2. Patients' outcome before and after Lerdsin DKA/HHS Hospital Protocol was implemented

	Control group	Protocol group	p-value
No. of hypoglycemia	0.20 ± 0.78	0.03 ± 0.20	0.047*
No. of hypokalemia	0.82 ± 0.18	0.38 ± 0.10	0.037*
No. of rebound hyperglycemia	2.09 ± 0.42	0.29 ± 0.13	<0.001**
Time to serum glucose at 250 mg./dl (hour)	11.95 ± 3.61	9.91 ± 2.40	0.633
Time to switch IV insulin to subcutaneous injection of intermediate insulin (hour)	50.76 ± 5.18	26.40 ± 3.32	<0.001**
Total regular insulin dose	111.99 ± 11.76	73.02 ± 6.95	0.005**
No. of finger stick test	17.74 ± 2.01	19.06 ± 1.84	0.623
No. of resident called	7.44 ± 0.79	3.03 ± 0.59	<0.001**

Data presented as mean ± SEM

** p-value < 0.05 using student-t test

* p-value < 0.05 using Mann-Whitney u-test

statistically significant less amount of insulin was used in the “protocol” group (73.02 vs. 111.99, $p = 0.005$). Average number of residents called was also statistically significantly lower in the “protocol” group (3.03 vs. 7.44, $p < 0.001$). Only the average time spent before blood sugar reached target of 250 mg/dl and the average number of finger sticks for blood sugar test were not statistically significantly different between two groups at p -value of 0.633 and 0.623 respectively.

Discussion

A well-arranged plan is the key to combat complex nature of DKA/HHS⁽⁴⁾. The concept of applying clinical disease protocol order set has been shown to improve results in the most delicate settings, in pediatric DKA patients, and in adults⁽¹⁰⁾. The most frequent complications during treatment are insulin induced hypoglycemia, hypokalemia, and brain edema in children. In 2009, concerning patient safety, the World Health Organization announced insulin as a high alert drug. They suggest three strategies to avoid insulin complication. These are (1) establishing a hospital standard insulin solution, (2) using pre-printed insulin orders to decrease error, and (3) discouraging regular insulin sliding scale administered subcutaneously to control blood sugar in any situation^(11,12). With this conceptual protocol integrated with the WHO safety policy, the authors anticipate fewer complications and better care.

There are various insulin infusion algorithms in the literature⁽⁷⁾. The basis for these is different from that of static insulin infusion in conventional DKA/HHS guidelines. Among those dynamic insulin delivery fashions, the differences are rates, concentrations and the steps used to adjust insulin to match each insulin resistance status. Most insulin algorithms are designed in three columns for low, normal, and high insulin resistance. One has to choose which columns to use. Then to adjust the insulin dose, one needs to add/subtract insulin units on top of that. Lately there is even computer insulin adjustment software developed for this difficult task⁽¹⁴⁾. Because of positive outcomes and the lower complications of the very low dose insulin infusion, the authors chose the very low insulin regimen ranging between 0.2 to 8 units per hour for Lerdsin DKA/HHS Hospital Protocol instead of the usual 10 units per hour.

The idea of very low insulin dosage was proposed by Kitabchi in 1989. He demonstrated that insulin six units per hour or less corrected metabolic abnormality as effectively as the dose of 10 units per

hour⁽⁸⁾. The idea is well supported by DeFronzo who in 1994, by using insulin clamp technique, showed that intravenous insulin one unit per hour could block ketones from lipid breakdown completely, while intravenous insulin two units per hour also blocked most of glucose production from the liver^(13,15). In 1999, the Wager group tested this idea clinically. This unique procedure gradually decreased serum glucose and was intended to slowly re-equilibrate metabolic abnormality. It yielded zero mortality rate and less hypokalemia⁽⁹⁾.

Though adjusting insulin in “dynamic fashion” is normal pancreas physiology, it is not easy to change the routine of medical personnel. The authors back up this new practice with the Van den Berghe 2001 study, which used insulin infusion protocol in critically ill patients. Her dynamic artificial pancreas-glucose feedback loop showed that the user could more often avoid hypoglycemia compared to usual “static” insulin administration⁽¹⁵⁾. Minor changes of insulin rate can be easily made in the order set according to blood sugar results from finger stick tests. The authors believe that both the lower hypoglycemia and the lower hypo-kalemia in the present study is the result of this highly physiologic insulin delivery.

The present study confirmed that using low insulin concentration worked by showing that with the same severity of acidosis and osmolarity, the abnormalities could be corrected with half the insulin dosage compared to the usual one. The time to reach serum glucose end point at 250 mg/dl is no more than the routine one (9 vs. 11). The very low insulin regimen did not require more finger stick tests. On the other hand, less frequent resident call was evident when the protocol was implemented. The time saved is very important in a community hospital where shortage of staff is a problem.

Reviewing glucose-insulin response hourly in glucose record charts, one can determine the insulin unit required in 24 hour or at least the insulin units required to maintain serum glucose in some narrow range per hour. Once the patient recovered from acidosis or high osmolarity, the total insulin requirement per day can be calculated and switch to intermediate acting insulin without using the insulin sliding scale. Experts discourage the sliding scale because it fluctuates blood sugar, then prolong hospital stay⁽¹⁶⁾. In the present study, the authors reduced time consumed before being able to switch intravenous insulin to intermediate acting insulin by half (26 vs. 50). Lerdsin DKA/HHS Hospital Protocol can significantly reduce

number of rebound hyperglycemia. Avoiding rebound hyperglycemia is avoiding unnecessary hospital stay and expense.

