



# SRI SIVANI COLLEGE OF PHARMACY

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## Using the Adverse Drug Event Report Database, we analyzed prednisolone-induced osteoporosis.

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### ABSTRACT –

**Purpose:** Osteoporosis is an adverse event of prednisolone. This study aimed to assess prednisolone-induced osteoporosis (PIO) profiles and patient backgrounds by analyzing data from the Japanese Adverse Drug Event Report (JADER) database.

**Methods:** The current study focused only on orally administered prednisolone. PIO was defined using preferred terms from the Medical Dictionary for Regulatory Activities. Reporting odds ratio (ROR) at 95% confidence interval (CI) and the time-to-onset profile of PIO were used to evaluate adverse events.

**Results:** The RORs (95% CI) of the female and male subgroups were 4.73 (4.17–5.38) and 2.49 (2.06–3.00), respectively. The analysis of time-to-onset profiles demonstrated that the median values (interquartile range: 25.0–75.0%) of PIO were 136 (74.0–294.0). The prednisolone treatment duration was significantly longer in the PIO patient group than in the non-PIO patient group. The findings suggest that patients with rheumatoid arthritis, systemic lupus erythematosus, and nephrotic syndrome receiving prednisolone have different age-related PIO profiles.

**Conclusions:** Our results suggest that longer prednisolone treatment duration and larger cumulative dose might be risk factors of PIO. The potential risk for PIO should not be overlooked, and careful observation is recommended.

### INTRODUCTION

Glucocorticoids are widely used to treat diseases including asthma, rheumatoid arthritis (RA), nephrotic syndrome, and systemic lupus erythematosus (SLE). Osteoporosis is a disease in which bone metabolism is lost, and fractures caused by falling or sneezing are readily revealed, as evidenced by their occurrence in as many as 30–50% of patients receiving glucocorticoid therapy (1). Prednisolone-induced osteoporosis (PIO) is the

most common and serious form of secondary osteoporosis (1) and can have a significant social impact on individuals and reduce their quality of life. Therefore, appropriate clinical care is required for this condition. Various risk factors contribute to osteoporosis, including age, sex, RA, glucocorticoid therapy, and most notably, prednisolone administration.

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## PHARMACOGNOSTICAL AND PRELIMINARY PHYTOCHEMICAL EVALUATION OF ROOT OF *ECBOLIUM VIRIDE* [FORSK.] ALSTON.

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### ABSTRACT

In ethnomedicinal practices the traditional healers use the roots of *Ecbolium viride* in the treatment of various ailments. Scientific information on their pharmacognosy is very scant. Scientific parameters are not yet available to identify the true plant material and to ensure its quality. Therefore the present work has been undertaken to establish preliminary phytochemical profile and the necessary pharmacognostic standards for evaluating the plant material. Various parameters like morphology, microscopy, powder analysis, fluorescence characteristics and physico-chemical constants of the roots were studied and the salient diagnostic features are documented. Obvious morphological features and the microscopic characteristics were found in the tissue structures of the roots, many diagnostic elements and preliminary phytochemical profile were found to be useful evidences for further scientific investigations of this medicinal plant.

**KEYWORDS:** *Ecbolium viride*, Ethnomedicine, Microscopy, Pharmacognostical Parameters, Preliminary Phytochemical.

### INTRODUCTION

*Ecbolium viride* (Forsk.) Alston. (Acanthaceae) locally known as "Nilambari", is a perennial woody undershrub found occasionally in plain soil in India and also found in Arabia, Sri Lanka and tropical Africa. In folk medicine, aqueous extract of dried roots of the plant are used for menorrhagia, rheumatism and jaundice (Datta and Maiti, 1968; Kirtikar and Basu, 1987). The rural people in Tirunelveli district of Tamil Nadu are used juice of the root of this plant to the treatment of jaundice by the vaidhyars. Most of the cases of accidental herbal medicine misuse start with wrong identification of a medicinal plant prescribed. Many of the traditional systems have records where one common vernacular is supplied in place of two or more entirely different species. However, no scientific parameters are available to identify the true plant material and to ensure its quality. For this all reasons we take a plant to bring out an official manner by the through investigation on this plant such as pharmacognostical and phytochemical studies of roots of *Ecbolium viride*, which could serve as a valuable source of information and provides suitable standards for the future identification of this plant.

### MATERIALS AND METHODS

#### Plant materials

Fresh plant was collected from Wastelands of Kadyanallur, Tirunelveli (District), Tamil Nadu, India. The plant specimen was authenticated by Dr. P. Jayaraman, M.Sc., Ph.D, Plant Anatomy Research Centre (PARC), Chennai Tamil Nadu, India (Voucher specimen No. PARC/2008/495). All the reagents used were of analytical grade obtained from Sigma Chemical Co., St. Louis, USA or Fine Chemicals Ltd., Mumbai, India.

#### Collection of Specimens

The roots of this plant were cut and removed from the plant and fixed in FAA (Formalin 5ml + Acetic acid 5ml + 70% Ethyl alcohol 90ml) for histological studies; transverse sections (T.S) of the different organs of the plant material. After 24 hours of fixing, the specimens were dehydrated with graded series of tertiary-butyl alcohol (TBA) as per the schedule given by Sass, 1940. Infiltration of the specimens was carried out by gradual addition of paraffin wax (melting point 58-68°C) until TBA solution attained supersaturation. The specimens were cast into paraffin blocks.

#### Sectioning

The paraffin embedded specimens were sectioned with the help of rotary microtome. The thicknesses of the sections were 10-12 µm. Dewaxing of the sections was performed by customary procedure (Johansen, 1940). The sections were stained with toluidine blue as according to the method prescribed by O'Brien *et al.*, 1964. Wherever necessary, the sections were also stained with saffranin and Fast-green. The microphotographs of these sections were made using Olympus BX 40 microscope attached with Olympus DP12 digital camera.

# Phytochemicals and antioxidants in leaf extracts of *Ginkgo biloba* with reference to location, seasonal variation and solvent system

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## ABSTRACT

**Aims:** To determine the influence of location, seasonal variation and solvent system in production of phytochemicals and antioxidants from ginkgo leaves.

