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A AMP Agradece!

AMP Says Thank You!

Carlos CORTES[1,2], Tiago VILLANUEVA✉[3]
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Entre 1 de janeiro e 31 de dezembro de 2024, a Acta Médica Portuguesa recebeu 1305 submissões através da sua plataforma eletrónica Open Journal Systems (OJS). Ao longo do ano, os nossos serviços editoriais publicaram 205 artigos distribuídos pelas 11 edições regulares, e 102 artigos em *ahead-of-print*, o que equivale a mais seis edições.

Decidir quais os trabalhos a publicar, procurando constituir uma mais-valia efetiva para os nossos leitores e assim contribuir para a promoção de boas-práticas na investigação científica, para a melhoria da prática clínica e para a divulgação do conceito da moderna autoria científica, é um processo complexo. A Acta Médica Portuguesa é a única revista científica médica portuguesa de âmbito generalista indexada na MEDLINE, com uma audiência de mais de 65 000 profissionais de saúde, chegando ainda a decisores institucionais e políticos, e à população em geral, já que todos os conteúdos publicados se encontram disponíveis em acesso aberto, universal e gratuito.

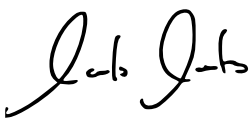
Neste contexto, é imprescindível o contributo de especialistas das várias áreas que nos apoiam na identificação dos temas de maior relevância, comentam a pertinência dos estudos propostos, realçam as linhas inovadoras das metodologias apresentadas, etc.

Gostaríamos de encorajar todos os médicos a reforçarem o seu envolvimento na progressão da Medicina, contribuindo para a revisão por pares da 'nossa' Acta Médica Portuguesa, independentemente da fase da carreira em que se encontram ou da sua especialidade. Só assim, todos juntos, alcançaremos o objetivo de consolidar a nossa posição enquanto referência nacional e até internacional.

A inscrição na plataforma OJS pode ser feita rapidamente nesta página: https://www.actamedicaportuguesa.com/revista/index.php/amp/user/register, e o *input* de todos quantos queiram arregaçar as mangas e ajudar-nos a "remar" nesta experiência única e enriquecedora será muitíssimo bem-vindo.

A todos e a cada um de vós, que de forma contínua doam generosamente o vosso tempo no espírito da verdadeira cidadania científica, expressamos o sincero reconhecimento da Ordem dos Médicos e da Acta Médica Portuguesa.

Lisboa, 12 de Janeiro de 2024.



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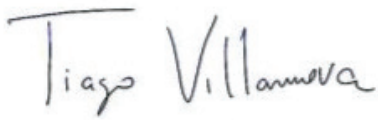

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Advancing Towards a Targeted Surveillance Strategy in Traumatic Brain Injury

Avançando Rumo à Estratégia de Vigilância Dirigida no Traumatismo Crânio-Encefálico

Vítor MOURA GONÇALVES[1,2]
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Keywords: Anticoagulants; Costs and Cost Analysis; Craniocerebral Trauma/diagnostic imaging; Craniocerebral Trauma/economics; Tomography, X-Ray Computed
Palavras-chave: Anticoagulantes; Custos e Análise de Custos; Tomografia Computorizada; Traumatismo Crânio-Encefálico/diagnóstico por imagem; Traumatismo Crânio-Encefálico/economia

Traumatic brain injury (TBI) is a major global healthcare problem, with significant economic and social implications. Managing TBI in patients with coagulopathy represents a substantial challenge for emergency departments due to the lack of consensus on balancing clinical benefit and resource allocation. Current national clinical guidelines for TBI, established by Portugal's Directorate-General of Health in 1999,[1] recommend 24-hour in-hospital surveillance with serial cranioencephalic CT scans for TBI patients with coagulopathies, even when initial imaging shows no intracranial lesions. However, evidence supporting this practice is limited, raising concerns about resource use, especially as healthcare costs rise.[2] The increasing prevalence of coagulopathic patients further underscores the urgent need for evidence-based recommendations.

Previous research by Ribeiro da Costa *et al*[3] offers compelling evidence that challenges the clinical relevance and cost-effectiveness of this practice. Their retrospective study, conducted at Unidade Local de Saúde de Santo António, provides a comprehensive economic evaluation comparing the current surveillance protocol (scenario A) with a hypothetical model (scenario B) where patients with normal initial CT scans are discharged without further imaging or surveillance. Among 440 patients, only 0.4% had new intracranial lesions on 24-hour follow-up CTs, none of which required targeted therapeutic intervention. Despite the minimal clinical findings, the current surveillance model incurred direct costs of €163 157 (n = 436 patients) compared to €29 480 (n = 440 patients) under the hypothetical scenario – a fivefold cost increase.[3] Moreover, the current model required twice as many emergency department shifts (9 *vs* 4.6 shifts), highlighting a substantial burden on medical staff.[3]

The findings align with international data showing similarly low rates of delayed intracranial hemorrhage (DIH) in comparable cohorts and question the utility of routine 24-hour surveillance for this specific subset of patients.[2] Controversies over DIH definition are not covered in this analysis. A national study by Duarte-Batista *et al*[4] reported a 2.3% DIH incidence among hypocoagulated patients, with no cases requiring neurosurgical intervention. Similar studies demonstrate that the risk of DIH in anticoagulated patients is low,[3,5] and that oral anticoagulants do not increase the risk of DIH[5] nor influence clinical outcomes.[6]

The present study raises important questions about the sustainability of the current surveillance strategy, which may have future implications for clinical practice. Economic analyses also corroborate these findings. Alali *et al* highlighted the importance of cost-effective strategies in TBI management, emphasizing the need for selective guidelines based on individual risk factors.[7] Collectively, these studies underscore the disproportionate resource allocation required for current surveillance practices, thus advocating for a more tailored approach. As global healthcare budgets face increasing pressures with escalating expenses, it is imperative to achieve a balance between clinical effectiveness and economic sustainability through the adoption of evidence-based and cost-efficient practices. Economic evaluations play a pivotal role in guiding resource allocation and aligning clinical outcomes with financial viability. For example, the Portuguese National Health Service (SNS) could save an estimated €9.3 million over a decade by adopting a more selective approach.[3] This would not only alleviate financial strain but also ensure that resources are directed to patients with the greatest clinical need. The operational burden of mandatory 24-hour surveillance significantly limits the availability of critical resources for higher-risk patients.

While the intention of surveillance is to mitigate risks, the non-negligible but relatively low incidence of DIH in coagulopathic patients with normal imaging prompts serious debate about the need for intensive monitoring. Predictive models that incorporate individual risk factors could guide

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targeted decision-making and more selective surveillance algorithms. These models could align clinical efforts with patient-specific risks, which may include, among other factors, high-energy trauma, presence of additional injuries, skull fractures, non-TBI trauma above the clavicle level, Glasgow Coma Score (GCS) < 15, neurological deterioration (decrease in GCS ≥ 2 points), age over 65, absence of home supervision, high risk of recurrent falls, prior neurosurgery, post-traumatic severe headache, loss of consciousness, amnesia, and/or vomiting.[2,3] Such an approach could enhance resource allocation and efficiency.

These insights challenge the status quo and highlight the urgent need for updated guidelines that prioritize both patient safety and resource management. In their research, Ribeiro da Costa *et al*[3] certainly do not intend to dismiss the potential risks associated with TBI in coagulopathic patients. Rather, they aim to advocate for a shift from indiscriminate surveillance to a stratified approach grounded in clinical evidence and risk assessment.

Transitioning to a targeted surveillance strategy could yield significant benefits. It would reduce the financial burden on the SNS while maintaining high standards of patient care. Updated guidelines reflecting contemporary evidence would improve emergency department adaptability and efficiency, particularly in resource-limited settings. Strategies such as risk stratification models and predictive analytics could optimize surveillance algorithms.

Future research should focus on high-quality, multicenter studies to validate these findings, explore potential regional and institutional variations, assess long-term outcomes of updated guidelines, and improve the management of TBI in coagulopathic patients. Such research could further refine the cost-benefit dynamics in TBI management and support the development of evidence-based guidelines.

The widespread implementation of standardized TBI electronic registries across national emergency departments is essential for identifying risk factors for DIH, particularly among coagulopathic patients. The establishment of a comprehensive nationwide targeted TBI surveillance program is therefore imperative. Large cohort data from these registries would provide an alternative to randomized controlled trials, which are often challenging to conduct in emergency settings. Technologies like big data analytics, artificial intelligence (AI), and machine-learning hold significant promise for revolutionizing TBI management. Large datasets with extensive information enable these technologies to identify complex patterns and predictive factors that conventional methods may neglect, facilitating research and the development of guidelines. By analyzing patient demographics, clinical data, injury mechanisms, laboratory results, and imaging findings, machine-learning algorithms could create personalized risk profiles. AI-driven prediction models may continually improve with new data, upgrading their accuracy over time and facilitating real-time decision-making in emergency settings. Such developments would enhance patient safety, optimize resource allocation, and decrease healthcare costs, therefore aligning clinical practices with the tenets of precision medicine and value-based healthcare.

Additionally, domiciliary hospitalization and telemedicine could reduce hospital stay costs and serve as valuable additions to TBI management guidelines for selected patients. Emerging biomarkers may also assist in stratifying TBI patients with coagulopathy.[8]

These tools and strategies would enable clinicians to direct surveillance towards high-risk patients while safely discharging those at lower risk, minimizing unnecessary interventions, reducing costs, and significantly enhancing resource allocation and clinical outcomes.

The study by Ribeiro da Costa *et al* challenges long-standing assumptions about the need for 24-hour in-hospital surveillance for coagulopathic TBI patients with normal initial CT scans. By highlighting the minimum clinical benefit and substantial economic burden of current practices, the study paves the way for a reevaluation of national and international guidelines with an indulgent eye. This evidence advocates for a shift toward more tailored surveillance strategies grounded in clinical evidence and economic evaluations.

Updated clinical guidelines should evolve alongside emerging evidence. By embracing a more comprehensive and data-driven approach to TBI surveillance, we can optimize outcomes for both patients and healthcare systems. Integrating economic evaluations into guideline development can prevent the implementation of costly and clinically ineffective practices. This paradigm shift will require collaborative efforts between clinicians, researchers, and policymakers, but the potential gains in efficiency and patient care make this effort worthwhile.

COMPETING INTERESTS

The author has declared that no competing interests exist.

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What Skills Should Be Acquired in Pre-School Education?

Que Competências Devem ser Adquiridas na Educação Pré-Escolar?

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Keywords: Child Development; Child, Preschool/education; Reading
Palavras-chave: Desenvolvimento da Criança; Leitura; Pré-Escolar/educação

INTRODUCTION

Healthcare professionals, both in primary and secondary healthcare settings, who deal with children on a daily basis are often asked about school readiness, that is, whether a child formally possesses the necessary skills to successfully integrate primary education.

To answer this question, it is essential to be familiar with the normative neurodevelopment expected at preschool age and the necessary skills for the successful learning process of reading, writing and calculating. The fulfilment of these requirements will determine whether the child is ready to enroll in primary school or not.

PSYCHOMOTOR DEVELOPMENT

Children are beings in constant motor, cognitive, emotional, and social development. In this dynamic process, the definition of stages and milestones makes it possible to monitor progress, allowing, however, for permissive variability. Therefore, it is important to know what is considered normal and to recognize possible warning signs, take an opportunistic approach during consultations and evaluate the findings observed, as well as any concerns from family members and teachers.[1]

The systematic application of screening instruments increases the sensitivity in detecting deviations from normality.[1] The Modified Mary Sheridan Developmental Assessment Scale is an example of a screening instrument that has been widely used for several decades. This document is an adaptation of the research work carried out by Dr. Mary D Sheridan in the publication "The Developmental Progress of Infants and Young Children" in 1968.[2] This work focused mainly on diagnosing and managing deviations from normal psychomotor development. Its modified version, on the other hand, also focuses on prevention, including actions designed to stimulate and promote development. Although this scale is not specifically standardized for the Portuguese population, it incorporates the National Child and Youth Health Program, formulated in 2013 by the Portuguese Directorate General of Health, and integrates the computer programs used in primary healthcare. The different milestones expected for each age are exemplified in Table 1.

The developmental milestones listed in Table 1, as well as the scarce warning signs mentioned, namely "the presence of hyperactivity and concentration difficulties, incomprehensible language, phonetic substitutions and stuttering, and behavioral disorders"[2] are, however, clearly not enough to predict a child's school readiness.

PRESCHOOL EDUCATION

There is a high level of consensus on the importance of preschool education (PSE), particularly in the development of cognitive, motor, and social skills, as well as its long-lasting impact on children's academic performance and long-term well-being.[3] It is, therefore, not surprising that PSE is compulsory in 18 countries of the Organization for Economic Co-operation and Development (OECD). In Portugal, however, PSE is optional,[4] targeting children between the age of three and the age at which they enroll in primary school. Surprisingly, despite being non-compulsory, more children are starting PSE earlier in Portugal than the average in other OECD countries.[5]

Primary school education has many goals, namely, the stimulation of the child's expressive and social abilities, the development of a sense of morality and responsibility, and the development of autonomy in day-to-day activities. In addition, it is a window of opportunity to detect possible difficulties and/or disorders and provide early referral.

Although each preschool teacher builds their own curriculum, they follow the Directorate-General for Education's curriculum guidelines for PSE, covering three content areas: 1) personal and social training; 2) expression and communication; 3) knowledge of the world.[3]

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Table 1 – The Mary Sheridan Developmental Assessment Scale

	18 months	2 years	3 years	4 years	5 years
Posture and large movements	- Walks well - Picks up toy from the floor	- Runs - Walks upstairs and downstairs, two feet to a step	- Can stand and walk on tiptoe - Can stand momentarily on one (preferred) foot when shown - Walks alone upstairs using alternating feet, comes downstairs two feet to a step	- Stands on one (preferred) foot for 3 - 5 seconds and hops on preferred foot - Walks or runs alone up and down stairs, one foot to a step - Can stand, walk and run on tiptoe	- Can stand on one foot 8 - 10 seconds, right or left, and usually also stands on preferred foot, with arms folded - Skips on alternate feet
Vision and fine movements	- Builds tower of three cubes - Spontaneous to and fro scribble, showing preference for using one hand - Enjoys simple picture books, turning several pages at a time	- Builds tower of six cubes - Spontaneous circular scribble. Imitates vertical line - Enjoys picture books, turning pages singly - Recognises familiar adults in photos after shown once	- Builds tower of nine to ten cubes - Copies circle. Imitates a cross - Matches two to three primary colours, usually red and yellow, but may confuse blue and green	- Builds three steps with six cubes after demonstration - Copies cross - Matches and names four primary colours correctly	- Builds four steps from ten cubes - Copies square and, at 5 ½ years, a triangle - Counts fingers on one hand with index finger of other - Names four or more primary colours and matches 10 or 12 colours
Hearing and speech	- Uses between six to 26 recognisable words and understands many more - Points to own or doll's hair, shoes, nose, feet	- Refers to self by name - Talks to self continually in long monologues during play, but may be incomprehensible to other - Puts two or more words together to form simple sentences - Echolalia almost constant - Names familiar objects	- Tells full name, sex, and sometimes age - Large vocabulary, intelligible even to strangers - Speech still contains may immature phonetic substitutions and unconventional grammatical forms	- Gives full name, home address and usually age - Speech grammatically correct and completely intelligible - Shows only a few immature phonetic substitutions	- Gives full name, age and usually birthday. Gives home address - Speech fluent, grammatically conventional and usually phonetically correct except for confusions
Social behaviour and play	- Lifts cup alone. Holds cup between both hands and drinks without much spilling - Holds spoon and gets food safely to mouth - Beginning to give notice of urgent toilet needs by restlessness and vocalisation - Fascinated by household objects and imitates simple, everyday activities	- Puts on hat and shoes - Feeds self with a spoon - Lifts cup and drinks well without spilling - Asks for food and drink	- Can pull pants up and down but needs help with buttons and other fastenings - Washes hands but needs adult supervision with drying - Eats with a fork and spoon	- Can dress and undress except for laces, ties and back buttons - Shows concern for younger siblings, and sympathy for playmates in distress - Understands taking turns as well as sharing	- Uses a fork and knife competently - Washes and dries face and hands but needs supervision for the rest - Dresses and undresses alone - Comprehends the need for order and tidiness, but needs constant reminders

In the personal and social development area, children are encouraged to: identify their individual characteristics (name, age, sex); recognize similarities and differences between their peers; carry out essential daily tasks with increasing autonomy (e.g., washing and dressing themselves, using cutlery); know how to wait for their turn in a dialogue or in a game.

The area of expression and communication encompasses various domains, such as physical and artistic education, oral language and approaches to writing and mathematics, which allow children to acquire fundamental skills for learning in these and other domains, both in their childhood and throughout their life. In physical education, the child is encouraged to: master movements that involve motion and balance (e.g., running, jumping, climbing), as well as manipulation (e.g., throwing and catching a ball); progressively internalize the body figure in relation to the surroundings. Artistic education includes the different artistic languages, such as plastic expression, music, dance and theatre, which enrich the child's possibilities for communication and expression. In the field of oral language and approach to writing, children are encouraged to: identify the different segments of sentences and their elements (known as phonological awareness); recognize the letters of the alphabet, distinguish between vowels; distinguish between upper and lowercase letters; recognize the directional sense of writing; take pleasure in reading. Mastering these fields undoubtedly eases the process of learning how to read and write in the future.

In mathematics, children are encouraged to: recognize the numbers from one to 10 and understand what they represent; recognize that addition means putting two groups together and subtraction means taking from one group; name geometric shapes; identify relative positions; compare two objects in terms of size and weight. This content will make learning simple calculations easier.

In the area of world knowledge, children are encouraged to: recognize basic time units (day, week, year); describe accounts of events, respecting their chronological order; describe daily itineraries; identify professions and services in their familiar environment.

SCHOOL READINESS

In Portugal, according to the Decree-Law 46/86 of the October 14, 1986, children who reach the age of six by the 15th of September of the current year are admitted to primary school, while those who reach the age of six between the 16th of September and the 31st of December are admitted on a conditional basis, depending on the vacancies available and their parent´s consent.[4]

The transition to primary school represents a decisive moment in any child's life, influencing their educational success and their social and emotional balance. It is, therefore, understandable that school readiness is a topic that raises questions and concerns on behalf of parents and guardians.

Although school readiness is a topic that still raises questions, both in terms of its definition and evaluation,[6] the Portuguese curriculum guidelines for PSE indicate three criteria that suggest that a child will have a successful enrolment in primary school: 1) The child's group behavior, namely their ability to follow orders; 2) The indispensable skills for the formal learning of reading, writing, and mathematics, namely, being aware of the correspondence between the oral code and writing, and having some basic concepts of space, time and quantity; 3) Their attitude towards learning, that is, showing curiosity and pleasure in the process.[3]

The evaluation of a child's readiness to enroll in primary school is carried out by the school. However, in the case of children enrolling on a conditional basis or postponing their enrollment, parents can seek advice from other education professionals, as well as healthcare professionals. The latter should, based on the above, assess the child's development and acquired competences, weighting the benefits of enrolling in primary school *versus* staying in preschool for another year.

CONCLUSION

Healthcare professionals who work with children daily must consider the psychomotor development and learning goals required for primary school so that they can provide parents with appropriate guidance, advise them on how to stimulate their child's specific skills, and, when necessary, refer them to a specialized professional. The right guidance for each child will largely determine their academic success.

PREVIOUS AWARDS AND PRESENTATIONS

This article was presented during the Pediatrics Service's weekly meeting at Centro Materno Infantil do Norte and at Unidade de Saúde Familiar Despertar, both integrating Unidade Local de Saúde de Santo António.

AUTHOR CONTRIBUTIONS

MBC, SS: Study conception and design, writing and critical review of the manuscript.

JQ: Study conception and design, critical review of the manuscript.

IVM, DG, ACV, CP: Critical review of the manuscript.

All authors approved the final version to be published.

COMPETING INTERESTS

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Translation and Cultural Adaptation of the ISTH-Bleeding Assessment Tool to European Portuguese

Tradução e Adaptação Cultural do Questionário ISTH-Bleeding Assessment Tool para Português Europeu

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ABSTRACT

Introduction: A distinctive bleeding history is the first diagnostic stage of congenital hemorrhagic diseases. Furthermore, since it is in fact an assessment of the patient's phenotype, it is not a (mere) complementary diagnostic method or test - it is an integral and intrinsic step to establish the patient's clinical history, which is a medical act. The International Society on Thrombosis and Haemostasis-Bleeding Assessment Tool (ISTH-BAT) is a standardized bleeding assessment tool used during the diagnostic workup of suspected bleeding disorders. This study aimed to translate and culturally adapt the ISTH-BAT questionnaire to the European Portuguese language.

Methods: The translation and cultural adaptation were based on the International Society for Pharmacoeconomics and Outcomes Research Guidelines and initiated after obtaining permission from the authors. The process involved three English to European Portuguese independent forward translations and a back translation. Discrepancies were gradually resolved. A harmonized version was presented to hemophilia patients and hemophilia carriers for cognitive debriefing.

Results: The forward and back translations did not produce important discrepancies. However, some issues were identified in the cognitive debriefing, which led to the cultural adaptation of medical terms for better understanding.

Conclusion: A formal translation and cultural adaptation process ensures that the new version maintains the same concepts as the original. After translation, several changes were necessary to ensure that the questionnaire was understandable by non-medical patients. We propose a European Portuguese version of the ISTH-BAT, which will require validation in further studies.

Keywords: Blood Coagulation Disorders; Patient Reported Outcome Measures; Portugal; Surveys and Questionnaires; Translation

RESUMO

Introdução: A identificação da história clínica completa da sintomatologia hemorrágica do doente é a primeira etapa no diagnóstico de qualquer coagulopatia congénita. Além disso, por se tratar de uma avaliação do fenótipo hemorrágico do doente, este não é (apenas) um método ou exame complementar de diagnóstico - é uma etapa essencial e intrínseca na definição da história clínica do doente, o que constitui um ato médico. O *International Society on Thrombosis and Haemostasis-Bleeding Assessment Tool* (ISTH-BAT) é um instrumento de avaliação da hemorragia padronizado, utilizado quando existe suspeita de doença hemorrágica. Este estudo teve como objetivo a tradução e adaptação cultural do questionário ISTH-BAT para o português europeu.

Métodos: A tradução e a adaptação cultural foram baseadas nas normas da International Society for Pharmacoeconomics and Outcomes Research e iniciadas após a obtenção da autorização dos autores da versão original. O processo envolveu três traduções independentes do inglês para o português europeu e uma retroversão. As discrepâncias foram gradualmente resolvidas. A versão traduzida conciliada foi apresentada a doentes com hemofilia e portadoras de hemofilia para identificarem problemas de compreensão do questionário.

Resultados: As traduções diretas e reversa não mostraram discrepâncias importantes. No entanto, foram identificadas algumas questões nas entrevistas cognitivas, que levaram à adaptação cultural de termos médicos para uma melhor compreensão do questionário pelos doentes.

Conclusão: Um processo formal de tradução e adaptação cultural garante que a nova versão mantém os mesmos conceitos que a versão original. Após a tradução, foi necessário realizar alterações para garantir que o questionário fosse compreensível para os doentes. Propomos uma versão em português europeu do ISTH-BAT, que deverá ser validada em estudos futuros.

Palavras-chave: Distúrbios da Coagulação Sanguínea; Inquéritos e Questionários; Medidas de Resultados Reportadas pelo Doente; Portugal; Tradução

KEY MESSAGES

- We propose a European Portuguese version of the International Society on Thrombosis and Haemostasis-Bleeding Assessment Tool (ISTH-BAT).
- The ISTH-BAT is recommended to evaluate bleeding phenotype in patients with suspected bleeding disorders.
- The European Portuguese version was translated and culturally adapted and must be collected by a physician like the original version.
- The absence of psychometric property analysis and its validation are the main study limitations.

