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CLINICAL PHARMACY NEWSLETTER

A Newsletter of Drug and Prescribing Information

Published by
Clinical Pharmacy Services Department, Govt. Medical College & Hospital, Ooty
(A Unit of Department of Pharmacy Practice, JSS College of Pharmacy, Ooty)

Volume XXX Issue 01 | **January - March 2025**

INSIDE THIS ISSUE

SUPERIORITY OF ONCE-WEEKLY INSULIN VERSUS ONCE-DAILY INSULIN IN ADULTS WITH TYPE-1 DIABETES: A PHASE 3 RANDOMISED NON-INFERIORITY TRIAL

Effective insulin treatment of Type 1 diabetes requires multiple daily injections of basal and bolus insulin or the use of continuous subcutaneous insulin infusion. Even with the use of technology, reaching and maintaining optimal glycaemic control is challenging. Basal insulin options require once or twice daily injections. Reducing the frequency of basal insulin injections has the potential to simplify treatment and ease the burden on people with diabetes and their caregivers, which could ultimately improve adherence and glycaemic outcomes. With the development of once-weekly basal insulins, a decrease in the number of basal insulin injections from about 365 to 52 per year could reduce this burden.

Insulin Efsitora alfa (Efsitora), a fusion protein combining a novel single-chain variant of insulin with a human IgG Fc domain, is an insulin receptor agonist designed to have a flat pharmacokinetic profile and long half-life, which allows for weekly dosing. These attributes have the potential to reduce glycaemic variability. Findings from a phase 2, 26-week trial in adults with type 1 diabetes showed the efficacy of Efsitora, as measured by HbA1c, to be non-inferior to insulin Degludec (Degludec), with a statistically significant treatment difference favouring Degludec. In the phase 2 study, fasting glucose levels were higher with Efsitora, and the rates of level 2 hypoglycaemia (<54 mg/dL [3·0 mmol/L]) and nocturnal hypoglycaemia were comparable between treatments. Another weekly basal insulin, icodec, has been evaluated in adults with type 1 diabetes and has shown non-inferiority in HbA1c reduction and increased level 2 and level 3 hypoglycaemia compared with Degludec.

The QWINT (Once-Weekly Insulin Therapy) phase 3 clinical development programme evaluated once-weekly Efsitora compared with once-daily insulin comparators across a range of populations, as previously described. This study, QWINT-5, aimed to assess the efficacy and safety of Efsitora compared with once-daily Degludec in adults with type 1 diabetes on basal-bolus multiple daily injection therapy. QWINT-5 was, parallel-design, open-label, randomised controlled study conducted at 82 health-care centres in Argentina, Japan, Poland, Slovakia, Taiwan, and the USA. The study comprised of a 3-week screening and lead-in period, a 52-week treatment period, and a 5-week safety follow-up period after the last visit in the treatment period.

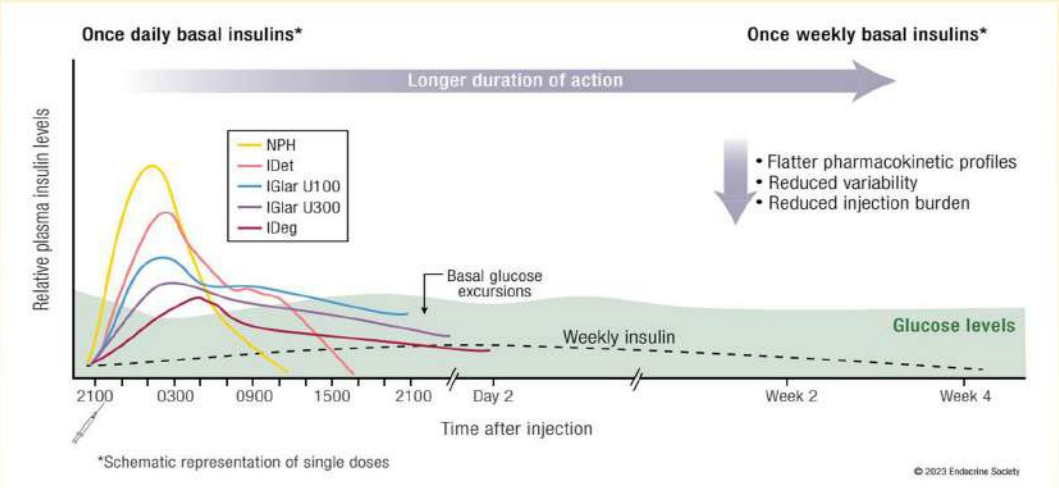


Fig 1: Schematic representation of mechanism of action of once daily insulins in comparison with basal insulins*

(Source*: Rosenstock J, Juneja R, Beals JM, Moyers JS, Ilag L, McCrimmon RJ. The Basis for Weekly Insulin Therapy: Evolving Evidence With Insulin Icodec and Insulin Efsitora Alfa. Endocr Rev. 2024 May 7;45(3):379-413.)

