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THE ROLE OF OBSTETRIC ULTRASONOGRAPHY IN PREVENTING LITIGATION DUE TO PRENATAL DIAGNOSTIC ERRORS

O PAPEL DA ULTRASSONOGRAFIA OBSTÉTRICA NA PREVENÇÃO DE LITÍGIOS POR ERRO DE DIAGNÓSTICO PRÉ-NATAL

EL PAPEL DE LA ECOGRAFÍA OBSTÉTRICA EN LA PREVENCIÓN DE LITIGIOS POR ERROR DE DIAGNÓSTICO PRENATAL

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ABSTRACT

Obstetric ultrasonography has become a fundamental tool in prenatal care, widely used both to confirm gestational parameters and to screen for fetal anomalies. However, its growing incorporation into obstetric routine reveals technical, operational, and human limitations that directly affect diagnostic safety. This article critically analyzes the main factors involved in obstetric ultrasonography practice, with emphasis on the method's limitations, the required professional qualification, ethical aspects related to informed consent, and doctor-patient communication. The study addresses the historical evolution of the method, technical challenges inherent to the examination, the influence of professional training and experience on diagnostic accuracy, and the ethical and documental responsibilities associated with the consent process. Through an integrated analysis, the article proposes reflections aimed at improving care quality and reducing conflicts arising from diagnostic errors in prenatal care.

Keywords: Obstetric Ultrasonography. Prenatal Diagnosis. Informed Consent.

RESUMO

A ultrassonografia obstétrica consolidou-se como método fundamental no acompanhamento pré-natal, sendo amplamente utilizada tanto para a confirmação de parâmetros gestacionais quanto para o rastreamento de anomalias fetais. No entanto, sua crescente incorporação à rotina obstétrica expõe limitações técnicas, operacionais e humanas que impactam diretamente na segurança diagnóstica. Este artigo analisa criticamente os principais fatores envolvidos na prática da ultrassonografia obstétrica, com ênfase nas limitações do método, na qualificação profissional exigida, nos aspectos éticos relacionados ao consentimento informado e na comunicação médico-paciente. A pesquisa aborda a evolução histórica do método, as dificuldades técnicas inerentes ao exame, a influência da formação e experiência do profissional na acurácia diagnóstica, além das responsabilidades éticas e documentais

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associadas ao processo de consentimento. Por meio de uma análise integrada, o estudo propõe reflexões que buscam contribuir para a melhoria da qualidade assistencial e para a redução de conflitos decorrentes de erros diagnósticos no pré-natal.

Palavras-chave: Ultrassonografia Obstétrica. Diagnóstico Pré-Natal. Consentimento Informado.

RESUMEN

La ecografía obstétrica se ha consolidado como un método fundamental en el seguimiento prenatal, siendo ampliamente utilizada tanto para la confirmación de parámetros gestacionales como para la detección de anomalías fetales. Sin embargo, su creciente incorporación a la rutina obstétrica expone limitaciones técnicas, operativas y humanas que impactan directamente en la seguridad diagnóstica. Este artículo analiza críticamente los principales factores involucrados en la práctica de la ecografía obstétrica, con énfasis en las limitaciones del método, en la calificación profesional requerida, en los aspectos éticos relacionados con el consentimiento informado y en la comunicación médico-paciente. El estudio aborda la evolución histórica del método, las dificultades técnicas inherentes al examen, la influencia de la formación y experiencia del profesional en la precisión diagnóstica, así como las responsabilidades éticas y documentales asociadas al proceso de consentimiento. A través de un análisis integrado, el trabajo propone reflexiones orientadas a mejorar la calidad asistencial y reducir los conflictos derivados de errores diagnósticos en el cuidado prenatal.

Palabras clave: Ecografía Obstétrica. Diagnóstico Prenatal. Consentimiento Informado.

1 INTRODUCTION

Obstetric ultrasonography has been consolidated in recent decades as one of the main instruments for monitoring pregnancy, being widely incorporated both in primary care and in reference centers for fetal medicine. Technological advances, combined with the growing appreciation of prenatal care, have made the exam an indispensable part of the care routine, creating new possibilities for the early detection of anomalies and for the planning of obstetric conducts.