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INTRODUCTION

Bleeding disorders include von Willebrand disease (VWD), platelet disorders, hemophilia, and other clotting factor deficiencies.[1] A bleeding history is important to identify those who may have an inherited bleeding disorder. A structured bleeding history should explore mucocutaneous bleeding symptoms (e.g., epistaxis, gum bleeding, prolonged bleeding from minor wounds, menorrhagia, gastrointestinal tract bleeding), bleeding in relation to previous hemostatic challenges (e.g., surgery, dental extractions, trauma) and bruising with minor trauma from an early age.[2]

A great deal of clinical information on a patient can be obtained using a Bleeding Assessment Tool (BAT) that can help prioritize those individuals who require laboratory testing. Multiple BATs have been published, and studies have shown them to be useful in the evaluation of patients with a possible bleeding disorder.[3] At present, the International Society on Thrombosis and Haemostasis (ISTH) endorses the BAT consensus, the ISTH-BAT, which reports a positive or abnormal bleeding score of ≥ 4 in adult men, ≥ 6 in adult women and ≥ 3 in children. Each domain is scored from zero (absence of bleeding symptoms) to four (symptoms requiring extensive medical intervention), and the overall bleeding score is determined by summing the scores for all domains.[4,5]

In 2019, an International Working Group was established by the European Hematology Association. It proposed a diagnostic approach for patients referred for investigation of bleeding symptoms, and decided that the first evaluation of bleeding phenotype must include the ISTH-BAT,[6] a tool that can help identify hemophilia patients. A study by Borhany *et al* showed that the bleeding score (BS) was significantly higher in hemophilia A and hemophilia B patients than in controls, with no significant difference between newly diagnosed and known hemophilia patients. Furthermore, there were no significant differences in the BS between hemophilia A and B patients. However, the BS was higher in severe hemophilia A patients than in mild hemophilia A patients and lower in pediatric patients than in adult patients.[7]

The use of a standardized bleeding score proved to be potentially useful to further dissect the association between von Willebrand factor function and bleeding, to establish an optimal diagnosis of type-1 VWD (VWD-1) and to evaluate the bleeding risk in VWD patients.[8] A 2019 Platelet Physiology Standardization Subcommittee (SSC) study tested the utility of the ISTH-BAT in a large cohort of patients with a well-defined diagnosis of inherited platelet disorder in comparison with two parallel cohorts, one of patients with VWD-1 and one of healthy controls (HC). They concluded that the ISTH-BAT discriminated inherited platelet function disorders (IPFD) from healthy controls efficiently, while having lower accuracy in distinguishing IPFD from VWD-1. Therefore, the ISTH-BAT appears to be useful for identifying subjects requiring laboratory evaluation for a suspected inherited platelet function disorders, once VWD is preliminarily excluded.[9] Although VWD is the most frequently inherited bleeding disorder, it remains heavily underdiagnosed. The identification and diagnosis of VWD patients will be improved through further improvements in the design and digital availability of BATs, as well as in ongoing and future outreach campaigns, including on social media. Some authors launched a website (www.vwdtest.com) that provides easily accessible information on VWD to individuals who may suffer from abnormal bleeding, as well as a simple online bleeding assessment tool and guidance on the next steps to diagnose a potential bleeding disorder.[10]

One of the largest studies on hemophilia carriers and the first to systematically document the use of the ISTH-BAT in this group showed that hemophilia carriers experience abnormal bleeding, including hemarthrosis. Overall, the bleeding score is higher in women with Type 1 VWD and in descending order in hemophilia carriers and Type 3 VWD obligate carriers.[11]

Based on these data, BATs have been recommended in a number of clinical settings by national and international guidelines.[6,12,13] BATs are not without limitations, including lack of sensitivity in those without hemostatic challenges (such as children and men), recall bias, score saturation with recurrent symptoms, and the inability of positive BATs to distinguish between different types of mild-to-moderate bleeding disorders.[14]

Given the current recommendations on the use of the ISTH-BAT to evaluate bleeding phenotype in patients with suspected bleeding disorders, we aimed to translate and culturally adapt the ISTH-BAT from the original English to European Portuguese.

METHODS

This study was approved by the Ethics Committee of São João Local Health Unit as part of the protocol with the reference CES/CHUSJ: 334/2021, entitled "*ImpaHCta - Avaliação da qualidade de vida das portadoras de hemofilia*". All patients gave written informed consent.

A formal translation and cultural adaptation process was performed, as recommended in the International Society for Pharmacoeconomics and Outcomes Research Guidelines regarding patient-reported outcomes measures (PROMs).[15]

In the preparation phase, the researchers contacted the developer of the original version of the ISTH-BAT and obtained permission for the translation and cultural adaptation. A working group was assembled, including physicians with experience in the treatment of patients with coagulopathy, a coordinator and a team of Portuguese native speaker

translators.

The forward translation from English to Portuguese was carried out by three independent translators with professional fluency in English. They were instructed to produce colloquial translations that would be easily understood by the general population. Discrepancies were then discussed and reconciled by a specialist in the coagulopathy area, and a Portuguese native speaker who had not been involved in any of the forward translations.

Back translation of the reconciled version of the ISTH-BAT was then performed by an English translator. A literal translation was emphasized. This translator was neither involved in the previous steps, nor familiar with the original questionnaire. The working group then compared the back translation against the original ISTH-BAT in order to identify discrepancies in the concepts.

Since no conceptual discrepancies were found between the original English version and the European Portuguese translation, the newly translated ISTH-BAT was tested for cognitive equivalence in a group of 14 Portuguese-speaking respondents. We chose respondents drawn from the questionnaire target population: female hemophilia carriers and male hemophilia patients, with a mean age of 42 ± 10 years, all recruited in the coagulopathy reference center of São João Local Health Unit, in Porto, Portugal. They were asked to fill in the questionnaire, paying special attention to the construction and phrasing of the sentences, and ensuring that the concepts were interpreted appropriately. All patients' difficulties and opinions were analyzed and used as a basis for rephrasing. The final translated version developed during the previous steps was reviewed by the developers, who corrected any remaining spelling, grammatical, or other mistakes. The first author wrote the final report with the description of all translation and cultural adaptation decisions.

RESULTS

The authorization to translate and culturally adapt the original version of the ISTH-BAT [Appendix 1, Table 1 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/22374/15587)] was obtained from the authors. In the translation process, several discrepancies occurred, namely, the expressions 'internal iliac ligation' and 'therapy'. All differences were discussed and resolved, and a final forward translation version was produced by consensus. The back translation was performed, and the resulting version showed no conceptual discrepancies with the original questionnaire.

Cognitive debriefing of the harmonized Portuguese version consisted of comprehensive reading and interpretation by seven hemophilia carriers and seven hemophilia patients from the coagulopathy reference center. We chose to implement a self-administered questionnaire to have a more realistic notion of the respondent's comprehension difficulties, thus avoiding procedural bias. The general opinion was that the questionnaire was easy to understand. Some medical terms, like 'epistaxis', 'antifibrinolytic', 'desmopressin', 'endometrial ablation', 'hysterectomy', 'menorrhagia', 'hemarthrosis', and 'hematuria' were pointed out as difficult to understand.

As the original ISTH-BAT is intended to be administered by a physician, we chose to culturally adapt the general terms used to define the site of bleeding, and we maintained drug classification terms because there was no way to simplify them. Another issue raised was the time frame of bleeding symptoms. The ISTH-BAT is intended to screen bleeding symptoms that may appear at any time, and we decided to include this information in the questionnaire header. The final European Portuguese version of the questionnaire [Appendix 1, Table 2 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/22374/15587)] was reviewed and accepted by the working group.

DISCUSSION

To the best of our knowledge, no European Portuguese translation of the ISTH-BAT has been described in the literature.

We propose a European Portuguese version of the ISTH-BAT questionnaire, resulting from a formal translation and cultural adaptation process. Difficulties were identified after the first version was presented to patients. Some medical terms were difficult for patients to understand, which lead us to add colloquial terms next to medical terms in the European Portuguese version. Although this contributes to an easier comprehension of the questionnaire, it does not allow for this to be a self-ISTH-BAT version.

This study's main strength is the use of a formal methodology, which ensures that the obtained version maintains the same concepts as the original scale. The forward-backward translation process that we used is the most widely accepted method.[15] Similar methods have been used for the translation of this questionnaire into other languages.[11,16]

Study limitations include the absence of psychometric property analysis and its validation, including acceptability, test-retest reliability, internal consistency, and construct validity, which should be evaluated in the future. There is also a sampling bias, since all the individuals that tested the ISTH-BAT have the same bleeding disorder. In our opinion, this does not compromise questionnaire cognitive debriefing.

CONCLUSION

The present study reports the translation and cultural

adaptation of the ISTH-BAT to the European Portuguese language so it can be used in the diagnostic workup of suspected bleeding disorders in a primary care or hospital setting on the Portuguese population. Further studies are necessary for the validation of this new version.

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AUTHOR CONTRIBUTIONS

All authors contributed equally to this manuscript and approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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Urinary Tract Infections in Children: Changing Trends in Etiology and Local Resistance Patterns over a Three-Year Period

Infeções do Trato Urinário em Pediatria: Evolução da Etiologia e Padrões de Resistências Locais ao Longo de Três Anos

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ABSTRACT

Introduction: Urinary tract infections are common in pediatrics. Knowledge of local resistance patterns is crucial to guide empirical antibiotic therapy. We aimed to review the pathogens implicated in urinary tract infections, local resistance patterns, and the impact of switching first-line empirical antibiotic regimens.

Methods: We conducted a cross-sectional study including pediatric patients performing urine cultures in a hospital in northern Portugal over two periods: 2019 (group 1) and 2022 (group 2). Between time periods, an internal guideline was implemented recommending cefuroxime as the first-line choice for empirical treatment of urinary tract infections, according to local resistance patterns. Uropathogens, empirical antibiotic choices and resistance patterns were compared among groups.

Results: The final sample included 402 cases of urinary tract infections in group 1 and 398 in group 2. *Escherichia coli* was the most common uropathogen (79.4 - 83.3%), followed by *Proteus mirabilis* and *Klebsiella spp*. The most common empirical antibiotic in group 1 was amoxicillin-clavulanate (A-C), as opposed to cefuroxime in group 2 ($p < 0.001$). The most common resistance was to ampicillin (39.3% - 39.7%). Resistance to A-C slightly decreased (33.1% *vs* 27.4%, $p = 0.079$), while resistance to cefuroxime (4.7% *vs* 3.3%, $p = 0.292$) and trimethoprim-sulfamethoxazole (TMP-SMX) remained similar (15.2% *vs* 14.1%, $p = 0.659$). Resistances to nitrofurantoin (9.0% *vs* 0.3%, $p < 0.001$) and fosfomycin (1.7% *vs* 0.3%, $p < 0.036$) significantly decreased from group 1 to group 2.

Conclusion: *E.coli* remains the predominant pathogen in pediatric urinary tract infections. Resistance to A-C in our sample was high (33.1%). The switch from A-C to cefuroxime as first-line agent resulted in a decreasing trend in A-C resistance, while cefuroxime resistance remained low and even slightly lower.

Keywords: Child; Drug Resistance, Bacterial; Urinary Tract Infections/drug therapy; Urinary Tract Infections/etiology; Urinary Tract Infections/microbiology

RESUMO

Introdução: As infeções do trato urinário são comuns em idade pediátrica. Conhecer a etiologia e os padrões de resistência locais é fundamental na determinação do tratamento empírico. Propusemo-nos a rever os patógenos implicados nas infeções do trato urinário, os padrões de resistência locais e o impacto do ajuste da antibioterapia de primeira-linha de acordo com as mesmas.

Métodos: Conduzimos um estudo transversal que incluiu os doentes pediátricos que realizaram urocultura num hospital do Norte de Portugal durante dois períodos: 2019 (grupo 1) e 2022 (grupo 2). Entre estes dois períodos, foi instituído um protocolo interno de atuação clínica que recomendava a utilização de cefuroxima como antibioterapia empírica de primeira linha, de acordo com a epidemiologia local. Os grupos foram comparados quanto aos uropatógenos identificados, respetivos padrões de resistência a antimicrobianos e antibioterapia empírica instituída.

Resultados: Foram identificados 402 casos de infeções do trato urinário no grupo 1 e 398 no grupo 2. A *Escherichia coli* (*E. coli*) foi o uropatógeno mais comum (79,4% - 83,3%), seguido do *Proteus mirabilis* e da *Klebsiella spp*. No grupo 1, o antimicrobiano empírico mais frequentemente selecionado foi a amoxicillina-clavulanato (A-C), enquanto no grupo 2 foi a cefuroxima ($p < 0.001$). A resistência mais frequentemente identificada foi à ampicilina (39.3% - 39.7%). A resistência a A-C não mostrou alterações estatisticamente significativas entre grupos (33,1% *vs* 27,4%, $p = 0,079$), tal como a resistência à cefuroxima (4,7% *vs* 3,3%, $p = 0,292$) e ao trimetoprim-sulfametoxazol (TMP-SMX) (15,2% *vs* 14,1%, $p = 0,659$). As resistências à nitrofurantoína (9,0% *vs* 0,3%, $p < 0.001$) e à fosfomicina (1,7% *vs* 0,3%, $p < 0,036$) diminuíram significativamente entre o grupo 1 e o grupo 2.

Conclusão: A *E.coli* mantém-se como o principal agente de infeções do trato urinário em pediatria. A resistência a A-C na nossa amostra é elevada (33,1%). A alteração de antibioterapia empírica de primeira-linha de A-C para cefuroxima resultou numa tendência de diminuição da resistência à A-C, sem aumento da resistência a cefuroxima.

Palavras-chave: Criança; Infeções do Trato Urinário/etiologia; Infeções do Trato Urinário/microbiologia; Infeções do Trato Urinário/tratamento farmacológico; Resistência Bacteriana a Medicamentos

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KEY MESSAGES

- *E.coli* remains the predominant pathogen in pediatric UTI.
- Antibiotic resistance patterns are crucial in guiding treatment selection.
- In our sample, uropathogen resistance to amoxicillin-clavulanate (A-C) was high (33.1%).
- Switching from A-C to cefuroxime as the first-line option to treat pediatric UTI resulted in a decreasing trend in A-C resistance, although not statistically significant. Cefuroxime resistance remained low.
- The continued use of cefuroxime as first-line option should help decrease A-C resistance in our population. Further studies would be of interest to evaluate the impact of this measure.

INTRODUCTION

Urinary tract infections (UTI) occur when microorganisms multiply in the urinary tract, causing an inflammatory response.[1] This is an important cause of hospital admissions and morbidity in pediatrics.[2] UTIs can affect the lower urinary tract, resulting in cystitis, or the upper urinary tract, resulting in pyelonephritis.[3] Because pyelonephritis typically presents with fever, as opposed to cystitis, the terms 'febrile' and 'afebrile' UTI are widely used to refer to each type of infection.[4]

Girls are more commonly affected, except during the first year of life.[5] Up to 11% of girls and 4% of boys experience a UTI before the age of 16 years.[3]

The presenting signs and symptoms are usually non-specific, which can contribute to a delayed diagnosis.[6] Fever is commonly the only symptom in children under the age of two, but it may also be accompanied by irritability, lethargy, vomiting, and diarrhea.[4] In older, particularly, potty-trained children, dysuria, urinary frequency, urgency, and suprapubic or flank pain may be present.[3]

The most common pathogens causing UTIs are *Escherichia coli* (*E. coli*), *Proteus* spp., *Staphylococcus saprophyticus*, *Klebsiella* spp., and other Enterobacteriaceae.[7-9] Bacteria typically reach the urinary tract by the ascending route, as the most frequent UTI agents are present in the gastrointestinal tract.[10] However, hematogenous spread can also occur, particularly in newborns.[10]

Diagnosis is confirmed by the proliferation of a single microorganism in a urine culture.[11] A late diagnosis can lead to short-term complications, such as renal abscess and sepsis, and long-term complications such as renal scarring, hypertension, and renal failure.[10,12] Therefore, early empirical antibiotic treatment should be started upon a strong suspicion of UTI.[13] However, antibiotic overuse, especially of a broader than necessary spectrum, can lead to an increase in antibiotic-resistant pathogens.[14]

The most commonly recommended antibiotics include trimethoprim-sulfamethoxazole (TMP-SMX), nitrofurantoin, ciprofloxacin, cephalosporins, and amoxicillin-clavulanate (A-C).[15] In Portugal, A-C and cefuroxime are both acceptable first-line choices for empirical treatment.[16] The choice of antibiotics should take into consideration local data on antibiotic resistance patterns, which vary greatly according to geographical location and population characteristics.[17,18] Hence, local surveillance of antibiotic resistance is crucial for determining the pattern of antimicrobial resistance and guiding empirical and directed therapy.[19]

In this study, we aimed to determine the resistance patterns of the most common pathogens causing UTIs in the pediatric population treated in a district-level hospital in the north of Portugal, before and after a guideline guided by local epidemiological data was implemented. Secondary outcomes included the clinical and demographic characterization of patients presenting with UTI.

METHODS

We performed a single-center, cross-sectional study including two groups separated by a three-year period. Firstly, we included patients between the ages of 29 days and 17 years and 364 days with urine cultures registered in our microbiology laboratory between January 1, 2019 and December 31, 2019. Only pure growth > 10^3 CFU/mL in samples collected by bladder catheterization and > 10^5 CFU/mL in samples collected by urinary midstream were included. Urine samples obtained by urine bag or to which the sampling method was not specified were excluded, as well as samples in which more than one microorganism was identified.

For included subjects, clinical records were examined to retrieve information on sex, age, sampling method, CFU/mL counts, identified microorganism, antibiogram, empirical antibiotic regimen, febrile/afebrile infection, chemoprophylaxis during infection, history of urologic abnormalities, discharge destination, and follow-up. These participants were labeled as group 1.

Based on the primary results, in January 2021 we implemented an internal guideline stating cefuroxime was the first-line choice for empirical antibiotic therapy for our population. This guideline also reviewed the appropriate urine

collecting methods and indications for follow-up in a pediatric nephrology consult.

In 2023, we then identified all urine cultures registered in our microbiology laboratory between January 1, 2022 and December 31, 2022 and collected data on the aforementioned variables, with the same inclusion criteria as the previous cohort. These participants consisted of group 2.

This study was approved by the institutional Ethics Committee.

Statistical analyses were performed using the statistical software R, version 4.4.2, and the packages 'glmmTMB' and 'interactions'.

The significance level was set at 0.1. In this study, the significance level between 0.05 and 0.1 is called 'marginal' and, roughly speaking, it corresponds to weaker effects. All significant results have been assessed through regression modeling. When compared to traditional statistical tests, regression models have several advantages such as: incorporating a family of distributions suitable for the dependent variable, performing multivariable analyses (including interactions), discarding *p*-value adjustment for multiple comparisons, and providing graphical complementary analyses. We used logistic models for dichotomous data, and Conway-Maxwell-Poisson models for count data.

RESULTS

Clinical and demographic characteristics

The final sample consisted of 402 cases of UTI in group 1 and 398 in group 2. Table 1 summarizes the clinical demographic characteristics of both groups.

Mean age was 4.7 (SD 5.56) years in group 1 and 3.0 (SD 4.67) years in group 2 ($p < 0.001$). There was a higher prevalence of the female sex in both groups, with a 4:1 distribution in the first and 2:1 distribution in the second ($p < 0.001$). Mean age was significantly lower in male patients in group 1 ($p = 0.023$) and in female patients in group 2 ($p < 0.001$).

Regarding the type of infection, in group 1, 226 (56.2%) were febrile and 176 (43.8%) were afebrile; in group 2, 272 (68.3%) were febrile and 126 (31.7%) were afebrile

Table 1 – Clinical and demographic characteristics

	Group 1 (n = 402)		Group 2 (n = 398)		*p*-value
Age (years)	4.7 (5.56)		3.0 (4.67)		< 0.001***
Sex – male (female)	78 (19.4%)		130 (32.7%)		< 0.001***
Febrile UTI (afebrile UTI)	226 (56.2%)		272 (68.3%)		0.004***
Collecting method – In-out catheterization (midstream)	171 (42.5%)		231 (58.0%)		< 0.001***
< 2 years-old	162 out of 213 (76.1%)		225 out of 279 (80.6%)		0.219
Uropathy	63 (15.7%)		56 (14.1%)		0.525
Chemoprophylaxis	8 (2.0%)		15 (3.8%)		0.139
Inpatient treatment	24 (6.0%)		38 (9.5%)		0.061^
Non-family doctor follow-up					
Pediatric nephrology consult (general paediatrician)	112 out of 185 (27.9%)		51 out of 198 (12.8%)		< 0.001***
Age (years)					
Male patients	3.6 (5.01)	0.023*	1.7 (3.27)	< 0.001***	*
Female patients	4.9 (5.66)		3.6 (5.10)		
Inpatient	2.3 (4.25)	0.002**	0.4 (1.17)	<0.001***	
Outpatient	4.8 (5.60)		3.3 (4.81)		
Febrile infections					
Male patients	40 (51.3%)	0.328	89 (68.5%)	0.972	
Female patients	186 (57.4%)		183 (68.3%)		
In-out catheterization					
Male patients	16 (20.5%)	< 0.001***	163 (60.8%)	0.107	
Female patients	155 (47.8%)		68 (52.3%)		

Continuous variables are represented as mean (SD) and categorical variables as counts (percentage). *p*-values were calculated using adequate regression modelling (logistic for dichotomous data, and Conway-Maxwell-Poisson for count data).
Each item assessed with a different model (a total of 13 models).
^$p < 0.1$; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

($p < 0.001$). For both groups, and in both sexes, febrile infections were more frequent.

For children under the age of two, in both groups, in-out catheterization was the most frequent urine-collecting method ($p = 0.219$). In group 1, 20.5% of male and 47.8% of female patients had a urine sample collected by in-out catheterization ($p < 0.001$). In group 2, the percentage of in-out catheterization was 60.8% in male and 52.3% in female patients ($p = 0.107$).

There was no statistically significant difference between groups regarding the presence of urologic abnormalities (15.7% *vs* 14.1%, $p = 0.525$) or chemoprophylaxis use (2.0% *vs* 3.8%, $p = 0.139$).

Most children were treated as outpatients and only 24 (6.0%) in group 1 and 38 (9.5%) in group 2 were admitted ($p = 0.061$). Median age was lower for inpatients in both groups ($p < 0.001$).

Most patients were followed-up by their family doctor: 217 (54.0%) in group 1 and 200 (50.3%) in group 2. In group 1, the second most common referral for follow-up was the pediatric nephrology consultation (27.9%), whereas in group 2, the second most common referral was to the general pediatrician (36.9%), with the difference being statistically significant ($p < 0.001$).

Microorganisms

Table 2 describes the relative frequency of the identified pathogens, and Fig. 1 represents the relative frequency of the most common bacteria according to type of infection. For afebrile infections, *E. coli* (n = 132, 75.0%), *Proteus mirabilis* (n = 25, 14.2%) and *Staphylococcus saprophyticus* (n = 12, 6.8%) were the most common pathogens in group 1. In group 2, *E. coli* (n = 87, 69.0%), *Proteus mirabilis* (n = 24, 9.0%) and *Klebsiella* spp. (n = 6, 4.8%) were the most common agents identified.

For febrile infections, the most commonly isolated microorganisms were *E. coli* (n = 203, 89.8%), *Proteus mirabilis* (n = 10, 4.4%) and *Klebsiella* spp. (n = 9, 4.0%) in group 1 as well as group 2: *E. coli* (n = 229, 84.2%), *Proteus mirabilis* (n = 21, 7.7%) and *Klebsiella* spp. (n = 12, 4.4%). For these microorganisms, there were no statistically significant differences between groups.

Empirical antibiotic regimen

Empirical antibiotic regimen choice is detailed in Table 3, and Fig. 1 shows the most frequently prescribed antibiotics according to type of infection. Amoxicillin-clavulanate was the most common antibiotic choice in group 1 for both febrile (51.8%) and afebrile infections (61.4%), as opposed to cefuroxime becoming the preferred drug in group 2 ($p < 0.001$), also for both febrile (67.6%) and afebrile infections (46.8%). Cefotaxime in febrile infections and fosfomycin in afebrile infections remained the third most frequent choice in both groups.

Resistance patterns

In vitro resistance patterns for the microorganisms identified in both groups are represented in Table 4 and were similar in both groups. The most commonly identified resistances were to ampicillin (39.3% in group 1 *vs* 39.7% in group 2, $p = 0.909$), A-C and TMP-SMX. Resistance to cefuroxime was 4.7% in group 1 and 3.3% in group 2, $p = 0.295$). Resistance to A-C was 33.1% in group 1 and 27.4% in group 2 ($p = 0.078$). Resistance to TMP-SMX, the most common agent in chemoprophylaxis, remained similar (15.2% in group 1 *vs* 14.1% in group 2, $p = 0.659$). Resistances to nitrofurantoin (9.0% *vs* 0.3%, $p < 0.001$) and fosfomycin (2.0% *vs* 0.3%, $p < 0.0496$) decreased significantly from group 1 to group 2.

Table 5 describes the *in vitro* resistance patterns to the two most frequent empirically prescribed antibiotics of the three most commonly isolated bacteria.

In both groups, resistance patterns were similar regardless of a history of urologic abnormalities (Table 4).

Resistance to cotrimoxazole was significantly higher in children under chemoprophylaxis in both groups (Table 4).