**Methods:** Total phenolic and flavonoid contents and antioxidant activity in ginkgo leaf extracts were estimated spectrophotometrically. Factorial analysis was performed to correlate the influence of location, season and solvent on production of phytochemicals and antioxidants.

**Results:** Total phenolic and flavonoid contents as well as the antioxidants were estimated maximum in autumn. Among solvents, acetone/water extracts gave best results for phenolic and flavonoid contents while methanolic extracts were best for antioxidants. Phenolic content, the predominant indicator of phytochemicals, showed significant correlation with antioxidant activity.

**Conclusion:** Factorial analysis among location, season and solvent with respect to the phytochemicals and antioxidants, was found to be statistically significant. Presence of phytochemicals along with the protective feature in the form of antioxidants is indicative of the importance of this species in pharmacological industry.

**Keywords:** *Ginkgo biloba* (ginkgo) Phytochemicals Phenolics Antioxidants Indian Himalayan Region (IHR)

## 1. Introduction

Medicinal plants are known potential source of many phenolic compounds and antioxidants. Among these, poly-phenols in particular, have been recognized for antioxidant activity and many other health benefits.<sup>1</sup> Phenolic and flavonoids, as natural antioxidants and free radical scavengers, have involved substantial interest due to their importance in food and pharmacological industry.<sup>2</sup> Factors, such as geographic location, age of the plant, season, associated microflora, nutritional status, and environmental stress are known to influence the secondary metabolite profile of a particular plant species. Seasonal variation in trees, for example from dormant to active phase, brings progressive changes in traits like production of phytochemicals.<sup>3</sup> Besides, optimization of methods with respect to solvent system is important for determination or extraction of the phytochemicals from any plant species.

*Ginkgo biloba* L. (family Ginkgoaceae), commonly known as living fossil, harbors many beneficial medicinal properties. Traditionally, it has been used on an extensive basis, either as food or medicinal component, almost all over the world. The leaf extract of ginkgo contains pharmaceutically imperative flavonoids, glycosides and ginkgolides which expand blood flow, act as antioxidant and mainly used as memory enhancer and anti-vertigo.<sup>4</sup> The present study is focused on the evaluation of phytochemicals and antioxidants in leaf extracts of ginkgo along with the factorial analysis among locations × seasons, seasons × solvents and locations × solvents.

## 2. Materials and methods

### Plant material

Ginkgo leaves were collected in three seasons from five different locations referred as GB1 (Kalika, Almora), GB2 (Chaubatia, Almora), GB3 (Snowview, Nainital), GB4 (High court, Nainital) and GB5 (Glenthorn, Nainital) in Uttarakhand, India.<sup>5</sup> The leaves, dried at room temperature, were grounded to fine powder and stored at 4 °C for further analysis.

### Preparation of extracts

Dried leaf powder (10 g) was mixed with 25 ml methanol (ME), ethyl acetate (EA), n-butanol (n-B), acetone/water (AW) (3:2) and



## Anticonvulsant potential of commonly practiced formulations of *Brahmi* (*Bacopa monnieri* Linn.) in Wistar rats

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### ABSTRACT

**Objective:** Brahmi (*Bacopa monnieri* Linn) is an important herb in Ayurved, reported to have a wide range of medicinal properties. In clinical practice it is usually prescribed in its various dosage forms. The most common of those are *Brahmi Ghrita* (BG) and *Saraswatarishta* (SW). Use of *Brahmi* as anti-convulsion drug is well documented in scientific literature however; no data is available on the effect of its commonly practiced dosage forms. Hence, the study was carried out to evaluate anti-convulsion potential of BG and SW.

**Method:** The anticonvulsant activity of BG and SW was studied against seizures induced by Maximal Electroshock (MES) in rats and phenytoin (25 mg/kg Intra Peritoneal) was used as standard. Different phases of convulsions (Hind limb extension, jerking, grooming, tail straub and recovery) were recorded as index of convulsion. The brain tissue was dissected out for biochemical analysis.

**Result:** Treatment of rats with SW and BG in Maximal Electroshock (MES) induced convulsions showed statistically significant potential as compared to control groups ( $P \leq 0.01$  or  $P \leq 0.001$ ). SW or BG showed significant improvement in all the phases of convulsion except grooming response. Brain tissues of test animals evaluated for malondialdehyde (MDA) levels showed the higher levels in phenytoin group than in BG and SW treated groups suggesting protection of brain tissue from oxidative damage.

**Conclusion:** The results indicated SW and BG to be effective in promoting restorative and neuroprotective action in convulsions thus suggesting a further scope of evaluation of these formulations as an adjuvant treatment for convulsions

### Introduction

*Medhya* drugs are the best gifts of traditional Ayurvedic system to mankind, which are commonly used for maintenance as well as treatment for a range of neurocognitive disorders. Many herbal, mineral and animal drugs are being practiced with the potential to be used in such conditions.<sup>1</sup> Single herbs and polyherbal formulations like *Brahmi* (*Bacopa monnieri* Linn), *Vacha* (*Acorus calamus* L.), *Shatavari* (*Asparagus race-mosus*), *Brahmirasayan* etc. mainly categorized in this special-ized group of *Medhya* drugs and have a long history of use in their myriad effects on the Central Nervous Systems.<sup>2</sup>

Of all these, *Brahmi* is one of the most commonly used herbs, the neurocognitive effects of which are well established.<sup>3</sup> The herb although very commonly practiced by Ayurvedic fraternity, it is mainly used in the form of its polyherbal formulations like *Saraswatarishta* (SW) and *Brahmi Ghrita* (BG), *Saraswat Choorna* etc. Other drugs associated with the herb and dosage form prepared is anticipated to boost the potential of herb and to reduce therapeutic dose. Most of the studies are found on evaluating neurocognitive benefits of these formulations.<sup>4,7</sup> In the traditional practice however formulations are also being used for their promising action on epileptic conditions to prevent the attacks and reduce after effects with reference to cognitive deficits.<sup>8</sup> However, very few studies can be found in evaluating these effects of the formulations.

