



Comparative Analysis of AmniSure® and Actim® PROM in Diagnosing Rupture of Membranes

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01 Introduction

Premature rupture of membranes (PROM) is a critical obstetric condition that can result in significant complications if not promptly managed. Conversely, over-diagnosis may lead to unnecessary and expensive interventions. Hence, accurate and timely detection of PROM is crucial for optimal patient care, yet often presents a major challenge in ambiguous cases. In Singapore General Hospital, Actim® PROM, which evaluates for the presence of insulin-like growth factor binding protein-1 (IGFBP-1), is commonly used in view of its high sensitivity, specificity and quick diagnostic turnaround. Another commercially available immunoassay, AmniSure®, which assesses for placental alpha microglobulin-1 (PAMG-1), has not yet been widely adopted in local practice but also promises high sensitivity and specificity, based on existing literature.

02 Objective

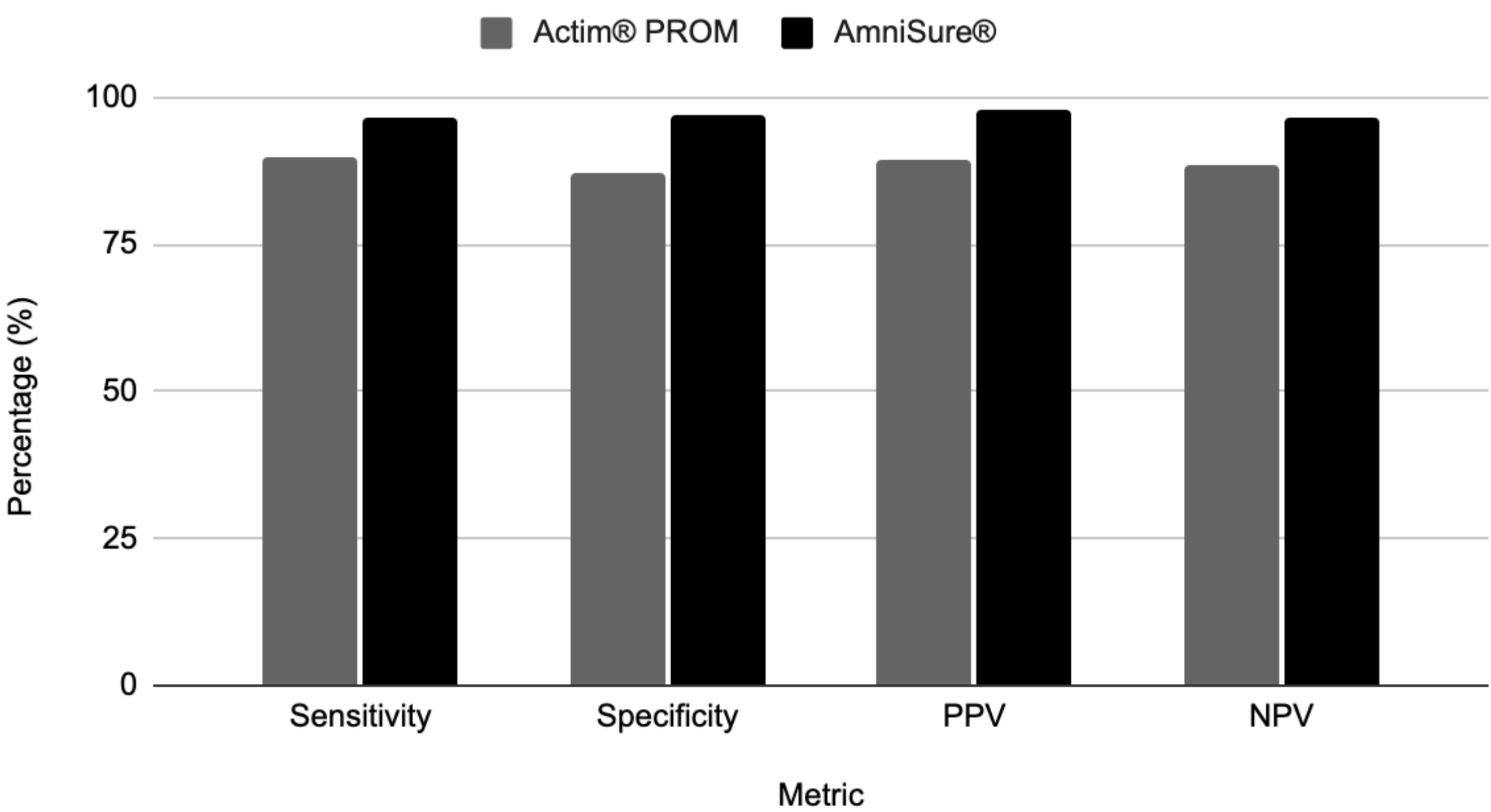
This study aims to compare the diagnostic performance of AmniSure® and Actim® PROM in detecting rupture of membranes (ROM) in pregnant women across different published studies.