DISCUSSION

In this study, we analyzed the epidemiology of UTIs in children, regarding the pathogens involved and their resistance patterns. We compared two time periods, before and after an internal guideline was published with cefuroxime

Table 2 – Pathogens identified in urine culture

Pathogen	Group 1	Group 2	*p*-value
Escherichia coli	335 (83.3%)	316 (79.4%)	0.457
Proteus mirabilis	35 (8.7%)	45 (11.3%)	0.265
Klebsiella spp.	13 (3.2%)	16 (4.0%)	0.578
Staphyloccus saprophyticus	12 (3.0%)	3 (0.8%)	**0.032***
Other pathogens	7 (1.7%)	18 (4.5%)	**0.034***

p-values were calculated using a unique logistic regression model with 'group' as dependent variable and 'microorganism' as independent variable.
Percentages have been rounded and thus may not add up to 100%.
^$p < 0.1$; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

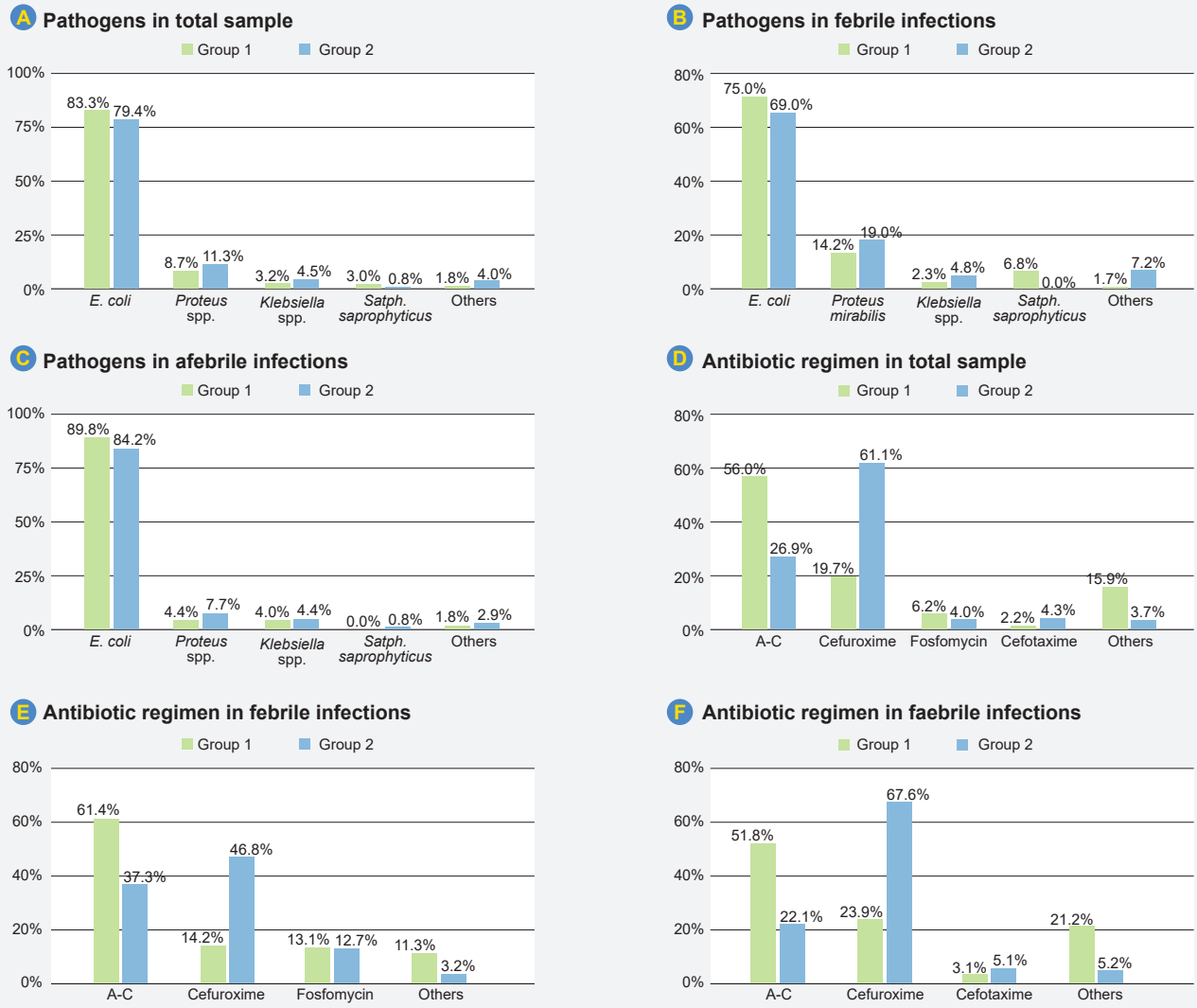

Figure 1 – Relative frequency of the pathogens identified according to type of infection. (A) Pathogens in total sample; (B) Pathogens in febrile infections; (C) Pathogens in afebrile infections; (D) Antibiotic regimen in total sample; (E) Antibiotic regimen in febrile infections; (F) Antibiotic regimen in febrile infections.
Numbers represent percentages.

Table 3 – Empirical antibiotics prescribed in both groups

Antibiotic	Group 1	Group 2	*p*-value
Amoxicillin-Clavulanate	225 (56.0%)	107 (26.9%)	**< 0.001*** **
Cefuroxime	79 (19.7%)	243 (61.1%)	**< 0.001*** **
Fosfomycin	25 (6.2%)	16 (4.0%)	0.163
Cefotaxime	9 (2.2%)	17 (4.3%)	0.123
Others	14 (3.5%)	12 (3.0%)	0.695
None	50 (12.4%)	3 (0.8%)	**< 0.001*** **

p-values were calculated using a unique logistic regression model with 'group' as dependent variable and 'empirical_antibiotic' as independent variable.
Percentages have been rounded and thus may not add up to 100%.
^$p < 0.1$; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

Table 4 – Resistance patterns to the 6 most frequent empirical antibiotic choices

Antibiotic	Group 1			Group 2		*p*-value
Ampicillin	158 (39.3%)			158 (39.7%)		0.909
A-C	133 (33.1%)			109 (27.4%)		**0.078^**
Cotrimoxazol	61 (15.2%)			56 (14.1%)		0.659
Nitrofurantoine	36 (9.0%)			1 (0.3%)		**< 0.001*** **
Cefuroxime	19 (4.7%)			13 (3.3%)		0.295
Fosfomycin	8 (2.0%)			1 (0.3%)		**0.0496***
None of these	206 (51.2%)			228 (57.3%)		**0.087^**
Urologic abnormalities						
	Yes 63	No 339	*p*-value	Yes 56	No 342	*p*-value
Ampicillin	30 (47.6%)	128 (37.8%)	0.143	26 (46.4%)	132 (38.6%)	0.268
A-C	26 (41.3%)	107 (31.6%)	0.134	21 (37.5%)	88 (25.7%)	**0.069^**
Cotrimoxazol	13 (20.6%)	48 (14.2%)	0.191	11 (19.6%)	45 (13.2%)	0.199
Nitrofurantoine	3 (4.8%)	33 (9.7%)	0.215	-	1 (0.3%)	0.988
Cefuroxime	16 (25.4%)	3 (0.9%)	0.988	4 (7.1%)	9 (2.6%)	0.091
Fosfomycin	7 (11.1%)	1 (0.3%)	0.804	-	1 (0.3%)	0.992
Chemoprophylaxis						
	Yes 8	No 394	*p*-value	Yes 15	No 383	*p*-value
Ampicillin	4 (50.0%)	154 (39.1%)	0.535	10 (66.7%)	148 (38.6%)	**0.038***
A-C	4 (50.0%)	129 (32.7%)	0.314	8 (53.3%)	101 (26.4%)	**0.029***
Cotrimoxazol	4 (50.0%)	57 (14.5%)	**0.014***	6 (40.0%)	50 (13.1%)	**0.007****
Nitrofurantoine	1 (12.5%)	35 (8.9%)	0.724	-	1 (0.3%)	0.991
Cefuroxime	-	19 (4.8%)	0.987	1 (6.7%)	12 (3.1%)	0.461
Fosfomycin	-	7 (1.8%)	0.995	-	1 (0.3%)	0.994

p-values were calculated using logistic regression models, one for each row.
Percentages have been rounded and thus may not add up to 100%.
^$p < 0.1$; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

being the first-line choice for empirical antibiotic treatment.

The mean age was lower in the second group. This could be related to the increasing awareness for older children with UTI symptoms and no red flags to seek medical care in primary care as opposed to hospital settings. This could also justify the increased prevalence of febrile infections in group 2.

As expected, febrile infections were more common than afebrile infections and the female sex was more prevalent in both groups, with a 4:1 distribution in the first and 2:1 distribution in the second.[5] Mean age was significantly lower in males in both groups, as UTIs in boys occur more frequently in the first year of life.[14]

For children under the age of two, in both groups, in-out catheterization was the most frequent urine collecting method, as it provides a sterile sample, is painless, and both parents and professionals prefer it to suprapubic aspiration.[20] The percentage of catheterization increased in group 2, particularly in male patients (from 20.5% to 60.8%). This is likely due to the continuous efforts in educating professionals on this procedure, as lack of training is a major concern reported by professionals for the resistance in using this collecting method.[20]

As expected, the hospital admission rate was low, as most children with UTI can be discharged home without complications.[2] Mean age was significantly lower in inpatients for both groups, as the main reason for inpatient treatment in UTIs is younger age.[2]

We observed a significant decrease in the percentage of patients followed-up in the pediatric nephrology clinic. Since the prevalence of urologic abnormalities was similar, we believe this is due to the continuous education programs on adequate UTI follow-up aimed at primary care doctors and general pediatricians.

E.coli was the most significant uropathogen identified in both groups, with a relative frequency of 79.4% - 83.3%,

Table 5 – Comparison of resistance patterns of the three most common microorganisms to the two most frequent empirical antibiotic choices

Microorganism / Antibiotic		Group 1	Group 2	*p*-value
E. coli		335 (83.3%)	316 (79.4%)	
	A-C	121 (36.1%)	94 (29.7%)	**0.084^**
	Cefuroxime	15 (4.5%)	8 (2.5%)	0.185
Klebsiella spp.		13 (3.2%)	16 (5.1%)	
	A-C	4 (30.8%)	8 (50.0%)	0.300
	Cefuroxime	2 (15.4%)	3 (18.8%)	0.812
Proteus mirabilis		35 (8.7%)	45 (14.2%)	
	A-C	6 (17.1%)	4 (8.9%)	0.276
	Cefuroxime	2 (5.7%)		0.987

p-values were calculated using logistic regression models, one for each antibiotic, which assessed the effect of the interaction 'microorganism * group' in A-C, cefuroxime, and ampicillin. Percentages have been rounded and thus may not add up to 100%.
^$p < 0.1$; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

similar to that reported by several studies performed in Turkey, Israel, and France.[14,21,22] Other frequently identified pathogens were *Proteus mirabilis*, *Klebsiella* spp. and *Staphylococcus saprophyticus*.

Regarding empirical antibiotic selection, A-C was the most common antibiotic choice in group 1 for both febrile (51.8%) and afebrile infections (61.4%), as opposed to cefuroxime becoming the preferred drug in group 2 ($p < 0.001$), also for both febrile (67.6%) and afebrile infections (46.8%). This suggests the intervention implemented between groups was effective in guiding empirical UTI treatment. Cefotaxime in febrile infections and fosfomycin in afebrile infections remained the third most frequent choice in both groups.

As expected, the most commonly identified *in vitro* resistance was to ampicillin, which remained similar among groups (39.3% - 39.7%).[7,23,24] We found a resistance rate to A-C in group 1 of 33.1%. Studies in France and Turkey reported resistance rates as high as 93%.[22,24] Studies in Israel, Greece, and Spain reported lower to similar rates, as well as an increase from 12% to 24% in a decade.[7,9,25] A previous study conducted in Portugal in 2009 - 2010 found an 18% rate of A-C resistance in pediatric UTIs.[26] These concerns prompted our internal guideline stating cefuroxime should be the first-line choice for our population. In the second group, recruited at least a year after guideline implementation, we observed a slight decrease in A-C resistance (27.4%). Conversely, cefuroxime resistance did not increase, displaying a decreasing trend from 4.7% to 3.3%. There were no statistically significant differences in resistance to TMP-SMX, the most common agent used in chemoprophylaxis (15.2% in group 1 *versus* 14.1% in group 2, $p = 0.659$).[27] Resistance to nitrofurantoin and fosfomycin remained low and significantly decreased from group 1 to group 2, as opposed to the increasing trend noted in previous studies.[24] Although 14.1% - 15.7% of our patients had a history of urologic abnormalities, only 2.0% - 3.8% were under chemoprophylaxis. The judicious use of chemoprophylaxis may have contributed to the finding of no evidence of increased resistance in patients with a history of urologic abnormalities, as opposed to that reported by Parry *et al*.[28] However, as expected, in both groups, resistance to TMP-SMX was significantly higher in children under chemoprophylaxis. Although antibiotic chemoprophylaxis for the prevention of recurrent UTI has proven successful,[29] its widespread use raises concerns of increased antibiotic resistance, supported also by this study.[23]

There are some limitations to our study. The single-center nature of this investigation limits the generalizability of our data to national and international populations. The sample size also limited the statistical power of some comparisons. However, our data provides useful information on resistance pattern trends of uropathogens, particularly to geographically neighboring populations. National and international multicenter studies such as the ESCAPE study are key to continuously monitoring antibiotic resistance in UTIs and update guidelines accordingly.[21]

In this study, we recognized the problem of A-C resistance in our population and evaluated the impact of switching to cefuroxime as first-line agent. Also, including all months of the year in the analysis prevented the effect of seasonal differences and including both in- and outpatients allowed for a representative sample regarding the distribution of sex, age and UTI severity.

CONCLUSION

Although overall more frequent in female children, UTIs are more prevalent in male patients at a younger age. *E.coli*

remains the predominant pathogen in pediatric UTI. The uropathogens resistance to A-C in our population is approximately of one-third. The switch from A-C to cefuroxime as first-line agent resulted in a decreasing trend in A-C resistance while cefuroxime resistance remained low and even slightly lower. The continued use of cefuroxime as first-line option should help decrease A-C resistance in our population. Further studies in the future would be of interest to evaluate the increased impact of this measure.

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AUTHOR CONTRIBUTIONS

PS: Study design, data acquisition and analysis, writing of the manuscript.

LD: Data acquisition and analysis.

SCO, CP: Data acquisition.

ÂD: Writing of the manuscript.

ACT: Study design.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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AMP ACTA MÉDICA PORTUGUESA
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Determinants of Adolescent Pregnancy in the Municipality of Malanje, Angola: A Case-Control Study

Determinantes da Gravidez na Adolescência no Município de Malanje, em Angola: Um Estudo Caso-Controlo

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ABSTRACT

Introduction: Adolescent pregnancy is a global public health problem, with some of the highest rates observed in Sub-Saharan Africa. This phenomenon contributes to maternal and neonatal mortality and may result in diverse economic and psychological consequences. Knowledge of its determinants can help decision-makers to design local policies of sexual and reproductive health. Therefore, the aim of this study was to analyze the determinant factors of adolescent pregnancy in the municipality of Malanje, Angola.

Methods: A case-control study was conducted from August to October, 2022. A sample of 411 adolescent women (137 pregnant and 274 non-pregnant) was compared in terms of socio-demographic, behavioral, family, and extra-family factors. Descriptive statistics, binary univariate and multivariate logistic analysis were applied, with *p*-values ≤ 0.05 indicating statistical significance. Adjusted odds ratio (AOR) and the respective 95% confidence interval (95% CI) were obtained.

Results: The multivariable analysis showed that a higher risk of adolescent pregnancy was associated with living in a *de facto* union or being married (AOR = 10.37; 95% CI = 1.05 - 102.83), having 0 - 4 (AOR = 7.40; 95% CI = 1.25 - 43.77) or 5 - 8 years of schooling (AOR = 5.21; 95% CI = 1.25 - 21.77), and a lower risk was related with having a family history of adolescent pregnancy (AOR = 0.30; 95% CI = 0.11 - 0.80) for women aged 15 - 17. For those aged 18 - 19, a higher risk of pregnancy was associated with early sex initiation (AOR = 3.75; 95% CI = 1.05 - 13.43), having multiple sexual partners (AOR = 3.02; 95% CI = 1.23 - 7.44), while a lower risk was related with peer pressure (AOR = 0.35; 95% CI = 0.15 - 0.82). In both groups, the likelihood of pregnancy was significantly increased for irregular or non-use of contraceptive methods.

Conclusion: In Malanje, adolescent pregnancy is a multifactorial phenomenon, and preventive strategies must consider the adolescents' age. Among adolescents aged 15 - 17, early marriages, should be reduced, through the promotion of education and the creation of specific laws. For older adolescents, preventive strategies should be focused on avoiding risky behaviors such as early initiation of sexual activity and multiple sexual partners. Comprehensive sexual education, including knowledge about contraceptive methods should be promoted.

Keywords: Angola; Pregnancy in Adolescence; Sexual Behavior; Sociodemographic Factors

RESUMO

Introdução: A gravidez na adolescência é um problema global de saúde pública, com taxas mais elevadas na África Subsariana. Este fenómeno contribui para mortalidade materna e neonatal e pode ter diversas consequências económicas e psicológicas. O conhecimento dos seus determinantes pode ajudar os decisores políticos no desenho de políticas locais de saúde sexual e reprodutiva. O presente estudo teve como objetivo analisar os fatores determinantes da gravidez na adolescência no município de Malanje, em Angola.

Métodos: Um estudo de caso-controlo realizado entre agosto e outubro de 2022. Uma amostra de 411 mulheres adolescentes (137 gestantes e 274 não gestantes) foi comparada quanto a fatores sociodemográficos, comportamentais, familiares e extrafamiliares. Foram aplicadas estatística descritiva e análises por regressão logística binária univariada e multivariada, com significância estatística quando $p \leq 0,05$.

Resultados: A análise multivariada demostrou que para as mulheres de 15 - 17 anos de idade, um risco mais elevado de gravidez na adolescência estava associada a estados civis de união de facto ou casada (ORA = 10,37; 95% IC = 1,05 - 102,83), ter 0 - 4 (ORA = 7,40; 95% IC = 1,25 - 43,77) ou 5 - 8 anos de escolaridade (ORA = 5,21; 95% IC = 1,25 - 21,77), enquanto um risco mais baixo estava relacionado com história familiar de gravidez na adolescência (ORA = 0,30; 95% IC = 0,11 - 0,80). Para as mulheres entre 18 - 19 anos de idade, um risco mais elevado de gravidez estava associado a início precoce da atividade sexual (ORA = 3,75; 95% IC = 1,05 - 13,43), múltiplos parceiros sexuais (ORA = 3,02; 95% IC = 1,23 - 7,44), enquanto um risco mais baixo estava associado a pressão dos pares (ORA = 0,35; 95% IC = 0,15 - 0,82). Em ambos os grupos, a probabilidade de engravidar foi significativamente aumentada para uso irregular ou não uso de contracetivos.

Conclusão: Em Malanje, a gravidez na adolescência é um fenómeno multifatorial e as estratégias preventivas devem ter em conta idade das adolescentes. Nas adolescentes com idades entre os 15 e 17 anos é importante reduzir o casamento precoce, através da promoção da educação e da criação de leis específicas. Nas adolescentes mais velhas, as estratégias preventivas devem estar focadas nos comportamentos de risco, como o início precoce da atividade sexual e múltiplos parceiros. Deve ser promovida a educação sexual incluindo conhecimentos sobre métodos contracetivos.

Palavras-chave: Angola; Comportamento Sexual; Fatores Sociodemográficos; Gravidez na Adolescência

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KEY MESSAGES

- This analysis may provide better support for defining accurate health policies in our setting concerning prevention of adolescent pregnancy according to age groups.
- Among adolescents aged 15 - 17, early marriage should be avoided, through the promotion of education and the creation of specific laws.
- Despite the difference in the determinants of getting pregnant between adolescents aged 15-17 and 18-19, regular contraceptive use and avoiding risky behaviors such as early initiation of sexual activity and multiple sexual partners play an important role in preventing teenage pregnancy. Therefore, reproductive and sexual education is a fundamental element in multidisciplinary interventions to prevent teenage pregnancy.

INTRODUCTION

Adolescent pregnancy is defined as pregnancy in women aged 10 - 19 years.[1] In 2023, the adolescent fertility rate per 1000 women aged 15 - 19 varied from 10 or less in Australia, New Zealand, East Asia, and Europe to 98 in sub-Saharan Africa.[2] In a meta-analysis of studies from 2016 to 2021, the pooled prevalence of adolescent pregnancy was 30% in Africa, and the highest value (33%) was in Western Africa.[3] In this region, Angola is among the countries with the highest adolescent fertility rate (163 per 1000 women),[4] where approximately 35% of adolescent women (15 - 19 years old) experience at least one pregnancy.[4,5] Reducing the adolescent fertility rate is an internationally desired target, and is included in the Millennium Development Goals and Sustainable Development Goals.[6,7] Despite a notable reduction in adolescent fertility worldwide, Sub-Saharan Africa continues to exhibit the highest rate.[1]

Besides its magnitude, adolescent pregnancy contributes to maternal complications such as pre-eclampsia, eclampsia,[8] anemia,[9,10] puerperal endometritis and systemic infections,[11] as well as adverse neonatal outcomes such as low birth weight, prematurity,[8] and neonatal mortality.[12,13] Socio-economically, adolescent mothers may face numerous difficulties in entering the labor market due to low education levels resulting of abandoning school.[14] In addition to the biological and economic consequences of adolescent pregnancy, some authors have also reported psychological outcomes. Some pregnant adolescent face mental health conditions such as depression, traumatic stress, and suicidal and homicidal ideation.[15] In short, adolescent pregnancy may lead to biological, psychological, and socioeconomic consequences.

Considering the sub-Saharan context, determinants of adolescent pregnancy operate at different levels including individual and family-related factors, health service-related factors and sociocultural, environmental, and economic determinants.[16] Individual determinants include age,[17,18] early marriage,[18-20] low education level,[17-21] and behavioral factors such as alcohol consumption and substance abuse,[16] multiple sexual partners,[17] poor knowledge of sexual and reproductive health,[20,22] and non-use or irregular use of contraception.[16,19] Adolescent pregnancy tends to be more common in large families, which are characterized by the poorest wealth quintiles, early pregnancy history, lack of communication, woman head of household, divorced or widowed head of household, maternal or paternal low educational level, and domestic violence.[16-23] The role of friendships and social and healthcare infrastructures affects adolescent sexual behavior at the community level. Lack of access to family planning, an unmet need for contraception, opportunities for leisure and recreation, as well as peer pressure, contribute to adolescent pregnancy due to increased high-risk behaviors such as early sex initiation, multiple sexual partners, and non-use of contraception.[17,19,23]

As previously mentioned, Angola is among the Sub-Saharan African countries with the highest adolescent fertility rate. However, there is a lack of knowledge of the factors associated with this phenomenon. Published research is essentially based on descriptive or cross-sectional studies carried out in the south of the country in the provinces of Huambo and Huila. In these studies, most pregnant adolescents were single, with completed primary education, and lived with both biological parents. Compared to non-pregnant adolescents, the pregnant ones had less school attendance and they reported alcohol consumption and having multiple sexual partners more frequently.[24,25] According to the Malanje Municipal Health Directorate, this municipality situated in the North of Angola registered around 2170 new cases of teenage pregnancy in the first half of 2022 (unpublished data), a worrying scenario without available studies. The aim of the present study was to analyze the determinant factors of adolescent pregnancy in the municipality of Malanje, Angola. The results of this study can help decision-makers to design local health policies with targeted interventions to promote knowledge about sexual and reproductive health for adolescents.

METHODS

Study design and location

We conducted an unmatched case-control study (two controls for one case) in the municipality of Malanje, Angola, from August 2nd to October 5th, 2022. The municipality of Malanje is located in northern Angola, in the province of Malanje, and comprises five urban areas, 22 peri-urban areas, and 212 rural areas. In 2014, the municipality had approximately 506 847 residents. Agriculture and commerce are the main economic activities in Malanje, and the government is the largest employer.

In 2022, the municipality of Malanje had 37 functional health units (36 being primary health care units), of which only 12 had antenatal care services. Family planning services are available to all women from menarche to 45 years old, and sexual and reproductive health education begins in the seventh grade, but with several limitations. According to the Malanje Municipal Health Directorate, there are several contraceptive methods available freely for the population in public health units such as condoms, injectables, pills, intrauterine devices, and implants. Among them, injectables are the most commonly used method, after condoms (unpublished data).

Population and sampling technique

The study population comprised adolescent women living in the municipality of Malanje. The sample consisted of 420 participants divided into two groups: cases (n_1 = 140) and controls (n_2 = 280). An appropriate sample size was calculated according to a proportion of cases living with both parents (P_1) of 0.356; a proportion of controls living with both parents (P_2) of 0.507; an average of proportions (P) of 0.4315; a control-to-case ratio (C) of 2:1; a critical value ($Z_{1-\alpha/2}$) of 1.96; a test power ($Z_{1-\beta}$) of 84%; and a non-response rate of 10%. The data were obtained from studies carried out in sub-Saharan Africa.[22,26]

A single-stage cluster sample was selected. According to existing resources and a list of healthcare units provided by the Health Directorate of the municipality, five healthcare centers (Cahala, Canambua, Catepa I, Maxinde II, and Ritondo) were selected at random. Due to the lack of a sample list to select the elements within the cluster, all eligible adolescents were included in the study. Therefore, healthcare centers with more patients (cases and controls) during the study period contributed with more participants. After data collection, nine survey forms were excluded from the analysis due to incomplete information. Therefore, the final sample comprised 137 cases and 274 controls.

The study included all women aged 15 - 19 years residing in the municipality of Malanje, who received antenatal care or emergency medical services. All cases were pregnant adolescents who received their first antenatal care visit. Non-pregnant adolescents were used as hospital controls recruited from those who received emergency medical services in the same healthcare units as the cases. To avoid sample heterogeneity concerning obstetric characteristics and the number of previous prenatal care visits, we excluded all adolescents in a return antenatal visit and who had been pregnant previously.

According to the United Nations Children's Fund,[27] around 94.1% of annual cases of teenage pregnancy occur in the 15 - 19 age group. Likewise, the Malanje Municipal Health Directorate reported that adolescents aged between 15 - 19 years old represent 98.2% of adolescent women who attended antenatal care in the first half of 2022. For this reason, the present study only covered women in this age group.

Measurements of variables and instruments

Adolescent pregnancy was chosen as the dependent variable, which was dichotomous (i.e., yes or no). Exposure factors were grouped as socio-demographic, behavioral, family, and non-family contextual variables (Table 1).

The survey form comprised five sections: (1) identification; (2) sociodemographic; (3) behavioral; (4) family; (5) nonfamily contextual data. The Parent-Child Conflict Tactics Scale (CTSPC) is an internationally known instrument comprising 18 items divided into two subscales of psychological abuse and physical violence.[28] In a pilot study with the same population as that of the present study, the translated scale had a Cronbach's alpha of 0.76. In the present study, the CTSPC was used to assess physical and psychological violence as dichotomous (yes or no) without considering the score. Therefore, the participant who reported any act of these forms of violence was classified as 'yes'. Physical violence was moderate and severe. Severe cases involved harsher acts such as being beaten for a long time, being strangled, and being burned with a hot liquid.