"Epilepsy" is a disorder of the brain characterized by an enduring predisposition to generate epileptic seizures and imbalance in brain electrical activity<sup>9</sup> which is commonly correlated to "Apasmara" or "Apasmriti" (loss of consciousness or memory) in Ayurved. It is the second most unrelieved common neurological disorder<sup>10</sup> fundamentally involving different neurological conditions/disturbances and symptoms with varying disease etiology in different people.<sup>11,12</sup> A known characteristic feature of epilepsy is seizures (periodic neuronal discharge), which is becoming important medical problem and needs urgent remedy.

Currently a number of Antiepileptic drugs (AEDs) are in practice with some beneficial effects, but none of these drugs can completely control seizures. Along with this, a number of side effects are eventually increasing the cost for epilepsy care and drug induced morbidity.<sup>13,14</sup> Thus it becomes imperative to search for a safer and potential alternative to the existing treatment from traditional medicinal systems. This study aims to evaluate the anti-convulsion potential of commonly used formulations BG and SW with well-known antiepileptic drug Phenytoin as standard by using Maximal Electroshock (MES) induced convulsions. Ingredients for the formulations were collected from a local *Ayurvedic* vendor and identified by *Ayurvedic* practitioner. Both the



## Analyzing the antibacterial and antioxidant properties of *Pimpinella tirupatiensis* extracts in sequence

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### ABSTRACT

**Background:** An increasing demand for natural additives has shifted the attention from synthetic to natural antioxidants. As leafy vegetables are found to be good source of antioxidants and the present study is to examine the antioxidant potential and antimicrobial activity of leaf extracts of *Pimpinella tirupatiensis*.

**Methods:** Antioxidant potential of leaves of *P. tirupatiensis* was studied using different methods like DPPH, nitric oxide, hydrogen peroxide scavenging activity. Reducing power and antimicrobial activity was estimated by using both gram positive and gram negative microorganisms by using DMF as solvent.

**Results:** The aqueous extracts showed maximum scavenging activity of DPPH followed by nitric oxide, hydrogen peroxide and reducing power respectively. Benzene and alcoholic extract showed maximum antimicrobial activity.

**Conclusion:** Substantial amounts of antioxidants including vitamins C and E, carotenoids, flavonoids, phenols and tannins etc. can be utilized to scavenge the excess free radicals from the body.

**Keywords:** Antioxidant potential Antimicrobial activity Leaf extracts *Pimpinella tirupatiensis*

### 1. Introduction

*Pimpinella tirupatiensis* (Apiaceae) is distributed in the forest of Tirupati in Andhra Pradesh commonly known as adavi kothimeera (Forest Coriander). It is used for the treatment of External inflammation, Diuretic, treatment of bladder distress, Asthma, Aphrodisiac, Skin diseases, Ulcers, Blood disorders, Toothache and Hepatoprotective. Free radicals have been implicated to the causation of ailments such as liver cirrhosis, atherosclerosis, cancer, diabetes etc.<sup>2</sup> Reactive oxygen species such as super oxide anions (O<sub>2</sub>), hydroxyl radicals (OH) and nitric oxide (NO) inactivate the enzymes and damage important cellular components causing injury.<sup>3</sup> Antioxidants may offer resistance against the oxidative

Table I: DPPH radical scavenging activity.

| S. No | Extracts | Concentration (mg/ml) and % inhibition (SEM SD)* |            |            |            |            | IC <sub>50</sub><br>e |
|-------|----------|--|------------|------------|------------|------------|-----------------------|
|       |          | 20*  | 40*        | 60*        | 80*        | 100*       |                       |
| 1     | PEE      | 19.80 0.46                                       | 24.39 0.75 | 27.26 0.62 | 31.38 0.87 | 34.28 0.77 | e                     |
| 2     | CHE      | 30.45 0.35                                       | 38.80 0.88 | 40.25 0.84 | 43.78 0.54 | 45.46 1.00 | e                     |
| 3     | ACE      | 35.13 0.89                                       | 38.42 0.32 | 41.99 0.22 | 45.52 0.42 | 480.16     | e                     |
| 4     | ETH      | 38.17 0.82                                       | 44.03 0.66 | 46.94 0.38 | 48.35 0.11 | 49.64 0.56 | 58                    |
| 5     | WTR      | 41.96 0.90                                       | 46.15 0.06 | 52.83 0.66 | 57.62 0.24 | 62.96 0.54 | 52                    |
| 6     | VitC     | 46.19 0.17                                       | 48.39 0.28 | 55.38 0.27 | 60.36 0.10 | 67.64 0.41 | 45                    |

PEE: pet. Ether, CHE: chloroform, ACE: acetone, ETH: ethanol, WTR: water, VitC: standard.

\*Values are mean SD, n=43.



## An attempt in Canada to choose success measures for hospital pharmacy practice

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### Abstract

Activity-based funding is a method of funding hospitals according to the type and volume of services provided and adjusted to their patient population. Currently, pharmacy practice is mainly evaluated with costs and volumes, which are insufficient to properly measure the contribution of pharmacists. Facing the province of Quebec statewide implementation of activity-based funding, expert committees were set up to develop a set of indicators using a predefined framework to assess pharmacy performance throughout all hospital activities and patient care. Through consultations, partners and stakeholders showed strong support for the initiative, putting more emphasis on the assessment of appropriateness as well as quality and safety. Among the different roles of pharmacists, respondents favoured the assessment of the pharmaceutical care and education of trainees and colleagues. Of the 150 candidate indicators initially identified, 24 were selected, of which 13 were prioritised for experimentation.

Keywords: hospital pharmacy service, benchmarking performance framework, quality of healthcare, task performance and analysis.

