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National implementation of the first-trimester anomaly scan: benefits, opportunities and challenges

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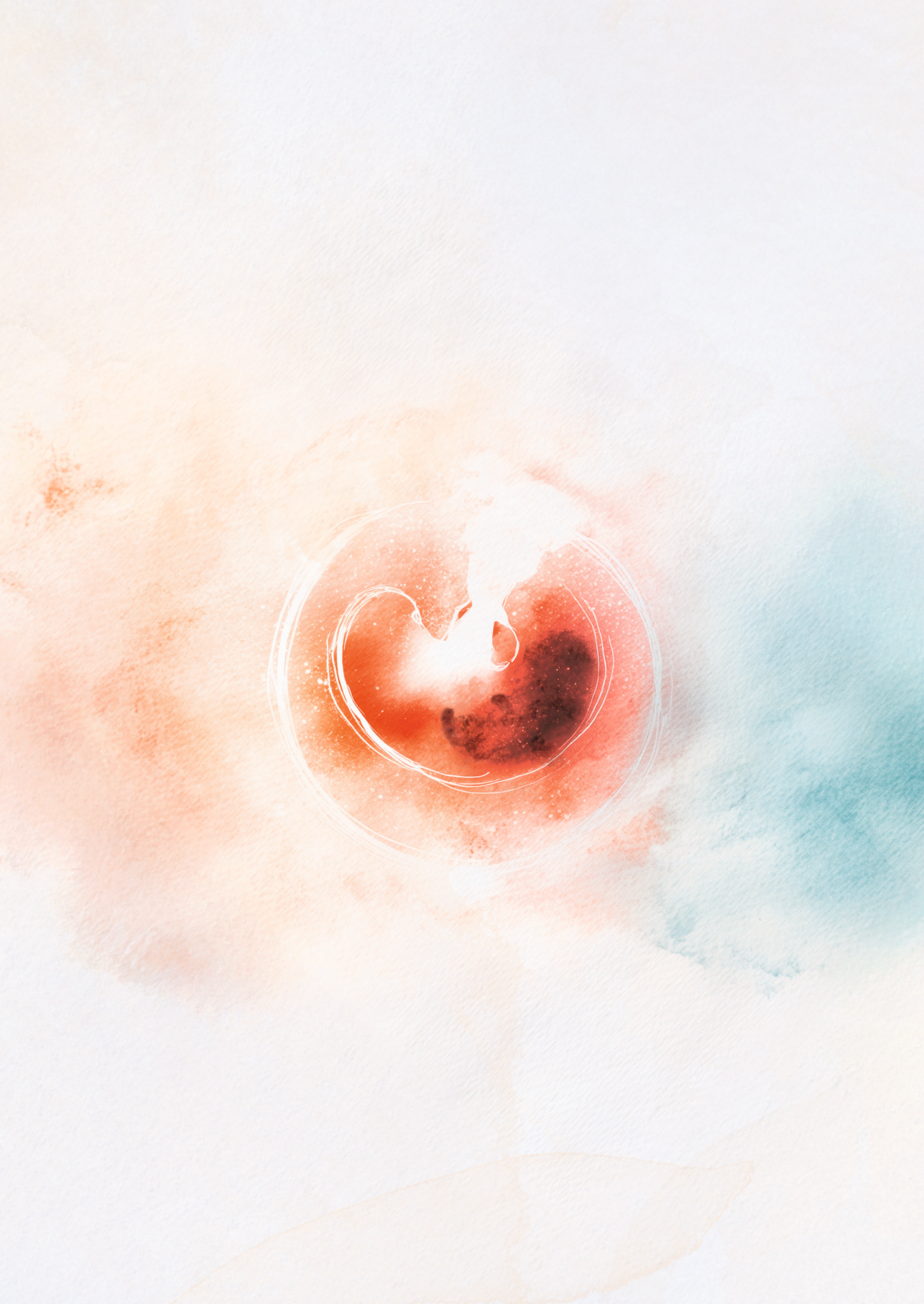
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APPENDICES

Summary

Nederlandse samenvatting

List of co-authors and their affiliations

Portfolio

Curriculum Vitae

Dankwoord

SUMMARY

This thesis assesses the uptake and test performance of the first-trimester anomaly scan (FTAS) and women's experiences regarding abnormal screening results.