Data collection and processing

A team of 10 inquirers (first-year nursing and clinical psychology students) was recruited and trained in completing the survey forms and ethics for scientific research, then allocated into non-fixed paired groups to collect primary and retrospective data from each healthcare center. The pilot study allowed the rewriting of some questions to facilitate the participants' understanding in the data collection phase. The inquirers completed data collection via a face-to-face conversation with each participant without their parent present. Each survey form was filled out twice: once with a pencil and again with a pen to confirm each entry. The maximum time to fulfill the data collection instruments was 11 minutes (seven for the survey form and four for the scale). Finally, the data were entered into a database and cleaned

Table 1 – Measurements of variables

Variables	Definition and measurements
Age	Completed age at the time of the study: 15 - 17 or 18 - 19 years
Residence type	The geographic space where adolescents live: urban, peri-urban, or rural
Education level	The highest year of schooling completed: 0 - 4, 5 - 8, 9 - 12, and ≥ 13
Literacy	Can read and write: yes or no
Alcohol consumption	Having consumed alcoholic beverages in the last 12 months: yes or no
Smoking habits	Having smoked one or more cigarettes in the last 30 days: yes or no
Multiple sexual partners	Having more than one partner in the past 12 months: yes or no
Early sex initiation	Had first sexual intercourse <15 years of age: yes or no
Contraceptive use	Frequency of condom use or other available method: never, sometimes, or always
Family structure	Who adolescents lived with in the last year: both parents, single parent, or no parent
Family size	Number of people at home in the last year: small (2 - 4), medium (5 - 9), or large (≥ 10)
Legal responsible occupation	Professional/technical, commerce, agriculture, other, or none
Peer pressure	Influence from friends to have sex: yes or no
Places of leisure	Sports clubs, parks, cinemas, swimming pools, and cultural centers: yes or no

for analysis.

Statistical analysis

Data analysis was performed with IBM SPSS version 27.0. Descriptive analysis was conducted by calculating absolute and relative frequencies, means, and standard deviations. The Kolmogorov-Smirnov test was used to assess sample normality. Means were compared using the independent *t*-test. Pearson's chi-squared and Fisher's exact tests were used to evaluate associations between the dependent variable and each exposure factor in a cross table. For all tests and models, statistical significance was given by a 95% confidence interval (95% CI) and a *p*-value of ≤ 0.05.

Adolescents aged 10 - 14, 15 - 17, and 18 - 19 years are biologically, psychologically, and legally different.[29] Moreover, pregnant adolescents do not share the same demographic and risk behavioral and adverse obstetric outcomes; therefore, the collection and disaggregated analysis of data by age may generate more representative results, understanding of the problem, and targeting of health interventions.[30-33] All variables with *p*-values of ≤ 0.10 in the bivariate analysis were candidates for logistic regression analysis disaggregated by age groups. Crude odds ratios were obtained by univariate binary logistic regression, followed by adjusted odds ratios (AORs) determined by multivariable logistic regression. Multicollinearity assessment determined all variance inflation factors below the cutoff value of 2.5.

Ethical aspects

This study was approved by the Independent Bioethics Committee of Agostinho Neto University's Faculty of Medicine (Deliberation No. 23/2022). The participants and some guardians received informed consent or assent forms. The participants were made aware of the study's objectives, risks, benefits, and beneficiaries. Participation in the study was not mandatory, and the participants' identities remained anonymous. There was no discrimination against the participants regardless of their outcome, sociodemographic condition, or behavior. In addition, the study did not have physical or biological risks.

RESULTS

Table 2 provides a comparison of the sociodemographic data between the case and control groups. Of the 411 participants, most were aged 15 - 17 years (n = 246; 59.9%), single (n = 386; 93.9%), and living in a peri-urban area (n = 381; 92.7%). Approximately 61.6 had 5 to 8 years of schooling, and 90.8% could read and write. The mean age of the study participants was 17.1 ± 1.3 years (case group = 17.4 ± 1.2 years; control group = 16.9 ± 1.3 years; $p < 0.001$), and the average number of school years successfully completed was 7.3 ± 2.3 (case group = 6.9 ± 2.4 years; control group = 7.6 ± 2.2 years; $p = 0.004$). The bivariate analysis showed that adolescent pregnancy was significantly ($p < 0.05$) associated with age, marital status, and education.

As seen in Table 3, more than 70% of the participants lived in an area without opportunities for leisure and recreation, or sexual and reproductive health programs, with no significant differences between groups. However, the case group was exposed to less peer pressure than the control group, and this difference was statistically significant (21.9% *vs* 38.0%, respectively; $p = 0.001$).

As seen in Table 4, on average, each participant lived in a family of 7.1 ± 2.8 people (case group = 7.1 ± 2.9; control group = 7.2 ± 2.8; *p* = 0.748). Most participants (n = 209; 50.9%) lived with both parents and a medium-sized family (n = 272; 66.2%) and did not experience moderate (n = 263; 64.0%) or severe (n = 370; 90.0%) physical violence in the last 12 months. Among these variables, only the family history of early pregnancy had a statistical association with adolescent pregnancy, which was higher in the control group than in the case group (80.7% *vs* 69.3%, respectively; *p* = 0.013).

As seen in Table 5, most participants reported safe behaviors such as no alcohol consumption (n = 326; 79.3%), single sexual partner (n = 239; 75.4%), and non-early sex initiation (n = 253; 79.8%). Comparing the case group with the control group, the former exhibited significantly higher rates of planning to become pregnant (40.1% *vs* 26.1%, respectively; *p* = 0.008), multiple sexual partners (32.8% *vs*

Table 2 – Comparative analysis of sociodemographic characteristics between pregnant and non-pregnant adolescents in Malanje, Angola

	Total		Cases (n = 137)		Controls (n = 274)			
Variables	N	%	n	%	n	%	χ^2	*p*-value
Age (years)								
15 - 17	246	59.9	70	51.1	176	64.2	6.56	0.010*
18 - 19	165	40.1	67	48.9	98	35.8		
Marital status								
Single	386	93.9	120	87.6	266	97.1	14.40	< 0.001*
De facto union or married	25	6.1	17	12.4	8	2.9		
Residence type								
Urban	9	2.2	4	2.9	5	1.8	2.62	0.270
Peri-urban	381	92.7	123	89.8	258	94.2		
Rural	21	5.1	10	7.3	11	4.0		
Literacy								
Yes	373	90.8	120	87.6	253	92.3	2.45	0.118
No	38	9.2	17	12.4	21	7.7		
Adolescent's education (years)								
0 - 4	36	8.8	20	14.6	16	5.8	11.50	0.003*
5 - 8	253	61.6	86	62.8	167	60.9		
9 - 12	122	29.7	31	22.6	91	33.2		

N: sample size; n: number of respondents; %: percentage; χ^2: chi-squared test; *: statistical significance

Table 3 – Comparative analysis of non-family contextual characteristics between pregnant and non-pregnant adolescents in Malanje, Angola

	Total		Cases (n = 137)		Controls (n = 274)			
Variables	N	%	n	%	n	%	χ^2	*p*-value
Peer pressure								
No	277	67.4	107	78.1	170	62.0	10.72	0.001*
Yes	134	32.6	30	21.9	104	38.0		
Places of leisure and recreation								
Yes	107	26.0	39	28.5	68	24.8	0.63	0.427
No	304	74.0	98	71.5	206	75.2		
SHR programs								
Yes	105	25.5	39	28.5	66	24.1	0.92	0.337
No	306	74.5	98	71.5	208	75.9		

AP: adolescent pregnancy; N: sample size; n: number of respondents; %: percentage; χ^2: chi-squared test; SRH: Sexual and Reproductive Health; *: statistical significance

Table 4 – Comparative analysis of family characteristics between pregnant and non-pregnant adolescents in Malanje, Angola

	Total		Cases (n = 137)		Controls (n = 274)			
Variables	N	%	n	%	n	%	χ^2	*p*-value
Family structure								
Both parents	209	50.9	69	50.4	140	51.1	0.81	0.666
Single parent	110	26.8	40	29.2	70	25.5		
No parent	92	22.4	28	20.4	64	23.4		
Family size								
Small	72	17.5	25	18.2	47	17.2	0.08	0.962
Medium	272	66.2	90	65.7	181	66.4		
Large	67	16.3	22	16.1	45	16.4		
Head of household's education (years)								
0 - 4	31	7.5	12	8.8	19	6.9	5.54	0.236
5 - 8	45	10.9	20	14.6	25	9.1		
9 - 12	111	27.0	29	21.2	82	29.9		
≥ 13	26	6.3	9	6.6	17	6.2		
Unknown	198	48.2	67	48.9	131	47.8		
Head of household's occupation								
Professional/technical	141	34.3	43	31.4	98	35.8	4.85	0.303
Commerce	65	15.8	21	15.3	44	16.1		
Agriculture	103	25.1	43	31.4	60	21.9		
Other	85	20.7	26	19.0	59	21.5		
None	17	4.1	4	2.9	13	4.7		
Family history of AP								
No	78	19.0	37	27.0	41	15.0	8.82	0.013*
Yes	316	76.9	95	69.3	221	80.7		
Unknown	17	4.1	5	3.6	12	4.4		
Physical violence								
No	263	64.0	88	64.2	175	63.9	0.01	0.942
Yes	148	36.0	49	35.8	99	36.1		
Severe physical violence								
No	370	90.0	122	89.1	248	90.5	0.22	0.642
Yes	41	10.0	15	10.9	26	9.5		

AP: adolescent pregnancy; N: sample size; n: number of respondents; %: percentage; χ^2: chi-squared test; *: statistical significance

18.3%, respectively; $p = 0.003$), and non-use of contraception (50.4% *vs* 26.7%, respectively; $p < 0.001$) than the latter.

From the multivariable analysis, the risk of adolescent pregnancy was significantly higher in women aged 15 - 17 who lived in *de facto* union or were married (AOR = 10.37; 95% CI = 1.05 - 102.83), had 0 - 4 (AOR = 7.40; 95% CI = 1.25 - 43.77) or 5 - 8 years of schooling (AOR = 5.21; 95% CI = 1.25 - 21.77), and used contraception irregularly (AOR = 6.02; 95% CI = 1.80 - 20.12) or did not use any contraceptive methods (AOR = 9.20; 95% CI = 2.79 - 30.35). For women aged 18 - 19, the likelihood of adolescent pregnancy was increased in case of early sex initiation (AOR = 3.75; 95% CI = 1.05 - 13.43), multiple sexual partners (AOR = 3.02; 95% CI = 1.23 - 7.44), and irregular (AOR = 4.04; 95% CI = 1.25 - 13.11) or non-use (AOR = 5.40; 95% CI = 1.50 - 19.40) of contraception, as seen in Table 6.

DISCUSSION

The aim of this study was to identify determinants of adolescent pregnancy in Malanje, Angola. According to our results, cohabitation with a sexual partner and having less

Table 5 – Comparative analysis of behavioral characteristics between pregnant and non-pregnant adolescents in Malanje, Angola

	Total		Cases (n = 137)		Controls (n = 274)			
Variables	N	%	n	%	n	%	χ^2	*p*-value
Alcohol consumption								
No	326	79.3	106	77.4	220	80.3	0.48	0.491
Yes	85	20.7	31	22.6	54	19.7		
Smoking habits								
No	401	97.6	132	96.4	269	98.2	1.28	0.312
Yes	10	2.4	5	3.6	5	1.8		
Early sex initiation								
No	253	79.8	103	75.2	150	83.3	3.21	0.073
Yes	64	20.2.	34	24.8	30	16.7		
Multiple sexual partners								
No	239	75.4	92	67.2	147	81.7	8.83	0.003*
Yes	78	24.6	45	32.8	33	18.3		
Contraception use								
Always	65	20.5	10	7.3	55	30.6	32.36	< 0.001*
Sometimes	135	42.6	58	42.3	77	42.8		
Never	117	36.9	69	50.4	48	26.7		
Planned to get pregnant								
No	215	67.8	82	59.9	133	73.9	7.02	0.008*
Yes	102	32.2	55	40.1	47	26.1		

N: sample size; n: number of respondents; %: percentage; χ^2: chi-squared test; *: statistical significance.

than nine years of schooling were significant predictors of adolescent pregnancy among girls aged between 15 and 17 years. Furthermore, older adolescents were associated with a higher risk of pregnancy if they had multiple sexual partners and early sex initiation, while a lower risk of getting pregnant was observed among those reporting peer pressure. Regardless of the age group of adolescents, not using or irregularly using contraception was associated with an increased risk of getting pregnant.

Although the present study differs from others due to the type of analysis we used (disaggregated by age), the results on early marriage are consistent with those found in other Sub-Saharan countries.[5,18,19,22] In Sub-Saharan Africa, the desire or planning for pregnancy can increase with the adolescent's age, and motherhood is a cultural element of a woman's identity. Hence, most women marry without a (traditional) religious or civil ceremony, and they do not use contraceptive methods.[34] According to the World Health Organization, early marriage (cultural or civil) occurs often in low- and middle-income countries and it may be prevented by keeping girls in school and by establishing laws that protect adolescents from early marriage.[35] Despite the United Nations Population Fund initiatives and the Angolan government's efforts to prevent school dropouts as a result of adolescent pregnancy, some pregnant teenagers drop out of school due to economic demands and feelings of shame by social judgment.[4,36] Once pregnant, the teenager cannot interrupt the pregnancy. In Angola, abortion is a crime, except in cases where the fetus is unviable, there is risk of death or irreversible damage to the woman's physical and mental integrity, there is an incurable disease or malformation of the fetus, and in cases of coercion, sexual violence, and rape.[37] In this context, there is still a gender disparity in terms of education and employability, so men assume the economic and protective role in the home, while women bear the domestic burden and prevent early pregnancy.[36] According to Saewvic,[38] due to the lack of access policies to contraceptive methods and cultural configurations regarding female sexuality, there has not been a focus on pregnancy prevention in boys.

Our findings are relatively consistent with studies conducted in other sub-Saharan countries, reporting a higher risk of getting pregnant among adolescents with early sexual initiation,[16,23,39-41] and those with multiple sexual partners,[19,23] although in our setting such associations were only observed among adolescents aged 18 or 19 years. The prevalence of early sexual initiation (before 15 years old) among girls in Sub-Saharan Africa is high (46%), although

Table 6 – Multivariable analysis of sociodemographic, behavioral, family, and non-family contextual factors associated with adolescent pregnancy in the municipality of Malanje, Angola, disaggregated by age

	15 - 17 years		18 - 19 years	
Variables	COR (95.0% CI)	AOR (95.0% CI)	COR (95.0% CI)	AOR (95.0% CI)
Marital status				
Single	1	1	1	1
De facto union/married	32.63 (4.12 - 258.12)***	10.37 (1.05 - 102.83)*	1.28 (0.41 - 3.99)	0.47 (0.13 - 1.71)
Adolescent's education (years)				
9 - 12	1	1	1	1
5 - 8	4.58 (1.35 - 15.57)*	5.21 (1.25 - 21.77)*	1.84 (0.95 - 3.55)	0.97 (0.44 - 2.15)
0 - 4	12.00 (2.85 - 50.52)***	7.40 (1.25 - 43.77)*	3.31 (0.99 - 11.06)	0.90 (0.20 - 4.00)
Peer pressure				
No	1	1	1	1
Yes	0.65 (0.35 - 21)	0.82 (0.35 - 1.88)	0.28 (0.13 - 0.59)***	0.35 (0.15 - 0.82)*
Early sex initiation				
No	1	1	1	1
Yes	1.39 (0.71 - 2.73)	1.08 (0.47 - 2.50)	3.10 (1.02 - 9.43)*	3.75 (1.05 - 13.43)*
Multiple sexual partners				
No	1	1	1	1
Yes	1.98 (0.98 - 4.03)	1.57 (0.64 - 3.87)	2.44 (1.14 - 5.27)*	3.02 (1.23 - 7.44)*
Contraception use				
Always	1	1	1	1
Sometimes	4.36 (1.50 - 12.64)**	6.02 (1.80 - 20.12)**	3.65 (1.24 - 10.75)*	4.04 (1.25 - 13.11)*
Never	11.83 (4.06 - 34.47)***	9.20 (2.79 - 30.35)***	4.87 (1.60 - 14.82)**	5.40 (1.50 - 19.40)**
Planned to get pregnancy				
No	1	1	1	1
Yes	2.13 (1.03 - 4.41)*	1.96 (0.81 - 4.78)	1.75 (0.91 - 3.36)	2.05 (0.96 - 4.38)
Family history of AP				
No	1	1		1
Yes	0.41 (0.22 - 0.79)**	0.30 (0.11 - 0.80)*	0.50 (0.22 - 1.14)	0.56 (0.20 - 1.58)
Unknown	0.66 (0.20 - 2.21)	0.50 (0.08 - 3.03)		

AOR: adjusted odds ratio; COR: crude odds ratio; CI: confidence interval; ***: $p < 0.001$, **: $p < 0.01$, *: $p < 0.05$

this prevalence presents large differences between countries.[42] In our study, one out of five girls reported early sexual activity. This behavior has been considered an important public health issue demanding prevention,[42] because it has been associated with multiple sexual partners and unprotected sexual activity, increasing the risk of adolescent pregnancy.[40] Despite the lack of association with the phenomenon under study, the present study demonstrates that moderate physical violence occurs in both groups (pregnant and non-pregnant women) with a relatively high frequency. Physical abuse and other forms of maltreatment are factors that contribute to early sex initiation and multiple sexual partners.[43]

Measures such as promoting women's education and preventing school dropout play an important role in avoiding early sexual initiation because educated adolescents can improve their knowledge, skills, and awareness about health issues, including reproductive health. This will lead to individuals who are more empowered and better informed about optimal timings for marriage and pregnancy.[39-42] Encouraging sexual abstinence can help delay sexual initiation with an impact on decreasing early pregnancy prevalence. However, promoting sexual abstinence without providing comprehensive sexuality education may not be effective.[40]

According to our results, irregular or no use of contraceptives was a strong predictor of pregnancy in both age groups of girls, corroborating the results from previous studies conducted in similar settings.[16,19,23] Negative perceptions

and misconceptions about contraceptive use,[16,44] particularly concerns of contraceptive-induced fertility impairment may contribute to low contraceptive uptake among adolescents.[45] The use of contraceptive methods is lower in adolescent women belonging to cultures or religions in which contraception is prohibited, and in those whose partners are unaware of contraception methods highlighting the impact of cultural aspects on the prevalence of adolescent pregnancy.[46] Also, low awareness and poor knowledge about contraceptive methods,[47] as well as the lack of adequate reproductive health services and skilled staff to attend to adolescents who require contraceptive methods are factors hindering their use.[16] According to the World Health Organization, increasing the use of contraception is an essential issue when preventing early and unwanted pregnancies is under discussion. To address these issues, we should be promoting the access to reproductive health services and adequate contraceptive information.[35] Besides contraception use, sexual health education should be more robust, encouraging greater autonomy and safety breaking down stereotypes, myths, and distorted beliefs associated with sexuality.[48] Educational policies established for new generations should take into account the need of comprehensive sexuality education for young people providing them with knowledge and skills in preventing sexual risk behaviors. Since abortions are illegal in Angola (with a few exceptions), early pregnancy puts girls at higher risk of unsafe abortion. Therefore, in this context, sexual health education plays an important role. A comprehensive sexuality education is particularly important in our setting, since boys are not educated about contraception, and this responsibility is delegated to women instead.

This study is a snapshot taken over a short period; therefore, more extensive and longitudinal studies are suggested to see possible variations in the results. More studies regarding cultural factors, family, and qualitative approaches are required to obtain a better understanding of this problem and determine effective solutions.

Our results did not corroborate findings from previous research reporting higher risk of pregnancy among adolescents with family history of early pregnancy.[22,23] Young women often learn values and attitudes from their mothers and older sisters and early pregnancy in the eldest daughter can trigger preventive conversation between family members about sexual activity and contraception.[27]

Opposite to previous research[16,19,23] our findings revealed a lower risk of pregnancy among girls reporting peer pressure to have sex, although such an association was only observed among older adolescents. Peer pressure to engage in unsafe sexual activity is one of the causes of adolescent pregnancy.[23] We can speculate that the participants of this study may have felt pressure to have sex, though not necessarily unsafe sex, or that these girls could have been pressured to become sexually active but have sought or received advice on preventing unwanted pregnancies.

Study limitations

Although the healthcare units were selected randomly, participants within each healthcare unit were not selected randomly due to the lack of a preliminary list of eligible women, which may affect the representativeness of our results.

As stated in the Methods section, this study relied on hospital controls who underwent medical interventions. This approach may have reduced or hidden the strength of association between variables.

Our research was based on a case-control study, retrospective in nature. This study design is prone to recall bias as girls have had to recall some events about their lives. Furthermore, we cannot exclude the observer bias, as we could not blind research staff to who was a case and who was a control.

CONCLUSION

For adolescents who attended the Malanje Healthcare Units between August and October of 2022, pregnancy appears to be a multifactorial phenomenon. These factors are not the same for different age groups and preventive strategies should consider these differences. Preventive strategies for adolescents aged 15 - 17 should aim to reduce early marriages, both civil and cultural, through the promotion of education and the creation of specific laws. For older adolescents, pregnancy was associated with risky behaviors such as early initiation of sexual activity and multiple sexual partners. These practices can be changed with the creation of educational programs combining primary sexual abstinence promotion and comprehensive sexual education. Sexual health education should provide in-depth knowledge about contraception and the use of contraceptives; that is a core issue for all age groups. These programs must be able to overcome cultural barriers, to promote gender equity, and develop girls' autonomy regarding sexuality.

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AUTHOR CONTRIBUTIONS

KA: Study design, data collection and analysis, database conception, writing and critical review of the manuscript.

ES: Data analysis, database conception, writing and critical review of the manuscript.

CT, PC: Study design, writing and critical review of the manuscript.

JVD: Study design, data collection, critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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ACTA MÉDICA PORTUGUESA
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Pembrolizumab plus Pemetrexed and Platinum in Metastatic Non-Squamous Non-Small Cell Lung Cancer: A Real-Life Study at a Portuguese Centre

Pembrolizumab com Pemetrexedo e Platina no Cancro do Pulmão Não Pequenas Células Metastático: Um Estudo de Vida Real num Centro Português

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ABSTRACT

First-line therapy for metastatic non-small-cell lung cancer without targetable mutations is platinum-based chemotherapy plus pembrolizumab if programmed death ligand 1 is < 50%. The aim of this real-life retrospective study is to assess the efficacy and safety of this therapy. This retrospective observational study was conducted at the Pulmonary Oncology Department in Unidade Local de Saúde Santa Maria, in Lisbon, Portugal. We included patients with stage IV non-squamous non-small-cell lung cancer with programmed death ligand 1 < 50% that started pembrolizumab plus platinum and pemetrexed between July 2020 and December 2022. Follow-up was carried out until September 2023. Progression-free survival, overall survival, response rate and safety were evaluated. Sixty-six patients were included. Median age 67 years, 72.7% male, 92.4% performance status 0 - 1, 90.9% current/former smokers. Programmed death ligand 1 < 1% in 63.6%. Median overall and progression-free survival were 12.2 months and 6.7 months, respectively. At the time of the cut-off, 21.2% of patients were alive and progression-free. The objective response rate was 42.4% (partial response). The disease control rate was 69.7%. Adverse events occurred in 92.4%, 43.9% had grade 3 - 4 adverse effects. The most common were anemia (50.0%), neutropenia (40.9%), and asthenia (36.4%). Treatment was discontinued in three patients due to adverse effects. There were no treatment-related deaths reported. With median progression-free survival and overall survival of 6.7 and 12.2 months, respectively, and no new safety signals, these results complement data from clinical trials, providing information from a real-world setting.
Keywords: Antibodies, Monoclonal, Humanized; Antineoplastic Combined Chemotherapy Protocols; Carcinoma, Non-Small-Cell Lung/drug therapy; Pembrolizumab; Pemetrexed; Platinum

RESUMO

A terapêutica de primeira linha para cancro do pulmão não pequenas células metastático sem mutações-alvo é quimioterapia à base de platina associada a pembrolizumab se o ligando 1 de morte celular programada (*programmed cell death ligand 1*) < 50%. Este estudo retrospetivo de vida real tem como objetivo avaliar eficácia e segurança desta terapêutica. Este estudo observacional retrospetivo foi realizado no Serviço de Pneumologia Oncológica da Unidade Local de Saúde Santa Maria, em Lisboa, Portugal. Foram incluídos doentes com cancro do pulmão não pequenas células não escamoso estádio IV com ligando 1 de morte celular programada < 50% que iniciaram pembrolizumab com platina/pemetrexedo entre julho 2020 e dezembro 2022. O *follow-up* foi realizado até setembro 2023. Foram analisados: sobrevida livre de progressão, sobrevida global, taxa de resposta e segurança. Foram incluídos 66 doentes. A mediana de idade foi 67 anos, 72,7% sexo masculino, 92,4% *performance status* 0 - 1, 90,9% dos doentes eram fumadores/ex-fumadores. Ligando 1 de morte celular programada < 1% em 63,6%. A mediana de sobrevida global e de sobrevida livre de progressão foi de 12,2 meses e 6,7 meses, respetivamente. À data do *cut-off*, 21,2% dos doentes estavam vivos e sem progressão. A taxa de resposta foi 42,4% (resposta parcial). A taxa de controlo da doença foi 69,7%. Ocorreram efeitos adversos em 92,4% dos doentes, dos quais 43,9% foram de grau 3 - 4. Os mais comuns foram anemia (50,0%), neutropenia (40,9%) e astenia (36,4%). O tratamento foi interrompido em três doentes devido a efeitos adversos. Não se registaram mortes relacionadas com o tratamento. Com mediana de sobrevida livre de progressão e sobrevida global de 6,7 e 12,2 meses, respetivamente, e sem novos sinais de segurança, estes resultados complementam os dados de ensaios clínicos, fornecendo informação sobre um contexto de vida real.
Palavras-chave: Anticorpos Monoclonais Humanizados; Carcinoma Pulmonar de Células não Pequenas/tratamento farmacológico; Pembrolizumab; Pemetrexedo; Platina; Protocolos de Quimioterapia Combinada Antineoplásica

INTRODUCTION

Current treatment for metastatic lung adenocarcinoma is determined according to the presence or absence of oncogenic drivers such as Epidermal Growth Factor Receptor (EGFR) and Anaplastic Lymphoma Kinase (ALK). In their absence, adequate treatment is dependent of programmed death-ligand 1 (PD-L1). Programmed death-ligand 1 inhibitors such as pembrolizumab have proven to be effective in combination with chemotherapy (ChT). In the KEYNOTE-189 trial, pembrolizumab-ChT (versus placebo-ChT) improved overall survival (OS) at 12 months (69.2% *vs* 49.4%) and median progression-free survival (PFS) (8.8 months *vs* 4.9 months).[1] Current guidelines recommend platinum-based ChT plus PD-L1 blockade for stage IV NSCLC with PD-L1 < 50%.[2]

METHODS

Study design

This retrospective observational study was conducted at the Pulmonary Oncology Department in Unidade Local de Saúde Santa Maria, in Lisbon, Portugal. The included patients had stage IV non-squamous NSCLC with PD-L1 < 50% that started pembrolizumab, platinum, and pemetrexed between July 2020 and December 2022. Follow-up was carried out until September 2023. The patients were

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identified through our department databases and data was obtained from medical record files. Since this was a retrospective study with no new intervention research, ethics approval was not necessary.

