

Stroke Hyperglycemia Insulin
Network Effort (SHINE) Trial
Treatment Protocols
Special Situations

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Protocol PI



Hypoglycemia Protocol

General Concepts

- The hypoglycemia prevention protocol begins when glucose falls <80 mg/dL
- But, actual hypoglycemia is defined as <70 mg/dL
- Severe hypoglycemia (our primary safety outcome) is defined as <40 mg/dL
- Any glucose level that falls <70 mg/dL requires additional info:
 - Laboratory serum glucose level – send but give D50 before result available
 - Symptomatic or asymptomatic status assessment



Detailed Look at Hypoglycemia Protocols

- Glucose 70-79 mg/dL
 - STOP all SQ and IV study treatments
 - Give D50 slow IV push
 - Control Group: 1/2 ampoule (25 ml)
 - Intervention Group: per GlucoStabilizer
 - Recheck glucose
 - Control Group: q 15 min and give another 1/2 ampoule (25 ml) D50 as long as glucose <80 mg/dL
 - Intervention Group: q 15 min per GlucoStabilizer



Detailed Look at Hypoglycemia Protocols

- Glucose <70 mg/dL (Add to steps for 70-79 mg/dL)
 - Send serum sample for glucose to lab. Do not delay D50.
 - DO NOT draw blood for glucose checks from same IV line where the D50 was given
 - Hypoglycemia symptom questionnaire needs to be done q15 min until glucose ≥ 80 mg/dL (plus one additional)
 - Neuro check each time glucose <70 mg/dL
 - NIHSS for worsening as soon as possible; if ≥ 4 point increase on the NIHSS from previous and persistent, recheck in 24-30 hrs
 - Once glucose ≥ 80 mg/dL resume treatment protocols



Hypoglycemia Symptomatic Questionnaire

- Adrenergic signs

- Diaphoresis
- Sweaty
- Nervous
- Shaky
- Palpitation
- Hungry
- Tingly
- Warm

- CNS signs

- Confused
- Drowsy
- Weak

Cognitive impairment usually starts when blood glucose <50 mg/dL



How to Sync Glucose Check Schedule in Control Group

- 1st check as soon as saline bag ready to drip
- Q 1hr check for a total of 4
 - If any of the 4 Q 1hr checks are close to the time of scheduled SQ insulin dosing, give the SQ insulin per protocol sliding scale
- After the 4th Q 1 hr check, start glucose checks on schedule, but if the 1st scheduled check is <1 hr after, then skip it



Pauses in SHINE protocol

- Rarely, there may be a need to pause the SHINE protocol – gone for a test or procedure, IV access lost
- Protocol pause for Control Group
- Protocol pause for Intervention Group



Pauses in SHINE Protocol

- Control Group

- As soon as ready to restart protocol, recheck glucose
 - Resume IV saline based on that glucose level
 - If SQ sliding scale insulin dose was missed, give it then based on that glucose level
- If SQ basal insulin dose was missed, give it then
- If next glucose check scheduled in <1 hr, then skip it
- If next insulin dose scheduled in <3 hrs, then skip it



Pauses in SHINE Protocol

Patient Lost IV Access

- Control Group
 - Monitor and enter glucose levels in SHINE computer per protocol
 - Give SQ insulin per protocol
 - When ready, restart IV saline drip based on latest glucose level (screen)



Pauses in SHINE protocol

- Intervention Group
 - As soon as ready to restart IV protocol recheck glucose
 - If IV drip off for <3 hrs, use “Resume” option in GlucoStabilizer
 - If IV drip off for ≥ 3 hrs, use “Start New Drip” option in GlucoStabilizer
 - If saline dose was missed, give 0.05 cc SQ saline then
 - If next saline dose scheduled in <3 hrs, then skip it
 - If a meal is eaten late, give SQ meal insulin with that meal as you would otherwise



Pauses in SHINE Protocol

Patient Lost IV Access

- Intervention Group
 - Monitor and enter glucose in GlucoStabilizer q 1 hr
 - Give SQ treatments per protocol
 - As soon as ready to restart IV infusion, recheck glucose unless done within 15 min
 - If IV drip off for <3 hrs, use “Resume” option in GlucoStabilizer
 - If IV drip off for ≥ 3 hrs, use “Start New Drip” option in GlucoStabilizer



NPO or Continuous Tube Feeds

- Control group
 - Follow sliding scale insulin Rx as usual
 - IV saline as usual
- Intervention group
 - Follow GlucoStabilizer recs as usual
 - **No meals so no meal insulin**
 - 2 doses of saline SQ given to maintain the blind (9AM and 9PM)



Bolus Tube Feeds

- Control group
 - Follow sliding scale insulin Rx as usual
 - IV saline as usual
- Intervention group
 - Follow GlucoStabilizer recs as usual
 - **Treat bolus tube feeds as meals** – except no need to estimate carbs - enter bolus carbs (should be 60) into GlucoStabilizer and follow dosing recs
 - NO SQ saline is needed



Early Discharge of SHINE Patient

- Any SHINE study patient who is clinically ready for discharge from the hospital prior to 72 hours of treatment may be discontinued from the SHINE protocol and this is NOT a protocol deviation
- Early d/c Control Group
- Early d/c Intervention Group



Discontinuation of SHINE Treatment Protocol – Control Group

- 6 hrs prior to discharge
 - D/C SHINE IV saline
 - D/C SHINE sliding scale SQ insulin protocol
- Any subsequent SQ insulin Rx **at discretion of treating physician** should be >3 hrs after last SHINE SQ insulin
- Oral diabetes Rx **at discretion of treating physician** usually resumed or started at discharge



Discontinuation of SHINE Treatment Protocol – Intervention Group

- 6 hrs prior to discharge
 - D/C SHINE IV insulin
 - D/C SHINE SQ saline and meal insulin Rx
- GlucoStabilizer Drip Weaning Report (24 hr insulin total) available for review
- Any subsequent SQ insulin Rx **at discretion of treating physician** should be >3 hrs after last SHINE SQ insulin
- Oral diabetes Rx **at discretion of treating physician** usually resumed or started at discharge



Transition to Standard Care

- Per ADA guidelines scheduled subcutaneous insulin that delivers basal, nutritional and correction components is preferred.
- Consider that oral agents are not recommended in hospitalized patients, but may be initiated or resumed in anticipation of discharge per ADA guidelines.
- Consider individualized discharge planning per ADA guidelines