Chapter 1 includes the general introduction of this thesis.

PART I: Project chapters

An overview of current first-trimester ultrasound screening policies in developed countries is presented in **Chapter 2**, based on an online survey. Structural anomaly screening is performed in the majority of the countries, however, large differences are reported in availability and use of screening protocols, extent of anatomy assessment, training and experience of sonographers and monitoring systems. As a results, the availability and quality of first-trimester scans vary considerably, and even within individual countries, leading to unequal access. These differences in both the provision and execution of screening should be carefully considered when interpreting or comparing scientific outcomes of first-trimester screening.

In **Chapter 3**, we describe the uptake, test performance and time to a final prenatal diagnosis after referral during the first year of FTAS implementation in the Netherlands. The FTAS uptake was 75% with a sensitivity of 85% for first-trimester major anomalies (FTMA) and 32% for all types of anomalies. This was accompanied by a referral rate of 1%, of which 59% involved cases where anomalies were either not confirmed at the first detailed diagnostic scan or resolved in the second trimester. Timing of diagnosis was around 16 weeks of gestation. Earlier diagnosis offers pregnant women and their partners more time for reproductive-decision making and if desired, a termination of pregnancy (TOP) earlier in pregnancy.

An analysis of undetected cases during the FTAS, but subsequently diagnosed at the second-trimester scan, is presented in **chapter 4**. Nearly 1% of pregnancies with a normal FTAS were diagnosed with a fetal anomaly in the second trimester. Of these, 2% comprised FTMA and 11% often detectable anomalies. Blinded image assessment of FTMA and normal control cases showed that missing mandatory planes and acquisition of suboptimal planes were the main explanations for not detecting the abnormality. This overview of undetected cases should inform the expectations of prospective parents and could provide a basis for improving performance of the FTAS.

In **chapter 5** the added value of the FTAS is evaluated by comparing its diagnostic yield, as outlined in chapter 3, to the situation before FTAS implementation with solely routine

scans before 18 weeks' gestation. The introduction of the FTAS resulted in a significant increase of detected fetal anomalies, particularly for anomalies not typically identified in routine care. Time to final diagnosis and gestational age at TOP increased by only two days following FTAS implementation. However, some anomalies required a prolonged diagnostic trajectory due to the structured protocol and advanced sonographer expertise, highlighting the important balance between clinical benefit and potential psychological burden.

The diagnostic potential of the routine dating scan for detecting major fetal anomalies is explored in **chapter 6**. More than 90% of referrals with a persistent suspicion of a fetal anomaly at the centre for prenatal diagnosis were diagnosed as FTMA. The severity of the anomaly was reflected by the fact that over 60% of all diagnosed anomalies resulted in TOP or intrauterine fetal death early in pregnancy. Discordant referrals occurred in 22%, and neither sonographer experience nor the introduction of FTAS significantly influenced this rate. These findings highlight the complementary value of routine dating scans to dedicated anomaly screening, which is particularly relevant in settings where pregnant individuals face limited access due to rural location or financial constraints.

In **chapter 7**, we assessed the psychological effects of abnormal screening results and compared this impact between FTAS and second-trimester anomaly scans (SAS). Our findings show that true-positive results were associated with substantial impact. False-positive results also led to elevated anxiety and depression levels compared to normal results. Overall anxiety, depression and decisional regret levels were higher following FTAS compared to SAS. These findings highlight the importance of clear counselling and support and illustrate the trade-off between early detection and potential emotional harm.

PART II: Collaboration chapter

Chapter 8 evaluates the psychological impact of early versus late TOP due to fetal anomalies using a prospective mixed-methods design. Questionnaire results demonstrated that early TOP is associated with lower psychological impact compared to late TOP. Qualitative interviews further illustrated that stronger fetal attachment and perceived time pressure related to legal gestational limits for TOP are more prominent in the late TOP group, whereas experiences following early TOP were more variable. These findings support the presumed benefit of earlier intervention, while emphasizing that TOP remains an emotionally impactful event regardless of gestational age.