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Title

A Comparative Study Using Patient- Reported Outcome Measures (PROMs) in Prenatal Screening among pregnant women in Canada

Priority 1 (Research Category)

Women's health

Presenters

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Abstract

Context: The integration of Non-Invasive Prenatal Screening (NIPS) as a universal first-tier screening could provide an earlier screening and if needed, diagnostic result compared to standard screening. While the clinical performance of NIPS is well-documented, to our knowledge, no research has documented its impact on pregnant women's health-related quality of life (HRQoL), thus hampering informed decision-making about prenatal options. Objective: We compared the impact of NIPS on HRQoL with that to standard care. Study Design and Analysis: In a prospective multicentric randomized 2:1 clinical trial, descriptive and multivariable analyses, mainly linear mixed models, were performed. Setting: Randomization considered age and recruitment site in Quebec and British-Columbia. Population Studied: Pregnant women (≥ 19 years) undergoing foetal chromosomal anomaly screening (T13, T18, T21). Intervention/Instrument: First-tier NIPS compared to standard care. Outcome Measures: HRQoL was assessed using the PROMIS-29 v2.1 at 10, 16, and 22 weeks of gestation. Results: A total of 7815 pregnant women have been recruited, with mean age of 32 years (Standard Deviation=4) and 64.7% of European origin in both groups. At 10, 16, and 22 weeks of gestation, the PROMIS-29 T-Scores of physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles, and pain were 47.2 to 53.0 (± 6 to 8) in both arms and the majority falls within the normal limits category of the T-score across all PROMIS-29 domains. The mean differences between first-tier NIPS group and standard care group were -0.27 (95% CI -0.87;0.33, P=0.2) for physical function, 0.21 (95% CI -0.55;0.98, P=0.35) for anxiety, 0.28 (95% CI -0.41;0.96, P=0.28) for depression, 0.55 (95% CI -0.19;1.30, P=0.08) for fatigue, 0.15 (95% CI -0.35;0.95, P=0.18) for sleep disturbance, -0.50 (95% CI -1.25;0.22, P=0.09) for ability to participate in social roles, and 0.12 (95% CI -0.50;0.74 P=0.48) for pain. Conclusions:

Trajectories of physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles, and pain interference T-Scores were similar between groups. No significant differences were detected between the two groups. Our findings offer initial evidence that choosing first-tier NIPS for prenatal screening maintains HRQOL through 22 weeks of gestation, similar to standard care. This evidence will inform future decision aids about prenatal screening.

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