Treatment

Patients received four cycles of carboplatin or cisplatin, pemetrexed, and pembrolizumab every three weeks, followed by pemetrexed and pembrolizumab every three weeks. At least one dose had to be administered. The treatment was discontinued in case of radiologic progression, unacceptable toxicity or death.

Assessment

Radiological assessment was performed every three to four cycles. Tumour response, including overall response rate, was evaluated according to the Response Evaluation Criteria in Solid Tumours (RECIST), version 1.1.[3] Adverse events were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.[4]

Statistical analysis

This study evaluated OS (time from the start of treatment until death), PFS (time from treatment start until disease progression or death, whichever occurred first), response rate (percentage of patients with partial/complete response), disease control rate (percentage of patients with complete/partial response or stable disease), duration of response (time from first radiological evaluation with response until progression or death) and safety. The Kaplan–Meier method was used to estimate OS and PFS. Patients who were alive or lost to follow-up were censored for OS at the time they were last known to be alive. Patients who were alive and did not have disease progression or who were lost to follow-up were censored for PFS at the time of the last imaging assessment before the cut-off. Confidence intervals were calculated using the Greenwood formula.

RESULTS

A total of 66 patients met the eligibility criteria, with the following characteristics:

- median age: 67 years, with 12.1% patients being ≥ 75 years old;
- 72.7% patients were male;
- performance status (according to Eastern Cooperative Oncology Group - ECOG) of 0 - 1 in 92.4%;
- 90.9% patients were current/former smokers;
- PD-L1 < 1% in 63.6%;
- 3 patients with EGFR mutation*;
- 1 with ALK translocation*.

The patients highlighted with * were included because the mutational study was only available after therapy was initiated. At the time of this study, first-line targeted therapy was only approved for EGFR and ALK at our center.

Further demographic and disease characteristics are described in Table 1.

At the time of cut-off, 41 patients (62.1%) had died. The median follow-up was 10.9 months. Median OS was 12.2 months (95% CI: 7.1 - 19.8) (Fig. 1A); 11.1 months (95% CI: 6.3 - 27.8) in the PD-L1 < 1% group, 12.2 months (95% CI: 6.5 - NR) in the PD-L1 1% - 49% group (Fig. 1B). Patients who progressed or interrupted therapy before starting maintenance ChT-immunotherapy (≤ 4 cycles) had a median OS of 4.7 months (95% CI: 2.8 - 5.9).

There were 52 events of progression or death; 21.2% of patients were alive and progression-free at cutoff. Median PFS was 6.7 months (95% CI: 4.6 - 10.4) (Fig. 1C); 6.4 months (95% CI: 3.7 - 10.4) in the PD-L1 < 1% group, 8.4 months (95% CI: 5.0 - 13.7) in the PD-L1 1% - 49% group (Fig. 1D).

From the total, 71.2% of patients completed at least four cycles. The median treatment time was 6.5 months (95% CI: 4.7 - 12.5). The objective response rate (ORR) was 42.4%, all with partial response. The disease control rate (DCR) was 69.7%. Tumor response was not assessed in nine patients (Table 2). The median duration of response was 12.0 months (95% CI: 6.0 - 17.7). At the time of cut-off, 15 patients were still receiving stipulated therapy. After disease progression, 28 patients (42.4%) received subsequent treatment.

Adverse events (AE) occurred in 92.4% of patients. The most common were anemia (50.0%), neutropenia (40.9%) and asthenia (36.4%). Thyroidism (four patients with hypothyroidism and three with thyroiditis, representing 10.6%:) and adrenal insufficiency (7.6%) were the most common immune AE. Grade 3 - 4 AE occurred in 43.9%, with 46 events reported, four of which were assumed immune-mediated AE (liver toxicity and colitis). Treatment was discontinued in three patients: immune-mediated colitis, immune-mediated pneumonitis and adrenal insufficiency (G2 AE but treatment was discontinued because the two events were present) and non-immune liver toxicity. There were no treatment-related deaths.

DISCUSSION

To the best of our knowledge, this study is the first real-life study in Portugal to provide data on the efficacy and safety of ChT-pembrolizumab for metastatic NSCLC. The baseline characteristics of patients were similar to patients in the KEYNOTE-189 trial, with a higher prevalence of male patients and similar median age (67 *vs* 65 years).

Median PFS and OS were 6.7 and 12.2 months respectively, lower estimates than those from KEYNOTE-189, but still with a higher PFS than their placebo-ChT group (4.9

Table 1 – Demographic characteristics of patients and disease characteristics at baseline

Demographic characteristic	Value, n = 66
Age (years)	
Median (range)	67 (41 - 79)
≥ 75 years, n (%)	8 (12.1)
Male, n (%)	48 (72.7)
Performance status, n (%)	
0	19 (28.8)
1	42 (63.6)
2	5 (7.6)
Smoking status, n (%)	
Current smoker	34 (51.5)
Former smoker	26 (39.4)
Never smoker	6 (9.0)
Previous cancer, n (%)	13 (19.7)
Arterial hypertension, n (%)	36 (54.5)
Dyslipidemia, n (%)	26 (39.4)
Chronic obstructive pulmonary disease, n (%)	15 (22.7)
Disease characteristics	
Histology, n (%)	
Adenocarcinoma	64 (97.0)
Adenosquamous carcinoma	1 (1.5)
Combined large cell neuroendocrine carcinoma with adenocarcinoma	1 (1.5)
Location, n (%)	
Upper right lobe	20 (30.3)
Medium lobe	4 (6.1)
Lower right lobe	12 (18.2)
Upper left lobe	24 (36.4)
Lower left lobe	6 (9.1)
Stage IV, n (%)	
IV-A, M1a	16 (24.2)
IV-A, M1b	10 (15.2)
IV-B	40 (60.6)
Metastatic sites, n (%)	
Brain	14 (21.2)
Liver	10 (15.2)
Bone	25 (37.9)
Adrenal gland	21 (31.8)
PD-L1 rate, n (%)	
< 1%	42 (63.6)
1% - 49%	24 (36.4)
Mutations, n (%)	
None	22 (33.3)
KRAS	26 (39.4)
EGFR	3 (4.5)
BRAF	3 (4.5)
MET	3 (4.5)
RET	3 (4.5)
ALK	1 (1.5)
Others (SMO, PI3KCA, HER2, TP53, MAP2K1)	6 (9.1)
NA	3 (4.5)

NA: not assessed

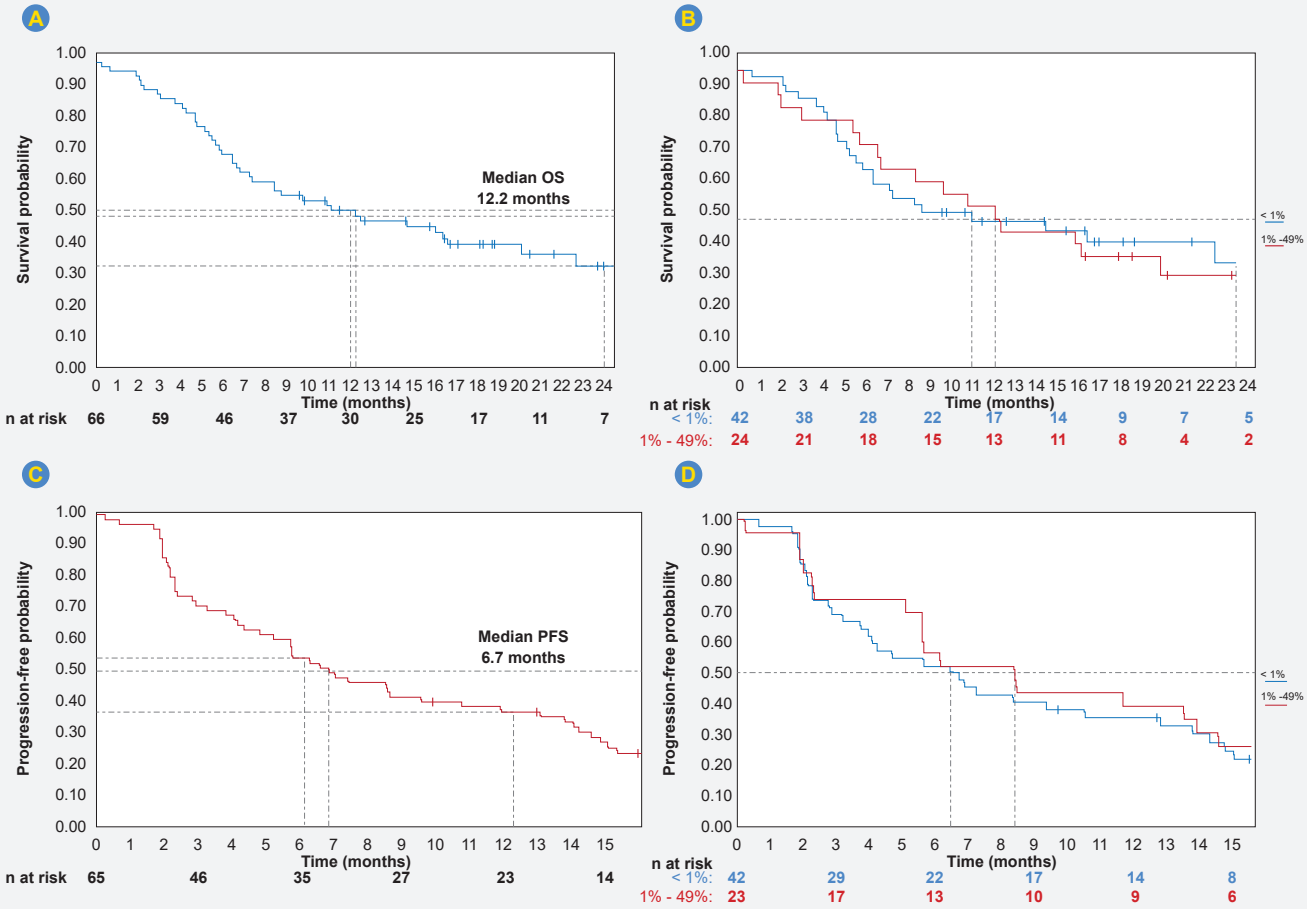

Figure 1 – Overall survival (A), overall survival according to the value of PD-L1 (B), progression-free survival (C), and progression-free survival according to the value of PD-L1 (D) of patients with metastatic non-squamous NSCLC treated with ChT-pembrolizumab

months). Our study did not include PD-L1 ≥ 50%, unlike the KEYNOTE-189 trial, and included an older sample (63.6% patients with ≥ 65 years old *vs* 52.0%), higher prevalence of ECOG 1 and included ECOG 2. Also, real-life studies are limited by hospital resources, which influenced treatment and imaging assessment timings. The OS is consistent with a real-world study by Waterhouse *et al*[5] and the PFS is also similar to Velcheti *et al*.[6] Subanalysis with PD-L1 levels did not reveal a major difference in OS but there was still a two-month difference in PFS favoring the 1% - 49% group. The ORR was 42.4%, similar to the KEYNOTE-189 trial (47.6%), and DCR was 69.7% (*vs* 84.6%). The median duration of response was slightly higher (12.0 *vs* 11.2 months). The AE rates were similar to the KEYNOTE-189 trial but grade ≥ 3 events were lower (43.9% *vs* 67.2%). In light of these results, ChT-pembrolizumab is still the first-line therapy for patients at our center, with benefits in OS and PFS, and an adequate safety profile.

Our study has multiple limitations. It is a retrospective study with a small sample; it did not include a control group; AE, especially grade 1 - 2, may be underreported, as this information is taken from clinical records, and sometimes less serious AE are not registered.

CONCLUSION

With a median PFS and OS of 6.7 and 12.2 months, respectively, and no new safety signals, these results complement data from clinical trials providing information from a real-world setting.

Table 2 – Tumor response

Variable	Value, n = 66
Best response, n (%)	
Complete response	0 (0)
Partial response	28 (42.4)
Stable disease	18 (27.3)
Progressive disease	11 (16.7)
Non-evaluable	9 (13.6)

AUTHOR CONTRIBUTIONS

MJS: Data collection and analysis, writing of the manuscript.

FF: Study design, critical review of the manuscript.

ALM, ASV, DH, PA: Critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

FF received payment or honoraria from MSD for lectures, presentations, speakers' bureaus, manuscript writing or educational events; received support from Takeda for attending meetings and/or travel.

ALM received payment or honoraria from Takeda, Bristol Myers Squibb, Pfizer and AstraZeneca for lectures, presentations, speakers' bureaus, manuscript writing or educational events; received support from Roche, Daichi Sankyo, Takeda and AstraZeneca for attending meetings and/or travel.

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ACTA MÉDICA PORTUGUESA
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Equidade no Acesso aos Cuidados de Saúde em Portugal: O que Sabemos?

Equity in Access to Health Care in Portugal: What Do We Know?

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RESUMO

Em Portugal, as normas constitucionais e legais estabelecem que o sistema de saúde deve estar organizado de forma a garantir a equidade no acesso aos cuidados. Para garantir este objetivo é habitualmente aceite que, perante idêntica necessidade, os indivíduos de diferentes estratos socioeconómicos deverão ter acesso à mesma utilização de cuidados. A presente revisão narrativa avalia o conhecimento atual sobre este tema. Apresenta-se uma breve resenha das características do sistema de saúde português que poderão influenciar a consecução do objetivo de equidade no acesso. É também descrita a evidência empírica disponível. Observa-se que, em Portugal, a equidade no acesso não tem sido atingida para a maioria dos cuidados de saúde. Sobretudo nos cuidados de saúde especializados, os indivíduos com maiores níveis de rendimento apresentam, para um mesmo nível de necessidade, maior utilização de cuidados. Estas situações de iniquidade deverão ser analisadas e corrigidas; deverão ser consideradas as potenciais barreiras ao acesso no âmbito do Serviço Nacional de Saúde, já que é ao sistema público que compete garantir a equidade.
Palavras-chave: Acessibilidade aos Serviços de Saúde; Disparidades nos Cuidados de Saúde; Equidade na Saúde; Portugal; Prestação de Cuidados de Saúde

ABSTRACT

In Portugal, constitutional and legal norms stipulate that the healthcare system should be organized to ensure equity in access to healthcare. To guarantee this objective, it is usually assumed that individuals from different socio-economic groups presenting equal levels of need should have access to the same level of care. The present narrative review describes current knowledge on this topic. It provides a brief overview of the characteristics of the Portuguese healthcare system, which may influence the achievement of the objective of equity in health care access. The empirical evidence on this issue is also presented. In Portugal, equity in access has not been achieved for most types of health care. Particularly in the case of specialized health care, better-off groups of the population used more care for a given level of need. The situations where inequity exists should be examined and corrected; potential access barriers within the National Health Service should be considered, as the public healthcare system bears the responsibility for ensuring equity.
Keywords: Delivery of Health Care; Health Equity; Health Services Accessibility; Healthcare Disparities; Portugal

INTRODUÇÃO

Segundo a Organização Mundial da Saúde, a equidade em saúde traduz-se na ausência de diferenças sistemáticas, evitáveis e injustas desse atributo entre diferentes grupos populacionais.[1,2] Este é um tema que aporta implicações de carácter ético e moral,[1,2] pois pressupõe que exista justiça na distribuição da saúde.[3]

Os documentos legislativos e políticos que norteiam sistemas de saúde como o português referem o objetivo da equidade no acesso à saúde.[4-7] Apesar de a equidade na própria saúde ser o objetivo primordial a atingir,[8-10] o foco não se encontra neste resultado final, mas sim nos processos de produção do mesmo.[11] Levesque *et al* definem o acesso aos cuidados de saúde como a possibilidade de identificar as necessidades de saúde, procurar os serviços, obter ou utilizar os cuidados e, por fim, ver satisfeitas as necessidades de cuidados de saúde.[12] Sendo um conceito abrangente, é de esperar que haja uma grande complexidade de fatores associados ao acesso, tanto do lado da oferta como da procura.

A perspetiva comummente aceite nos países europeus é a de que, para proporcionar equidade no acesso, o sistema de saúde deve estar organizado de forma que a prestação de cuidados se faça de acordo com as necessidades dos cidadãos, não havendo discriminação de acordo com as suas características socioeconómicas.[9]

Este princípio tem sido empiricamente testado pelo cumprimento da premissa "utilização igual para necessidades iguais".[8,13] Caso se verifique que, para idêntica necessidade, os indivíduos de maior estatuto socioeconómico utilizam mais cuidados de saúde estaremos perante uma situação de iniquidade a favor destes. Poderá também ocorrer a situação inversa, de favorecimento dos indivíduos de menor estatuto socioeconómico (quando estes utilizam mais cuidados, para as mesmas necessidades). O parâmetro socioeconómico mais frequentemente utilizado nas análises empíricas é o rendimento familiar, averiguando assim se estamos perante situações de equidade no acesso a cuidados ou de iniquidades a favorecer os indivíduos mais

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ricos ou mais pobres.

Os estudos internacionais em que são realizadas análises comparativas mostram que Portugal faz parte de um conjunto de países em que existem maiores iniquidades a favorecer os indivíduos de maior rendimento, achado este que justifica a revisão.[14,15]

Com este trabalho pretende-se fazer uma revisão narrativa do conhecimento atual relativo à consecução do princípio da equidade no acesso a diferentes cuidados de saúde em Portugal.

O sistema de saúde português e a sua relação com a equidade no acesso

A equidade é um objetivo explícito do sistema de saúde português. A Constituição da República Portuguesa determina que cumpre ao Estado "garantir o acesso de todos os cidadãos, independentemente da sua condição económica, aos cuidados da medicina preventiva, curativa e de reabilitação".[5] Por conseguinte, esta questão apresenta-se como um dos fundamentos das políticas de saúde descritos na Lei de Bases da Saúde,[7] e dos objetivos estratégicos do Plano Nacional de Saúde 2030.[6]

A responsabilidade do Estado pelo direito à proteção da saúde efetiva-se pela existência do Serviço Nacional de Saúde (SNS), universal, geral e tendencialmente gratuito.[7] Cabe ao SNS garantir a equidade, "promovendo a correção dos efeitos das desigualdades no acesso aos cuidados, dando particular atenção às necessidades dos grupos vulneráveis".[7] Apesar do papel determinante do SNS para que se atinja a equidade na prestação, algumas características do sistema poderão interferir na consecução deste objetivo.

Para além do SNS, o sistema de saúde português caracteriza-se pela existência de subsistemas, representando determinados grupos profissionais, e de seguros de saúde privados voluntários.[16] Estes sistemas suplementam o papel do SNS, sendo financiados diretamente pelas contribuições dos seus beneficiários, e indiretamente por deduções fiscais no imposto de rendimento das empresas prestadoras e dos consumidores.[16] Esta característica estrutural poderá ser potenciadora de iniquidades, uma vez que estes indivíduos poderão apresentar uma maior utilização de cuidados.[17]

Em Portugal, os pagamentos *out-of-pocket* (copagamentos e pagamentos diretos) constituem uma parte considerável do financiamento da saúde. O elevado peso das despesas de saúde no orçamento das famílias portuguesas[18] poderá desincentivar a utilização de cuidados pelos indivíduos com menor capacidade para pagar. Contudo, o SNS emprega alguns mecanismos de proteção, como a isenção das taxas moderadoras.[19] Este copagamento no sistema público foi progressivamente eliminado ao longo do tempo, subsistindo apenas nalgumas situações de utilização dos serviços de urgência[20,21]; outro exemplo consiste na existência de um regime especial de comparticipação de medicamentos, em que é tido em conta o rendimento dos pensionistas.[22]

Para além do papel de financiador da saúde, o SNS é também prestador de serviços, sendo de esperar que tenha uma oferta que abranja todos os tipos de cuidados. No entanto, alguns cuidados são prestados em grande parte pelo setor privado, ainda que com financiamento público (p.ex. exames complementares de diagnóstico).[16,23]

Um aspeto que poderá ser potenciador de iniquidades é a oferta demorada ou insuficiente de alguns cuidados pelo SNS. O elevado número de utentes sem médico de família,[24] o sistema de referenciação pelo médico de família (*gatekeeping)* para acesso aos cuidados hospitalares não urgentes e as listas de espera (que se verificam, sobretudo, para cuidados hospitalares e exames de diagnóstico)[16] poderão constituir uma barreira. Indivíduos de maior estatuto socioeconómico e/ou que beneficiem de dupla/tripla cobertura conseguem contornar estes constrangimentos recorrendo (mais facilmente) à prestação privada. Este fenómeno poderá, ainda, ocorrer nas áreas em que têm sido identificadas lacunas ao nível da oferta do SNS, como no caso da saúde mental, dos cuidados dentários[25] e dos cuidados paliativos.[16]

Dadas as especificidades na utilização de diferentes tipos de cuidados, sumarizam-se na Tabela 1 algumas possíveis barreiras à utilização de cuidados prestados pelo SNS. Estas poder-se-ão traduzir em iniquidades, caso existam diferenças na utilização de cuidados que sejam determinadas por outros fatores que não a necessidade.

MÉTODOS

Efetuou-se uma revisão narrativa da literatura,[26,27] com o objetivo de saber até que ponto o princípio de equidade no acesso a cuidados de saúde tem sido atingido em Portugal. Inicialmente, pesquisou-se a PubMed (inclui MEDLINE), identificando artigos de língua portuguesa e inglesa, entre os anos 1990 e 2023. Foram pesquisados os termos "healthcare equity" OR "healthcare inequity" OR "health services accessibility" OR "healthcare use" OR "healthcare delivery" OR "horizontal inequity" OR "healthcare utilization" AND "income" AND "Portugal", e foram encontrados 47 artigos, dos quais foram selecionados os mais pertinentes. As referências bibliográficas destes estudos foram pesquisadas e foram também contactados especialistas nacionais da área com o objetivo de encontrar publicações adicionais. No final, foram incluídos não apenas artigos de revistas científicas, mas também capítulos de livro, relatórios de organismos internacionais, teses e dissertações.

Os critérios de seleção usados incidiram particularmente em estudos de cariz económico, que utilizaram a

Tabela 1 – Características do financiamento e prestação que poderão constituir potenciais barreiras à utilização de cuidados de saúde no SNS no período em análise (1980-2019)

Tipo de cuidado	Características de financiamento no SNS		Fatores relacionados com a organização e oferta de cuidados
	Encargo dos utilizadores	Mecanismos de proteção	
Consulta de Medicina Geral e Familiar	Copagamento (até janeiro de 2020)[19]	Isenção de taxas moderadoras em determinados grupos populacionais, entre os quais situação de insuficiência económica.[19]	Elevado número de pessoas sem médico de família.[24]
Consulta de outras especialidades	Copagamento (até junho de 2022)[19]		Sistema de referenciação (através do Médico de Família). Listas de espera.[16]
Consultas de saúde mental	Copagamento (até junho de 2022)[19]		Sistema de referenciação (através do Médico de Família). Reduzida oferta de cuidados (inclusivamente não médicos, como por exemplo, psicólogos). Assimetrias geográficas.[48]
Exames complementares de diagnóstico e terapêutica	Copagamento (até janeiro de 2021)[19]		Listas de espera.[16]
Consultas de medicina dentária	*Out-of-pocket*	Cheque dentista: destinado inicialmente a crianças e jovens, mas posteriormente alargado a outros grupos, entre os quais idosos carenciados.[46]	Prestação maioritariamente privada. Integração de cuidados dentários na rede de Cuidados de Saúde Primários (implementada e com expansão relativamente recente).[25]
Medicamentos sujeitos a receita médica	Copagamento consoante o grupo terapêutico	Comparticipação adicional para beneficiários do complemento solidário para idosos. Regime especial de comparticipação.[22]	-
Medicamentos não sujeitos a receita médica	*Out-of-pocket*	-	-
Internamento	N.A.	-	Lista de espera para procedimentos eletivos.[16]

N.A.: não se aplica.
Notas: Elaboração própria.

metodologia das curvas e índices de concentração,[9] ou outras técnicas comparáveis, para medir o grau de equidade no acesso aos cuidados de saúde em Portugal. Considerámos apenas estudos que se basearam em amostras representativas da população portuguesa, o que excluiu análises a nível local; e selecionámos unicamente trabalhos que consideraram o nível socioeconómico como critério de segmentação da população. A maior parte dos estudos recorre ao rendimento familiar como critério, embora não tivéssemos excluído outros indicadores de nível socioeconómico, como a educação ou profissão. Foram consideradas fora do âmbito da revisão análises que tiveram como objetivo medir o acesso em relação a fatores demográficos, como o sexo, região, nacionalidade ou etnia.