Between Aug 12, 2022, and May 7, 2024, of 893 participants enrolled, 692 (77%) participants were randomly assigned to once-weekly Efsitora or once-daily Degludec, and 623 (90%) participants completed the study. Mean HbA1c decreased from 7·88% (62·66 mmol/mol) at baseline to 7·41% (57·5 mmol/mol) at week 26 with Efsitora and from 7·94% (63·3 mmol/mol) at baseline to 7·36% (56·9 mmol/mol) at week 26 with Degludec. Mean HbA1c change from baseline to week 26 was -0·51% with Efsitora and -0·56% with Degludec (estimated treatment difference 0·052%, 95% CI -0·077 to 0·181; p=0·43), confirming a non-inferiority margin of 0·4% for Efsitora compared with Degludec. Rates of combined level 2 (<54 mg/dL [3·0 mmol/L]) or level 3 severe hypoglycaemia were higher with Efsitora compared with Degludec (14·03 vs 11·59 events per patient year of exposure; estimated rate ratio 1·21, 95% CI 1·04 to 1·41; p=0·016) during weeks 0-52, with the highest rates during weeks 0-12. Severe hypoglycaemia incidence was higher with Efsitora (35 [10%] of 343) versus Degludec (11 [3%] of 349) during weeks 0-52. Overall incidence of treatment-emergent adverse events was similar across treatment groups. One death not related to the study treatment occurred in the Degludec group.

Conclusion:

QWINT-5 is the only phase 3 clinical trial of the QWINT programme to evaluate the efficacy and safety of once weekly Efsitora in combination with a bolus insulin (insulin lispro) in adults (i.e, those aged 18 years and older) with type 1 diabetes. The phase 2 study of insulin Efsitora in people with type 1 diabetes showed non-inferior HbA1c reduction compared with insulin Degludec without increased combined level 2 (<54 mg/dl [3·0 mmol/l) or level 3 hypoglycaemia over 26 weeks of treatment, but with statistically significantly higher HbA1c and fasting glucose than Degludec. Thus, a new dosing approach was implemented in the QWINT-5 study based on the phase 2 results to balance glycaemic efficacy with hypoglycaemia risk.

In QWINT-5, Efsitora compared with Degludec treatment showed comparable improvement in HbA1c and fasting glucose, with a higher rate of combined level 2 (<54 mg/dL [3·0 mmol/L]) or level 3 severe hypoglycaemia during the 52-week treatment period.In adults with type 1 diabetes, once-weekly Efsitora (once weekly basal insulin) showed non-inferior HbA1c reduction compared with daily insulin Degludec (once daily insulin). Higher rates of combined level 2 or level 3 hypoglycaemia and greater incidence of severe hypoglycaemia in participants treated with Efsitora compared with participants treated with Degludec might suggest the need for additional evaluation of Efsitora dose initiation and optimisation in people with type 1 diabetes.

Further reading:

• Bergenstal RM, Weinstock RS, Mathieu C, Onishi Y, Vijayanagaram V, Katz ML, Carr MC, Chang AM. Once-weekly insulin Efsitora alfa versus once-daily insulin Degludec in adults with type 1 diabetes (QWINT-5): a phase 3 randomised non-inferiority trial. Lancet. 2024;404(10458):1132-1142.

• Wysham C, Bajaj HS, Del Prato S, Franco DR, Kiyosue A, Dahl D, Zhou C, Carr MC, Case M, Firmino Gonçalves L; QWINT-2 Investigators. Insulin Efsitora versus Degludec in Type 2 Diabetes without Previous Insulin Treatment. N Engl J Med. 2024;391(23):2201-2211.

• Bergenstal RM, Philis-Tsimikas A, Wysham C, Carr MC, Bue-Valleskey JM, Botros FT, Blevins T, Rosenstock J. Once-weekly insulin Efsitora alfa: Design and rationale for the QWINT phase 3 clinical development programme. Diabetes Obes Metab. 2024;26(8):3020-3030.

• Rosenstock J, Juneja R, Beals JM, Moyers JS, Ilag L, McCrimmon RJ. The Basis for Weekly Insulin Therapy: Evolving Evidence With Insulin Icodec and Insulin Efsitora Alfa. Endocr Rev. 2024;45(3):379-413.

Unveiling complexity: A detailed case report on type 1 diabetes and its rare camptodactyly complication

Introduction

Diabetes mellitus (DM) type 1 is an autoimmune disorder leading to the destruction of pancreatic beta-cells, resulting in insulin deficiency and chronic hyperglycemia. The global burden of diabetes has been increasing steadily, with type 1 diabetes accounting for about 5-10% of all cases. The disease is known for its vascular complications, which are the primary causes of morbidity and mortality. However, DM's impact extends beyond these well-documented concerns, affecting multiple organ systems, including the musculoskeletal system. Musculoskeletal disorders in DM are diverse, ranging from stiff hand syndrome and adhesive capsulitis to more complex conditions such as Dupuytren's contracture and camptodactyly. Camptodactyly, characterized by a nontraumatic, progressive flexion deformity of the proximal interphalangeal joints, while reported, is not frequently discussed in diabetes-related musculoskeletal complications. The literature suggests an association with chronic hyperglycemia leading to glycosylation of tissues, which may induce fibrotic changes in the palmar fascia and result in such deformities. This case report examines an uncommon presentation of bilateral long finger camptodactyly in a patient with a longstanding history of type 1 diabetes mellitus. The complexity of the case is underscored by the presence of additional complications such as diabetic dyslipidemia, bilateral cataracts, and a rare association with genetic markers indicating a predisposition to Fabry disease. These complications present a convoluted picture that challenges clinical management and necessitates a nuanced approach.

