Evaluation of the use of Serum Human Chorionic Gonadotropin (hCG) and Progesterone in Triaging Pregnancy of Unknown Location

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BACKGROUND

The current practice in the management of Pregnancy of Unknown Location (PUL) at the National Maternity Hospital (NMH) utilises ultrasound scan and hCG-ratio which involves repeated hospital visits for patients with low-risk PUL [Intrauterine Pregnancy (IUP) and Failed PUL (FPUL)] and high-risk PUL [Ectopic Pregnancy (EP) and Persisting PUL (PPUL)]. Studies indicate that an algorithm developed in the United Kingdom called the M6 model could potentially differentiate between high-risk and low-risk PUL at triage. Moreso, studies showed that low serum progesterone level on presentation with PUL could be predictive of failing pregnancy.

AIMS

To determine a cut-off level for serum progesterone that could serve as a once-off triaging threshold criteria for classifying PUL cases as low-risk. To evaluate and compare the potential of an in-house M6 model in relation to the hCG-ratio. This study has potential to benefit the NMH in reducing visits especially for the low-risk PUL patients and focus resources on the high-risk PUL cohorts.

METHODS

The M6 incorporates serum hCG and progesterone into its algorithm. The verification of progesterone was required as part of this study. This was achieved by determining the assay performance and trueness via laboratory in-house procedures. Suspected PUL patients were recruited over a period of 6 months. Data was collected and analysed for measured progesterone and hCG at 0h, and hCG at 48h. Progesterone cut-off level was determined by utilising ROC curves. Comparison between the M6 model and hCG-ratio was statistically analysed by determining the index tests of sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratio outcomes.

RESULTS

Table 1: Index tests with corresponding sensitivity, specificity, Negative Predictive Value (NPV), Positive Predictive Value (PPV), Positive Likelihood Ratio (PLR) and Negative Likelihood Ratio (NLR)

Index Test	Sensitivity, % (95%CI)	Specificity, % (95%CI)	PPV (95%CI)	NPV (95%CI)	PLR	NLR
hCG-ratio	37.50	92.00	60.00	82.10	4.69	0.68
M6 Model	87.50	88.00	70.00	95.70	7.00	0.96

Legend: hCG: Human Chorionic Gonadotropin; M6: Model 6 protocol; NPV: Negative Predictive Value; PPV: Positive Predictive Value; PLR: Positive Likelihood Ratio; NLR: Negative Likelihood Ratio.

Of the 49 participants, 67.0% were eligible for M6 and hCG-ratio triaging models, while 81.0% were eligible for triage by progesterone. M6 had sensitivity and specificity of 87.5% and 88.0% and the hCG-ratio had sensitivity and specificity of 37.5% and 92.0% for high-risk PULs respectively. 0h progesterone cut-off at ≤33nmol/l had sensitivity and specificity of 87.0% and 17.6% for triaging failing pregnancy.

Conclusion

M6 model has the highest sensitivity for predicting high-risk PUL and also had a negative predictive value of 95.7%. Despite three FPUL misclassifications using progesterone cut-off at ≤33nmol/l, measuring progesterone at the first visit could help clinicians assess the risk of early pregnancy complications. Overall, there were limitations to the study due to the small sample size. Further patient recruitment would be beneficial in determining M6 application in a high-risk PUL cohort.