The evolution of the technique, however, has brought with it a series of challenges that go beyond the purely diagnostic sphere. The high expectation for accurate results, often fueled by the very way the exam is socially perceived, has increased the level of demand on professionals who work in the area. At the same time, the complexity inherent in the interpretation of sonographic findings and the technical limitations of the method maintain the possibility of diagnostic errors, especially in contexts where external factors, such as the quality of the equipment and the training of the examiner, directly interfere with the accuracy of the results.

This combination of high social demand, methodological limitations, and variability in the qualification of professionals has exposed the field of obstetric ultrasonography to an environment of vulnerability. This is not just a technical debate. The discussion also involves ethical, psychosocial and legal aspects, since prenatal diagnosis has implications that go beyond the limits of traditional medicine, directly affecting family dynamics, reproductive planning and, in extreme cases, the decision itself about maintaining pregnancy.

Within this scenario, understanding the role of obstetric ultrasonography in the prevention of litigation arising from prenatal diagnostic error becomes a necessary exercise. The analysis should not be restricted to the technology used or the individual performance of the professional, but should include a critical evaluation of the entire care process involved, from the indication of the exam to the communication of the results and the proper recording of the information provided.

The present study aims to investigate, in a systematic manner, the main factors that influence diagnostic safety in obstetric ultrasonography, as well as the strategies that can be adopted to reduce the risk of conflicts between patient and professional. To this end, the article adopts an approach that covers different dimensions of the theme, structuring the discussion in five central axes.

Initially, a historical analysis of the evolution of obstetric ultrasonography is made, focusing on the progressive incorporation of the method as a prenatal screening test and the expansion of its clinical indications. Next, the technical limitations of the method are discussed, addressing the factors that can compromise the quality of the diagnosis, such as the resolution of the equipment, the maternal-fetal conditions and the specificities of different types of anomalies.

The third axis of the analysis focuses on professional qualification, exploring the relationship between specific training in Fetal Medicine and the diagnostic accuracy of the exams. In this section, the recommendations of the main class entities are discussed, as well as proposals to improve the quality of the services provided.

Next, the article moves on to reflect on communication with the patient, free and informed consent, and the ethical aspects that involve the practice of ultrasound. The approach favors the analysis of the psychosocial impacts of the exam on the pregnant woman and the need for the professional to adopt clear and humanized communication strategies.

Finally, the work ends with the synthesis of the main points discussed, emphasizing the importance of an integrated approach that contemplates the technical, human and ethical aspects of obstetric ultrasound, as a fundamental strategy for reducing the risk of conflicts and for promoting safer and more responsible prenatal care.

2 THE EVOLUTION OF OBSTETRIC ULTRASONOGRAPHY AND ITS IMPORTANCE AS A PRENATAL SCREENING TOOL

Obstetric ultrasound has come a long way since its introduction into antenatal care. Initially, it was a test with a restricted indication, reserved for clinical situations that required specific diagnostic clarification (Gomes; Piccinini, 2005). Its use was limited to cases of suspected fetal anomalies or difficulties in determining gestational age. It was not common, for example, for pregnant women to have access to images during the procedure, a fact that illustrates the exclusively technical nature of ultrasonography in its first decades of application (Gomes; Piccinini, 2005).

With the advancement of imaging technologies and the evolution of equipment, obstetric ultrasonography has come to occupy a central place in the prenatal routine. This transformation was not restricted only to the diagnostic capacity, but also to the change in the paradigm of maternal-fetal care, by enabling greater interaction between the pregnant woman and the intrauterine environment (Peralta; Barini, 2011). In addition to the identification of

anomalies, the test has become a resource for the humanization of prenatal care, conferring on the fetus the status of patient (Gomes; Piccinini, 2005).

The literature indicates that, over the last decades, ultrasonography has consolidated itself as one of the main strategies for prenatal screening, especially for the detection of structural malformations and chromosomal abnormalities (Peralta; Barini, 2011). However, the expansion of its use has brought to light a relevant debate about the need for standardization of procedures. Bruns et al. (2012) draw attention to the risk inherent in the lack of uniformity in the protocols for performing the tests, which can generate diagnostic failures and negatively impact the legal certainty of medical practice.

