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Identification by HPLC of Undeclared Active Ingredients in Aphrodisiac Teas and Coffees Sold in Kinshasa and Kisangani (DRC)

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ABSTRACT

Introduction

This study aims to identify the presence of undeclared active ingredients in aphrodisiac products sold as teas and coffees in Kinshasa and Kisangani (DRC). Sexual dysfunction is widespread, and many individuals in the Democratic Republic of the Congo rely on aphrodisiac teas and coffees. However, their unregulated nature raises concerns about adulteration with undeclared substances (sildenafil and tadalafil) and potentially harmful compounds (aristolochic acid), posing significant health risks.

Purpose

To detect, by HPLC, the presence of PDE-5 inhibitors (sildenafil, tadalafil) and toxic compounds (aristolochic acid) in aphrodisiac products marketed without regulation.

Methods

Nine samples, including seven from Kinshasa and two from Kisangani, were analysed by HPLC after sample-preparation protocols adapted from validated studies.

Results

Sildenafil was detected in 9/9 products and tadalafil in 8/9; traces of aristolochic acid were identified in two products. Quantitative variation suggests deliberate adulteration.

Conclusion

These products contain undeclared and potentially harmful substances, posing a significant health risk such as cardiovascular complications, drug interactions, and possible carcinogenic effects, underscoring the urgent need for stricter regulation.

INTRODUCTION

Male sexual dysfunction is increasingly managed using aphrodisiac products marketed as teas or dietary supplements, particularly in Central Africa. In the Democratic Republic of Congo (DRC), Kinshasa and Kisangani were selected as study sites due to their large populations, vibrant informal markets, and widespread consumption of herbal and aphrodisiac products. Kinshasa, the capital city, is home to over 14 million inhabitants and represents the largest commercial hub of the DRC (United Nations, 2022). The informal pharmaceutical and herbal product trade is particularly active in this city, with previous studies reporting the circulation of unregulated aphrodisiac products (Kayembe et al., 2014). Kisangani, the third-largest city with an estimated 1.6 million inhabitants, is an important regional trading center in the northeast of the country, where herbal medicine plays a critical role in primary healthcare (Mukonzo et al., 2021). Sampling in both cities allowed comparison between a mega-city and a regional urban center, thereby providing a broader representation of the market, where such products are widely sold without regulatory oversight.

Several studies have reported the presence of phosphodiesterase-5 (PDE5) inhibitors, such as sildenafil and tadalafil, in these products (Baume et al., 2006; Vaclavik et al., 2014). Scientific literature also reports severe complications linked to the uncontrolled use of these compounds (Kaufman et al., 2003; El Zahran et al., 2016). Simultaneously, the adulteration of herbal products for their supposed aphrodisiac and therapeutic properties is known to introduce toxic substances, including aristolochic acid, which has been documented in Asia and Africa (Debelle et al., 2008; Grollman & Shibutani, 2010). According to the World Health Organization (2017), the use of unregulated herbal aphrodisiacs exposes consumers to major health risks. Despite international bans, their continued use in uncontrolled herbal products raises serious concerns about possible contamination or adulteration of aphrodisiac products sold in informal markets.

Although several studies worldwide have reported the adulteration of dietary supplements and herbal aphrodisiacs with undeclared PDE5 inhibitors or aristolochic acid (Arlt et al., 2011; Baume et al., 2006; Vaclavik et al., 2014), data from Central Africa remain scarce. In the DRC, where informal markets dominate access to such products, there is little systematic evidence on their chemical composition or safety. Previous investigations in Africa have mainly focused on general quality issues of herbal medicines (Kagoya et al., 2022) but have not provided detailed analytical confirmation of adulteration with sildenafil, tadalafil, or aristolochic acid in commonly consumed aphrodisiac teas and coffees. This study therefore addresses a critical knowledge gap by applying validated high-performance liquid chromatography (HPLC) methods to identify and quantify these substances in products sold in Kinshasa and Kisangani, providing the first systematic evidence of such adulteration in the DRC.

METHODS

Study Design and Study Sites

Nine samples of aphrodisiac teas and coffees were collected from popular markets in Kinshasa (n = 7) and Kisangani (n = 2), DRC. A convenience sampling strategy was employed, targeting products labeled as natural aphrodisiacs and readily available to the general public. Selection criteria included diversity in brand, packaging, and type (tea or coffee). All samples were purchased anonymously without involving human subjects. Ethical approval was obtained from the University of Kisangani Ethics Committee (Ref: UNIKIS/CER/022/2024) for the acquisition and analysis of commercially available herbal products.

Chemicals and Reagents

- Standards: Sildenafil, tadalafil, aristolochic acid I
- Solvents: Acetonitrile, methanol
- Buffer components: Ammonium formate, hydrochloric acid

All reagents were analytical grade and used without further purification.

Materials

C18 column (250 × 4.6 mm, 5 µm), HPLC system with UV detector at 254 nm, and 0.45 µm filters.