The present study demonstrated that the new practice, which is based on a recent understanding of DKA/HHS in a published paper, is safe and effective to use as a hospital model. In addition, the authors deliver this in the R to R (routine to research) program.

In conclusion, the authors carefully reviewed the concept of DKA/HHS treatment published in the last decade. The authors followed WHO patient safety policy for insulin. The authors developed pre-printed Lerdsin DKA/HHS Hospital Protocol using very low dose insulin instead of the usual insulin regimen in general guideline, adjusted insulin dosage in dynamic insulin infusion fashion, corrected fluid, electrolyte imbalance, and treat precipitating causes. This retrospective, routine to research study showed that the Lerdsin DKA/HHS Hospital Protocol improved better care of DKA/HHS by decreasing hypoglycemia, hypokalemia and length of hospital stay. It is safe and effective to use in the institute and should be implemented as a new practice.

Potential conflicts of interest

None.

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ประสิทธิภาพของแบบแผนการรักษาภาวะแทรกซ้อนเฉียบพลันจากโรคเบาหวานในโรงพยาบาล แห่งหนึ่งในประเทศไทย

ธนพร รัตนสุวรรณ, วินัย รัตนสุวรรณ

ภูมิหลัง: ภาวะแทรกซ้อนเฉียบพลันที่เกิดจากโรคเบาหวานและจัดเป็นภาวะฉุกเฉิน มี 2 ชนิด คือ DKA และ HHS และมักเริ่มให้การรักษาด้วยแพทย์เวชปฏิบัติ แม้ว่าจะมีแบบแผนการรักษาเดิมให้ปฏิบัติตาม แต่เนื่องจากผู้สั่งการรักษาจะต้องเขียนคำสั่งการรักษาเอง และการรักษาทั้ง 2 ชนิดนี้มีรายละเอียดมาก ทำให้การรักษามีความหลากหลาย และผู้ป่วยเกิดภาวะแทรกซ้อนได้บ่อยๆ โรงพยาบาลเลิดสินจึงได้พัฒนาแบบแผนการรักษา DKA และ HHS เป็นคำสั่งที่มีการจัดพิมพ์หัวข้อการรักษาไว้ล่วงหน้าและบริหารปริมาณอินซูลินโดยใช้หลักการใช้อินซูลินขนาดต่ำมาก (Lerdsin DKA/HHS Hospital Protocol) และประเมินผลการใช้แบบแผนดังกล่าวในโรงพยาบาล

วัตถุประสงค์: เพื่อประเมินผลการรักษา DKA และ HHS ที่โรงพยาบาลเลิดสิน ก่อนและหลังการนำ Lerdsin DKA/HHS Hospital Protocol มาใช้

วัสดุและวิธีการ: ได้ศึกษาจากเวชระเบียนผู้ป่วยที่รับไว้ในโรงพยาบาลด้วย DKA และ HHS จำนวน 34 ราย ก่อนและหลังการนำ Lerdsin DKA/HHS Hospital Protocol มาใช้

ผลการศึกษา: ผู้ป่วยทั้ง 34 ราย ในแต่ละกลุ่มมีความรุนแรงของโรค ค่าสัญญาณชีพ ผลตรวจทางห้องปฏิบัติการต่างๆ เช่น ระดับน้ำตาลในเลือด ระดับเกลือแร่ต่างๆ ความเป็นกรด ต่าง ของเลือด เป็นต้น ใกล้เคียงกัน แต่ผลการรักษามีความแตกต่างกัน กล่าวคือ กลุ่มที่ได้รับการรักษาด้วย Lerdsin DKA/HHS Hospital Protocol มีภาวะแทรกซ้อนหลังการรักษาน้อยกว่าอย่างมีนัยสำคัญทางสถิติ ทั้งภาวะน้ำตาลต่ำในเลือดภาวะเกลือแร่โปแตสเซียมต่ำในเลือด ภาวะน้ำตาลในเลือดกลับมาสูงอีกนอกจากนี้ ระยะเวลาที่บริหารอินซูลินทางหลอดเลือดดำสั้นกว่าปริมาณรวมของอินซูลินที่ใช้ให้น้อยกว่า และจำนวนครั้งที่แพทย์ถูกตามกลับมาดูแลผู้ป่วยน้อยกว่า เมื่อพ้นจากภาวะฉุกเฉินก็สามารถคำนวณปริมาณอินซูลินที่ต้องใช้ฉีดเข้าใต้ผิวหนังต่อวันได้ง่ายกว่า

สรุป: แบบแผนการรักษา Lerdsin DKA/HHS Hospital Protocol ช่วยทำให้การรักษาภาวะแทรกซ้อนฉุกเฉินจากโรคเบาหวานได้ผลดีขึ้น และผู้ป่วยเกิดภาวะแทรกซ้อนจากการรักษาลดลงอย่างมีนัยสำคัญ