The problem of the absence of standardization is not only technical, but also involves an ethical and legal dimension. As Bruns et al. (2012) point out, the lack of clear guidelines on which structures should be evaluated in each type of examination makes it difficult to standardize clinical practice and increases the risk of subjective interpretations. The authors' proposal is the adoption of well-defined protocols, capable of reducing interobserver variability and increasing the reproducibility of the findings.

From the point of view of institutional recommendations, the Brazilian Federation of Gynecology and Obstetrics Associations (FEBRASGO) has positioned itself in favor of performing three ultrasonographic exams as a minimum routine in low-risk pregnant women: one in the first trimester, one morphological in the second trimester, and one to assess fetal growth in the third trimester (Santana et al., 2018). This guideline is in line with the precepts advocated by international organizations, such as the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG), which reinforce the importance of specific protocols for each gestational stage (Santana et al., 2018).

The first trimester exam, performed between 11 and 13+6 weeks, stands out for the possibility of early evaluation of fetal anatomy, screening for aneuploidies, and accurate determination of gestational age (Santana et al., 2018). According to Peralta and Barini (2011), the measurement of nuchal translucency, associated with other ultrasonographic and biochemical markers, allows the identification of up to 95% of chromosomal abnormalities, with a false-positive rate of only 3%. In addition, first-trimester US also enables the detection of major structural malformations, such as acrania, encephalocele, and congenital diaphragmatic hernia (Peralta; Barini, 2011).

From the 18th week of gestation, it is recommended to perform second-trimester morphological ultrasound, a fundamental exam for the detailed screening of structural

anomalies (Bruns et al., 2012). This evaluation is considered the main fetal morphological screening test, allowing the identification of most malformations compatible with postnatal life (Peralta; Barini, 2011). However, despite its importance, Bruns et al. (2012) warn of the persistent lack of consensus in Brazil regarding the precise definition of the cuts and minimum mandatory parameters for their implementation.

In the third trimester, fetal growth ultrasonography has as its main objective to evaluate the evolution of fetal development and diagnose possible cases of intrauterine growth restriction (Peralta; Barini, 2011). It also allows the analysis of fetal position, volume of amniotic fluid and placental location, fundamental parameters for the definition of obstetric strategies aimed at reducing perinatal risks (Bruns et al., 2012).

In addition to its technical usefulness, the literature emphasizes the emotional and psychological impacts of ultrasonography on pregnant women. Studies indicate that the test can strengthen the maternal-fetal bond, increase adherence to prenatal care and reduce anxiety levels, especially when the result confirms fetal normality (Gomes; Piccinini, 2005). On the other hand, there is evidence that ultrasound, by anticipating the revelation of bad news, can trigger significant emotional distress, especially in cases of diagnosis of abnormalities (Gomes; Piccinini, 2005).

This ambivalent aspect of ultrasonography is also the focus of criticism by some scholars. Authors such as Courvoisier (1985) and Soulé (1987), cited by Gomes and Piccinini (2005), suggest that the exam can interrupt maternal fantasies prematurely, creating a "short circuit" between the baby's imaginary image and the reality visualized on the device's screen. Such a rupture, according to these authors, could generate difficulties in establishing the mother-fetus bond, especially when the findings are incompatible with the expectations of the pregnant woman.

On the other hand, studies that analyze the role of ultrasonography in the early identification of anomalies highlight its potential to reduce perinatal morbidity and mortality, in addition to enabling intrauterine interventions and better delivery planning (Peralta; Barini, 2011). Early detection of diseases such as congenital diaphragmatic hernia and urinary obstructions, for example, allows referral to referral centers and implementation of therapeutic approaches during pregnancy (Peralta; Barini, 2011).

Although there are divergences regarding psychological and social aspects, the technical consensus remains clear: ultrasonography is an essential tool for screening for anomalies, as long as it is performed within strict criteria of quality and standardization (Bruns

et al., 2012). This position is reinforced by FEBRASGO, which has published detailed protocols in order to ensure the safety and efficacy of the test (Santana et al., 2018).