Sample Preparation and Validation

Each sample (200 mg) was dissolved in 5 mL of acetonitrile, sonicated for 10 minutes, and filtered through a 0.45 µm

PTFE membrane filter. Validation parameters were as follows:

- Limit of Detection (LOD): 0.001 mg/g for sildenafil, tadalafil, and aristolochic acid I
- Limit of Quantification (LOQ): 0.003 mg/g
- Recovery: 95–102%
- Precision: Relative standard deviation (RSD) < 5% intra-day and inter-day

Validation confirmed the method's reliability, accuracy, and sensitivity for detecting low-level adulteration.

Chromatographic Analysis

- HPLC analysis was performed using a C18 column (250 × 4.6 mm, 5 µm) with a UV detector at 254 nm.
- Mobile phase: Gradient elution with acetonitrile and pH 3.8 ammonium formate buffer
- Flow rate: 1 mL/min
- Injection volume: 10 µL
- Column temperature: 25°C

Quantification and Statistical Analysis

- Peak integration and quantification were performed using Chromeleon v7.3 (Thermo Scientific).
- Mass percentages of analytes were calculated relative to the net weight of each sample.
- Statistical analyses, including mean, standard deviation, and RSD, were conducted with GraphPad Prism 9.5.

Units and Reporting

All concentrations are expressed in mg/g or % w/w. Decimal points are used consistently, volumes in mL, masses in mg, and concentrations in mg/g or % w/w.

RESULTS

Detected Analyte Concentrations

HPLC analysis revealed the presence of sildenafil, tadalafil, and aristolochic acid I in the aphrodisiac tea and coffee samples. All concentrations are expressed in mg/g for consistency.

Detection and Regulatory Limits

- Limit of Detection (LOD): 0.001 mg/g
- Limit of Quantification (LOQ): 0.003 mg/g
- Sildenafil/tadalafil: prohibited in herbal products sold without a prescription
- Aristolochic acid: banned in the EU and USA, no safe concentration authorized

Table 3:
Detected Analyte Concentrations in Samples (mg/g)

Sample	Aristolochic Acid I *(mg/g)*	Sildenafil *(mg/g)*	Tadalafil *(mg/g)*
Control	0.01	0.01	0.01
B01	ND	0.6786	0.4588
B02	ND	0.5654	0.8594
B03	ND	16.6197	15.9706
B04	0.0217	0.3145	0.4593
B05	ND	0.8784	0.3484
B06	ND	0.8272	ND
B07	0.0476	2.1481	0.9293
B08	ND	18.5071	14.0012
B09	ND	1.933	1.6001

ND = Not detected

Measurement Confidence

All measurements were performed in triplicate, and standard deviations (SD) were calculated:

Table 4:
PDE5 Inhibitor Concentrations with Standard Deviation (mg/g ± SD)

Sample	Sildenafil *(mg/g ± SD)*	Tadalafil *(mg/g ± SD)*
B01	0.679 ± 0.012	0.459 ± 0.010
B02	0.565 ± 0.009	0.859 ± 0.015
B03	16.620 ± 0.345	15.971 ± 0.298
B04	0.315 ± 0.007	0.459 ± 0.009
B05	0.878 ± 0.016	0.348 ± 0.008
B06	0.827 ± 0.015	ND
B07	2.148 ± 0.041	0.929 ± 0.018
B08	18.507 ± 0.370	14.001 ± 0.280
B09	1.933 ± 0.038	1.600 ± 0.032

Interpretation of Results

The results indicate that most samples contained undeclared PDE5 inhibitors.

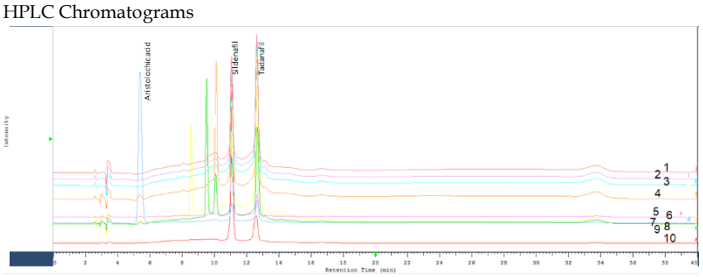
- **Sildenafil:** detected in all samples except B04, with concentrations ranging from 0.565 to 18.507 mg/g, some exceeding the therapeutic dose of a Viagra® tablet (25–100 mg/dose) (Pfizer, 2020).

- **Tadalafil:** absent only in B06, present in other samples at 0.348–14.001 mg/g, corresponding to pharmacologically active doses (Eli Lilly and Company, 2020).
- **Aristolochic Acid I:** detected in B04 and B07 (0.0217–0.0476 mg/g). Even at these low levels, aristolochic acid is toxic and carcinogenic, posing cumulative health risks (Debelle et al., 2008; Grollman & Shibutani, 2010).

Samples B03, B08, and B09 showed the highest concentrations of sildenafil and tadalafil, capable of delivering therapeutic doses if consumed according to traditional usage. The simultaneous presence of sildenafil and tadalafil in some samples could lead to additive or unpredictable pharmacodynamic effects (Pawar & Grundel, 2017).