É importante atentar as seguintes definições para melhor entendimento da revisão. Ao estudarem a equidade de acesso, a maior parte dos autores consideram que este objetivo se alcança, em termos práticos, quando o tratamento está de acordo com a necessidade. Habitualmente, é focada a ideia de equidade horizontal (utilização igual para necessidades iguais). A revisão considera diferentes tipos de cuidados, consultas da especialidade de medicina geral e familiar (MGF), consultas de outras especialidades médicas, cuidados dentários, consultas de saúde mental, internamento hospitalar, consumo de medicamentos e cuidados preventivos e de diagnóstico. A literatura propõe várias definições para o conceito de necessidade.[3,28] Nos estudos sobre equidade, a operacionalização empírica deste conceito parte do princípio de que a necessidade pode ser estimada através de informação sobre o estado de saúde atual dos indivíduos, pelo que se utilizam indicadores de saúde associados a dados demográficos.[8,13] Finalmente, a noção de rendimento considerada por todos os autores nos trabalhos passados em revista é a de rendimento familiar equivalente, ou seja, corrigido pela dimensão e estrutura das famílias.

Equidade no acesso aos cuidados de saúde – evidência empírica para Portugal

Desde há três décadas, a metodologia preferencial para a realização de estudos sobre a equidade na prestação de cuidados tem sido a desenvolvida por Wagstaff e Van Doorslaer.[29,30] O método, baseado em curvas e índices de concentração, verifica inicialmente se existem desigualdades na utilização de cuidados. Eventuais desigualdades não implicam obrigatoriamente uma quebra do princípio de equidade; se resultarem de diferenças de necessidade, são consideradas justas. Numa segunda fase, os estudos empíricos ajustam as características de necessidade dos indivíduos (recorrendo a dados sobre o seu estado de saúde, idade e sexo, e eventualmente a variáveis como tipo de família, região, isolamento social, etc.) para avaliar a equidade. Se a utilização padronizada para a necessidade for distribuída de igual forma ao longo da distribuição do rendimento dos indivíduos, estaremos perante uma situação de equidade; distribuições desiguais, favorecendo os mais ricos ou os mais pobres, serão consideradas iníquas.

Apesar do relevo dado pelos documentos legislativos e políticos à equidade em saúde, o estudo empírico da equidade na prestação de cuidados de saúde em Portugal não tem sido frequente. A primeira análise no nosso país foi realizada por Pereira, tendo por base dados do Inquérito Nacional de Saúde (INS) de 1987.[31,32] Foi considerada a despesa global proveniente da utilização de consultas de clínica geral, consultas de especialidade e internamentos hospitalares (conforme classificados à época). Verificou-se um favorecimento dos indivíduos com maior rendimento – para a mesma necessidade, apresentavam maior utilização.

Estudos posteriores fazem a análise desagregada dos diferentes tipos de cuidados, pelo que, nesta revisão, são apresentados por categorias.

Consultas

Consultas de medicina geral e familiar

No caso das consultas de medicina geral e familiar (MGF), os resultados têm sido heterogéneos. Simões *et al*,[33] utilizando dados do INS 1998 – 1999, observaram maior utilização destas consultas entre indivíduos de menor rendimento. Porém, ao considerarem a necessidade dos indivíduos, avaliando indicadores de morbilidade, identificaram iniquidade a favor dos mais ricos. Lopes[34] construiu indicadores a partir de diferentes questões do inquérito; além disso, utilizou a metodologia entretanto proposta por Wagstaff e Van Doorslaer,[29] tendo concluído haver favorecimento dos mais pobres. Também Furtado,[35] com dados do INS 2005/2006, encontrou iniquidades a favorecer os indivíduos de maior rendimento. Estudos mais recentes, com dados de 2014[36] e 2019[37,38] não obtiveram índices estatisticamente significativos, sugerindo equidade na prestação.

Esta diversidade de resultados também se verificou em comparações internacionais. Bago d'Uva *et al,*[39] num estudo longitudinal com dados entre 1994 e 2001, identificaram iniquidade a favor dos indivíduos de maior rendimento em Portugal, um dos poucos países com este resultado. Van Doorslaer *et al,*[40] com dados de 1996, não encontraram evidência estatisticamente significativa de iniquidade. Já um estudo do *Health Equity Research Group* da Organização para a Cooperação e Desenvolvimento Económico (OCDE), com dados de 2000,[14,15] apontou para algum favorecimento dos indivíduos de maior rendimento no número de consultas de MGF.

Numa análise distinta, Tavares *et al*[41] analisaram dados do *Survey of Health, Ageing and Retirement in Europe* 2011 e observaram favorecimento dos indivíduos com maior nível socioeconómico. Este estudo incidiu sobre a população com idade igual ou superior a 50 anos, tendo utilizado a educação (anos de escolaridade) como indicador socioeconómico.

Consultas de outras especialidades

Nas consultas de outras especialidades (não MGF, excluindo também as de medicina dentária, que são tratadas na secção seguinte) a evidência empírica tem mostrado uma maior utilização por parte dos indivíduos de maior rendimento. Quando contemplada a informação sobre a necessidade, identificaram-se iniquidades a favorecerem também os indivíduos de maior rendimento.[34-37] Simões *et al*[33] estudaram a prestação de consultas de cardiologia e chegaram a idêntica conclusão. O nível de iniquidade das consultas de outras especialidades parece ter diminuído durante o período de intervenção económica por parte do Fundo Monetário Internacional, Comissão Europeia e Banco Central Europeu (2011 - 2014), mas voltou a subir quando considerada informação mais recente de 2019.[34-38]

Em estudos internacionais,[39,41] Portugal foi o país em que se verificou maior favorecimento dos indivíduos de maior nível socioeconómico na prestação de consultas de outras especialidades. No estudo da OCDE, considerando dados de 2000,[14,15] o índice de iniquidade foi superior apenas nos Estados Unidos da América, México e Finlândia. Na comparação mais recente da OCDE, com dados de 2014,[42] os resultados estavam de acordo com os anteriores, surgindo Portugal como o terceiro país, entre 32, com maior iniquidade nestas consultas. Numa análise de decomposição do nível de iniquidade em consultas de outras especialidades, Van Doorslaer *et al*[14] mostraram que, no caso português, o rendimento familiar, a região e o grau de urbanização da área de residência contribuem substancialmente para a iniquidade a favor dos mais ricos.

Cuidados dentários

À semelhança do que se verifica para as consultas de outras especialidades não MGF, também a utilização de consultas de medicina dentária é superior nos indivíduos de maior rendimento.[14,33,35,37,42]

Este foi o tipo de consulta para o qual Simões *et al* encontraram índices de iniquidade mais elevados,[33] e o segundo mais elevado na análise de Fernandes.[37] Tem sido observado favorecimento dos indivíduos de maior rendimento no acesso a consultas de medicina dentária em todos os países da OCDE, mas Portugal destaca-se com iniquidades particularmente expressivas.[14,42]

Furtado[35] calculou índices para consultas de medicina dentária com fins preventivos e também observou um favorecimento dos indivíduos de maior rendimento, o mais expressivo entre os cuidados avaliados no estudo.

Consultas de saúde mental

O primeiro estudo que analisa a equidade na prestação de cuidados de saúde mental em Portugal foi realizado por Fernandes.[37] Foram consideradas as consultas com psicólogo, psicoterapeuta ou psiquiatra, tendo-se verificado a existência de maior utilização para idêntica necessidade entre os indivíduos de maior rendimento.

Todas as consultas médicas

Vários estudos analisaram a equidade nas consultas médicas totais, ou seja, sem desagregação por especialidades. Lopes[34] identificou índices de iniquidade positivos para todos os preditores de necessidade estudados. O favorecimento de indivíduos de maior rendimento foi também demonstrado em estudos posteriores,[35,36] e no mais recente, com dados de 2019, de Antunes *et al*.[38]

Alguns trabalhos internacionais[14,15,42] avaliaram a probabilidade de ter uma consulta médica e o número de consultas utilizadas. Em ambos os casos, Portugal apresentou iniquidades a favorecer os indivíduos de maior rendimento, destacando-se em relação à maioria dos países, pois estes atingiram equidade na distribuição do número de consultas.

Internamento hospitalar

Os estudos da OCDE avaliaram a equidade na probabilidade de admissões hospitalares. No primeiro estudo, com dados do *European Community Household Panel* 2000, foi observada iniquidade significativa a favorecer os indivíduos de maior rendimento (tendo Portugal, aliás, o valor mais elevado entre os países estudados).[14] No entanto, no estudo mais recente,[42] com dados de 2014, o índice obtido não foi estatisticamente significativo. Os estudos que analisaram a equidade na prestação relativamente ao número de dias de internamento[14,37] também não obtiveram resultados estatisticamente significativos, pelo que não foi excluída a existência de equidade.

Consumo de medicamentos

Furtado[35] e Fernandes[37] analisaram a equidade no acesso aos medicamentos em Portugal. Os resultados mostraram que, para idêntica necessidade, a probabilidade de utilização de medicamentos foi superior nos indivíduos de maior rendimento. No entanto, observaram-se diferenças consideráveis entre os índices de equidade obtidos para os medicamentos sujeitos a receita médica (MSRM) e para os medicamentos não sujeitos a receita médica (MNSRM). Para estes últimos, os índices obtidos em ambos os estudos foram muito superiores, indicando iniquidades mais expressivas a favorecer os indivíduos com rendimento mais elevado.

Cuidados preventivos e de diagnóstico

O estudo da equidade na prestação de cuidados preventivos tem incidido sobre diferentes cuidados. Lopes[34] concluiu que, para idênticas necessidades, indivíduos de maior rendimento utilizam mais testes laboratoriais, raio-X e eletrocardiograma.

O trabalho de Furtado[35] analisou os seguintes cuidados preventivos: vacina da gripe, controlo da pressão arterial, controlo do colesterol, mamografia, citologia cervicovaginal (CCV) e cuidados dentários preventivos (já mencionados). Para todos, verificou favorecimento dos indivíduos de maior rendimento, mais expressivo nalguns cuidados, nomeadamente, nos cuidados dentários e realização de CCV. Noutros, como o controlo da pressão arterial, a distribuição aproximou-se da equitativa.

Um trabalho da OCDE[42] analisou alguns cuidados preventivos, tendo sido observado que, em Portugal, existiam iniquidades a favorecer os indivíduos de maior rendimento na probabilidade de realização de CCV e na probabilidade de realização de rastreio do cancro colorretal (pesquisa de sangue oculto nas fezes ou colonoscopia). Para a vacinação contra a gripe e para as mamografias não foram observadas iniquidades.

Numa análise específica aos rastreios do cancro do colo do útero e do cancro da mama, Quintal *et al*[43] observaram iniquidades para citologias, favorecendo os indivíduos de maior rendimento; no caso das mamografias não foram observadas iniquidades.

Os dados mais recentes relativos à equidade nos cuidados preventivos em Portugal são de 2019 e mostram iniquidades a favor dos indivíduos de maior rendimento para todos os cuidados preventivos analisados (controlo da tensão arterial e do colesterol, mamografias, CCV e colonoscopias).[37] Estas foram mais expressivas para as colonoscopias.

DISCUSSÃO

A evidência empírica mostra que, em Portugal, o objetivo de equidade na prestação de cuidados de saúde não tem sido atingido, salvo algumas exceções. Para a maioria dos cuidados, parece existir um favorecimento dos indivíduos com mais elevados níveis de rendimento. Este é mais expressivo em cuidados especializados, como as consultas de outras especialidades não MGF e as consultas de medicina dentária, em que, mesmo nas comparações internacionais, Portugal se destaca pela negativa.

Existem características do sistema de saúde português que se podem relacionar com estes resultados: a existência do sistema de referenciação no SNS para cuidados hospitalares contrapõe-se à maior facilidade em recorrer à prestação privada por parte dos indivíduos de maior rendimento; a abertura de novas instituições privadas nos últimos anos aumentou também a oferta de cuidados fora do sistema público.[44] Para além da maior disponibilidade para pagar, os indivíduos de maior rendimento poderão, ainda, beneficiar de mecanismos adicionais de cobertura. As diferenças no nível educacional e na literacia em saúde[45] também poderão contribuir para uma maior procura de cuidados de saúde por parte destes indivíduos, já que poderão mais facilmente percecionar a necessidade de cuidados.

As análises empíricas têm sido unânimes ao indicar que existem iniquidades na prestação de cuidados dentários. Têm sido implementadas algumas medidas com vista a promover o acesso, com destaque para o chamado 'cheque-dentista' e para a disponibilização de consultas pelos cuidados de saúde primários.[46] No entanto, a expansão da oferta do SNS aparenta ser insuficiente, com a grande maioria da prestação a ser feita pelo setor privado.

O estudo empírico da equidade no acesso aos cuidados de saúde mental conta apenas com dados de 2019. Verificou-se que a prestação é iníqua, com favorecimento dos indivíduos de maior rendimento. Esta observação vai ao encontro da multiplicidade de problemas conhecidos no âmbito da saúde mental.[47,48] Os dados avaliados disponibilizam apenas informação sobre consultas com psicólogo, psicoterapeuta ou psiquiatra.[37] No futuro, o estudo da equidade na prestação deste tipo de cuidados deverá ser aprofundado.

Relativamente aos medicamentos, os estudos disponíveis apontam iniquidades a favorecer os indivíduos de estatuto socioeconómico mais elevado. Estas são mais acentuadas no acesso aos MNSRM. Apesar dos MNSRM serem disponibilizados sem necessidade de prescrição, o custo é, neste caso, suportado integralmente pelos utentes. A maior disponibilidade para pagar e maior literacia em saúde poderão fazer com que os indivíduos mais ricos utilizem mais MNSRM.[49] Ainda que não tão expressivas, foram observadas também iniquidades para os MSRM. Apesar de existirem mecanismos de proteção dos mais vulneráveis (regimes especiais de comparticipação, complemento solidário para idosos, entre outros), os indivíduos de maior rendimento terão mais facilidade em obter uma prescrição médica, uma vez que acedem mais facilmente às consultas de especialidade.

Quanto aos cuidados preventivos, os estudos têm também mostrado, salvo algumas exceções, um tendencial favorecimento dos indivíduos de maior rendimento. As iniquidades parecem ser mais expressivas em cuidados altamente especializados, como as colonoscopias. A este propósito, importa salientar que, em Portugal, têm sido reportadas dificuldades de acesso dos utentes do SNS a prestadores com financiamento público que poderão justificar as iniquidades observadas, nomeadamente lacunas na rede de prestadores públicos e convencionados, com assimetrias regionais.[50] Em contraste, nalguns estudos, a equidade no acesso foi verificada (ou esteve próxima) para cuidados cujo acesso apresenta, à partida, menos barreiras, como a vacina contra a gripe ou o controlo da pressão arterial.[35]

Estudos recentes têm sido unânimes quanto ao atingimento da equidade na prestação de consultas de MGF e nos internamentos,[36,37,42] sugerindo que, no SNS, estes terão menos barreiras ao acesso relativamente a outros cuidados de saúde. No entanto, relativamente às consultas de MGF, é de considerar que os indivíduos de maior rendimento poderão ter preferência pela utilização direta de cuidados mais especializados, apresentando, assim, menor procura destas consultas, comparativamente aos indivíduos mais pobres. Em consequência destes fatores, os resultados referentes às consultas totais mostram que, embora a equidade no acesso às consultas de MGF seja alcançada, o acesso às consultas médicas em geral permanece iníquo. No caso dos internamentos, importa referir que estes refletem apenas a prestação de cuidados hospitalares nas situações que são mais graves, ou seja, os dados dos estudos apresentados neste âmbito não permitem inferir sobre a prestação de cuidados em ambulatório, o que seria relevante, dado que o número tem vindo a aumentar.[23]

Mesmo considerando que a metodologia dos estudos considerados é a mais consensual atualmente, é importante ter em conta as limitações das análises empreendidas para o estudo da equidade de acesso. Em primeiro lugar, garantir a igualdade na utilização dos serviços para iguais necessidades é um objetivo necessário, mas não suficiente para a equidade de acesso. Um contacto com o sistema só poderá traduzir-se em melhores resultados de saúde se a prestação de cuidados estiver alinhada com as melhores práticas médicas. Assim, seria importante considerar a equidade na qualidade dos cuidados, aspeto que nenhum

estudo em Portugal até hoje analisou explicitamente e que permitiria, por exemplo, aferir se o nível de atenção, tempo e esforço dedicados aos utentes é ou não equitativo.[1]

Poder-se-á considerar que os cuidados preventivos se baseiam em recomendações clínicas e, portanto, podem ser utilizados, em certa medida, para medir a qualidade dos sistemas de saúde. No entanto, esta abordagem é limitada, uma vez que a qualidade dos cuidados é um conceito mais abrangente e multidimensional. Justifica-se, assim, no futuro, uma análise mais detalhada das diferenças na qualidade dos cuidados recebidos pela população.

A literatura empírica que considerámos nesta revisão analisa o cumprimento da equidade pela premissa de que deverá existir igual utilização para iguais necessidades. Embora reúna consenso na literatura económica,[9,13] esta abordagem não permite capturar todas as dimensões do acesso. O acesso resulta da interação entre diversos fatores de acessibilidade aos serviços e a forma como as pessoas interagem com esses fatores (capacitação). A acessibilidade é influenciada por fatores como localização geográfica, custos, continuidade e adequação dos cuidados. Como fatores de capacitação destacam-se a literacia em saúde, crenças, valores sociais, autonomia, mobilidade, ambiente, capacidades financeiras e envolvimento com os cuidados de saúde.[12]

Adicionalmente, há pelo menos dois outros aspetos que são relevantes para a questão da equidade no acesso e que não foram considerados nesta revisão. Por um lado, as diferenças nas necessidades não satisfeitas de cuidados. Veja-se, a este propósito, trabalhos[42,51] que avaliaram indicadores como a probabilidade de atraso/ausência de cuidados devido à distância ou a longos tempos de espera e a não satisfação de necessidades por razões financeiras. Por outro lado, a questão da proteção financeira para os custos dos cuidados de saúde (equidade no financiamento).[52,53] Embora estejam para além do âmbito desta revisão, estes elementos proporcionariam uma base para discussão mais completa das opções políticas a adotar.

A pandemia de COVID-19 poderá ter tido impacto ao nível da equidade no acesso. Os constrangimentos e adaptações na atividade assistencial, como a redução da atividade presencial, poderão ter desprotegido os mais vulneráveis. Espera-se que futuros estudos tragam alguma evidência sobre este tema.

CONCLUSÃO

Existem, em Portugal, iniquidades no acesso a grande parte dos cuidados de saúde, com especial relevo para as consultas de especialidade não-MGF, cuidados dentários, saúde mental e cuidados preventivos.

O papel do SNS é essencial para que se atinja a equidade no acesso. As insuficiências e lacunas do sistema público têm impacto no acesso das populações aos cuidados de saúde, sobretudo nas que apresentam menos rendimentos, pelo que devem ser avaliadas e mitigadas.

A generalidade das análises disponíveis considera o rendimento familiar como variável fundamental para avaliar a existência de iniquidades no acesso. No entanto, os restantes determinantes sociais e económicos da saúde também poderão contribuir para os resultados observados.

CONTRIBUTO DOS AUTORES

JF: Pesquisa bibliográfica, redação e aprovação final do manuscrito.

CF: Revisão crítica e aprovação final do manuscrito.

JP: Redação, revisão crítica e aprovação final do manuscrito.

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Os autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

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ACTA MÉDICA PORTUGUESA
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Warthin's Tumor: A Rare Case Report of a Bilateral Multifocal Parotid Tumor Associated with an Ectopic Tumor

Tumor de Warthin: Apresentação de um Caso Raro de um Tumor Parotídeo Bilateral Multifocal em Associação a um Tumor Ectópico

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ABSTRACT

Warthin's tumor is the second most common benign neoplasm of the parotid gland and frequently presents with multifocal and bilateral involvement, either synchronously or metachronously, up to 20% - 30% of cases. More rarely, extraparotid locations may also occur. This case report describes a Warthin's tumor presenting synchronously as a multifocal bilateral parotid tumor in association with an extraparotid localization, which, according to the existing literature, appears to be a rare event. This low incidence is likely underestimated and could be explained by several reasons. Increased awareness of this potentially higher incidence may aid physicians in better evaluating and treating their patients.
Keywords: Adenolymphoma; Parotid Neoplasms

RESUMO

O tumor de Warthin é o segundo tumor benigno da parótida mais comum e apresenta envolvimento multifocal e bilateral (síncrono ou metácrono) em até 20% - 30% dos casos. Mais raramente pode ter localização extraparotídea. Descreve-se o caso de um tumor parotídeo multifocal bilateral e síncrono em associação a um tumor extraparotídeo, um caso raro segundo a literatura existente. Esta baixa incidência está, provavelmente, subestimada e pode ser explicada por vários motivos. O seu reconhecimento pode ajudar a comunidade médica a melhor avaliar os seus doentes e orientar o seu tratamento.
Palavras-chave: Adenolinfoma; Neoplasias da Parótida

INTRODUCTION

Warthin's tumor (WT), also known as papillary cystadenoma lymphomatosum, is the second most common benign neoplasm of the parotid gland, following pleomorphic adenoma.[1]

There is a male predominance, with the mean age at diagnosis between the fifth and the seventh decades.[1] These tumors occur predominantly in the parotid gland and its lymph nodes, and have frequent multifocal and bilateral involvement (synchronous or metachronous), up to 20% - 30% of cases.[2] More rarely, extraparotid localizations may also occur.[3] Malignant transformation is extremely rare.[2]

Herein we describe the rare case of a synchronous bilateral multifocal parotid Warthin's tumor associated with an extraparotid WT.

CASE-REPORT

A 46-year-old man presented to the emergency department with a history of left neck swelling over the past five years and a rapid increase in size over the previous three days. The patient was subfebrile. Physical examination revealed a warm and painful mass in the left carotid triangle, measuring 4 x 5 cm. A contrast-enhanced computed tomography (CT) scan demonstrated a well-circumscribed neoplasm measuring 4 x 3 x 3 cm, located anterior to the sternocleidomastoid muscle, suggestive of an infected second branchial cleft cyst. Additionally, the CT scan revealed multiple bilateral parotid lesions.

With a suspected infected second branchial cyst, the patient was hospitalized for intravenous antibiotic treatment, with the resolution of the acute infection. Unexpectedly, fine needle aspiration cytology showed lymphocytes and dispersed oncocytic cells, suggesting a diagnosis of Warthin's tumor. The cytological examination of the lesions in both parotid glands confirmed the same diagnosis.

Two months later, a right superficial parotidectomy with facial nerve dissection was performed. Histological examination was consistent with WT (Fig. 1). Six months after the initial episode, surgical excision of the left cervical mass was planned. The incision was positioned over the lesion and subplatysmal flaps were elevated. The anterior border of the sternocleidomastoid muscle was identified and retracted laterally. The mass was carefully dissected from deep structures, including the internal and external carotid arteries, as well as the glossopharyngeal and hypoglossal nerves. No tract towards the oropharynx was identified. A mass consisting of two connected nodules was removed, the larger measuring approximately 4 x 2.5 cm and the smaller about 2 x 1 cm. The histopathological examination revealed WT in both nodules (Fig. 2). After a 16-month follow-up, no signs of recurrence were observed in either

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Figure 1 – Pre-operative photo of right parotid tumor (A). Right deep parotid lobe and facial nerve after tumor removal (B). Right parotid tumor consisting of multifocal nodules (C). Pathological examination: well demarcated tumor (arrow) with adjacent parotid gland (*) (D).

lesion.

The WT in the left parotid was not resected and is currently under close observation (Fig. 3).

DISCUSSION

The pathogenesis of Warthin's tumor remains controversial. Many theories have been put forward, but only two have persisted. The most favored hypothesis is the heterotopia hypothesis, which suggests that WT arises from epithelial inclusions in intra- or peri-parotid lymph nodes. This happens as epithelial cells migrate from the oral mucosa into the lymphoid tissue during parotid gland embryogenesis. Due to the absence of a complete capsule, the precursors of the salivary duct-acinar system become entrenched within the lymphoid component. This results in the existence of intraparotid lymph nodes and heterotopic salivary gland remnants entrapped in the parotid lymph nodes.[4] This hypothesis also explains the almost exclusive occurrence of WT in the parotid gland and its related lymph nodes. According to the second theory, WT may constitute

Figure 2 – Pre-operative photo of extra-parotid tumor on left carotid triangle (A). CT image showing a left cervical neoplasm measuring 4 x 3 x 3 cm, located anteriorly to the sternocleidomastoid muscle, suggesting an infected second branchial cleft cyst (B). Extra-parotid tumor prior its removal (C). Extra-parotid lesion consisting of two connected nodules (D). Pathological examination: papillary structures lined by bilayered oncocytic epithelial cells and surrounded by a lymphoid stroma, consistent with Warthin's tumor (E).

an adenoma followed by intense lymphocytic infiltration of the stroma.[5]

Another topic of debate is whether WT occurs as a true neoplasia or rather a reactive oncocytic metaplasia, given that both the epithelial component and lymphocytic infiltrations are polyclonal.[6] Either way, it seems to be triggered by various pathogenetic factors, including environmental, immunologic, viral, and genetic events.

Smoking seems to be an important etiological factor, as a notable number of patients are smokers,[7] in contrast to those with other salivary gland neoplasms. The association between WT and autoimmune disease has also been hypothesized, possibly as a form of delayed hypersensitivity type reaction, supported by the detection of viruses such as Epstein-Barr virus DNA or human herpesvirus 8 DNA in tumor cells.[8] Finally, despite strong evidence supporting a polyclonal origin, some studies have identified a clonal subset of WT arising from the CRTC1-MAML fusion oncogene,

Figure 3 – Pre-operative photo of right parotid tumor (A). Pre-operative photo of left parotid tumor and extra-parotid tumor on left carotid triangle (B). Post-operative photo after excision of right parotid tumor (C). Post-operative photo after excision of left extra-parotid tumor (left parotid tumor under surveillance) (D).

which may predispose to malignant transformation.[9]

Bilateral tumors occur in 4% - 27% of cases,[1,2] predominantly metachronous, while multifocal tumors are observed in 6% - 30% of cases.[1,4] These characteristics – the bilaterality and the multicentric nature of WT – can be explained by the aforementioned hypothesis of heterotopia.

