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PRECLINICAL VALIDATION OF SIDA RHOMBIFOLIA L. (MALVACEAE) FOR ANTIDIARRHEAL USE: METHODOLOGICAL FRAMEWORK AND EXPECTED OUTCOMES

Ombouma Joanna Grace Génia [1]

Iradukunda Sengesho Benigne2

Nizeyimana Jean Baptiste3

1. Joint Reseacher at Lisala University and UNCR University, Department of Quality, Health, Safety& Environment
2. Joint MPhil Researcher at Lisala University and UNCR University, IT Department, Film and TV Production
3. Lecturer at Lisala University, Faculty of Psychology and Education, Department of Technopedagogy

ABSTRACT

The scientific validation of medicinal plants is essential for their safe and effective integration into healthcare systems. This article presents the methodological framework for the preclinical validation of Sida rhombifolia L. (Malvaceae) for antidiarrheal use in Gabon. The research comprises four complementary components: an ethnopharmacological survey to document traditional uses; phytochemical analysis to identify bioactive compounds; biological activity

[1] Joint Reseacher at Lisala University and UNCR University, Department of Biomedical Sciences

testing to assess antimicrobial, antispasmodic, anti-inflammatory, and antioxidant activities; and toxicity assessment to evaluate safety. The expected outcomes include a comprehensive profile of the plant's traditional uses, phytochemical composition, biological activities, and safety margin. The article discusses the ethical considerations, including informed consent, authorization from relevant authorities, respect for traditional knowledge, and animal welfare standards. The methodological framework is designed to generate robust, reproducible evidence that can support the development of a standardized phytomedicine for the complementary treatment of diarrhea in Gabon.

Keywords: Sida rhombifolia, preclinical validation, antidiarrheal activity, phytochemistry, toxicity assessment, Gabon.

RÉSUMÉ

La validation scientifique des plantes médicinales est essentielle pour leur intégration sûre et efficace dans les systèmes de santé. Cet article présente le cadre méthodologique pour la validation préclinique de Sida rhombifolia L. (Malvaceae) pour l'usage antidiarrhéique au Gabon. La recherche comprend quatre composantes complémentaires : une enquête ethnopharmacologique pour documenter les utilisations traditionnelles ; une analyse phytochimique pour identifier les composés bioactifs ; des tests d'activité biologique pour évaluer les activités antimicrobienne, antispasmodique, anti-inflammatoire et antioxydante ; et une évaluation de la toxicité pour évaluer la sécurité. Les résultats attendus comprennent un profil complet des utilisations traditionnelles de la plante, de sa composition phytochimique, de ses activités biologiques et de sa marge de sécurité. L'article discute des considérations éthiques, y compris le consentement éclairé, les autorisations des autorités compétentes, le respect des savoirs traditionnels et les normes de bien-être animal. Le cadre méthodologique est conçu pour générer des preuves robustes et reproductibles qui peuvent soutenir le développement d'une phytomédecine standardisée pour le traitement complémentaire de la diarrhée au Gabon.

Mots-clés : Sida rhombifolia, validation préclinique, activité antidiarrhéique, phytochimie, évaluation de la toxicité, Gabon.

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Auteurs correspondant: *Ombouma Joanna Grace,Iradukunda Sengesho Benigne and Nizeyimana Jean Baptiste*
Adresses électroniques: *omboumajoannagrace@cirep.ac.cd,benigneira0@gmail.com, nizeyimana.jb@dphu.ac.cd ,*
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1. INTRODUCTION

The scientific validation of medicinal plants is essential for their safe and effective integration into healthcare systems. The World Health Organization (2022) has emphasized the importance of evidence-based traditional medicine, calling for rigorous research to validate the efficacy and safety of traditional remedies.

This article presents the methodological framework for the preclinical validation of Sida rhombifolia L. (Malvaceae) for antidiarrheal use in Gabon. The research is designed to generate robust, reproducible evidence that can support the development of a standardized phytomedicine for the complementary treatment of diarrhea.

The article is organized as follows. Section two presents the research components. Section three discusses the data analysis methods. Section four addresses ethical considerations. Section five presents the expected outcomes. Section six concludes.

2. RESEARCH COMPONENTS

2.1 Ethnopharmacological Survey

The ethnopharmacological survey aims to document the traditional uses of Sida rhombifolia in Gabon. The survey will be conducted in areas where the plant is known to be used, including rural and peri-urban communities.

Data collection will involve semi-structured interviews with traditional healers, community elders, and other knowledgeable individuals. The interview guide will cover the plant parts used, preparation methods, dosage, duration of treatment, indications, contraindications, and perceived efficacy.

The sample will include a purposive sample of participants with knowledge of the traditional use of Sida rhombifolia. The sample size will be determined by saturation, with data collection continuing until no new information emerges.