The experience accumulated during the COVID-19 pandemic has also brought new reflections on the execution of obstetric ultrasound. According to Peixoto Filho et al. (2021), even in scenarios of high biological risk, the maintenance of routine exams was considered essential, with adaptations aimed at protecting patients and health professionals. This experience further highlighted the importance of ultrasonography as a central axis in prenatal surveillance.

When analyzing the evolution of obstetric ultrasonography from a critical perspective, it is noted that the expansion of its use has brought unequivocal benefits, but also challenges that need to be faced. The absence of a widely disseminated national protocol, as warned by Bruns et al. (2012), places the Brazilian health system in a situation of legal vulnerability, especially in cases of false-negative diagnosis.

This analysis shows that, although technological advances have significantly expanded the role of ultrasonography in prenatal care, the Brazilian scenario still lacks clear and effective guidelines regarding the standardization of exams. The literature, while recognizing the clinical benefits associated with the early detection of anomalies, also reveals a recurrent concern with the heterogeneity of practices and the legal risks arising from this normative gap (Bruns et al., 2012; Santana et al., 2018). This context, in turn, reinforces the need to discuss in greater depth the medico-legal repercussions of possible diagnostic errors in obstetric ultrasonography, a topic that will be addressed in the following study.

3 TECHNICAL LIMITATIONS AND FACTORS THAT INFLUENCE ULTRASOUND DIAGNOSIS

Despite technological advances, obstetric ultrasonography remains a method with well-defined technical limitations. Among the main factors that affect diagnostic accuracy are the quality of equipment resolution, fetal position at the time of examination, the presence of oligohydramnios and maternal obesity, in addition to the inadequacy of gestational age for the identification of certain fetal structures (Barros et al., 2012).

With regard to the resolution of the equipment, there is a significant disparity between the different health services. Bruns et al. (2012) point out that, although there are high-performance devices available in reference centers, the reality of many basic units is still low

resolution equipment, which directly compromises image quality and, consequently, diagnosis.

Fetal position is another factor often pointed out as limiting. The difficulty in obtaining adequate anatomical sections can make it impossible to evaluate essential structures, such as the heart and central nervous system, even when the examination is conducted by experienced professionals (Barros et al., 2012). Oligohydramnios, in turn, reduces the acoustic window and impairs fetal visualization, accounting for approximately 25% of false-negative cases in diagnoses of central nervous system malformations (Barros et al., 2012).

As for maternal aspects, obesity deserves special attention. The increase in abdominal adipose tissue negatively impacts the penetration of the ultrasound wave, limiting the sharpness of the images obtained (Bruns et al., 2012). This limitation is particularly worrisome in a context of increasing prevalence of obesity among women of childbearing age, which enhances the technical challenges faced in the routine of prenatal diagnostic services.

In the field of diagnostic sensitivity, studies reveal important variations according to the type of malformation investigated. Neto et al. (2009) demonstrated that, in a referral center, the sensitivity of ultrasonography for the detection of central nervous system anomalies reached 96%, while for cardiovascular system alterations this rate was only 45.2%. These data show that, although ultrasonography is highly efficient for some categories of anomalies, it has significant limitations for others, especially for complex heart defects.

This finding is corroborated by Barros et al. (2012), who reported a false-negative rate of 20.5% in the detection of malformations of the central nervous system, especially in cases in which oligohydramnios was present. These results indicate that the risk of diagnostic error cannot be underestimated, even in institutions with experienced professionals and good quality equipment.

Another aspect frequently discussed in the literature concerns the type of technology used in the exam. Two-dimensional ultrasonography (2D US) remains the method of choice for most evaluations, due to its wide availability and relatively low cost (Araujo Júnior, 2016). However, three-dimensional ultrasonography (3D ultrasonography) and four-dimensional ultrasonography (4D ultrasound) have been progressively incorporated into clinical practice, especially in specialized centers.

According to Araujo Júnior (2016), 3D US allows the simultaneous evaluation of fetal structures in the three orthogonal planes, in addition to enabling the storage of volumes for later analysis. This technology also has less dependence on operator skill, unlike 2D US,

which requires greater technical dexterity to obtain adequate diagnostic cuts. However, the author acknowledges that doubts still persist as to the real superiority of 3D US over 2D in the detection of complex structural anomalies.