Case Presentation

A 34-year-old individual with a significant medical background of type 1 diabetes mellitus, initially diagnosed at the age of 9 and managed with insulin therapy, presented with progressive stiffness and flexion deformity of the fingers. This condition, described as camptodactyly, was most pronounced in the proximal interphalangeal joints and had progressively worsened over five years, impairing daily functions and work-related tasks. The deformity was accompanied by chronic intermittent paraesthesia in the extremities, an additional source of discomfort for the patient. The patient's medical history was notable for bilateral cataracts, which had developed by the age of 16 and were subsequently resolved with surgical intervention. Despite ongoing treatment, dyslipidemia remained a challenge, with target lipid profiles being inconsistently achieved. The family history revealed a genetic predisposition to diabetes and potentially related musculoskeletal disorders, with similar conditions noted in close relatives. Genetic evaluations uncovered markers suggestive of Fabry disease; however, there were no reported phenotypic manifestations. Psychosocially, the patient conveyed significant distress due to the functional limitations imposed by the hand deformities.

"Insulin is not a cure for diabetes; it is a treatment. It enables the diabetic to burn sufficient carbohydrates, so that proteins and fats may be added to the diet in sufficient quantities to provide energy for the economic burdens of life."

Clinical Findings

On physical examination, the patient presented with significant bilateral camptodactyly. Notably, the proximal interphalangeal joints of the long fingers exhibited permanent flexion deformities that were resistant to passive extension. The range of motion was most limited in the morning and improved slightly throughout the day, yet never reached full extension. Skin over the affected joints was intact without lesions or signs of inflammation. Additionally, palpation of the hands revealed no warmth or tenderness over the joints, indicating an absence of acute inflammatory process. Phalen's and Tinel's signs were positive bilaterally, suggesting nerve involvement consistent with the patient's complaints of paraesthesia. The patient's grip strength was reduced, and dexterity tests such as the O'Connor Tweezer Dexterity Test and the Purdue Pegboard Test confirmed functional impairment. Systemic examination revealed no further diabetic complications at the time of assessment. The patient had a stable gait but reported intermittent paraesthesia extending to the lateral aspects of both lower extremities, without significant motor weakness or reflex changes.

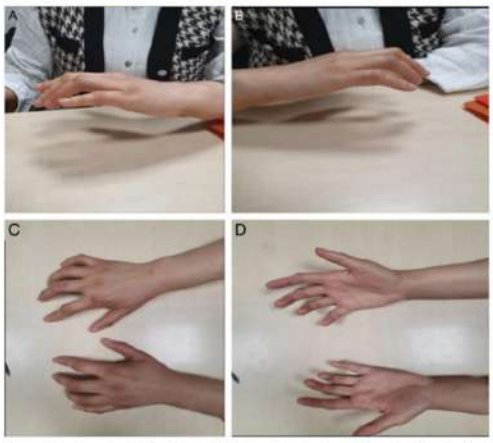


Figure 1 A visual case study of camptodactyly in type 1 diabetes. A. Front view of the patient's hands displaying the characteristic flexion deformities associated with camptodactyly. B. Lateral view of the right hand illustrating the restricted extension and curvature of the fingers. C. Lateral view of the left hand further demonstrating the limited range of motion and the camptodactyly deformity. D. Top view of the patient's hands while attempting to lay flat on the surface, highlighting the flexion contractures of the fingers. E. Bottom view of the hands showing the inability to achieve full extension, with the camptodactyly clearly visible from this angle.

Diagnostic Assessment

The diagnostic evaluation of the patient involved a comprehensive series of tests and assessments to address the complex symptoms presented. Initial physical examinations revealed bilateral camptodactyly with a notable reduction in finger extension and positive Phalen's and Tinel's signs, suggesting potential nerve entrapment. Laboratory tests were regularly conducted, focusing on HbA1c levels to monitor diabetes control and lipid profiles to manage dyslipidemia. Imaging studies, including MRI, played a crucial role by confirming the absence of erosive disease in the joints, effectively ruling out inflammatory arthropathies such as rheumatoid arthritis. Electromyography was utilized to confirm peripheral neuropathy, aligning with the expected complications of longstanding diabetes. The patient also underwent genetic testing, which identified markers suggestive of Fabry disease, although no clinical signs of this condition were present. The diagnostic process faced several challenges, including navigating the complexities of the healthcare system to access specialized tests and consultations, financial constraints due to the high costs of ongoing and multifaceted diagnostic requirements, and ensuring effective communication to overcome any cultural barriers in understanding and managing the condition.

Therapeutic Interventions

1.Pharmacological Management: The patient's management includes a combination of pharmacological, surgical, and supportive interventions. Insulin therapy has been the cornerstone of diabetes management since diagnosis at age 9, with dosing tailored through ongoing monitoring of blood glucose and HbA1c levels.

Table 1 Timeline.

