Alternate Site Glucose Testing: Close, but not close enough?

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Does Site Matter? Phase 1

Initial Study

- Fingerstick blood glucose sampling and monitoring is current practice
- Suggestions from patients regarding less pain with alternative site testing (AST) prompted initial study comparing standard finger stick with AST.
- Phase 1 study found AST to be less painful compared with standard method, with little difference in glucose values (r=0.98).
- Though statistically significant, change from standard practice to AST requires r=0.99 per institutional recommendations.

STUDY DESIGN – Phase 1

- Prospective Convenience study
- Two period, two treatment crossover trial
- Two methods of obtaining blood glucose sample were studied.
- Fingerstick compared with sample from palm of dominant hand.
- Eligible patients were randomized.
- Preoperative surgical patients from SAS and off-site areas (MRI, CT)

METHODS – Phase 1

How study was conducted

Eligibility criteria reviewed

Verbal consent obtained

Computer generated randomization scheme used to determine which method used first

Subjects received both finger stick and palm stick glucose for comparison

RESULTS – Phase 1

84 patients; data analyzed on 81

Mean Pain Analog Scale (PAS)

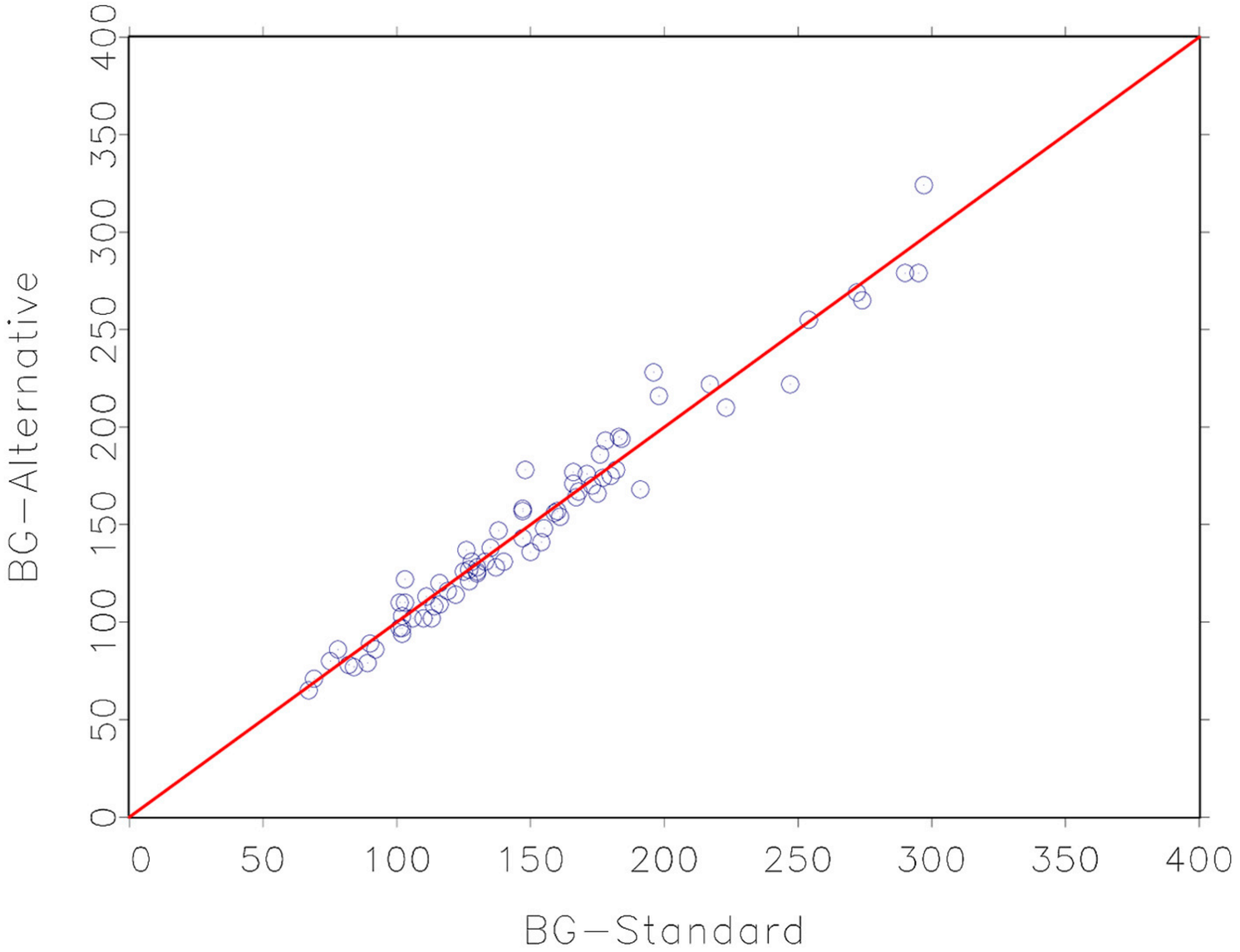
- 2.83 with finger stick
- 1.65 with palm