Regarding 4D ultrasound, its main benefit is its real-time visualization, which is especially useful for the analysis of fetal movements and for the evaluation of facial changes. However, as Araujo Júnior (2016) points out, the higher cost and limited access to state-of-the-art equipment restrict its routine use to a minority of services.

External factors also exert a significant influence on the diagnostic quality of the tests. Bruns et al. (2012) highlight that the excessive workload of the services, associated with the limitation of time per exam, can compromise the detailed evaluation of fetal structures. This aspect is especially relevant when considering that the identification of certain anomalies requires prolonged observation time and multiple cutting planes.

In addition, the sonographer's training and experience are critical determinants in diagnostic accuracy. Neto et al. (2009) demonstrate that referral centers, with specialized professionals and continuous training, have significantly higher sensitivity rates compared to primary care units. This finding reinforces the need for regular training programs, as defended by Bruns et al. (2012), who also warn of the lack of a national policy for the accreditation of professionals who perform obstetric examinations in Brazil.

Even in exceptional contexts, such as the COVID-19 pandemic, FEBRASGO maintained the guidance that obstetric exams should not be postponed, recommending, however, the prioritization of more experienced sonographers, precisely to reduce exposure time and minimize the need for reexams (Peixoto Filho et al., 2021).

Finally, when critically evaluating the limitations inherent to the method, it becomes evident that obstetric ultrasonography, despite its wide use, is not an infallible test. False-negative rates, interobserver variability, and external technical factors are elements that need to be considered in the analysis of each clinical case. These aspects, if not properly recognized and informed to patients, can increase the risk of litigation, especially when the diagnosis of an anomaly is not made during prenatal care.

4 PROFESSIONAL QUALIFICATION AND IMPACT ON DIAGNOSTIC ACCURACY

The discussion about the qualification of professionals who perform obstetric ultrasonography has gained space in the literature, especially in view of the finding that diagnostic accuracy depends directly on the technical training and clinical experience of the

examiner. Performing an ultrasonographic examination, especially those aimed at screening for fetal anomalies, involves a complex combination of technical, cognitive, and interpretative factors (Bruns et al., 2012).

FEBRASGO, through its technical committees, has been reinforcing the need for only physicians with specific training in Gynecology and Obstetrics or Radiology, and with additional training in ultrasound, to perform obstetric exams (Peixoto Filho et al., 2021). This orientation is supported by evidence that demonstrates a direct relationship between the degree of specialization of the professional and the accuracy of the prenatal diagnosis.

The absence of a national policy of mandatory certification for obstetric sonographers, however, remains a worrying gap. According to Bruns et al. (2012), the lack of minimum criteria for the accreditation of professionals has generated great heterogeneity in diagnostic imaging services in Brazil. This disparity has a direct impact on the sensitivity and specificity indicators of the tests, with relevant implications not only for clinical outcomes, but also in the legal sphere.

Studies carried out in reference centers, such as the one carried out by Neto et al. (2009), demonstrate that the detection of fetal anomalies is significantly higher when the exams are conducted by professionals with specific training in Fetal Medicine. In this study, the overall sensitivity for identifying malformations was 96%, with a specificity of 79%, which contrasts with the results observed in primary care services, where such rates tend to be considerably lower.

In addition, the literature indicates that the experience of the examiner directly influences the ability to identify more subtle morphological changes. Bruns et al. (2012) point out that, while evident anomalies such as anencephaly are often detected even by professionals with less experience, complex malformations, such as congenital heart diseases, require in-depth knowledge of fetal anatomy and mastery of specific assessment techniques.

The use of more sophisticated technologies, such as three-dimensional ultrasonography (3D US) and real-time ultrasonography (4D US), does not replace the need for adequate training. Araujo Júnior et al. (2007) emphasize that the manipulation of volumetric reconstruction software, such as VOCAL™ and 3D XI,™ requires specialized training, since the interpretation of the images depends on a detailed knowledge of normal fetal structures and possible pathological variations.