### INTRODUCTION

With the pressure of demand–supply balance increasing on the healthcare system, hospital activity-based funding, or 'pay-per-performance', is growing in popularity among governing administrations.<sup>1-4</sup> Under activity-based funding, hospitals are paid a predefined amount of money for each patient.<sup>5,6</sup> This is based on patients' specific conditions and factors that may add complexity or cost to their care.<sup>5,6</sup> As such, many pharmaceutical activities may be considered intangible and costly extras if adequate tools are not available to assess their contribution to performance.<sup>7</sup> Consequently, there is a need to better quantify the activities, impacts, and performance of hospital pharmacy practice. Such information could provide valuable data to establish, maintain, or even expand pharmacy services based on an objective evaluation of pharmacists' contribution to the patient care continuum.<sup>8</sup> A reliable performance assessment can also guide policy development, improve the quality of care, and increase accountability.<sup>9</sup>

Many authors looked at the selection or implementation of different indicators to assess the quality of care, the workload, or for the benchmarking of a pharmacy department.<sup>8-15</sup> Shawahna conducted a scoping review to identify, describe, and summarise different studies using the Delphi technique to develop quality indicators of pharmaceutical care.<sup>16</sup> This author found 24 studies related to the provision of pharmaceutical services relevant to medicines, most of which were published in the last decade. Not only were these studies limited to clinical care activities, many of them only concerned single hospitals or single practice sectors.<sup>16</sup>

A few attempts to assess hospital pharmacy performance on a large scale have been reported. Initiatives from the United States<sup>8,11</sup> and Europe<sup>10,12-15</sup> used frameworks to assemble a set of indicators. Such benchmarking projects vary between countries in line with the variation in priorities, activities, and methods of developing and evaluating pharmacy practices. In Canada, no nationwide system enables comparisons and benchmarking of hospital pharmacy practice. The Canadian Society of Hospital Pharmacy has promoted the Clinical Pharmacy Key Performance Indicators (cpKPIs), which were developed via a robust approach and are of utmost significance to assess pharmaceutical care.<sup>9</sup>





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# Assessing pharmacy high-needs criteria: a method for determining which hospitalized patients are most likely to have adverse drug reactions

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## Abstract

Clinical pharmacy services can be costly, and in resource-constrained healthcare services, should be prioritised towards patients with the greatest potential risks. At our health network, high-needs pharmacy criteria were developed to identify patients at greatest need of clinical pharmacy services. This retrospective study of 761 patients admitted to four hospitals in metropolitan Melbourne aimed to evaluate the ability of the high-needs pharmacy criteria to identify patients at increased risk of medication-related adverse clinical outcomes. Patients' clinical records were reviewed to determine if the patient met one or more elements of the high-needs criteria. Data on length of stay, 30-day readmission rate, medication-related problems, and medication-related incidents were obtained from the electronic records. Patients meeting one or more high-needs criteria had a longer length of stay (mean 6.7 days vs 3.1 days,  $p < 0.01$ ), were more likely to be readmitted within 30 days (27% vs 16%,  $p < 0.01$ ) and had a higher rate of medication-related problems (15% vs 7.6%,  $p < 0.01$ ). The sensitivity of the high-needs criteria to identify patients with medication-related problems, medication-related incidents, or readmission within 30 days was above 80%. In conclusion, the high-needs pharmacy criteria identified older patients with longer length of stay who are at greater risk of 30-day readmission and medication-related problems.

Keywords: clinical pharmacy, medication risk, medication review, pharmaceutical needs assessment, pharmacist consultation.

## BACKGROUND

Clinical pharmacy services aim to minimise medication risks, improve patient safety, and optimise health outcomes.<sup>1</sup> Inpatient clinical pharmacist activities in Australia include medication reconciliation, medication clinical review, therapeutic drug monitoring, adverse drug event (ADE) management, providing medicine-related information to patients, and ensuring continuity of medication management at transitions between care settings.<sup>1</sup>

Medication-related problems (MRPs) refer to circumstances which involve a patient's drug treatment that actually or potentially interferes with the achievement of an optimal outcome.<sup>2</sup> MRPs include medication errors, ADEs, and adverse drug reactions (ADRs). An ADE is defined as harm caused by appropriate or inappropriate use of a drug whereas an ADR is a subset of these events, where harm is directly caused by a drug under appropriate use.<sup>3</sup>

Clinical pharmacy services can be costly and in resource-constrained healthcare services should be prioritised towards patients with the greatest potential risks.<sup>2,4</sup> Among healthcare organisations, prioritisation is commonly achieved via organisational policies or individual clinical judgement.<sup>5,6</sup> Tools which have been developed to date frequently target specific patient groups and are often not validated against clinical outcomes.<sup>2</sup>

The few tools which have been validated against clinical outcomes have been validated against the patients' risks of developing an ADE or MRP.<sup>7-9</sup> Less commonly, outcomes used to validate risk assessment tools include the 30-day readmission rate.<sup>10</sup> Previous studies have often been limited to specific clinical populations, including obstetrics,<sup>11</sup> geriatrics,<sup>9-12</sup> paediatrics,<sup>13</sup> or cardiology,<sup>7</sup> thus limiting the generalisability of these tools.

At our health network, prioritisation of clinical pharmacy services occurs through the use of high-needs (HN) criteria (Table 1), a modification of the Society of Hospital Pharmacists of Australia (SHPA) *Fact Sheet: Risk factors for medication-related problems*.<sup>14</sup> The risk factors identified by SHPA were considered too extensive for efficient use in daily practice, therefore the HN