Mean capillary BG values similar between both methods

- 150 mg/dl – finger stick
- 149 mg/dl – AST (palm)

No significant statistical difference in glucose measurements between standard care and intervention

RESULTS – Phase 1



Correlation = 0.9815;

R2 = 0.9633; 95%

95% Confidence Interval:
(- 2.1, 2.8)

indicates accuracy between standard and AST values.

PUBLICATION

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Does Site Matter? Comparing Accuracy and Patient Comfort of Blood Glucose Samples Taken From the Finger and Palm of the Perioperative Patient

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Purpose: *This study compared two blood glucose (BG) point of care sampling methods to determine which is least painful yet accurate.*

Design: *The two-period, two-treatment crossover trial compared the traditional fingertip sampling method to a form of alternative site testing (AST), palm of the hand.*

Methods: *Subjects received both methods of BG sampling to compare comfort and accuracy. They were randomly assigned to determine which method was used first. Pain rating (0 to 10) and glucose results for both methods were documented.*

Finding: *Results indicated that pain rating was significantly lower with AST (1.65) than with the standard site (2.83) ($P < .001$). There was no significant difference in mean glucose measurements between standard care (150 mg/dL) and AST (149 mg/dL). The numbers were closely correlated ($r = 0.9815$).*

Conclusions: *Findings support AST via the palm of the hand as an accurate and less painful method of obtaining BG results on diabetic patients.*

Keywords: *alternative site testing, glucose, comfort, accuracy.*

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Conflict of interest: None to report.

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SO CLOSE…..BUT YET SO FAR

DISCUSSION

Correlation of 0.98 = near perfect positive linear relationship

R2 = 0.96 - R2 of 1 means regression predictions perfectly fit the data

95% Confidence Interval: (- 2.1, 2.8)

These are all great statistics, however, not good enough to elicit change in practice

INTRODUCTION – Phase 2

BACKGROUND

In effort to support previous findings, a replication study was conducted with a power analysis generating a larger volume of subjects.

The hypothesis, “Would an increased sample size support similar findings from previous study?”

STUDY DESIGN and METHODS

WHAT STAYED THE SAME AS PHASE 1

- Prospective Convenience study
- Two period, two treatment crossover trial
- Two methods of obtaining blood glucose sample were studied.
- Fingerstick compared with sample from palm of dominant hand.
- Eligible patients were randomized.

STUDY DESIGN and METHODS

CHANGES MADE FROM INITIAL STUDY

- Variables controlled by decreasing number of research team members from six data collectors to two.
- Scripting developed
- AST Blood glucose monitoring competency completed by both team members.
- Time between palm stick and finger stick limited to two minutes.