However, there are authors who relativize the expectation that only formal certification is sufficient to ensure diagnostic quality. Bruns et al. (2012) argue that, in addition to initial training, it is essential that professionals undergo continuous processes of updating and recycling. According to the authors, the rapid evolution of imaging techniques and the constant incorporation of new evaluation parameters make any training that is not accompanied by continuing medical education obsolete.

The implementation of regular training programs, including refresher courses and participation in specialized congresses, has been pointed out as an effective strategy to reduce interobserver variability and increase diagnostic accuracy (Araujo Júnior et al., 2007). A systematic review of cases with known outcomes is another recommended resource, as it provides professionals with the opportunity to correlate ultrasound findings with postnatal outcomes, increasing their ability to interpret (Neto et al., 2009).

The COVID-19 pandemic has also brought to light the importance of having experienced professionals in performing obstetric exams. FEBRASGO, in its official position during the pandemic period, advised that services prioritize the allocation of more qualified sonographers to perform the exams, in order to reduce the exposure time of patients and staff, in addition to avoiding the need for reexaminations due to failures in execution or interpretation (Peixoto Filho et al., 2021).

In addition to training and updating, other strategies have been discussed as a way to ensure greater diagnostic safety. Among them, the proposal for periodic auditing of the reports stands out, with the objective of identifying error patterns and implementing corrective measures (Bruns et al., 2012). This practice, already adopted in some centers of excellence, has shown a positive impact on the reduction of interpretative failures and the improvement of quality indicators.

The adoption of care protocols also emerges as an essential tool to standardize diagnostic conducts. According to Bruns et al. (2012), the absence of a widely disseminated and followed national protocol aggravates the problem of heterogeneity in test results. The establishment of diagnostic flowcharts and checklists for the evaluation of fetal structures is indicated as a measure capable of minimizing the subjective component of ultrasound interpretation.

Although the literature recognizes the benefits of such measures, the effective implementation of diagnostic quality programs faces logistical and financial barriers. The lack

of institutional incentives for continuing training and the lack of a national accreditation system are challenges that remain unsolved (Bruns et al., 2012).

In the context of daily clinical practice, work overload is another factor that can compromise diagnostic quality. Peixoto Filho et al. (2021) reinforce that the high demand for tests and the limitation of time per patient can lead to a hasty execution of the procedure, increasing the risk of failures in the identification of fetal anomalies. This reality is particularly worrisome in public health services, where the pressure for productivity often overlaps with the concern with the quality of care.

On the other hand, it is necessary to recognize that the mere existence of protocols or guidelines does not guarantee, by itself, the quality of the exam. As Bruns et al. (2012) point out, effective adherence to the established standards depends on the awareness and commitment of the professionals involved, in addition to inspection by health institutions.

The heterogeneity in diagnostic quality among different services and professionals also raises ethical issues. The provision of a service that varies considerably according to the operator represents a risk not only to the health of the pregnant woman and the fetus, but also to the legal security of professionals and institutions (Bruns et al., 2012).

Although training in Fetal Medicine represents an important differential, there is no consensus in the literature on the obligation of such specialization to perform all obstetric ultrasonographic examinations. Some authors argue that the requirement of specific qualification should be restricted to highly complex exams, such as detailed morphological ultrasonography and Doppler studies (Bruns et al., 2012). Others, however, argue that even routine exams should be conducted by professionals with advanced training, considering the potential impact of a misdiagnosis.

Data from the study by Neto et al. (2009) corroborate this concern. When analyzing the validation of ultrasound diagnoses of fetal anomalies at a referral center, the authors identified high sensitivity and specificity, a result attributed to the experience of the examiners and the infrastructure to support the diagnosis. On the other hand, in services without equivalent structure, the malformation detection rate may be significantly lower, increasing the risk of underdiagnosis.

In view of this scenario, the creation of a national certification system for professionals who perform obstetric ultrasonography has been advocated by different authors as a necessary measure to ensure greater patient safety and reduce the incidence of litigation (Bruns et al., 2012). In addition to initial certification, participation in continuing education

programs and adherence to systematic audits are pointed out as complementary strategies for maintaining diagnostic quality over time.

