Comparison of Menstrual Pictogram Scoring to the Validated Alkaline Hematin Assay as Techniques for Measuring Blood Loss on Feminine Hygiene Products

Pamela E. Burnett, B.S., Scott Chudnoff, M.D., M.S., FACOG, Lisa Turner, B.S., and Dari Dadgar, PhD.

INTRODUCTION

To invalidate Menstrual Pictograms (MP) for measurement of menstrual blood loss (MBL) on feminine hygiene products.

Prospective experimental analysis

Control Samples: Measured volumes of blood were applied to Kotex Regular Maxi Pads or Tampax Super Tampons. The MP (G. Warrilow et al. The Obstetrician and Gynecologist 2004; 6:88-92) score was recorded and compared to actual volumes applied.

Clinical Samples: Patient feminine hygiene samples were scored using the MP and results were compared to a fully validated alkaline hematin (AH) assay, proven accurate and precise.

CLINICAL SAMPLES

Menstrual Pictogram: Is the Maximum Score Realistic?

For 166 patients in a clinical trial undergoing MBL measurement by alkaline hematin, actual average volumes measured on samples consisting of pads only or tampons only were compared to the pictogram maxima (12 mL – Tampon; 15 mL – Pad).

23 Patients, 102 Cycle Days

MP Volume (ml) VS AH Assay Volume (ml)

Table shows data points in increasing order of AH volume, left to right, top to bottom row. Correct expected whether alkaline hematin and MP volumes are within 15% of each other (4%)

MP score 1 mL

MP score 3 mL

MP score 10 mL

Pictogram Method Shortcomings:

• Lack of clinically relevant accuracy
• Vastly different blood volumes appear the same and produce the same pictogram score.
• Pictogram – estimated blood volumes are inaccurate
• Volumes are underestimated at higher (more clinically relevant) volumes
• Clinically relevant ceiling effect (lack of dynamic range)
• Pictogram can't be validated to current FDA ±15% accuracy and precision standards.

CONCLUSION

We propose a validated alkaline hematin method should be the method of choice when measuring blood loss in a clinical trial of menorrhagic conditions.

ACKNOWLEDGEMENTS

Jenny McNown for the lab support; Glen Dixon for dbase support and clinical supply logistics; Bonnie Davidson for web-based data reporting.