Multifocal tumors involving both parotid glands are particularly rare. Xu *et al*, in a retrospective study of 1084 WT cases, found bilateral multifocal tumors in 0.65% of patients.[1] More recently, Maiorano *et al* identified 6.4% out of 78 patients.[4]

Additionally, ectopic neoplasms have also been reported, accounting for 8% of cases, mainly in cervical lymph nodes, the larynx and the submandibular gland.[1] Once again, the hypothesis of heterotopia also justifies the rare extraparotid location of WT.

Nonetheless, the occurrence of bilateral synchronous multifocal parotid WT in association with an extraparotid WT, as in this case, seems to be an even more uncommon event, with few reports available in the literature.[3] However,

this low incidence is surprising given its pathogenesis and is probably explained by several reasons. First, WT can be partially surgically removed, leaving other clinically undetectable small WTs in the gland. This can lead to a second WT in the same gland being diagnosed as a recurrence once it becomes clinically evident. Additionally, histopathological evaluations may miss small multiple WTs if whole-specimen sectioning is not performed. Moreover, a second contralateral WT can be misinterpreted as an independent tumor if the patient's previous medical history is unknown. Finally, asymptomatic extraparotid WT may go unnoticed, unless incidentally discovered during a CT scan.

After a 16-month follow-up, no signs of recurrence of either lesion were observed. The patient opted for conservative management with close observation of the left parotid, which may be a reasonable approach given the low risk of malignancy and the considerable risk of iatrogenic facial nerve injury.[10]

CONCLUSION

Bilateral multifocal parotid WT in association with an extraparotid WT is a rare event. However, its overall prevalence, isolated or in association, may increase with careful workup. Awareness of this potentially higher incidence may help physicians better assess their patients and guide their treatment.

AUTHOR CONTRIBUTIONS

JCS, SR: Data collection, writing of the manuscript.
NT: Writing of the manuscript.
NR: Critical review of the manuscript.
All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

PATIENT CONSENT

Obtained.

COMPETING INTERESTS

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ACTA MÉDICA PORTUGUESA
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Aquagenic Wrinkling of the Palms in a Patient with Cystic Fibrosis

Queratodermia Aquagénica num Doente com Fibrose Quística

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Keywords: Cystic Fibrosis; Cystic Fibrosis Transmembrane Conductance Regulator; Hand Dermatoses; Water/adverse effects
Palavras-chave: Água/efeitos adversos; Dermatose da Mão; Fibrose Quística; Regulador de Condutância Transmembrana em Fibrose Quística

Figure 1 – Whitish and hyperkeratotic papules on both palms, predominantly on the left hand (A). Worsening of right palmar lesions after five minutes of water immersion (B).

A 16-year-old female patient with cystic fibrosis (CF) presented with asymptomatic palmar lesions with five months of evolution. She reported worsening after water exposure and palmar hyperhidrosis.

A physical examination revealed whitish, hyperkeratotic papules on both palms. The patient's right hand was immersed in water for five minutes, followed by worsening of lesions with evident wrinkling and edematous whitish papules – the 'hand-in-bucket' sign (Fig. 1). A diagnosis of aquagenic wrinkling of palms (AWP) was established. Topical aluminum chlorohydrate was initiated, with modest improvement.

Aquagenic wrinkling of palms association with CF is well established, and a diagnosis of AWP should prompt CF investigation, as it may represent the only sign of mild CF or carrier status, allowing early diagnosis.[1–3] Less common associations include drugs (such as acetylsalicylic acid and selective cyclooxygenase inhibitors) and hyperhidrosis.[4–6] The diagnosis is clinical and the 'hand-in-bucket' sign is pathognomonic.[5,6] Treatment focuses on avoiding water exposure and managing hyperhidrosis with topical aluminum chlorohydrate or botulinum toxin.[4–6]

AUTHOR CONTRIBUTIONS

All authors contributed equally to this manuscript and approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

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PATIENT CONSENT

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COMPETING INTERESTS

The authors have declared that no competing interests exist.

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Diagnóstico da Doença Renal Crónica em Adultos em Portugal: Orientações Práticas de Peritos Clínicos e Laboratoriais Nacionais

Diagnosis of Chronic Kidney Disease in Adults in Portugal: Practical Recommendations from National Clinical and Laboratory Experts

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RESUMO

A doença renal crónica representa um problema de saúde pública significativo, afetando cerca de 9,8% da população adulta em Portugal. Pese embora este número, o diagnóstico precoce desta doença nos grupos de alto risco é reduzido. Apesar de serem apenas dois os parâmetros cruciais para o seu diagnóstico – a taxa de filtração glomerular estimada (TFGe) e a albuminúria – em Portugal, mais de 50% dos doentes em estádio 3 - 5 não foram alvo de avaliação concomitante da TFGe e albuminúria. A falta de implementação destas duas métricas em simultâneo, leva à avaliação inadequada da população em risco. Um grupo de trabalho composto por 17 peritos portugueses nas principais especialidades médicas envolvidas na gestão da doença renal crónica (Nefrologia, Medicina Geral e Familiar) e em Patologia Clínica/Análises Clínicas (representantes dos principais laboratórios nacionais) reuniu-se para criar um documento de orientações práticas que visa padronizar os procedimentos de prescrição, determinação, emissão de resultados e interpretação dos parâmetros de diagnóstico (albuminúria e TFGe baseada na creatinina sérica) da doença renal crónica em Portugal, baseando-se na prática clínica, conhecimento científico e recomendações internacionais. Este consenso nacional entre os principais intervenientes no processo de rastreio e diagnóstico, culminou na elaboração de quatro orientações práticas que irão permitir fornecer de forma consistente a TFGe e albuminúria, independentemente da especialidade médica do médico assistente, laboratório de análises ou localização geográfica. Além disso, com este esforço coletivo, os peritos pretendem sensibilizar as autoridades nacionais para a redação de novas normas de orientação clínica, fundamentadas em evidência científica e na prática clínica, para abordar a subavaliação da albuminúria e da TFGe na gestão desta doença.

Palavras-chave: Albuminúria; Doença Renal Crónica/diagnóstico; Portugal; Taxa de Filtração Glomerular

ABSTRACT

Chronic kidney disease represents a significant public health issue, affecting approximately 9.8% of the adult population in Portugal. Despite this figure, early diagnosis of this disease in high-risk groups remains limited. Although only two parameters are essential for its diagnosis – estimated glomerular filtration rate (eGFR) and albuminuria – in Portugal, over 50% of stage 3 - 5 patients have not undergone simultaneous assessment of eGFR and albuminuria. The insufficient implementation of the simultaneous assessment of these two metrics results in an inadequate evaluation of high-risk populations. A task force of 17 Portuguese experts from the main medical specialties involved in chronic kidney disease management (Nephrology and Family Medicine) and in Clinical Pathology/Laboratory Medicine (representatives of major national laboratories) convened to develop guidelines aimed at standardizing procedures for the prescribing, determination, reporting, and interpretation of diagnostic parameters (albuminuria and eGFR based on serum creatinine)

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in Portugal. This effort is based on clinical practice, scientific knowledge, and international recommendations. This national consensus among the key stakeholders in the chronic kidney disease screening and diagnosis process culminated in the development of four practical guidelines. These guidelines will enable the consistent provision of eGFR and albuminuria measurements, regardless of the attending physician's medical specialty, the laboratory, or geographic location. Additionally, through this collective effort, experts want to raise awareness among national authorities to the need of developing new guidelines, based on scientific evidence and clinical practice, to address the underassessment of albuminuria and eGFR in this disease's management.
Keywords: Albuminuria; Glomerular Filtration Rate; Portugal; Renal Insufficiency, Chronic/diagnosis

INTRODUÇÃO

A doença renal crónica (DRC) é um desafio significativo em termos de saúde pública a nível global e nacional.[1] A prevalência global de DRC é estimada em 9,8% na população adulta em Portugal.[2] Apesar do reconhecimento, enquanto doença altamente impactante na qualidade de vida dos doentes e nos sistemas de saúde,[3,4] a consciencialização para a DRC é ainda reduzida, com apenas 10% da população de alto risco (doentes com hipertensão, obesidade, diabetes mellitus tipo 2) estando adequadamente diagnosticada.[5] Segundo a organização internacional Kidney Disease: Improving Global Outcomes (KDIGO), o rastreio formal da DRC deve incluir a avaliação da taxa de filtração glomerular estimada (TFGe) e albuminúria – dois parâmetros que, isoladamente e de forma conjunta, são ferramentas para o diagnóstico e monitorização da resposta terapêutica, do risco de progressão da DRC e da ocorrência de complicações associadas (lesão ou doença renal aguda, falência renal e comorbilidades cardiovasculares).[5]

Segundo a KDIGO, o diagnóstico de DRC é formalmente definido por uma razão albumina/creatinina na urina (RAC) ≥ 30 mg/g ou TFGe < 60 mL/min/1,73 m^2, persistente durante pelo menos três meses (prova de cronicidade).[5] De forma global, estas orientações internacionais recomendam i) o doseamento da creatinina sérica e utilização de uma equação estimativa para a avaliação inicial da TFGe, assegurando a utilização da mesma equação dentro da mesma região geográfica; ii) a avaliação da albuminúria através do cálculo da RAC; iii) a preferência pela medição laboratorial da albuminúria em detrimento da proteinúria; e iv) a preferência pela colheita da primeira amostra de urina da manhã em adultos para avaliação da albuminúria.[5]

Apesar da existência de diretrizes internacionais, um estudo nacional revelou que mais de 50% dos doentes portugueses com DRC diagnosticada em estádios 3 - 5 não foram alvo de avaliação concomitante da TFGe e albuminúria.[2] Adicionalmente, apenas 33,6% da coorte estudada possuía, pelo menos, duas avaliações de TFGe e 22,3% duas avaliações da RAC, separadas por três ou mais meses.[2] Depreende-se que este subdiagnóstico é ainda maior nos estádios 1 e 2 da DRC. Consequentemente, a falta de implementação destas duas métricas de doença renal contribui para uma inadequada avaliação do risco da progressão da doença, da presença de comorbilidades associadas e da ocorrência de eventos cardiovasculares frequentes nesta população. Por outro lado, nos doentes com DRC por diagnosticar, esta lacuna resulta na privação de medidas para melhorar o seu prognóstico.

É, assim, urgente estabelecer um consenso nacional entre os principais intervenientes no processo de prescrição, deteção, reportagem (emissão de resultado) e interpretação da albuminúria, visando um rastreio e diagnóstico da DRC mais eficaz, independentemente da especialidade (com especial foco na Nefrologia pela abordagem especializada na gestão e tratamento da doença, e na Medicina Geral e Familiar pelo seu papel fundamental no rastreio precoce e como elo crucial entre os cuidados de saúde primários e especializados), laboratório de análises ou local do país.

Neste sentido, foi constituído um grupo de trabalho de 17 peritos, em colaboração com a Sociedade Portuguesa de Nefrologia (SPN), a Sociedade Portuguesa de Patologia Clínica (SPPC), a Associação Portuguesa de Medicina Geral e Familiar (APMGF), a Unidade de Saúde Familiar Associação Nacional (USF-AN), a Associação Nacional de Laboratórios Clínicos (ANL), a Associação Portuguesa de Analistas Clínicos (APAC), representantes dos laboratórios CUF, Grupo Germano de Sousa, Joaquim Chaves Saúde, Luz Saúde, Laboratório Prof. Nunes Oliveira, SYNLAB, Trofa Saúde e Unilabs, e ainda médicos especialistas de Nefrologia e de Medicina Geral e Familiar, que se reuniram para criar um conjunto de quatro orientações destinadas aos profissionais de saúde e laboratórios.

As orientações práticas produzidas pelo grupo de trabalho visam apoiar procedimentos baseados no conhecimento, evidência e recomendações internacionais, que permitirão a prescrição, determinação, reportagem e interpretação dos parâmetros de diagnóstico (RAC e TFGe baseada na creatinina sérica) de DRC, de forma estandardizada nos cuidados de saúde a nível nacional.

Recomendação 1

- O rastreio da DRC em doentes adultos de risco deverá ser efetuado através da requisição conjunta dos exames de i) albumina e creatinina urinárias, para determinação da RAC; e ii) creatinina sérica, para estimativa da TFGe.

O grupo de trabalho reforçou a necessidade urgente

de estandardizar os procedimentos para rastreio da DRC a nível nacional, que deverá ser baseado sempre no cálculo da RAC e estimativa da TFGe – em alinhamento com as orientações internacionais da KDIGO 2024.[5]

A heterogeneidade atualmente existente na requisição informática dos exames de albuminúria e creatininúria, com a existência de múltiplos códigos de requisição redundantes, origina confusão e ineficiências no sistema. Consequentemente, a prática clínica diária é dificultada e causa potenciais omissões de informação importante para o rastreio atempado destes doentes. Para efeitos de rastreio e diagnóstico da DRC, os peritos identificaram a necessidade de uniformizar as requisições de exames laboratoriais. Desta forma será possível estruturar um fluxograma claro com os dois parâmetros necessários para a deteção da DRC, para que os clínicos estejam sensibilizados para a importância de requisitar corretamente os exames de albumina e creatinina urinárias, bem como para a creatinina sérica. É, portanto, urgente a criação de códigos informáticos de prescrição precisos e únicos para a TFGe e RAC, que permitam a todas as especialidades, nomeadamente aos médicos de Medicina Geral e Familiar, evitar erros ou omissões nas requisições, assegurando um rastreio atempado da DRC.

Os métodos laboratoriais na avaliação da albuminúria, de acordo com as diretrizes internacionais da KDIGO CKD-2024,[5] deverão ser privilegiados em detrimento dos testes semiquantitativos *in loco* (tiras-teste) dadas as possíveis falhas de deteção, impossibilidade de quantificação ou eventuais 'falsos-positivos' (sobretudo no caso de doentes do sexo feminino) decorrentes dos métodos tradicionais.

Recomendação 2

- Os laboratórios deverão reportar a RAC sempre que for solicitado, em conjunto, o exame da albuminúria/'microalbuminúria' e da creatinina na urina.

Recomendação 2.1

- O valor de RAC deverá ser expresso em mg/g creatinina, com indicação do valor-referência "< 30 mg/g creatinina".

Recomendação 2.2

- Deverão ser indicados *disclaimers* ou mensagens associadas aos resultados referentes à i) necessidade de avaliação e interpretação do resultado obtido em conjunto com o médico assistente, e ii) necessidade de repetição após três meses para efeitos de diagnóstico de DRC.

A padronização na reportagem da RAC é igualmente crucial – um ponto crítico comum partilhado por todos os peritos do grupo de trabalho. Os laboratórios devem reportar a RAC sempre que solicitado em conjunto com a análise de albuminúria/'microalbuminúria' e creatinina na urina, expressando-o em mg/g de creatinina e utilizando o valor de referência '< 30 mg/g creatinina'. É fundamental ainda incluir *disclaimers* ou mensagens associadas aos resultados que enfatizem a necessidade de interpretação dos resultados em conjunto com o médico assistente, bem como a importância da repetição do exame após três meses para a confirmação diagnóstica da DRC.

Em Portugal, estão identificados laboratórios que fornecem automaticamente a RAC, quando são solicitados os exames de albuminúria e/ou creatininúria, devido à consciencialização sobre a importância desta métrica e da sua utilidade como ferramenta de diagnóstico. No entanto, várias unidades laboratoriais não procedem à análise e reportagem da RAC de forma espontânea e automática, resultando assim em expectativas frustradas entre os profissionais de saúde. Esta observação, apesar da compreensão para a utilidade do biomarcador para efeitos de diagnóstico, resulta do facto de apenas o parâmetro da albuminúria ser solicitado pelo médico. Outra justificação identificada pelos peritos advém de constrangimentos informáticos na reportagem da RAC no sistema informático atual, que exige que o doseamento urinário de creatinina e albumina seja solicitado simultaneamente, apesar de as técnicas laboratoriais serem rotineiras e de os biomarcadores estarem padronizados. Além disso, os códigos de prescrição e reporte vigentes codificam apenas o parâmetro específico, impossibilitando a reportagem da RAC via sistema informático, pois este cálculo requer a análise de dois parâmetros [por exemplo, o código LOINC (*Logical Observation Indentifiers Names and Codes*) que codifica o parâmetro "albumina de baixa concentração" não corresponde diretamente à RAC], logo o envio de informação ao médico fica condicionado.

Para evitar esquecimentos na prescrição por parte dos profissionais de saúde e assegurar que os resultados esperados sejam fornecidos, o grupo de trabalho apontou como fundamental a criação de um código de requisição único para a prescrição da RAC. Desta forma, o laboratório é informado da necessidade de realizar ambas as determinações laboratoriais e garante a sua integração no sistema informático, que deverá ser devidamente ajustado para acomodar este parâmetro laboratorial. Dados de uma análise interna de várias unidades laboratoriais representadas no grupo de trabalho demonstrou que apenas cerca de 0,44% dos doentes com requisição para albuminúria naquela instituição (universo de 14 400 doentes), tinham em simultâneo a requisição para creatininúria, obrigatória para o cálculo da RAC (dados internos não publicados).

Outros fatores impeditivos do cálculo da RAC de forma automática pelas unidades laboratoriais relacionam-se

com o custo financeiro associado ao esforço de realizar as dosagens não solicitadas, e a problemática associada à comunicação entre unidades distintas, nomeadamente entre clínicas/cuidados de saúde primários e laboratórios externos. A linha de comunicação revela-se assim bastante dificultada pela ausência de códigos padronizados de requisição e de reportagem, o que, nestes casos, inviabiliza a prescrição do cálculo da RAC pelos médicos assistentes e a consequente transmissão dos resultados pelos laboratórios.

De realçar que apenas dois laboratórios presentes no painel de peritos fazem a reportagem da RAC na urina pontual de forma sistemática. Esta decisão surge com base numa necessidade antiga de garantir maior confiança no resultado reportado na dosagem da microalbuminúria em urina de 24 horas, por ser um exame altamente falível pela dependência do rigor na colheita pelo doente. Com base neste pressuposto de busca por maior rigor na reportagem dos dados e evitar repetições de colheitas, as instituições assumem o esforço financeiro com a realização da dosagem da creatinina e, posterior reportagem da RAC utilizando a primeira amostra de urina da manhã. As unidades laboratoriais garantiram a continuação da reportagem da RAC, mas apelaram de igual forma à criação de um código único de prescrição, e à celeridade da sua implementação no sistema informático clínico com a criação do respetivo código LOINC, para que esta prática se aplique de forma universal a todas as unidades laboratoriais nacionais.

Recomendação 3

- Os laboratórios deverão reportar a TFGe sempre que é solicitada a dosagem da creatinina sérica em indivíduos adultos.

Recomendação 3.1

- A fórmula CKD-EPI 2009 deverá ser usada para o cálculo da TFGe, sem considerar o coeficiente da raça.

Recomendação 3.2

- O valor da TFGe deverá ser acompanhado da indicação da fórmula usada e do valor-referência '≥ 60 mL/min/1,73 m²'.

Recomendação 3.3

- O valor da TFGe deverá ser emitido com a cifra real até um limite máximo de 120 mL/min/1,73 m², a partir do qual deverá ser emitido como '≥ 120 mL/min/1,73 m²'.

Recomendação 3.4

- Deverão ser indicados *disclaimers* ou mensagens associadas aos resultados referentes à i) necessidade de avaliação e interpretação do resultado obtido em conjunto com o médico assistente, e ii) necessidade de repetição após três meses para efeitos de diagnóstico de DRC.

Os laboratórios devem reportar a TFGe calculada pela fórmula CKD-EPI 2009, sem considerar o coeficiente racial (Fig. 1),[6] sempre que a creatinina sérica for solicitada em adultos, apresentando a cifra real até 120 mL/min/1,73 m², acompanhado da indicação da fórmula usada e do valor de referência '≥ 60 mL/min/1,73 m²'. Adicionalmente, deve-se considerar a inclusão de avisos destinados ao doente sobre a necessidade de interpretação médica e repetição do exame após três meses para diagnóstico de DRC, embora seja importante realçar que estes avisos podem gerar ansiedade no doente.

A utilização da equação desenvolvida pela Colaboração de Epidemiologia de Doença Renal Crónica (CKD-EPI) em 2009 (Fig. 1) deverá ser promovida face ao uso da equação de Cockcroft-Gault para a estimativa da TFGe[6,7] – equação de cálculo tradicionalmente utilizada no sistema atual dos cuidados de saúde primários, contrariamente ao recomendado pelas diretrizes internacionais.[5] Porém, é importante realçar a necessidade de excluir o coeficiente para 'raça negra' da equação CKD-EPI, dada a inadequação à população portuguesa (perante doentes de raça negra, e de acordo com o critério clínico, o coeficiente da raça poderá ser aplicado *a posteriori*).

FÓRMULA CKD-EPI 2009[6]

$$TFGe = 141 \times \min(SCr/\kappa, 1)^{\alpha} \times \max(SCr/\kappa, 1)^{-1.209} \times 0{,}993^{Idade} \times 1{,}018 \text{ (se mulher)}$$

SCr = creatinina sérica (mg/dL); Idade - em anos
κ = 0,7 (feminino) ou 0,9 (masculino)
α = -0,329 (feminino) ou -0,411 (masculino)
min(Scr/κ, 1) é o mínimo de Scr/κ ou 1,0
max(Scr/κ, 1) é o máximo de Scr/κ ou 1,0

Figura 1 – Fórmula CKD-EPI 2009 para cálculo da Taxa de Filtração Glomerular estimada (TFGe)

Recomendação 4

- O doseamento da creatinina deverá ser sempre acompanhado do método analítico utilizado para a sua determinação laboratorial.

Esta recomendação do grupo de trabalho advém do facto de que um dos métodos mais utilizados para o doseamento da creatinina, o método de Jaffé, apresenta, em comparação com o método enzimático, um maior número de interferências, nomeadamente, a presença de concentrações elevadas de glicose (entre outras substâncias, tipicamente compreendendo cerca de 20% da substância medida relatada como creatinina em adultos em concentrações fisiológicas de creatinina).[5] Desta forma, para garantir a correta interpretação dos resultados e a consistência e comparabilidade entre exames, é recomendada a inclusão do método laboratorial utilizado no relatório.

CONCLUSÃO

O objetivo deste grupo de trabalho prendeu-se com a necessidade urgente de estabelecer orientações claras e padronizadas para a requisição e reportagem da RAC e TFGe a nível nacional. De uma forma compreensiva, envolvendo clínicos e laboratórios, foram elaboradas quatro orientações práticas que, aliadas a uma crescente sensibilização da comunidade médica para esta questão, irão permitir fornecer consistentemente este dado crítico para o rastreio precoce e gestão eficaz da DRC de forma estandardizada e eficiente em Portugal (Fig. 2).

Este documento de consenso pretende ainda alavancar a fundação de um esforço conjunto com as entidades oficiais responsáveis (Administração Central do Sistema de Saúde, IP; Serviços Partilhados do Ministério da Saúde, EPE; Direção-Geral da Saúde), para a implementação de um conjunto de alterações altamente impactantes no rastreio da DRC. Nomeadamente, criar um código informático de prescrição e reportagem da RAC e TFGe; codificar a DRC [no contexto da Classificação Internacional de Cuidados de Saúde Primários-2 (ICPC-2)]; ajustar os indicadores de qualidade das Unidades de Saúde Familiar tendo em vista a gestão da DRC e as suas causas e complicações; e, por último, a atualizar as Normas DGS relativamente à DRC.

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CONTRIBUTO DOS AUTORES

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CR e EC são funcionários da BIAL – Portela & Ca, S.A.

Os restantes autores declaram não ter conflitos de interesse relacionados com o presente trabalho.

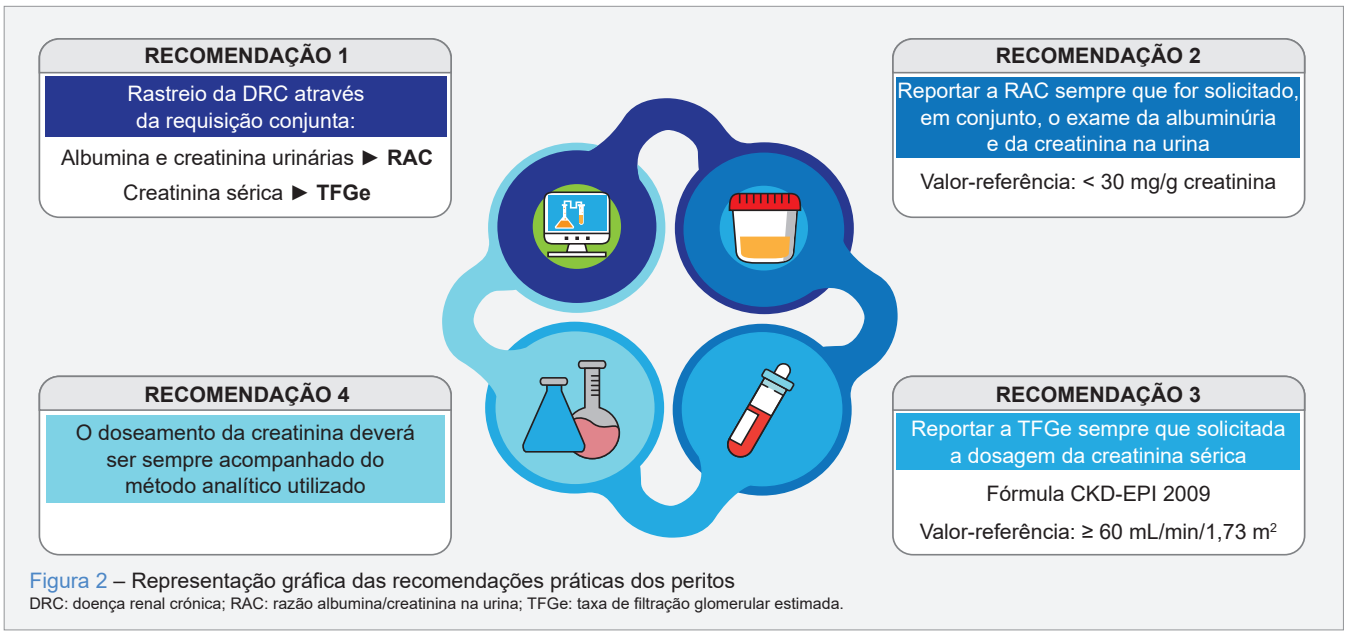

Figura 2 – Representação gráfica das recomendações práticas dos peritos
DRC: doença renal crónica; RAC: razão albumina/creatinina na urina; TFGe: taxa de filtração glomerular estimada.