The experience accumulated in referral centers indicates that the combination of specialized training, use of standardized protocols, periodic audit of reports, and continuous updating of knowledge is the best strategy to minimize diagnostic errors and ensure the effectiveness of ultrasonography as a prenatal screening tool. This finding, however, should not be understood as a definitive solution, but as a continuous process of improvement that requires the joint involvement of professionals, institutions and regulatory entities.

5 COMMUNICATION, INFORMED CONSENT AND ETHICAL ASPECTS IN OBSTETRIC PRACTICE

The practice of obstetric ultrasonography involves not only technical mastery, but also an ethical dimension that requires attention to the particularities of the doctor-patient relationship. In the legal field, the Free and Informed Consent (ICF) is an indispensable requirement for the performance of diagnostic procedures, including ultrasound exams (Ferreira; Ferreira, 2025). In the context of Fetal Medicine, this requirement takes on even more sensitive contours, given the emotionally charged nature of prenatal tests and the risks inherent to possible diagnostic errors.

The legal conception of the ICF, as highlighted by Mabtum and Marchetto (2015), stems directly from the principle of autonomy of will, considered one of the pillars of modern bioethics. The patient has the right to receive clear, complete and accessible information about the proposed procedure, its benefits, limitations and possible risks. In the case of obstetric ultrasound, this obligation includes clarifying that the exam, no matter how good the available technology, has diagnostic limitations inherent to the method (Piber et al., 2020).

This informative obligation is reinforced by the guidelines of the Federal Council of Medicine (CFM) and FEBRASGO, which recognize the ICF as a protection mechanism for both the patient and the health professional (Peixoto Filho et al., 2021). The absence of this consent, in addition to constituting an ethical violation, may represent an aggravating factor in possible litigation due to diagnostic error, especially when the pregnant woman claims not to have been previously warned about the technical limitations of the test (Ferreira; Ferreira, 2025).

In addition to the legal aspects, the literature emphasizes the need for consent not to be treated as a mere documentary formality. The study by Ferreira and Ferreira (2025) points

out that, in many health services, the term is presented in a standardized way, with excessively technical language, which compromises its effectiveness. Educational, cultural and linguistic barriers can make it difficult for pregnant women to understand, making the purpose of clarifying the risks and limitations involved ineffective.

The importance of clear and humanized communication becomes even more evident when considering the psychosocial impact of obstetric ultrasound. Gomes and Piccinini (2005) demonstrated that the exam is experienced by pregnant women as a moment of intense emotional charge, characterized by ambivalent feelings of expectation and anxiety. According to the authors, ultrasonography represents, for many women, the first visual contact with the baby, promoting the anticipation of the maternal-fetal bond.

On the other hand, the same authors point out that the test can trigger negative emotional reactions, especially when the findings do not correspond to the expectations of the pregnant woman. The diagnosis of a fetal anomaly or even the simple diagnostic doubt can generate anguish, fear and feelings of helplessness (Gomes; Piccinini, 2005). These reactions reinforce the need for a careful communicational approach, which goes beyond the technical delivery of the result.

From an ethical point of view, the literature points to the professional's responsibility to ensure that the pregnant woman understands not only the results obtained, but also the limitations inherent to the test. Piber et al. (2020) recommend that sonographers adopt accessible language, avoid technical jargon, and use practical examples to illustrate methodological limitations, such as the possibility of not seeing certain structures due to factors such as fetal position or maternal obesity.

Another point often neglected is the obligation to properly record all the information provided to the patient. The legal literature emphasizes that the absence of documentation on the guidance provided to the patient can weaken the professional's defense in cases of allegation of omission of information (Mabtum; Marchetto, 2015). It is recommended, therefore, that in addition to the formal completion of the informed consent, the medical record contains detailed notes on the explanations given, the questions asked by the patient and the answers provided.

Ferreira and Ferreira (2025) point out that the simple collection of signatures on a pre-printed term does not comply with the ethical and legal requirements of informed consent. It is essential that the pregnant woman receives sufficient time to read and clarify doubts before formalizing the consent. This dialogical approach, although it requires greater dedication on

the part of the professional, contributes to strengthening trust and minimizing the possibility of future disputes.