## Neuropsychiatric side effects described by patients using bictegravir with emtricitabine/tenofovir alafenamide

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### Abstract

The integrase-inhibitor bictegravir combination antiretroviral therapy (ART) Biktarvy became available in Australia in October 2018. Neuropsychiatric adverse drug reactions (ADRs) are associated with bictegravir and may affect persistence and adherence to treatment. The aim of this study was to describe the type and frequency of reported neuropsychiatric reactions in people dispensed Biktarvy. Ethics approval was obtained from Alfred Hospital Ethics Committee (Project No. 541/20). Data were collected from records of people dispensed Biktarvy between October 2018 and May 2020 and who subsequently had a new neuropsychiatric reaction reported to the organisation's ADR Review Committee. Data were sourced from ADR reports, medical and dispensing records, and included demographics, medical history, and concurrent medicines with known psychiatric adverse reactions. Data were analysed descriptively. Biktarvy was dispensed to 1265 patients. Twenty-two (1.7%, 95% confidence interval [CI] 1.0–2.5%) people reported 50 neuropsychiatric ADRs, including abnormal dreams ( $n = 13$ ), sleep disorders ( $n = 5$ ), and headaches ( $n = 5$ ). The median time from initiation to reaction was 13 (interquartile range [IQR] 4–94) days. Eighteen patients discontinued Biktarvy (1.4%, 95% CI 0.85–2.24). There was no statistically significant difference in discontinuation of Biktarvy between people who did or did not have a pre-existing psychiatric diagnosis ( $p = 0.58$ ). Concurrent medicines with known psychiatric adverse reactions were used by 10 people. A low rate of reported neuropsychiatric ADRs lead to discontinuation of Biktarvy, similar to rates in Biktarvy trials. This study adds to the post-marketing surveillance data of Biktarvy tolerance amongst people living with human immunodeficiency virus (HIV).

Keywords: adverse drug reactions, bictegravir, anti-infectives, neuropsychiatric adverse effects, antiretroviral.

### INTRODUCTION

First-line therapy for treatment naïve Australians with HIV-1 is an integrase inhibitor-based regimen.<sup>1</sup> Options for this regimen include a combination tablet consisting of bictegravir, tenofovir alafenamide, and emtricitabine (Biktarvy), which became available in Australia in October 2018 to a limited number of people prior to listing on the Pharmaceutical Benefits Scheme (PBS) on 1 March 2019. Biktarvy provides an advantage over existing treatment options due to the single tablet combination therapy, once daily dosing and no requirement for HLA-B\*5701 testing prior to initiation. Adherence and persistence to antiretroviral therapy is essential to reduce the transmission, morbidity, and mortality of HIV.<sup>3,4</sup> Persistence can be affected by adverse rea-

ctions.<sup>5</sup> Biktarvy discontinuation rates from neuropsychiatric adverse reactions in the initial randomised controlled trials (RCTs) were reported to be 0–1%.<sup>6</sup>

<sup>9</sup> Neuropsychiatric adverse reactions appear to be associated with the integrase strand transfer inhibitor class and have been more frequently associated with dolutegravir.<sup>10</sup> Neuropsychiatric adverse reactions identified in the original trials for Biktarvy included headache and insomnia.<sup>6</sup> <sup>7</sup> Post-marketing evidence indicates, however, that neuropsychiatric reactions may be of greater concern with Biktarvy.<sup>11</sup> This study aimed to investigate the frequency and nature of neuropsychiatric adverse reactions reported in people dispensed Biktarvy.

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## A practice update on medication dose estimate in people with chronic renal disease

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### Abstract

The increasing prevalence of chronic kidney disease (CKD) and the disparities in treatment availability make it a pressing public health issue. A person's glomerular filtration rate (GFR) is the most essential metric for drugs that the kidneys filter out of the blood, and it is also the most reliable indicator of general renal function. It is common practice in clinical practice to utilize equations that estimate GFR based on verified prediction equations. Clinical pharmacists from the Australian Society of Hospital Pharmacists (SHPA) Specialty Practice streams in nephrology, oncology and haematology, critical care, and infectious diseases formed the Working Group that drafted this practice update. For clinical pharmacists who make dosage choices based on estimated GFR using equations, this article is meant to provide practical advice. Summarized and contrasted with direct measurements of kidney function using exogenous markers are the limitations of the many equations in use, including the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI), the Modification of Diet in Renal Disease, and the Cockcroft-Gault equation. Regular use of the CKD-EPI equation as the principal metric for renal function is advised. When deciding on a new dosage, it is important to take the patient's and the disease's specific characteristics into account. Monitoring the signs, symptoms, and illness outcomes, the appearance of adverse reactions or medication-induced diseases, and the use of therapeutic drug monitoring (if available) to modify dosages appropriately are all important ways to continually check kidney function and the response to treatment.

**Keywords:**chronickidneydisease,medicationdosing,eGFR,estimationofkidneyfunction,glomerularfiltrationrate.

### INTRODUCTION

The increasing prevalence of chronic kidney disease (CKD) and the disparities in treatment availability make it a pressing public health issue. About 1.7 million persons, or one in ten, in Australia suffer from chronic kidney disease (CKD). As a result of socioeconomic determinants of health, the prevalence of chronic kidney disease (CKD) is double among individuals of Aboriginal and Torres Strait Islander descent compared to non-Indigenous adults, and rates are much higher for those residing in rural and isolated locations.<sup>3</sup> Nevertheless, only around 10% of the population is aware that they have CKD, which means that treatments that might decrease the disease's progression are not started until much later. Individuals at risk are also more likely to take their medications incorrectly, which may worsen their acute kidney damage (AKI). Approximately 20% of all AKI cases are medication-induced, and this kind of AKI may either cause new instances of CKD to develop or worsen preexisting CKD. To avoid unfavorable medication-related consequences, such as renal function loss and other metabolic problems, and to ensure that patients get the best possible therapy, it is crucial to accurately estimate kidney function in order to diagnose AKI or CKD.<sup>6</sup> The most essential way to describe the clearance of medications that are removed by the kidneys is by measuring the glomerular filtration rate (GFR), which is widely recognized as the greatest overall indicator of kidney function. In clinical practice, validated prediction equations for estimated GFR (eGFR) are often used.

Standards of practice in nephrology, oncology and haematology, critical care, and infectious illnesses have been developed by the Society of Hospital Pharmacists of Australia (SHPA) to outline the best practices for the safe and effective administration of medications to patients. Clinical pharmacists from various Specialty Practice streams formed a SHPA Working Group to develop this practice update. For clinical pharmacists who employ GFR estimation equations in medicine dosage choices, it is meant to provide realistic recommendations. It explains potential sources of bias or imprecision and draws attention to the many shortcomings of these equations.