Data analysis will involve descriptive statistics, including frequencies and percentages, to characterize the traditional uses. Qualitative data will be analyzed using thematic content analysis.

2.2 Phytochemical Analysis

The phytochemical analysis aims to identify and quantify the bioactive compounds in Sida rhombifolia. Plant material will be collected from multiple sites to account for geographic variation.

Extracts will be prepared using different solvents (water, ethanol, methanol) to mimic traditional preparations and to capture a broad range of compounds. Standard phytochemical screening methods will be used to detect the presence of alkaloids, flavonoids, tannins, saponins, steroids, terpenoids, and phenolic compounds.

Quantitative analysis will be conducted using high-performance liquid chromatography or gas chromatography-mass spectrometry to measure the concentration of specific compounds. The analysis will be repeated on multiple batches to assess consistency.

2.3 Biological Activity Testing

The biological activity testing aims to assess the antimicrobial, antispasmodic, anti-inflammatory, and antioxidant activities of Sida rhombifolia.

Antimicrobial activity will be assessed using the agar diffusion method and the broth microdilution method to determine minimum inhibitory concentrations. The test panel will include diarrheal pathogens, including Escherichia coli, Shigella dysenteriae, Salmonella typhimurium, and Staphylococcus aureus.

Antispasmodic activity will be assessed using isolated rat ileum. The effect of Sida rhombifolia extracts on spontaneous contractions and on contractions induced by acetylcholine, histamine, and potassium chloride will be evaluated.

Anti-inflammatory activity will be assessed using the carrageenan-induced paw edema model in rats. The effect of Sida rhombifolia extracts on paw volume will be measured at regular intervals.

Antioxidant activity will be assessed using the DPPH radical scavenging assay and the ferric reducing antioxidant power assay.

2.4 Toxicity Assessment

The toxicity assessment aims to evaluate the safety of Sida rhombifolia. Acute toxicity will be assessed according to the OECD guidelines. A single dose of Sida rhombifolia extract will be administered orally to rats, and the animals will be observed for 14 days for signs of toxicity and mortality.

Subacute toxicity will be assessed by administering Sida rhombifolia extract daily for 28 days. Clinical signs, body weight, food consumption, hematological parameters, biochemical parameters, and organ weights will be monitored. Histopathological examination of major organs will be conducted.

Genotoxicity will be assessed using the Ames test for bacterial reverse mutation and the micronucleus test for chromosomal damage.

3. DATA ANALYSIS

Data will be analyzed using appropriate statistical methods. For the ethnopharmacological survey, data will be analyzed using frequencies and percentages. For the phytochemical analysis, data will be expressed as mean ± standard deviation. For the biological activity testing, data will be expressed as mean ± standard deviation, and comparisons between groups will be made using analysis of variance followed by post-hoc tests. For the toxicity assessment, data will be expressed as mean ± standard deviation, and comparisons between groups will be made using analysis of variance. A p-value of less than 0.05 will be considered statistically significant.

4. ETHICAL CONSIDERATIONS

The research will be conducted in accordance with international ethical guidelines. Informed consent will be obtained from all participants in the ethnopharmacological survey. The purpose of

the research will be explained, and participants will be assured of their right to withdraw at any time.

Authorization to conduct the research will be obtained from the relevant national and local authorities. The research will respect traditional knowledge and will involve traditional healers as partners rather than merely as subjects.

For the animal studies, approval will be obtained from the institutional animal care and use committee. The animals will be housed under standard conditions and will receive humane care. All procedures will be designed to minimize pain and distress.

5. EXPECTED OUTCOMES

The expected outcomes of the research include a comprehensive profile of the traditional uses of Sida rhombifolia in Gabon; a detailed phytochemical profile of the plant, including the identification and quantification of bioactive compounds; evidence of antimicrobial, antispasmodic, anti-inflammatory, and antioxidant activities; a safety profile, including the acute and subacute toxicity and genotoxicity; and a standardized extract for further development.

These outcomes will provide the scientific evidence needed to support the development of a standardized phytomedicine for the complementary treatment of diarrhea in Gabon. The research will also contribute to the preservation and valorization of traditional knowledge and will support the integration of traditional medicine into the formal healthcare system.

6. CONCLUSION

This article has presented the methodological framework for the preclinical validation of Sida rhombifolia for antidiarrheal use in Gabon. The research comprises four complementary components: an ethnopharmacological survey, phytochemical analysis, biological activity testing, and toxicity assessment. The expected outcomes include a comprehensive profile of the plant's traditional uses, phytochemical composition, biological activities, and safety margin. The research is designed to generate robust, reproducible evidence that can support the development of a standardized phytomedicine for the complementary treatment of diarrhea in Gabon.

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