Year	Month	Event	HbA1c (%)	Note on diabetes management
1999	-	Diagnosis of type 1 diabetes & start of insulin therapy	9.5	Initial diagnosis with elevated HbA1c requiring insulin
2006	-	Bilateral cataract surgery	8.8	Cataract development likely related to poor glycemic control
2015	-	Onset of camptodactyly & conservative management begins	8.2	Suboptimal control; HbA1c remained above target
2020	January	Genetic markers for Fabry disease identified	7.8	Moderate control achieved through intensive insulin regimen
2020	October	Electromyography indicates peripheral neuropathy	8.1	Glycemic control still challenging, contributing to neuropathy
2021	-	Persistent dyslipidemia & paraesthesia	8.5	Ongoing management needed; statins and glucose monitoring
2022	-	Worsening hand deformities & sensory symptoms	8.3	HbA1c slightly improved but not enough to prevent symptoms
2023	March	Re-evaluation of management strategies; surgical options considered	8.0	Glycemic control stabilizing, but complications persist
2024	March	Persistent paraesthesia; advanced splinting trial	8.1	Consistent glycemic levels, monitoring continued

This timeline illustrates the key medical events in the patient's history alongside HbA1c levels, providing an overview of the patient's glycemic management. The fluctuating HbA1c percentages highlight the ongoing challenge of achieving optimal glycemic control and its impact on the development of diabetes-related complications, such as cataracts, peripheral neuropathy, and camptodactyly.

2.Surgical intervention: Surgically, the patient underwent successful bilateral cataract removal, significantly improving vision. Although surgical correction for camptodactyly was considered, it was not pursued due to associated risks and a high chance of recurrence.

3.Supportive care: It has played a vital role in preserving function and quality of life. This includes physical therapy and hand splints to address camptodactyly-related discomfort and mobility issues, as well as occupational therapy to assist with daily activities and maintain employment. All interventions have been guided by regular assessments, focusing on clinical effectiveness, patient safety, and long-term quality of life.

Challenges in Management

Despite stabilization in glycemic control, the patient's hand deformities showed limited improvement. Conservative measures yielded only temporary symptomatic relief, and surgical intervention posed risks. The interplay between genetic predisposition and chronic disease further complicated the clinical picture.

Multidisciplinary Approach

The management of this case required collaboration across endocrinology, genetics, neurology, and orthopedics. Regular follow-ups and comprehensive monitoring ensured a dynamic and responsive treatment plan tailored to the patient's evolving needs.

Conclusion

The main takeaway from this case is the importance of considering atypical complications in the management of type 1 diabetes. The report highlights that, beyond the well-recognized vascular complications, diabetes can lead to complex musculoskeletal issues such as bilateral camptodactyly. Despite ongoing insulin therapy and attempts to stabilize glycemic control, the persistence of hand deformities—along with other diabetic complications—underscores the need for a multidisciplinary approach. This case also calls for further research into the interplay between chronic hyperglycemia, tissue glycosylation, and fibrosis, which may contribute to such uncommon presentations. Ultimately, individualized patient care and early screening for musculoskeletal abnormalities may improve overall outcomes in diabetic patients.

Reference

Donati, D., Lando, M., Caselgrandi, F., Boccolari, P., Vita, F., & Tedeschi, R. (2025). Unveiling complexity: A detailed case report on type 1 diabetes and its rare camptodactyly complication. Morphologie, 109, 100921. https://doi.org/10.1016/j.morpho.2024.100921

Drug Profile
Blujepa (Gepotidacin)

Pharmacological Class

Gepotidacin is a triazaacenaphthylene bacterial type II topoisomerase inhibitor.

Indications

Gepotidacin indicated for the treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis.

Dosage Forms And Strengths

- Each film coated tablet contains 750 mg of Gepotidacin.
- Gepotidacin tablets are yellow, capsule shaped, and debossed with "GS GU3" on one side and plain on the other side.

Contraindications

- Gepotidacin is contraindicated in patients with a history of severe hypersensitivity to Gepotidacin.

Warning and Precautions

- QTc Prolongation: Avoid use of Gepotidacin JEPA in patients with a history of QTc prolongation, or with relevant pre-existing cardiac disease, and in patients receiving drugs that prolong the QTc interval. Due to an increase in Gepotidacin exposure, avoid concomitant administration of Gepotidacin with strong CYP3A4 inhibitors and in patients with severe hepatic impairment (Child-Pugh Class C) and in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min.
- Acetylcholinesterase inhibition: Dysarthria and other adverse reactions have been reported in patients receiving Gepotidacin. Monitor patients with underlying medical conditions that may be exacerbated by acetylcholinesterase inhibition and patients receiving succinylcholine-type neuromuscular blocking agents, systemic anticholinergic medications, or non-depolarizing neuromuscular blocking agents.
- Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving Gepotidacin. If an allergic reaction to Gepotidacin occurs, discontinue the drug and institute appropriate supportive measures.
- Clostridioides difficile Infection (CDI): CDI has been reported with nearly all systemic antibacterial agents, including Gepotidacin. Evaluate patients who develop diarrhea.

Overdosage

- There is a risk of QTc prolongation with overdosage. Intermittent hemodialysis is not likely to substantially remove Gepotidacin from the systemic circulation.

Mechanism of Action

- Gepotidacin is a triazaacenaphthylene antibacterial that inhibits Type II topoisomerases including bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, thereby inhibiting DNA replication.
- Gepotidacin has bactericidal activity against pathogens as determined by time-kill studies. In vitro studies demonstrated a Gepotidacin post-antibiotic effect ranging from 1.8 to 2.2 hours for E. coli, 1 to >6.6 hours for K. pneumoniae, 1.4 to 3 hours for P. mirabilis, 1 to 2.6 hours for C. freundii, 2.7 to 4.3 hours for S. saprophyticus, and 1.2 to 2.7 hours for E. faecalis at 5 times the MIC.