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Metástases Cutâneas de Carcinoma de Células Renais: A Propósito de Dois Casos Clínicos

Cutaneous Metastases of Renal Cell Carcinoma: Report of Two Clinical Cases

Palavras-chave: Carcinoma de Células Renais; Neoplasias da Pele/secundárias; Neoplasias do Rim
Keywords: Carcinoma, Renal Cell; Kidney Neoplasms; Skin Neoplasms/secondary

As metástases cutâneas (MC) são manifestações raras da doença oncológica, presentes em menos de 10% dos casos de cancro metastático.[1-3] Embora o carcinoma de células renais (CCR) possa metastizar para vários órgãos, as MC de CCR são particularmente incomuns, ocorrendo em apenas 3% dos casos de CCR metastático,[3] mais frequentemente entre os seis meses e os cinco anos após o diagnóstico do tumor primário,[3] podendo ser o primeiro sinal de progressão sistémica.[1-4] Apresentam-se geralmente como nódulos eritematosos na região da cabeça e pescoço,[1-3] representando um desafio diagnóstico pela semelhança com lesões cutâneas benignas e malignas (ex.: hemangioma, granuloma piogénico, angiossarcoma, sarcoma de Kaposi).[1,3]

Descrevemos dois casos de MC em doentes com CCR de células claras (CCRcc) estádio IV, do sexo masculino, com 79 e 80 anos, respectivamente. No primeiro caso, um nódulo eritematoso na região periocular (Fig. 1A), que surgiu oito meses após o diagnóstico do tumor primário e quatro meses após suspensão de imunoterapia (ipilimumab + nivolumab) por hepatotoxicidade, foi excisado e o exame histopatológico (EH) revelou células claras com atipia. O doente faleceu cinco meses após a deteção da lesão cutânea. No segundo caso, um nódulo eritematoso malar esquerdo (Fig. 1B), que surgiu cinco anos após o diagnóstico do tumor primário, foi excisado e o EH foi compatível com MC de CCRcc com tumor presente na margem profunda. Verificou-se recidiva no local cirúrgico e progressão da doença visceral. O doente iniciou cabozantinib com resolução da lesão cutânea e permanece atualmente em seguimento multidisciplinar.

Estes casos ilustram a importância do diagnóstico precoce e da abordagem multidisciplinar de MC. A confirmação diagnóstica foi baseada no EH e na imunohistoquímica, que permitem diferenciar MC de outras lesões cutâneas. A marcação positiva para CK AE1/AE3, CD10 e anidrase carbónica IX, observada em ambos os casos, foi essencial para confirmar a origem metastática do CCRcc.[5]

As MC de CCR são um sinal de doença avançada, com um prognóstico reservado.[1,3,4] Apesar da sua raridade, devem ser consideradas em doentes oncológicos com lesões cutâneas atípicas. O tratamento consiste na excisão cirúrgica das MC e controlo da doença sistémica, destacando-se a necessidade de uma gestão coordenada entre as especialidades de dermatologia, oncologia e outras.[2,4] A referenciação precoce à dermatologia é crucial para melhorar o prognóstico destes doentes.

Com o aumento da incidência de neoplasias, é essencial que os médicos, especialmente oncologistas e médicos de família, estejam alertas para a apresentação atípica das MC, garantindo uma referenciação rápida e adequada.

CONTRIBUTO DOS AUTORES

MMC: Desenho do estudo, aquisição de dados, revisão da literatura, elaboração do manuscrito.

Figura 1 – Exame físico revelando um nódulo eritematoso, brilhante, friável, com cerca de 1 cm de diâmetro localizado externamente ao olho esquerdo (A); Exame físico revelando um nódulo eritematoso, brilhante, de 1 cm, com telangiectasias na região malar esquerda (B).

MVC: Revisão crítica do manuscrito.

RB: Aquisição de dados, revisão crítica do manuscrito.

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PROTEÇÃO DE PESSOAS E ANIMAIS

Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia da Associação Médica Mundial atualizada em outubro de 2024.

CONFIDENCIALIDADE DOS DADOS

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CONSENTIMENTO DO DOENTE

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Manutenção da Autonomia em Unidade de Cuidados Intensivos: Doentes que Votaram para as Eleições Legislativas em Portugal

Preserving the Autonomy in Intensive Care Units: Patients Voting for General Elections in Portugal

Palavras-chave: Autonomia Pessoal; Oxigenação por Membrana Extracorporal; Unidades de Cuidados Intensivos; Votação
Keywords: Extracorporeal Membrane Oxygenation; Intensive Care Units; Personal Autonomy; Voting

A autonomia e a vulnerabilidade constituem, juntamente com a dignidade e a integridade, os princípios bioéticos básicos a ser respeitados na prestação de cuidados de saúde, sendo referidos na Declaração de Barcelona.[1] Em unidades de cuidados intensivos (UCI), os doentes encontram-se frequentemente impossibilitados de cumprir as premissas subjacentes à definição de autonomia, como a capacidade de envolvimento político e responsabilidade pessoal. Frequentemente, mas não sempre.

O suporte por oxigenação por membrana extracorporal veno-venosa (ECMO V-V) é utilizado na insuficiência respiratória refratária à terapêutica convencional. Acordar estes doentes e promover a extubação precoce mitiga as complicações associadas à ventilação mecânica invasiva.[2] Este conceito (*awake* ECMO) apresenta benefícios para os doentes em ponte para transplante, como maior capacidade para a marcha e melhor função pulmonar, com estudos a mostrar superior taxa de sobrevida.[3]

Traz-se à consideração dos leitores o caso de dois doentes internados em UCI, que exerceram o seu direito de voto nas eleições legislativas portuguesas de março de 2024, de acordo com a lei em vigor (artigo 79-B, da Lei n.º 14/79, de 16 de maio, "Lei Eleitoral para a Assembleia da República").[4] Foi requerido o voto antecipado à Administração Eleitoral da Secretaria-Geral do Ministério da Administração Interna, justificada pelo médico assistente e pela direção hospitalar, com posterior deslocação duma equipa nomeada pela Comissão Nacional de Eleições para recolher o voto.

Um dos doentes, com 58 anos, encontrava-se sob suporte de ECMO V-V como ponte para transplante pulmonar por doença parenquimatosa difusa em adição a oxigenoterapia de alto fluxo. O outro doente, com 37 anos, internado há 41 dias por hemopneumotórax bilateral com ponto de partida em pneumonia cavitada, necessitou de suporte por ECMO V-V durante 25 dias, e à data da eleição encontrava-se ainda sob oxigenoterapia convencional por cânula de traqueostomia.

Os doentes em questão foram avaliados diariamente de forma multidisciplinar, incluindo a aplicação da escala *Confusion Assessment Method for Intensive Care Unit*, de forma a garantir a manutenção da vigília e da atenção. Nos dias próximos do voto, foi verificada sistematicamente a inexistência de quaisquer outros fatores que pudessem comprometer a tomada de decisão.

A humanização dos cuidados de saúde está cada vez mais presente no exercício da medicina. Incorpora a personalização da comunicação, empatia e compaixão, respeitando e promovendo os princípios bioéticos explicitados na Declaração de Barcelona. O presente artigo demonstra que os doentes particularmente vulneráveis podem exercer o seu direito de voto promovendo deste modo a autonomia, incluindo doentes em UCI.

CONTRIBUTO DOS AUTORES

ACR, MCC: Conceptualização e redação do manuscrito.

PGC, SCR: Conceptualização e revisão crítica do manuscrito.

PF: Revisão crítica do manuscrito.

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Os autores declaram ter seguido os protocolos do seu centro de trabalho acerca da publicação de dados.

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The Hidden Cost of Medical Training: Resident Burnout

O Custo Oculto da Formação Médica: *Burnout* em Médicos Internos

Keywords: Burnout, Professional; Internship and Residency; Portugal
Palavras-chave: Esgotamento Profissional; Internato e Residência; Portugal

Dear Editor,

We increasingly hear and read in the media that doctors are dissatisfied with their working conditions, but little is said about the specificities of resident doctors (RD), who provide a large part of the care in the Portuguese National Health Service. Moreover, there has never been so much talk about mental health and well-being as there is now.

Paradoxically, the study "*Avaliação do Burnout no Internato Médico Português – Relatório de Estudo Nacional 2023*", carried out by the Conselho Nacional do Médico Interno, reports worrying results that deserve attention: 55.3% of residents were at risk of developing burnout, and one in four had severe symptoms of the syndrome, with a prevalence of severe burnout more than three times higher than that of other Portuguese doctors.[1]

To understand this data, it is important to note that, in addition to their 40-hour working week, of which at least 12 hours are spent in the emergency department, RD have to carry out training or research activities outside of working hours. This means that they end up 'working' many more hours at 'home' in order to achieve the curricular goals. It is also worth reflecting on the basic gross salary of RD, which varies between €2078.11 and €2349.15,[2] and the lack of economic support for training activities, which is expensive. In a country where the salaries of RD are not adjusted to the rising cost of living and where they have to pay for their training activities, what inevitably happens is that they have to do paid overtime, sacrificing their quality, leisure, and rest time, creating the conditions for the onset of burnout syndrome.

The argument too often used that RD 'have to be more resilient and acquire coping mechanisms to address and prevent burnout' seems insufficient and counterproductive to help prevent it. As the World Health Organization[3] states, burnout is an occupational hazard and therefore needs to be addressed at a political, institutional, and organizational level, with a structural change in the residency schedule, the curriculum, and the integration of non-clinical activities into working time. Believing that this is an individual issue, as well as a personal 'weakness' is inadequate and perpetuates a serious situation.

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AUTHOR CONTRIBUTIONS

APC: Conceptualization, writing and critical review of the manuscript.

AMP: Critical review of the manuscript.

All authors approved the final version to be published.

COMPETING INTERESTS

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Carta ao Editor Referente a "Obesidade Infantil: A Realidade de um Centro de Saúde"

Letter to the Editor Concerning "Childhood Obesity: The Reality of a Health Center"

Palavras-chave: Criança; Obesidade Pediátrica
Keywords: Child; Pediatric Obesity

Caro Editor,

O artigo "Obesidade Infantil: A Realidade de um Centro de Saúde", publicado em 2011 na vossa revista, da autoria de Susana Branco *et al*, teve o objetivo de determinar a prevalência de excesso de peso/obesidade e identificar fatores de risco associados, numa população de crianças em idade pré-escolar de um Centro de Saúde da área de Famalicão. O estudo demostrou que a prevalência de excesso de peso e obesidade em crianças com idades entre os cinco e os seis anos foi de 46,9% e 28,5% respetivamente, ultrapassando claramente a tendência a nível nacional.[1]

Na nossa realidade, o excesso de peso/obesidade infantil é um dos problemas mais frequentemente identificados nas consultas e gerador de grande dificuldade na gestão e obtenção de resultados.

Apesar de ser uma problemática que aumentou significativamente nas últimas décadas, o estudo *Childhood Obesity Surveillance Initiative* da Organização Mundial da Saúde/Europa, refere que, entre 2008 e 2019, Portugal apresentou consistentemente uma tendência invertida da prevalência destas patologias em relação ao resto da Europa,[2] apresentando uma estabilização ou ligeira redução das taxas de obesidade infantil comparativamente a outros países europeus em que estas continuavam a aumentar.

Assim, se os valores presentes no estudo de Susana Branco *et al* eram alarmantes face aos valores a nível nacional e até em relação a outros países da Europa (que apontavam para uma prevalência de excesso de peso de 30%), à data de hoje, entende-se que o panorama mudou drasticamente e ter-se-á tornado ainda mais preocupante.

Efetivamente, em 2022, a prevalência de excesso de peso aumentou de 29,7% para 31,9%, e a de obesidade infantil de 11,9% para 13,5%, posicionando Portugal a par da média europeia (29%).[2]

Acrescenta-se que, apesar dos números nacionais apontarem para uma melhoria dos hábitos alimentares tanto das famílias como das escolas, também apontam para uma taxa mais elevada de sedentarismo paralela ao aumento do consumo de ecrãs,[2] exigindo uma reflexão sobre o impacto do uso destas tecnologias no escalar desta problemática.

Acreditamos, enquanto médicas, que as medidas preventivas serão fulcrais para fazer face a este problema, permitindo obter ganhos em saúde.[3] No entanto, tal como o estudo de Susana Branco *et al* aponta, os tutores e as escolas devem ser envolvidos em todo o processo, para que possamos ter maiores ganhos, maior consciencialização e maior sucesso na prevenção.[1]

Em particular, devemos começar por olhar para a obesidade infantil como uma doença crónica. Para isso, pode fazer sentido (tal como acontece para outras doenças, como a hipertensão arterial) organizar programas de vigilância periódica, com apoio da consulta médica e de nutrição, permitindo a estas crianças ter um acompanhamento mais atento e organizado.

CONTRIBUTO DOS AUTORES

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CONFLITOS DE INTERESSE

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Double Aortic Arch: The Importance of Computed Tomography Diagnosis

Duplo Arco Aórtico: A Importância do Diagnóstico por Tomografia Computadorizada

Keywords: Aorta, Thoracic/abnormalities; Aorta, Thoracic/diagnostic imaging; Computed Tomography Angiography
Palavras-chave: Angiografia por Tomografia Computorizada; Aorta Torácica/anomalias congénitas; Aorta Torácica/diagnóstico por imagem

Dear Editor,

The double aortic arch (DAA) is a congenital anomaly arising from abnormal embryogenesis, where the right segment of the fourth aortic arch fails to regress.[1] This results in two aortic arches, one on each side, often causing tracheal and esophageal compression.[2] Symptoms vary from mild to severe depending on the extent of obstruction. The right arch is typically dominant, but codominance is possible.[3]

A 77-year-old woman presented to the emergency department with severe dyspnea, thoracic discomfort, and postural instability. Pulmonary thromboembolism was initially suspected, but a computed tomography angiography (CTA) of the chest revealed DAA with codominant arches that slightly compressed the esophagus (Fig. 1); the trachea and bronchi remained patent. Other findings included cardiac enlargement, aortic and coronary atheromatosis, multiple bilateral ground glass opacities (pneumonia), small pleural effusions, and normal additional vascular structures in the mediastinum. She was treated with inhaled fenoterol and oral prednisone, improving her symptoms, and was started on levofloxacin. Follow-up with a pulmonologist and cardiologist was recommended.

Double aortic arch, the most common type of complete vascular ring, is usually diagnosed in childhood, often presenting with symptoms like stridor, vomiting, dysphagia, and breathing difficulties.[4] Asymptomatic cases may go undetected, being found incidentally in adulthood.[1] Adults may develop symptoms later in life due to reduced vascular compliance from aging, atherosclerosis, and hypertension.[1]

Adults with DAA symptoms, such as dyspnea and epigastric pain, face diagnostic delays, often receiving long-term symptomatic treatment instead.[5] Thoracic aorta CTA is the preferred diagnostic tool, providing high quality and high-resolution images, that can be reconstructed in multiple 2D and 3D planes.[1] In patients with dysphagia, retrosternal pain and pronounced epigastric symptoms, chest CT with positive oral contrast may help to detect esophageal compression, replacing esophagram technique, while tracheal compression can be identified with chest X-ray or CT scan.[2] Yang et al suggest combining echocardiography and CT for optimal preoperative evaluation.[4] Magnetic resonance imaging (MRI) is also useful for diagnosing vascular rings, as it is radiation-free and can detect associated congenital heart defects. But, in infants, its use is limited in symptomatic infants due to the need for anesthesia.[4]

Double aortic arch may coexist with other congenital anomalies, including DiGeorge syndrome, tetralogy of Fallot, ventricular septal defects, and truncus arteriosus.[1] Treatment depends on symptom severity. Patients with mild symptoms are managed conservatively,[1] as in the described case. However, severe cases with chronic wheezing, dyspnea, or dysphagia may require surgical intervention, which generally involves dividing the smaller arch.[4] It remains uncertain whether intrauterine intervention could prevent DAA.[4]

AUTHOR CONTRIBUTIONS

All authors contributed equally to this manuscript and approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

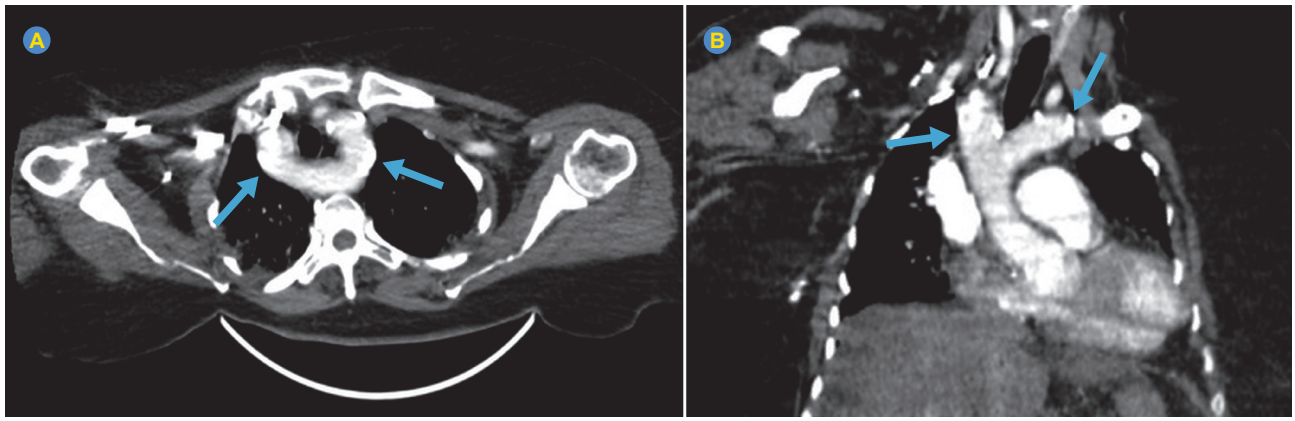

Figure 1 – 64-multislice CTA MIP images (7 mm) in axial (A) and coronal (B) demonstrating the double aortic arch (arrows) with a slight impression on the esophagus

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

PATIENT CONSENT

Obtained.

COMPETING INTERESTS

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How do Children Play Nowadays? Habits and Strategies for Promoting Healthy Development

Como é que as Crianças Brincam Hoje em Dia? Hábitos e Estratégias para Promover um Desenvolvimento Saudável

Keywords: Child Development; Child; Child Health; Health Promotion; Play and Playthings
Palavras-chave: Criança; Desenvolvimento da Criança; Jogos e Brinquedos; Promoção da Saúde; Saúde da Criança

Dear Editor,

Childhood is a crucial phase for physical, cognitive, emotional, and social development. Numerous studies highlight the importance of play in promoting healthy development.[1–3] In today's digital era, selecting suitable toys and managing screen time presents a challenge.

We conducted a study with the aim of understanding current play habits, assessing parental knowledge, and developing future community interventions. A survey was distributed to parents of preschool-aged children admitted to the pediatric ward of a tertiary hospital in Portugal over a six-week period in 2024. No ethics committee approval was required. The objectives and methods of the work were previously explained to the parents. The first question on the questionnaire was parental consent and the data was collected anonymously, without any possibility of identifying the children or their parents. The collected data was not sensitive.

The study included 65 children, with a well-distributed sample in terms of sex (52% female, 48% male) and age (mean of 3.41 years; standard deviation of 1.80 years). Most children attended daycare (65%), while 22% were cared for by parents, and 8% by grandparents. Caregivers were predominantly in their mid-thirties to early forties, with 65% holding higher education degrees. Almost half (49%) of the children had no siblings.

The findings showed that 68% of children owned more than 20 toys, and 71% had toys with sensory-overstimulating features (e.g., sounds, lights, fast animations). Evidence suggests that fewer, simpler, and more versatile toys encourage longer playtime and foster deeper, more imaginative exploration.[1] Parental involvement in play is essential for bonding, modeling behavior, stimulating cognitive and language development, and problem-solving skills. Still, 45% of parents reported spending less than an hour per day playing with children, underscoring the need for strategies that encourage parental engagement and offer practical ways to integrate play into routines. Furthermore, 29% of children lacked access to outdoor areas, which is essential for developing motor skills, increasing physical activity, and promoting mental well-being and social interaction.[2]

Regarding screen time, the American Academy of Pediatrics (AAP) recommends no screen exposure for children < 24 months, and limits screen time for ages 2 - 5 to one hour per day of high-quality content, with parental supervision.[4] In 2024, the Portuguese Society of Neuropediatrics (SPNP) published more stringent recommendations, advising against screen use for children < 3 years, except for supervised video calls, and limiting to 30 minutes per day of high-quality content for children aged 4 - 6 years, always under adult supervision. Furthermore, the SPNP advises

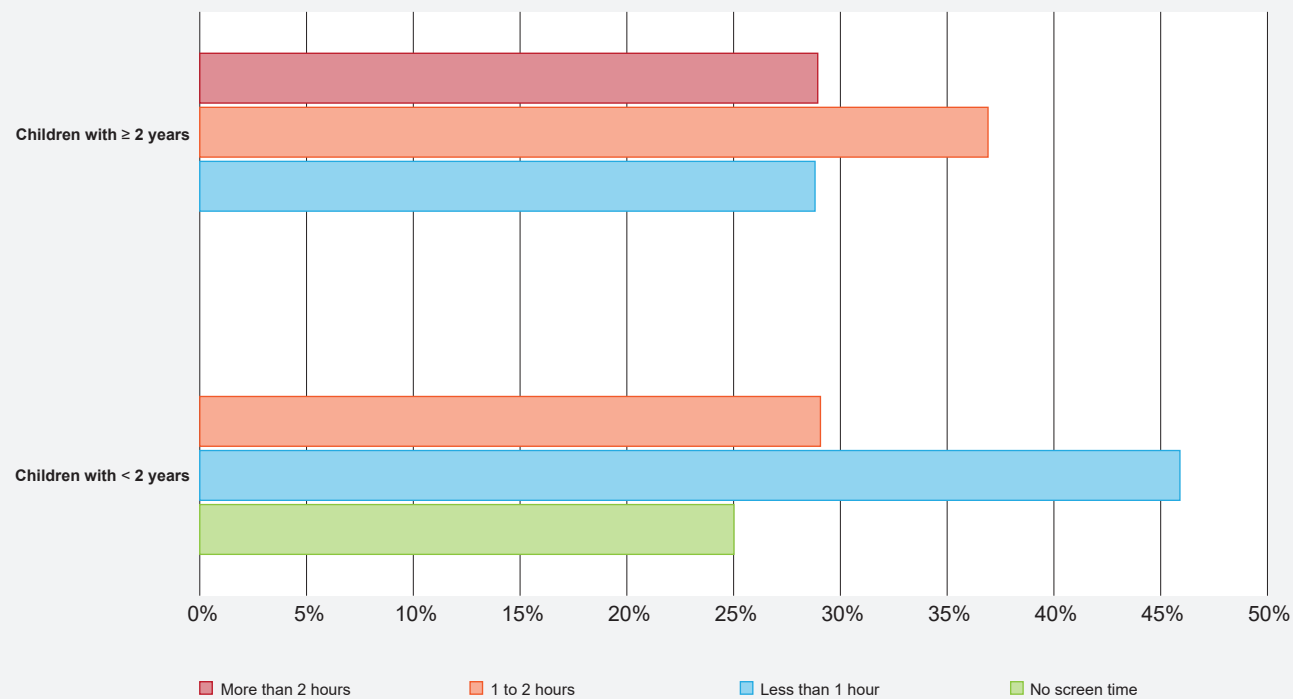

Figure 1 – Screen time distribution among children by age group: < 2 years and ≥ 2 years

that screens should not be used at any age to facilitate meals, manage waiting times (that is, keeping the children entertained while waiting in a queue, a medical appointment or other similar contexts), or control tantrums.[5] In our study, 73% of the children exceeded AAP guidelines recommendations (Fig. 1), raising concerns about the potential negative impact on cognitive and linguistic development, as well as an increased risk of obesity. In 51% of cases, consistent supervision was lacking. Screen time was more frequent among children with educated caregivers (88%), cared for by grandparents (80%), and with siblings (94%). Finally, parental knowledge assessments revealed some misconceptions: 25% believed that more toys led to better development, and 40% thought that overstimulating toys were more beneficial than simpler ones.

These findings underscore the need for community interventions. Potential strategies could include educational seminars for parents (pediatric hospitalization presents a valuable opportunity), collaborations with daycare centres, public awareness campaigns (through social media, podcasts or radio), and pediatrician/family doctor involvement during routine well-child clinics.

PREVIOUS AWARDS AND PRESENTATIONS

This work was previously presented in the form of a poster with discussion at *Congresso Nacional de Pediatria*.

AUTHOR CONTRIBUTIONS

MFS: Study design, data collection and analysis, writing of the manuscript.

ACP: Survey development, data collection, critical review of the manuscript.

MB: Critical review of the manuscript.

MAR: Study conception and design, survey development, critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in October 2024.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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