### GLOMERULARFILTRATIONRATE

By monitoring the serum concentrations of endogenous filtration markers or the clearance of exogenous filtration markers, one may determine the glomerular filtration rate (GFR), which is the rate at which the kidney glomerulus filters plasma to create an ultrasound.<sup>10</sup>

#### Assaying Glomerular Filtration Rate using External Filtration Markers

Serial measurements of glomerular filtration rate (GFR) utilizing an external marker constitute the gold standard for accurate evaluation of renal function. Medication dosage selections in routine clinical practice do not need the time-consuming and expensive procedure. For this aim, exogenous filtration markers including inulin, sinistrin, iothexol, and iohalamate are used. These markers are neither reabsorbed or released by the tubules, and they are freely filtered by the glomerulus.<sup>10</sup>



## Thyroid disease treatment for the elderly

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### Abstract

Thyroid disorders are common in older people and cause significant morbidity. There may be fewer symptoms at presentation and increased susceptibility to adverse events, making diagnosis and management more challenging. The approach to management of thyroid disorders in older people differs from that for younger individuals. Factors that need to be considered include frailty, concurrent illness, polypharmacy, drug–drug interactions, and target organ sensitivity to treatment. This review discusses the clinical presentation, pathophysiology, and management of thyroid disorders and the effects of medications on thyroid function in older people.

Keywords: thyroid diseases, drug therapy, aged.

### INTRODUCTION

The incidence of thyroid disorders in older people is increasing worldwide, primarily due to increased life expectancy.<sup>1</sup> The clinical presentation of thyroid disorders often differs in older people compared to younger people. Symptoms may be subtle, making diagnosis more difficult. Untreated thyroid disorders can have significant morbidity.<sup>2</sup> In this review, we discuss changes in thyroid anatomy and physiology, overt and subclinical hypo- and hyperthyroidism, thyroid cancer, impact of thyroid disorders on cardiovascular disease, effects of medications on thyroid function, and thyroid hormone supplementation.

### CHANGES IN THYROID ANATOMY AND PHYSIOLOGY WITH AGEING

Physiological alterations within the thyroid gland and the hypothalamic pituitary thyroid axis occur with ageing. Older people, including those without thyroid disease, may have higher concentrations of thyroid stimulating hormone (TSH). The NHANES III study examined 17 353 people  $\geq 12$  years.<sup>3</sup> In participants without thyroid disease, 40% of individuals  $>80$  years had a TSH greater than 2.5 mIU/L compared to 10.6% of individuals in their 20s.<sup>4</sup> Not all population-based studies have demonstrated rising TSH levels in older people, for example the converse was noted in the Rotterdam study.<sup>5</sup> Generally, free t4 (ft4) levels remain stable; however, free t3 (ft3) levels decrease, with or without an associated increase in reverse t3 (the metabolically inactive form of ft3).<sup>6,7</sup>

The cause of rising TSH levels with ageing is unknown. It may be a central response to mitigate excessive catabolism and reduction in basal metabolism. Alternatively, it may be reactive, secondary to reduced physiological metabolism inherent with ageing.<sup>8,9</sup> Given ft4 levels remain stable despite a change in TSH, it is not thought to be related to higher rates of thyroid pathology.<sup>7</sup>

Changes in absolute TSH levels cannot be considered in isolation because changes also occur on a molecular and receptor level. TSH bioactivity changes, affecting its signalling capacity on the thyroid gland, iodine absorption is decreased, and there is a likely change in the set-point of the thyroid receptor, affecting the way thyrocytes respond to TSH.<sup>6,8</sup> Consequently, there may be decreased ft4 and ft3 production. Furthermore, older people are affected by blunted thyrotropin-releasing hormone (TRH) response and loss of circadian variation in TSH release.<sup>9-11</sup>

Distinguishing between age-related changes versus pathology with likely adverse outcomes without treatment is a challenge for clinicians.



## Approaches to reporting medication errors at a regional hospital: a qualitative investigation

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### Abstract

To set the stage, medication mistakes are occurrences that have the potential to result in the improper administration of medications or injury to patients. When compared to urbanites, the health results for Australians residing outside of major cities are much worse. Different healthcare providers have different attitudes, which in turn causes different medication error reporting (MER) methods. MER has the potential to enhance hospital and community-based patient safety.

The purpose of this study is to investigate how healthcare providers (HCPs) at an Australian rural hospital view, use, and advise on MER.

Approach: Healthcare providers' perspectives, routines, and suggestions about the most effective use of drug error reports were elicited using semistructured interviews. From November 2021 to February 2022, healthcare providers (nurses, pharmacists, and physicians) from all areas of practice were recruited for the research. Using theme analysis, the interviews were recorded and transcribed. The Human Research Ethics Committee at Goulburn Valley Health (GVH) gave its stamp of approval (Reference no: GVH 35/21). Participants were asked to read an information leaflet and fill out a written permission form in order to demonstrate their informed consent.

Twelve healthcare providers were interviewed, and four themes emerged: factors that encourage or discourage reporting, the advantages and drawbacks of reporting prescription errors, and suggestions for improving the reporting process. The advantages of MER were well-understood among regional HCPs. Pharmacists were worried about how reporting may affect their relationships with other professions, whereas nurses reported more prescription mistakes than physicians. Among their suggestions was the need to improve electronic system education and to standardize the definition of pharmaceutical errors.

Conclusion: Health care providers' knowledge of MER's importance did not translate to uniform application. We suggest instituting more structured feedback to clinicians after tests, educating students about pharmaceutical mistakes, providing more protected learning time, and training using the incident reporting program. We advocate the adoption of further solutions, such as electronic prescription, and the implementation of modifications to workplace cultural practices that improve organizational procedures and facilitate mistake reporting without fear of penalties.