Adverse Reactions

The following adverse reactions are discussed in greater detail in other sections of the labelling:

- QTc Prolongation.
- Acetylcholinesterase Inhibition.
- Hypersensitivity Reactions.
- Clostridioides difficile Infection.

Adverse Reaction	BLUJEPA N = 1,570 n (%)	Nitrofurantoin N = 1,558 n (%)
Diarrhea	258 (16)	51 (3)
Nausea	146 (9)	64 (4)
Abdominal pain[a]	60 (4)	34 (2)
Flatulence	43 (3)	8 (<1)
Headache	38 (2)	40 (3)
Soft feces	37 (2)	8 (<1)
Dizziness	29 (2)	19 (1)
Vomiting	28 (2)	10 (<1)
Vulvovaginal candidiasis	20 (1)	18 (1)

[a] Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, abdominal tenderness, abdominal discomfort, and gastrointestinal pain.

Pharmacodynamics

- The 24-hour free-drug AUC to minimum inhibitory concentration (MIC) ratio has been shown in animal infection and in vitro pharmacokinetic -pharmacodynamic (PK-PD) models to be the PK-PD index predictive of Gepotidacin antibacterial efficacy.

Cardiac Electrophysiology

The effect of Gepotidacin on the QTc interval was evaluated in a randomized, active (moxifloxacin 400 mg) and placebo-controlled, double-blind cross-over trial in healthy subjects who received single intravenous (IV) infusions of Gepotidacin over 2 hours. A dose- and concentration-dependent QTc prolongation effect of Gepotidacin was observed. The mean placebo-corrected change from baseline heart rate values around Tmax were approximately 6 bpm at 1,000 mg IV (not an approved dosing regimen and route of administration) and approximately 10 bpm at 1,800 mg IV (not an approved dosing regimen and route of administration). The mean placebo-corrected change from baseline QTcF values around Tmax were 12 msec at 1,000 mg IV and 22 msec at 1,800 mg IV. The Cmax of Gepotidacin following a single 1,000 mg IV dose (not an approved dosing regimen and route of administration) is approximately 1.7 times that of the Cmax at steady state for the 1,500 mg oral dose twice daily.

Pharmacokinetic Parameters

The pharmacokinetic properties of Gepotidacin are summarized in Table as mean (standard deviation [SD]) unless otherwise specified.

General Information	
Exposure	
Cmax (mcg/mL)[a]	4.2 (1.0)
AUC_{0-12} (mcg*hour/mL)[a]	22.8 (4.8)
Dose Proportionality	Approximately dose proportional from 1,500 to 3,000 mg
Accumulation	40% and steady state was achieved by Day 3
Absorption	
Absolute Bioavailability	~45%
Tmax, (hours)	~2.0
Effect of food (moderate fat meal)[b]	No clinically significant effect on PK
Distribution	
Vss (L)[a]	172.9 (42.5)
Plasma Protein Binding	~25 to ~41%
Elimination	
Terminal Half-life (hours)[a]	9.3 (1.3)
Total Clearance (L/hour)[a]	33.4 (6.7)
Metabolism	
Primary Pathway	Oxidative metabolism mediated by CYP3A4, producing several circulating metabolites
Major Metabolite (%)	M4 which is ~11% of circulating drug-related materials
Excretion	
Feces	~52% (30% unchanged drug)
Urine	~31% (20% unchanged drug; major route of elimination for absorbed gepotidacin)

[a] Pharmacokinetic parameters are presented at steady state in patients with uUTI and eGFR greater than or equal to 90 mL/min after oral administration of BLUJEPA 1500 mg every 12 hours over 5 days.
[b] Studies evaluating the effect on food were performed with standard and moderate fat meal. Clinical studies were not performed with a high fat meal (1000 calories, 50% fat).

Storage and Handling

- Gepotidacin tablets are supplied as yellow, film-coated, capsule-shaped tablets debossed with "GS GU3" on one side and plain on the other side, containing 750 mg of Gepotidacin.

Bottle of 20 tablets (NDC 0173-0922-45).

- Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

Reference

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218230s000lbl.pdf

भारतीय भेषज संहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सेक्टर - २३, राज नगर,
गाजियाबाद - २०१ ००२, उत्तर प्रदेश, भारत

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector - 23, Raj Nagar
Ghaziabad- 201 002 (U.P.), INDIA

File No. P.17019/03/2025-DSA **Dated: March 12, 2025**

Monthly Drug Safety Alerts

The analysis of Adverse Drug Reactions (ADRs) from the PvPI database revealed the following;

S. No.	Suspected Drugs	Indication(s)	Adverse Drug Reactions
1	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Acute Generalised Exanthematous Pustulosis (AGEP)
2	Luliconazole	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris.	Chloasma/Melasma
3	Dalteparin	For the extended treatment of symptomatic Venous Thromboembolism (VTE) proximal Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer.	Muscle spasms
4	Gliclazide	Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults.	Erythema multiforme
5	Tramadol	For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain.	Fixed Drug Eruption

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side Effect Reporting Form for Consumer (**http://www.ipc.gov.in**), through **PvPI Helpline No. 1800-180-3024.**

