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PROCEEDINGS ABSTRACT

Serum soluble fms-like tyrosine kinase-1 as an ancillary diagnostic biomarker in molar pregnancy: histological correlates and differentiation of a complete from a partial hydatidiform mole in Iraqi women

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Hydatidiform moles (HMs) – subclassified into complete (CHMs) and partial (PHMs) ones – represent the commonest gestational trophoblastic disease and carry malignant transformation risks between 15% and 20% and between 0.5% and 5% respectively, making accurate subclassification essential for post-evacuation surveillance. Their histopathological examination remains the diagnostic cornerstone, yet early-evacuation specimens increasingly lack fully developed hallmark features, while ancillary molecular techniques are not universally accessible. Soluble fms-like tyrosine kinase-1 (sFlt-1; also designated sVEGFR-1), a circulating anti-angiogenic splice variant overproduced by syncytiotrophoblasts in molar tissues, represents a candidate serum biomarker, but its quantitative relationship with specific histological parameters of the molar pregnancy and its utility in CHM-*versus*-PHM differentiation had not yet been characterised in a controlled three-group design prior to the present study. This study aimed at evaluating the serum sFlt-1 as an ancillary diagnostic biomarker in HM, at correlating its concentration with binary histological features of molar tissue, and at determining its discriminatory accuracy for CHMs *versus* PHMs and for molar *versus* normal pregnancies in Iraqi women. A cross-sectional observational study was conducted between March 2024 and May 2025 at the Al-Zahrawi Clinical Laboratory (Babylon, Iraq). The patients enrolled in this study were primarily admitted and treated at the Imam Al-Sadiq Teaching Hospital (Babylon, Iraq). A total of 65 subjects were enrolled: 51 women with histologically confirmed HMs (of which 7 with CHMs and 44 with PHMs) and 14 gestational age-matched women with normal pregnancies serving as controls. Uterine evacuation specimens were sent to the Al-Zahrawi Clinical Laboratory for their histopathological examination, and haematoxylin-and-eosin-stained sections were examined independently by two blinded pathologists, who scored seven binary histological parameters. The serum sFlt-1 and beta-human chorionic gonadotrophin (β-hCG) levels were measured in the blood samples (collected at the time of the specimen submission) using the Snibe MAGLUMI 800 fully automated chemiluminescence immunoassay (CLIA) analyser (Snibe Diagnostic, China). Our statistical analysis employed the Kruskal–Wallis and Bonferroni-corrected Mann–Whitney *U* tests, Spearman rank correlations with bootstrap 95% confidence intervals, Fisher's exact test, and receiver operating characteristic analysis with

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Youden's J optimisation. The herein measured serum sFlt-1 levels differed significantly across all three of the studied groups, with median values rising 6.7-fold in PHM cases (1,721.5 pg/mL) and 16.0-fold in CHM cases (4,123.0 pg/mL) over normal controls (257.5 pg/mL; all Bonferroni-corrected at $p<0.001$), with complete separation of distributions. In the case of the molar-*versus*-normal discrimination, the serum sFlt-1 levels achieved an area under the curve (AUC) of 1.000 at a cut-off of ≥1,024 pg/mL (with a sensitivity and a specificity that were both 100%), thereby outperforming the β-hCG levels (AUC of 0.980). In the case of the CHM-*versus*-PHM differentiation, the serum sFlt-1 levels achieved an AUC of 0.997 at a cut-off of ≥3,089 pg/mL (with a sensitivity of 100%, a specificity of 97.7%, and an overall accuracy of 98.0%), with the single false-positive case correctly resolved by the concurrent serum β-hCG levels (AUC of 1.000 at ≥79,120 IU/mL). The CLIA-measured serum sFlt-1 levels correlated significantly ($p<0.001$) with trophoblastic hyperplasia ($r_s=0.54$), cistern formation ($r_s=0.53$), and stromal vascularity ($r_s=-0.55$), thereby mechanistically grounding this biomarker to the histological parameters of trophoblastic overactivity. Our findings establish the automated serum sFlt-1 measurement (through CLIA) as a highly accurate ancillary diagnostic biomarker for molar pregnancy in Iraqi women.

Keywords

gestational trophoblastic disease; hydatidiform mole; β-hCG; sFlt-1; sVEGFR-1

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Conflicts of interest statement

None to declare.

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