In the specific scenario of obstetric ultrasound, the content of the informed consent must include the explanation that the exam has technical limitations and that not all fetal anomalies can be identified, even when the exam is performed by experienced professionals with high-resolution equipment (Piber et al., 2020). This warning is essential for the patient to understand that the absence of sonographic findings does not completely exclude the possibility of anomalies.

In addition, it is recommended that the term addresses the possibility of incidental findings, that is, changes not previously suspected and that may require further investigations, not always risk-free (Piber et al., 2020). This point is especially relevant in a context in which ultrasonography is often idealized by pregnant women as an examination free of diagnostic uncertainties.

The emotional aspect of the ultrasound experience also deserves attention from professionals. Gomes and Piccinini (2005) point out that the exposure of fetal images can generate a significant emotional overload, being experienced as a "test of the truth" by the pregnant woman. Such perception can intensify reactions of anguish in the face of unexpected findings, requiring the professional to be sensitive to handle these situations ethically and empathetically.

The literature also indicates that the traditional model of doctor-patient communication, often based on a paternalistic posture, is inadequate in the face of the emotional and ethical complexity involved in obstetric ultrasonography (Mabtum; Marchetto, 2015). The authors advocate the adoption of a more participatory and deliberative relationship model, in which pregnant women are encouraged to express their doubts, fears and expectations, being duly welcomed in their informational demands.

In this context, the training of health professionals should include, in addition to technical aspects, communication and emotional management skills. Ferreira and Ferreira (2025) suggest that training to obtain informed consent should be incorporated into ultrasound training programs, including modules on effective communication, clinical ethics, and legal aspects of medical practice.

Finally, the adequate documentation of the guidance provided, in addition to representing an ethical requirement, constitutes a measure of legal protection for the professional. The Code of Medical Ethics and the CFM resolutions reinforce the obligation to

record in detail all information provided to the patient, including any refusals by the pregnant woman to undergo complementary tests or to accept medical recommendations (Ferreira; Ferreira, 2025).

The effectiveness of informed consent, therefore, goes beyond mere administrative formality, requiring an active ethical posture on the part of the health professional. In the context of obstetric ultrasound, this practice takes on an even more relevant dimension, as the examination involves not only clinical diagnoses, but also expectations, emotions and, often, decisions with a profound impact on the life of the pregnant woman and her family.

6 CONCLUSION

The critical analysis of obstetric ultrasonography, as a prenatal screening tool, shows that its diagnostic efficacy cannot be understood in an isolated or technical way. The test, although widely disseminated and socially valued, has clear methodological limitations that require recognition by professionals and patients.

The detection of fetal anomalies, far from being an infallible process, depends on a complex interaction between technology, examiner's qualification, maternal-fetal clinical conditions and, above all, the ability to communicate between the health professional and the pregnant woman. The lack of standardization in care protocols, associated with heterogeneity in the training of sonographers, increases the risks of diagnostic failures and, consequently, of potential conflicts in the doctor-patient relationship.

Technical qualification, by itself, does not eliminate the problem. Even in referral centers, the literature shows that external factors, such as time limitations for performing the test and variables related to the clinical condition of the pregnant woman, continue to interfere with the accuracy of the results. This data reinforces the need for a realistic approach to the scope of obstetric ultrasonography, recognizing its virtues, but also its weaknesses.

From the ethical point of view, the adequate obtaining of free and informed consent emerges as a central element in the construction of safer care. It is not just a formal requirement, but a practice that requires time, technical preparation and sensitivity for the pregnant woman to effectively understand the limits and possibilities of the exam.

Clear communication, careful documentation, and the adoption of continuing education strategies appear as essential measures to mitigate risks and avoid misinterpretations by patients. In this sense, the construction of an institutional culture

oriented towards diagnostic safety and humanization of care can represent an important step in reducing litigation related to prenatal diagnostic error.

More than reinforcing the importance of technology, the reflection proposed throughout this work points to the need to strengthen the human, ethical and structural aspects that sustain the practice of obstetric ultrasonography. Recognizing the limitations of the method, investing in the training of professionals and improving communication processes are possible ways to build a more responsible and legally secure care scenario.

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