Reference

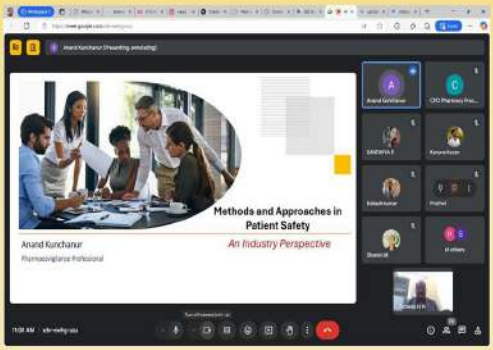
https://www.ipc.gov.in/images/Drug_Safety_Alert_March_12_2025.pdf

EVENT CORNER
Industrial Expert Interaction series - 2025

Resource Person:
Mr Anand Kunchanur
Senior Manager/Affiliate Safety Representative
AbbVie, Bangalore, Karnataka, India

Organized by:
Dept. of Pharmacy Practice & Pharmacy Education Unit,
JSS College of Pharmacy, Ooty.
Date: 08.02.2025

Mr Anand is presently working as Senior Manager-Affiliate Safety Representative, AbbVie, Bangalore. He has more than 17 years of experience in the pharmacovigilance & clinical research industry. He also has experience of handling Project management and people management (up to team size 900) and has experience in handling software like SCEPTRE, ARGUS, Trilogy and SafetyEasy. The Industrial expert interaction series was hosted in online platform 'Google meet'. Mr Anand started on the presentation by providing basic aspects of Pharmacovigilance. He stressed on major incidents which led to the establishment of pharmacovigilance departments. Mr Anand elaborated the industrial perspectives related to pharmacovigilance. He explained in detailed about serious and non-serious adverse drug reaction. Mr Anand stressed about aspects like how industry operates the drug safety information and how this data helps the industry to get marketing approval. Further, Mr Anand elaborated on aspects like 'patient safety frame work' and also explained about the roles of various stake holders. Mr Anand briefed about the signal detection process in pharmacovilance industry. Finally, Mr Anand explained how artificial intelligence and machine learning software are helping the industry in case processing, aggregate report preparation. Mr Anand elaborated and stressed the students to learn programing and coding and explained about novel job opportunities for young graduates in the pharmacovigilance industry. Few students clarified their doubts related to aspects in the presentation. A total of 84 students from M Pharm and Pharm D courses witnessed the event. The event was coordinated by Dr S Ponnusankar, Mr Vishwas H N & Dr Rajamohamed H, Faculty, Department of Pharmacy Practice.



Pharmacotherapy Coursework

Resource Person:
Dr. Logharaj
Orthopedic Surgeon
Government Medical Colllege & Hospital, Ooty

Organized by:
Dept. of Pharmacy Practice , JSS College of Pharmacy, Ooty.
Date: 18.02.2025, 19.02.2025 & 20.02.2025

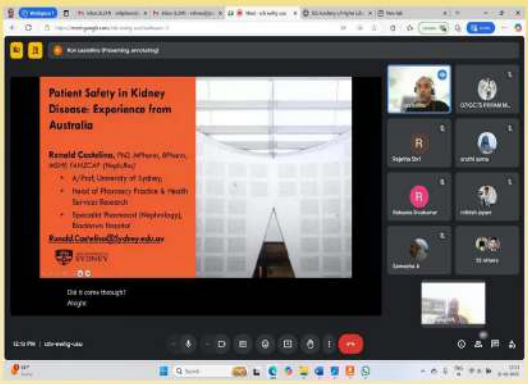
The coursework was strategically scheduled over a span of three days, catering to different academic levels and was meticulously designed to align with the Pharmacotherapeutics syllabus, ensuring relevance to the students' academic and clinical learning objectives. The coursework materials were distributed to students in advance, ensuring structured learning and active participation in discussions. To facilitate collaborative learning and interactive engagement, students were divided into groups to enhance teamwork and foster peer-assisted learning. The coursework included simulated case-based discussions, allowing students to apply theoretical knowledge to practical clinical scenarios. A key highlight of the coursework was the interprofessional knowledge exchange conducted by Dr. Logharaj, an esteemed orthopedic surgeon, on the first two days. He provided an in-depth understanding of various clinical conditions and treatment approaches, fostering a multidisciplinary perspective crucial for effective patient management. He critically appraised the students presentation and delivered his clinical knowledge regarding Clinical manifestations, pathophysiology and Pharmacological and non-pharmacological treatment strategies of diseases to the students. A total of 95 students from IV, III, and II PharmD programs actively participated and gained invaluable knowledge from the coursework. Attendance records, duly signed by the students, were collected for documentation purposes. The coursework successfully met its objective of bridging theoretical knowledge with clinical application, preparing students for real-world pharmacy practice. Dr. Logharaj commended the initiative, emphasizing the importance of conducting such pharmacotherapeutic activities to strengthen students' clinical competencies. The Department of Pharmacy Practice aims to continue refining and expanding such educational initiatives to further enrich the learning experience of PharmD students.