**Keywords:** medication errors, medication error reports, medication safety, hospital.

### INTRODUCTION

Around 1.2 billion Australian dollars (AUD) is spent each year on hospital admissions that are thought to be medication-related, accounting for 2-3% of total admissions.<sup>1</sup> In addition, there is a 28% increase in the likelihood of hospital readmission during the next month due to inadequate medication management either during or soon after admission.<sup>2</sup> According to the World Health Organization (WHO), an adverse drug event (ADE) is any negative medical occurrence that might happen when taking a pharmaceutical, even if it isn't directly related to the therapy.<sup>3</sup> Adverse drug responses (ADRs) caused by the drug's characteristics, prescription mistakes, and overdosing all fall under this category.<sup>3</sup>

Inappropriate medicine usage or injury to patients may occur as a result of pharmaceutical mistakes, which are avoidable occurrences. There are a variety of approaches to error detection, but voluntary reporting is among the most common.<sup>4</sup> Medication safety relies on the voluntary reporting of mistakes since it allows us to get insight into the effects of medication errors and learn from them. Finding system weaknesses, prioritizing actions, and aiding planning are all aided by medication error reporting (MER).<sup>5</sup> Future patient harm in both community and hospital settings may be reduced by systemic improvements that are a result of analyzing drug mistake reports.<sup>6</sup>

## An unusual occurrence of extra pyramidal side effects perhaps caused by a combination between paliperidone and voriconazole

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### Abstract

**Setting the Scene:** It is believed that paliperidone, an active metabolite of risperidone, has negligible pharmacokinetic drug-drug interactions (DDI) potential because of its low metabolism by CYP3A4 and CYP2D6. A potential interaction between paliperidone and voriconazole has been observed, however, based on interactions between risperidone and strong CYP3A4 inhibitor azoles, there have been reports of DDIs regarding other drugs.

**Purpose:** To detail the first known case of a drug-drug interaction (DDI) resulting in extrapyramidal side effects (EPSEs) involving paliperidone and voriconazole. **Medical information:** Confidence that clozapine was the cause of febrile neutropenia led a 34-year-old man to seek medical attention. Due to a suspected fungal infection, the patient's empiric piperacillin/tazobactam medication was adjusted to include voriconazole and paliperidone instead of clozapine. It is believed that the patient had antipsychotic-induced tremors and stiffness in all of her limbs two days after beginning voriconazole. Withholding paliperidone caused the EPSEs to resolve.

**Results:** The patient was able to take greater dosages of paliperidone for an extended period of time before switching to clozapine. A possible paliperidone adverse drug response (ADR) owing to significant CYP3A4 inhibition by voriconazole was indicated by the development of EPSEs two days after azole commencement. Additional research, including therapeutic medication monitoring, is necessary to validate these results, but this example seems to be the first recorded instance of this earlier theoretical DDI in reality.

It is important to keep an eye on patients for adverse drug reactions (ADRs) when paliperidone is given with CYP3A4 inhibitors because of the potential for pharmacokinetic drug-drug interactions.

**Keywords:** paliperidone, voriconazole, azole, drug interaction, CYP3A4.

### INTRODUCTION

An active metabolite of risperidone, paliperidone is an atypical antipsychotic. Paliperidone has a higher incidence of extrapyramidal side effects (EPSEs) compared to other atypical antipsychotics. Paliperidone is mostly eliminated from the body via the kidneys (59% unaltered in urine), and only 6.5% of the dosage is accounted for by cytochrome P450 3A4 (CYP3A4) and cytochrome P450 2D6 (CYP2D6) metabolism. Paliperidone is a substrate for the P-glycoprotein (P-gp).<sup>1</sup>

Paliperidone DDIs have been reported seldom (Table 1). Some of the mechanisms include alterations in gastric transit and altered CYP3A4, CYP2D6, or renal P-gp function. Some DDIs have caused significant shifts in paliperidone concentrations 3-5,<sup>7</sup> and severe psychosis (9, 10).<sup>10</sup> According to Stockley's Drug Interactions, paliperidone has the potential to interact with

voriconazole, a powerful CYP3A4 inhibitor, in a way that might increase the corrected QT interval (QTc). This is based on the DDIs between risperidone and azoles. It seems that no instances of this hypothetical interaction have been documented so far.

### CASEREPORT

The Royal Melbourne Hospital Human Research Ethics Committee (10 July 2023, Coordinator, Office for Research) exempted this study from local policy regulations that pertain to research. The patient's consent to be published was acquired and recorded in a way that was free, prior, and informed.

It was thought that clozapine was the cause of febrile neutropenia when a 34-year-old male patient arrived to a quaternary referral metropolitan teaching hospital in Melbourne, Australia. Previous stabilization of the patient was achieved on



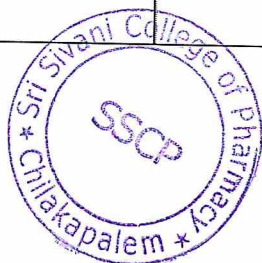


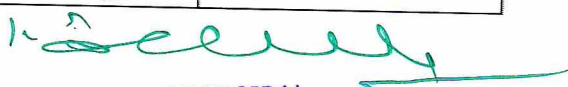
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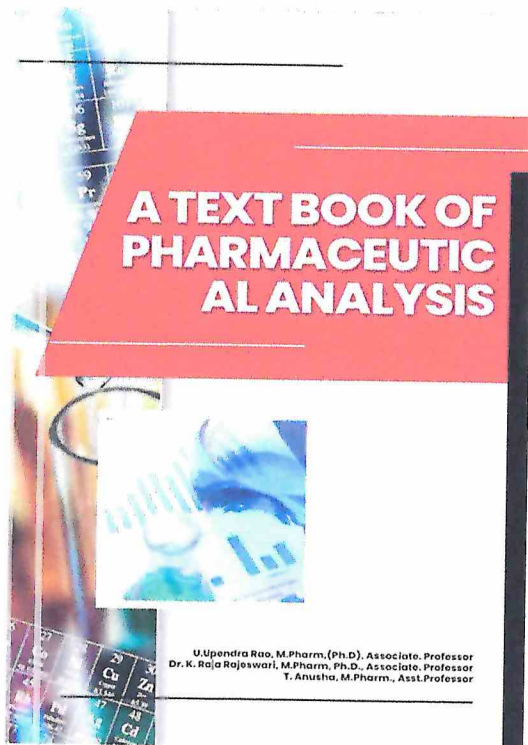
  
