



External Validation of the M6-Progesterone Model in an Australian Population of Pregnancies of Unknown Location

Authors: Dr. Katie Ryan¹, Dr. Sara Ooi¹, Ms. Sarah Mead¹, Ms. Hayley Diplock¹, Ms. Melissa Wang¹, A/Prof. Bradley De Vries^{1,2}, Dr. Joanne Ludlow¹

1. Royal Prince Alfred Hospital, Women's and Babies Department, Sydney, Australia
2. University of Sydney, Sydney, Australia

Objective: The two-step M6 with Progesterone (M6P) mathematical model for management of Pregnancy of Unknown Location (PUL)¹, was shown to perform the best in a cohort of women compared with M4 and M6 without progesterone². Subsequently, the M6P model became our guideline for managing PULs at an Australian Tertiary Hospital. This study was to externally validate the prospective application of the M6P model in predicting ectopic pregnancy (EP) and persistent PUL (PPUL) in women diagnosed with PUL at initial visit.

Design: A single-centre, retrospective cohort study using the M6P mathematical model in an Australian tertiary hospital Early Pregnancy Assessment Service (EPAS) from 01/06/2020 to 31/05/2021.

Methods: For women with an ultrasound diagnosis of PUL at our EPAS; demographic data, clinical history, initial serum progesterone, initial and 48-hour serum BHCG, whether high risk or low risk from the prediction model, pregnancy outcomes and interventions were recorded. These results were cross tabulated to calculate the sensitivity, specificity, negative predictive value and area under the ROC-curve of the model in predicting EP and PPUL.

Results: Of 200 women, 25 were initially excluded as they did not meet the inclusion criteria. Of 175 eligible women, primary analysis excluded 6 who were lost to follow-up. 17.1% had an ectopic pregnancy or PPUL and 82.9% had a failing PUL, a viable IUP or non-viable IUP. The area under the ROC curve for the M6P was 0.8445. (Image 1) Sensitivity for predicting EP/PPUL was 89.7%, specificity of 65.7% and negative predictive value of 96.8%. 29 women underwent laparoscopic surgical intervention for suspected or confirmed ectopic pregnancies with a 34.5% negative laparoscopy rate.

Conclusions: This study shows the utility of the two-step M6P triage model in an Australian early pregnancy population. This optimises management by minimising unnecessary intervention whilst maintaining patient safety. The high negative predictive value of low risk PULs allows these to be managed expectantly. This two-step M6P model allows for risk stratification based on a single face to face visit.

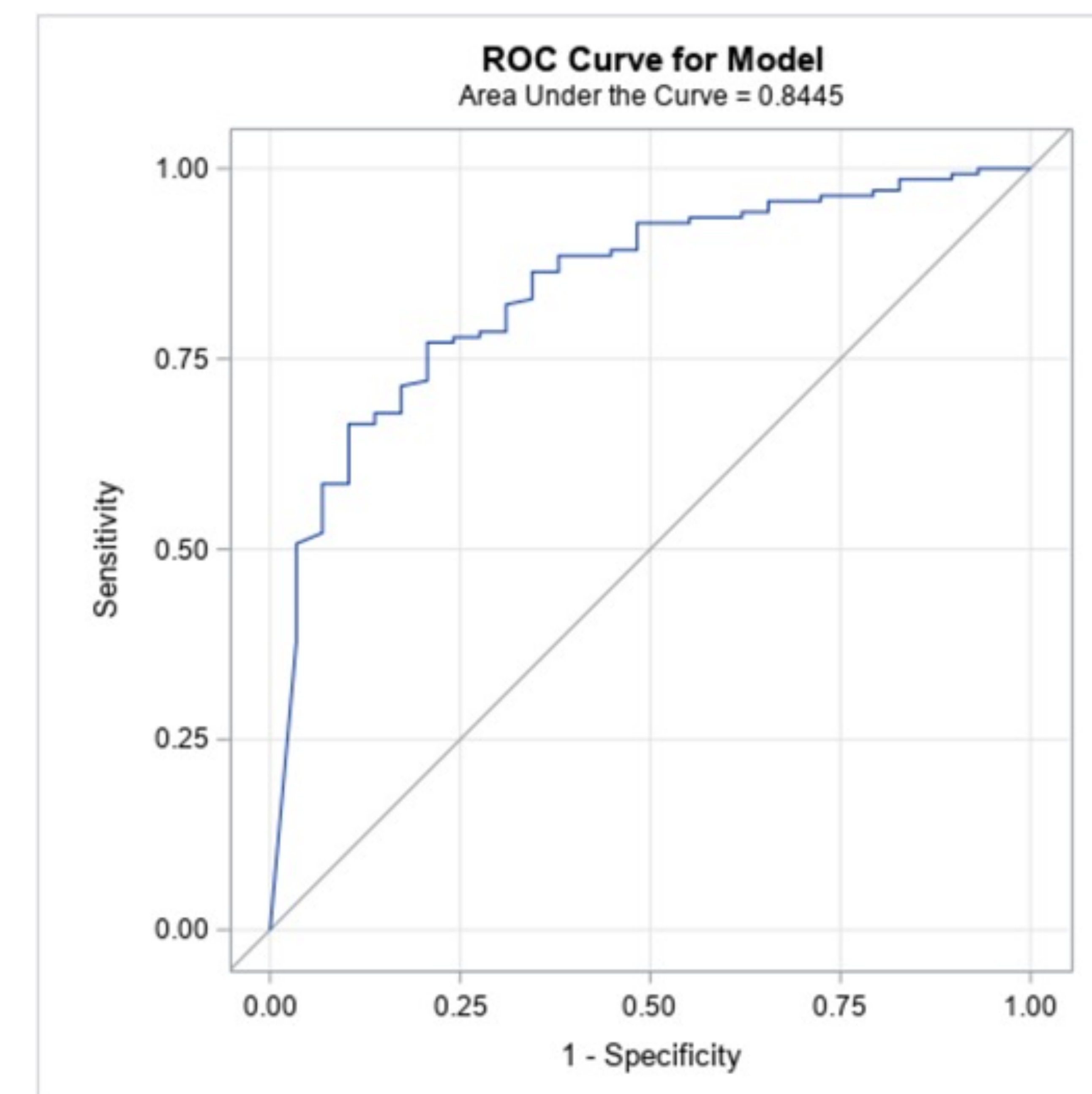


Image 1

References:

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2. Ooi,S., Vries,B. and Ludlow,J. (2020). How do the M4 and M6 models perform in an Australian pregnancy of unknown location population? *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 61(1), pp.100–105. doi:10.1111/ajo.13252