Competency Validation Form

Alternate Site Blood Glucose Testing Study Competency Verification Record University of Virginia Health System Employee Name: _____ Employee ID # _____ Date: _____	Evaluator's Initials
Section One: A. Introduces Study to Patient (per script) B. Determine patient interest in study C. Assess eligibility D. Review study with patient (per script) including risks and benefits E. Obtain verbal consent	
Section Two: A. Obtain data collection tool B. Ensure correct corresponding patient number (upper right corner) C. Ensure study number on randomization slip and envelope match	
Section Three: A. Proceeds with study per randomization slip and records findings B. Select study site (either fingertip of dominate fourth finger or palm) as directed on randomization slip. C. Perform Blood Glucose test per Lippincott's Nursing Procedures D. Document results and complete data collection tool for first glucose E. Within two minutes perform second glucose analysis per Lippincott's Nursing Procedures F. Document results for second glucose and complete remainder of data collection tool G. Ensure entire data collection tool is complete *Competency Verified by:* _____ Date: _____ Evaluator's Name (Printed) Evaluator's Signature	

RESULTS

PHASE 2

N = 148 (larger sample size)

On average, participants rated pain about one category lower than standard site (Mean diff – 1.29(0.15)).

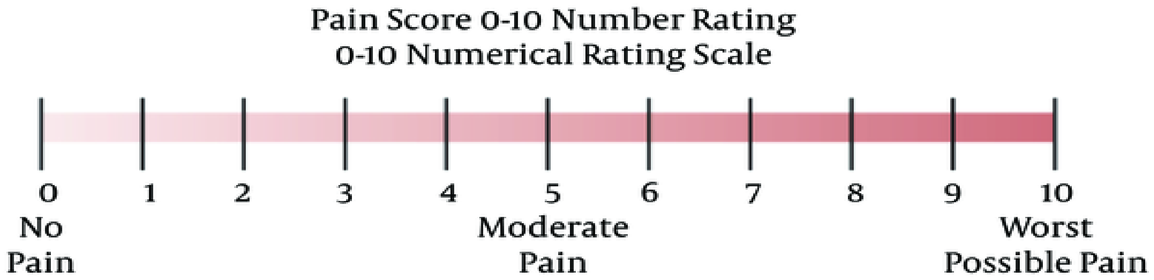
Blood glucose results also similar to original study (partial correlation = 0.98).

Correction for phase 2 was comparable to phase 1 (r=0.978 compared to r=0.98).

CONCLUSION

Replication study supports initial findings:

- Less PAIN experienced with AST compared with standard site



- Similar findings related to accuracy of blood glucose values between finger stick and AST

- Further analysis still needed to confirm accuracy of AST blood glucose values compared to standard site

Barriers and Obstacles

Values are great, however, not quite good enough for practice change per UVA laboratory

R=.98 (our results = not sufficient per lab)

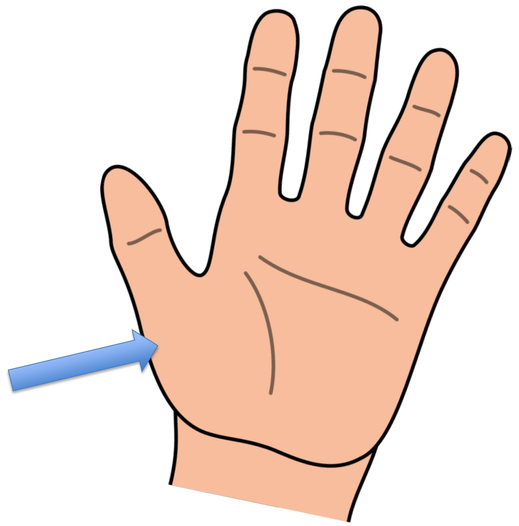
R=.99 needed for change in practice

AST considered off-label use; only RN's would be able to perform test. *impact on utilization of resources if PCT's couldn't perform

Inquired about FDA approval for change - costs millions of dollars and many, many years

DISCUSSION/IMPLICATIONS

While more research is needed to confirm the accuracy of AST, it may be an alternative option in the future.



NEXT STEPS

Exploring other vendors for AST monitoring in outpatient setting

Consider conducting brief, same-patient BG accuracy study.

QUESTIONS?

THANK YOU!

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