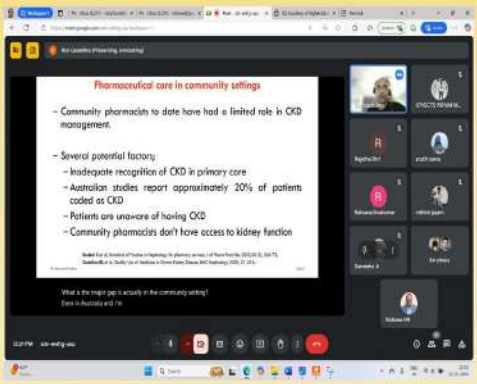
Invited Impact Pharmacy Lecture series - 2025

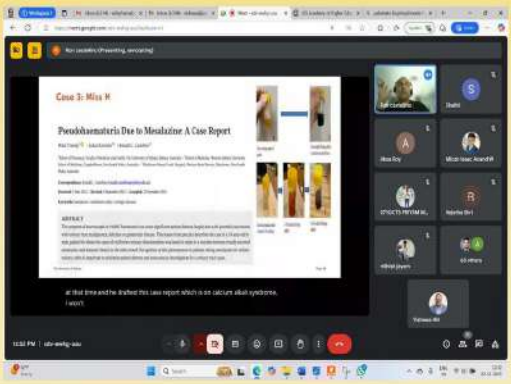
Coordinator: Dr. Ronald Castelino, Associate Professor,
Head of Pharmacy Practice and Health Services Research, School of Pharmacy,
University of Sydney, Australia

Organized by: Dept. of Pharmacy Practice & Pharmacy Education Unit, JSS College of Pharmacy, Ooty.
Date: 22.02.2025

Dr. Ronald Castelino is an Associate Professor, Head of Pharmacy Practice and Health Services Research at the School of Pharmacy, the University of Sydney and a Specialist Renal Pharmacist at Blacktown Hospital, NSW. He currently leads the medication safety research in kidney disease at the University of Sydney with 3 post- doctoral researchers, 4 PhD students, and 1MPhil student. He is also a Fellow of the Australia New Zealand Advanced College of Pharmacy (FANZCAP) as a consultant (Nephrology and Research) and a member of the Australia New Zealand Society of Nephrology (ANZSN). Dr Ronald Castelino's research mainly focusses on developing interventions to improve medication safety and quality use of medicines especially in kidney disease. The Academic expert interaction series was hosted in online platform 'Google meet'. Dr Roland started the presentation by discussing the burden of kidney diseases in Australia. He explained about the common types of kidney disorders prevalent in Australia. Further Dr Roland elaborated the important pharmaceutical care services offered by Hospital Pharmacy & Community Pharmacy at Australia. Dr Roland explained how community pharmacists are doing major health promotion activities for general public of Australia. Further, Dr Ronald explained few research findings from study conducted at Australia about 'Impact of pharmacy-led screening and intervention in people at risk of or living with CKD in primary care setting: a cluster randomized trial'. Further, Dr Ronald shared four clinical cases related to chronic kidney diseases and how these interesting cases led to publishing case reports at reputed peer reviewed journals. Few students clarified their doubts related to clinical pharmacist responsibilities in CKD patient care. A total of 74 students from M Pharm and Pharm D courses witnessed the event. The event was coordinated by Dr S Ponnusankar, Mr Vishwas H N & Dr Rajamohamed H, Faculty, Department of Pharmacy Practice.





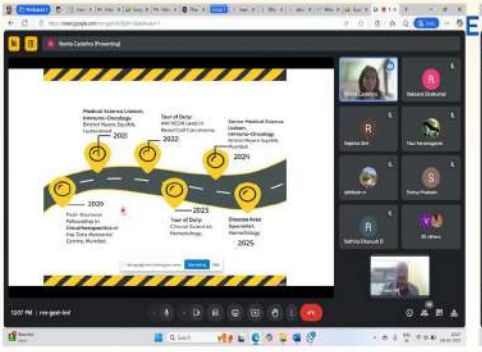


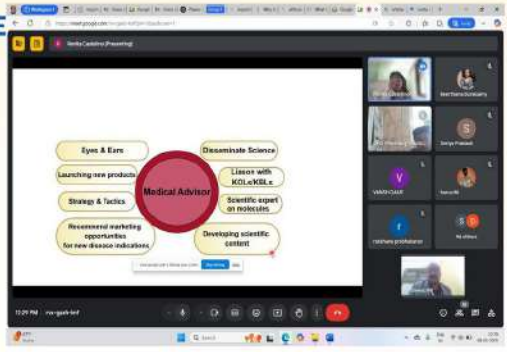
Alumni Interaction series - 2025

Resource Person:
Dr. Renita Castelino
Disease Area Specialist-Hematology
Bristol-Myers Squibb,
Mumbai, India

Organized by: Dept. of Pharmacy Practice & Pharmacy Education Unit, JSS College of Pharmacy, Ooty.
Date: 08.03.2025