HPLC Chromatograms of Aphrodisiac Tea and Coffee Samples

Figure 1:
HPLC Chromatograms



- X-axis: Retention time (min)
- Y-axis: Peak area (UA)
- Codes: Control (standard), B01–B09 (samples)

Peaks indicate the presence of sildenafil, tadalafil, and aristolochic acid I, allowing comparison of relative concentrations among samples.

DISCUSSION

Summary of Principal Findings

This study identified undeclared pharmacologically active substances in aphrodisiac teas and coffees sold in Kinshasa and Kisangani. Sildenafil and tadalafil were present in most samples at concentrations ranging from 0.565 to 18.507 mg/g and 0.348 to 15.970 mg/g, respectively, while aristolochic acid I was detected in two samples at low but potentially harmful levels (0.0217–0.0476 mg/g). These results indicate widespread adulteration of products marketed as natural, posing serious health risks to consumers (El Zahran et al., 2016; Chen et al., 2013).

Comparison with Therapeutic Doses

The concentrations of sildenafil and tadalafil detected in several samples are comparable to standard pharmaceutical doses: sildenafil tablets (Viagra®) typically contain 25–100 mg per dose, while tadalafil tablets (Cialis®) contain 5–20 mg per dose (Pfizer, 2020; Eli Lilly and Company, 2020). For example, consuming 1 g of sample B08 could deliver 18.5 mg of sildenafil and 14 mg of tadalafil, approaching or exceeding a single therapeutic dose. Such unregulated exposure can cause hypotension, cardiovascular complications, and adverse drug interactions, especially in hypertensive or cardiac patients (El Zahran et al., 2016; Chen et al., 2013).

Sources of Adulteration

The presence of PDE5 inhibitors may reflect deliberate adulteration to enhance the perceived efficacy of natural aphrodisiacs, consistent with findings in other African and European surveys (Avula et al., 2009; de la Torre et al., 2020). In contrast, aristolochic acid I may result from either contamination or intentional inclusion of Aristolochia plant material, known for traditional medicinal use despite its nephrotoxic and carcinogenic properties (Debelle et al., 2008; Grollman & Shibutani, 2010). The variability in concentrations suggests inconsistent manufacturing practices rather than accidental contamination alone.

Public Health and Policy Implications

These findings underscore a major public health concern in the DRC, where herbal aphrodisiacs are widely consumed without quality control. Regulatory frameworks for natural health products remain weak, allowing unauthorized inclusion of potent pharmaceuticals and toxic compounds.

To mitigate risks, the DRC could:

1. Implement routine screening of herbal products for PDE5 inhibitors and known toxins using HPLC or LC-MS methods.
2. Establish clear labeling and advertising regulations to prevent misleading health claims.
3. Educate consumers and traditional vendors on the dangers of undeclared pharmaceuticals and toxic plant components.

4. Strengthen collaboration between the Ministry of Health, pharmacovigilance authorities, and research laboratories to enforce standards comparable to international guidelines (WHO, 2019).

Limitations

This study has some limitations. First, the sample size was small (n = 9) and only included products from two cities, limiting generalizability. Second, the analysis targeted only sildenafil, tadalafil, and aristolochic acid I, while other undeclared or toxic compounds could be present. Finally, triplicate analyses provide a measure of analytical precision but may not fully capture batch-to-batch variability.

Mechanistic and Safety Considerations

Unregulated exposure to PDE5 inhibitors can trigger pharmacodynamic interactions, especially when sildenafil and tadalafil are present simultaneously, increasing the risk of adverse cardiovascular events (Pawar & Grundel, 2017). Even trace amounts of aristolochic acid I can contribute to cumulative nephrotoxicity and urothelial malignancy (IARC, 2002; Grollman & Shibutani, 2010). These mechanisms reinforce the urgent need for regulatory oversight, routine analytical testing, and consumer awareness.

CONCLUSION

Aristolochic acid, as well as PDE5 inhibitors (sildenafil and tadalafil), were detected in aphrodisiac teas and coffees sold in Kinshasa and Kisangani, DRC. Sildenafil and tadalafil were present in most samples at concentrations approaching therapeutic doses, while traces of aristolochic acid were found in two products, highlighting potential nephrotoxic and carcinogenic risks. These findings indicate that products marketed as natural aphrodisiacs may contain undeclared and potentially harmful compounds, posing a significant public health threat. To mitigate these risks, it is essential to implement mandatory laboratory testing of aphrodisiac products, enforce clear labeling requirements, and establish a robust regulatory framework with systematic quality control, including periodic inspections and enforcement mechanisms. Public awareness campaigns should complement these measures to inform consumers about the potential dangers of unregulated aphrodisiac products (WHO, 2019).

Ethical Approval: Ethical approval for this study was obtained from the University of Kisangani (UNIKIS/CER/022/2024).

Conflicts of Interest: None declared.

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