03 Methodology

A meta-analysis of six independent published studies comprising a total sample size of 691 women was conducted to compare the diagnostic performance of AmniSure® and Actim® PROM in detecting ROM. Only studies that compared both tests directly on the same sample population were included. For each study, key diagnostic metrics - namely sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) - were analysed. Weighted averages for each metric were then calculated based on the sample sizes of each study.

04 Analysis

Diagnostic Performance of Actim® PROM vs AmniSure®



05 Limitations

- Variability in sample size, clinical settings, reference standards and operator training may impact consistency
- Impact of blood contamination, which is known to affect the accuracy of Actim® PROM, was inconsistently evaluated
- No evaluation of cost or accessibility was performed, which are important considerations especially for implementation in resource-limited settings

06 Conclusion

- Our analysis suggests that AmniSure® offers superior diagnostic performance in detecting ROM compared to Actim® PROM
- We acknowledge that this preliminary analysis is limited by study heterogeneity, variability in data completeness and the lack of formal statistical synthesis
- To address these gaps, ongoing work is focused on applying more advanced statistical approaches to improve the synthesis of evidence across studies and account for cross-study variability
- Additionally, we are working on conducting our own prospective clinical trial involving our local patient cohort, to contribute to and expand on our current meta-analysis findings
- Our efforts will also include examining the cost effectiveness and accessibility of each test to better guide implementation in different real-world contexts
- Ultimately, our end goal is to generate high-quality evidence to contribute to the safe, cost-effective, accurate and timely diagnosis of PROM in diverse clinical settings

- While both tests display high diagnostic accuracy, AmniSure® consistently demonstrates superior performance across all key metrics
- AmniSure®’s higher sensitivity means reduced risk of missed PROM diagnoses
- AmniSure®’s higher specificity means fewer false positives, thus minimising unnecessary interventions/hospitalisations
- Strong internal validity: all studies directly compared both tests within the same sample cohort, eliminating inter-patient variability
- The consistent results across multiple studies lends support to the generalisability of the findings

References

Deniz, A. (2020). Comparison of PAMG-1 versus IGFBP-1 and Nitrazine in Diagnosis of Rupture of Membranes. *Jinekoloji-Obstetrik ve Neonatoloji Tıp Dergisi*, 17(1), 262-265.

Ramsauer, B., Duwe, W., Schlehe, B., Pitts, R., Wagner, D., Wutkewicz, K., ... & Lachmann, R. (2015). Effect of blood on ROM diagnosis accuracy of PAMG-1 and IGFBP-1 detecting rapid tests. *Journal of Perinatal Medicine*, 43(4), 417-422.

Liang, D. K., Qi, H. B., Luo, X., Xiao, X. Q., & Jia, X. Y. (2014). Comparative study of placental a-microglobulin-1, insulin-like growth factor binding protein-1 and nitrazine test to diagnose premature rupture of membranes: A randomized controlled trial. *Journal of Obstetrics and Gynaecology Research*, 40(6), 1555-1560.

Abdelazim, I. A., & Makhlof, H. H. (2013). Placental alpha microglobulin-1 (A mni S ure test) versus insulin-like growth factor binding protein-1 (A ctim PROM test) for detection of premature rupture of fetal membranes. *Journal of Obstetrics and Gynaecology Research*, 39(6), 1129-1136.

Marcellin, L., Anselem, O., Guibourdenche, J., De la Calle, A., Deput-Rampon, C., Cabrol, D., & Tsatsaris, V. (2011). Comparison of two bedside tests performed on cervicovaginal fluid to diagnose premature rupture of membranes. *Journal de gynecologie, obstetrique et biologie de la reproduction*, 40(7), 651-656.

Tagore, S., & Kwek, K. (2010). Comparative analysis of insulin-like growth factor binding protein-1 (IGFBP-1), placental alpha-microglobulin-1 (PAMG-1) and nitrazine test to diagnose premature rupture of membranes in pregnancy.