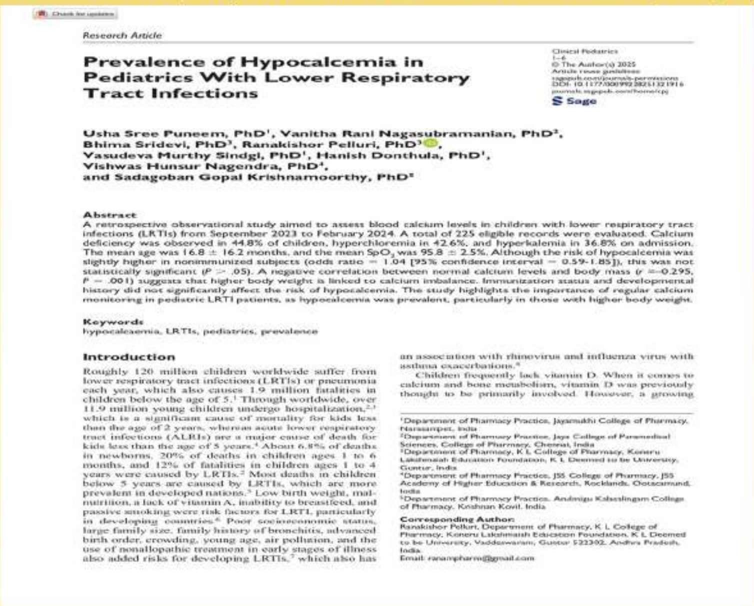
Dr Renita Castelino was an alumnus from Department of Pharmacy Practice, she pursued her Pharm D from 2014-2020 batch. She was a meritorious student who actively worked in various committees of the college (Blood donor's club, Youth Redcross club & Rotaract club). She was very good in academics as well as extracurricular activities. She was a voracious debater and represented the institution in various debate competitions. She was one of the fortunate Interns to get trained from University of North Carolina, USA during her Internship. Dr Renita is presently working as Disease Area Specialist in Hematology at Bristol-Myers Squibb. She previously worked as Senior Medical Science Liaison in Immuno-Oncology at BMS. Dr Renita worked as Fellow in Oncotherapeutics at the Tata Memorial Centre, Mumbai after completing her Pharm D degree. The Alumni interaction series was hosted in online platform 'Google meet'. Dr Renita started the presentation by discussing the basics of medical affairs. Dr Renita elaborated her journey of Pharm D and how JSS College of Pharmacy, Ooty helped her to achieve various recognitions. Dr Renita explained her journey as 'Fellow in Oncotherapeutics' at the Tata Memorial Centre, Mumbai. She elaborated how she contributed for the hospital and enhanced her research skills. She elaborated the professional roles as 'Medical advisor' and qualities students should possess to enter this field for their career perspective. She shared her professional experience at various positions at BMS. She explained 6 qualities a student should possess in order to enter 'Medical affairs' departments at various MNCs across India. Few students clarified their doubts with Dr Renita. A total of 60 students from M Pharm and Pharm D courses witnessed the event. The event was coordinated by Dr S Ponnusankar, Mr Vishwas HN & Dr Rajamohamed H, Faculty, Department of Pharmacy Practice.





Publications from the Department of Pharmacy Practice (January - March 2025)

- **Deepalakshmi M**, Arun K P, Srikanth Jupudi, Akila A, Kailash Kumar S, Sanjay V, Yogesh V. P- glycoprotein (P-gp) Mediated Drug Interaction between Digoxin & Orange Juice - An Exploratory Study by in-silico Approach. Cuestiones de Fisioterapia. 2025;54(1): 424-452.
- Usha Sree P, Vanitha Rani N, Bhima S, Ranakishor P, Vasudeva Murthy S, Hanish D, **Vishwas Hunsur Nagendra**, Sadagoban GK. Prevalence of Hypocalcemia inPediatrics With Lower RespiratoryTract Infections. Clinical Pediatrics. 2025;1-6.
- Sandrea Alby, Reshma George, Aksa Roy, Y Joel Isaac, Roja B, Someshwaran S, **Mohsina Hyder***, V Arun Kumar, V. Jothibasu. Perception of patients with diabetes comorbidities on polypharmacy and deprescribing in a public healthcare setting. South Eastern European Journal of Public Health. 2025;XXVI:3194-3213.
- Suguna Kotte, Vishwas HN, Balasubramaniam V, **Ponnusankar S***. Unlocking Urban India's awareness of oral anticoagulatoin: implications for healthcare education. Turkish Journal of Pharmaceutical Sciences 2025;22(1):19-25.
- Aman Khandelwal, Gowthamarajan K, Nirmal J, **Ponnusankar S***. Exploring the therapeutic potential of anti-VEGF drugs for the management of diabetic retinopathy: an overview. Current Diabetes Reviews, 2025;21(9):18-32.



Research Article

Prevalence of Hypocalcemia in Pediatrics With Lower Respiratory Tract Infections

Usha Sree Puneem, PhD, Vanitha Rani Nagasubramanian, PhD, Bhima Sridevi, PhD, Ranakishor Pelluri, PhD, Vasudeva Murthy Sindgi, PhD, Hanish Donthula, PhD, Vishwas Hunsur Nagendra, PhD, and Sadagoban Gopal Krishnamoorthy, PhD

Perception of Patients with Diabetes Comorbidities on Polypharmacy and Deprescribing in a Public Healthcare Setting

Sandrea Alby, Reshma George, Aksa Roy, Y Joel Isaac, Roja B, Someshwaran S, Mohsina Hyder*, V. Arun Kumar, V. Jothibasu

ORIGINAL ARTICLE

Unlocking Urban India's Awareness of Oral Anticoagulation: Implications for Healthcare Education

REVIEW ARTICLE

Exploring the Therapeutic Potential of Anti-VEGF Drugs for the Management of Diabetic Retinopathy: An Overview

Aman Khandelwal, Kuppusamy Gowthamarajan, Jayabalan Nirmal and S. Ponnusankar

For clarifications/ feedback, write to:

The Chief Editor
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