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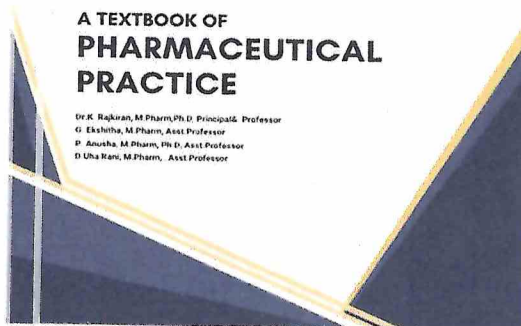
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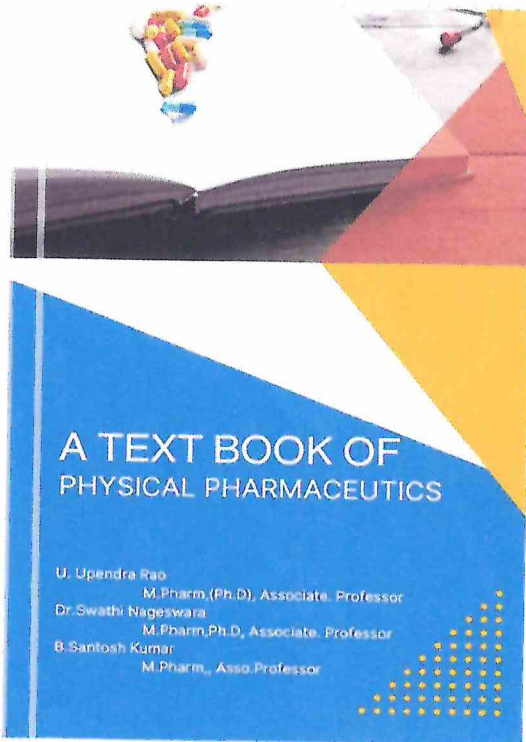
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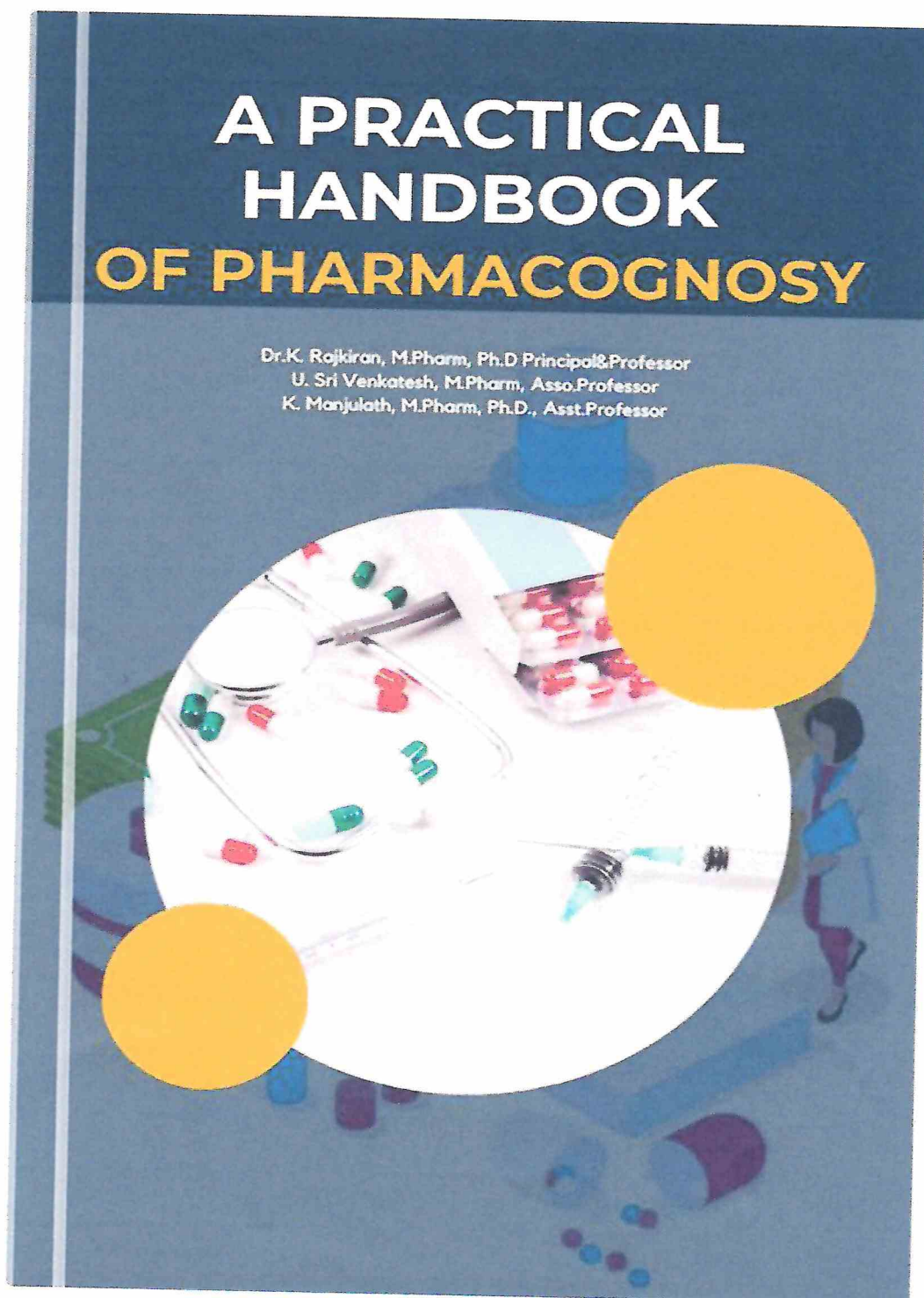
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