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Table of Contents

EDITORIAL

DONANEMAB FOR ALZHEIMER'S DISEASE: PROGRESS, PROMISE, AND PERSISTENT UNCERTAINTY

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The search for disease-modifying therapies in Alzheimer's disease (AD) has, for decades, yielded more frustration than success. However, the development of anti-amyloid monoclonal antibodies—most recently donanemab—signals a cautious but genuine shift in the treatment landscape. Results from the Phase 3 TRAILBLAZER-ALZ 2 trial suggest that donanemab, an antibody targeting N3pG-modified amyloid-β (Aβ) plaques, slows clinical decline in early symptomatic AD [1]. While the results are encouraging, they invite critical reflection on efficacy, safety, and the implications for real-world clinical practice. Donanemab's distinguishing mechanism lies in its high affinity for pyroglutamate-modified Aβ—a post-translationally altered form that is thought to seed and stabilize amyloid plaques [2]. In the TRAILBLAZER-ALZ 2 trial, donanemab achieved robust amyloid clearance and significantly slowed cognitive and functional decline, particularly in patients with low to intermediate tau burden [1]. Among this subgroup, disease progression was slowed by up to 35% over 76 weeks, measured using the integrated Alzheimer's Disease Rating Scale (iADRS). These findings mark a meaningful scientific advance. Unlike earlier failed anti-amyloid therapies, donanemab provides compelling biological and clinical evidence that amyloid reduction can translate into cognitive benefit—albeit modest in magnitude. The strategy of stopping treatment after amyloid clearance, guided by PET imaging, introduces a novel approach that may optimize efficacy while minimizing exposure and costs. However, important concerns remain. Amyloid-related imaging abnormalities (ARIA), particularly ARIA-E (vasogenic oedema), were observed in over 24% of donanemab-treated participants, and symptomatic cases occurred in nearly 6% [1]. The risk of ARIA is especially high in APOE ε4 carriers, necessitating genotype-informed risk stratification and frequent MRI monitoring. These safety requirements may limit broad clinical applicability, especially in health systems with constrained resources. Additionally, the trial's enrichment design—selecting patients with confirmed amyloid and tau pathology—enhances internal validity but raises questions about generalizability. Will real-world patients, often with comorbidities, atypical presentations, or late-stage disease, derive comparable benefit? Another critical point is the modest effect size. Slowing of progression by several months, while statistically significant, may fall short of the transformative outcomes patients and families hope for. Furthermore, donanemab does not target tau aggregates, neuroinflammation, or synaptic dysfunction—key contributors to neurodegeneration. Thus, its role may ultimately be as one component of a multi-pronged therapeutic regimen. Nevertheless, donanemab's success affirms a central principle: that early, biology-driven intervention can alter the course of AD. It underscores the importance of precision diagnostics, such as amyloid and tau PET or plasma biomarkers, and reorients the field toward early detection and prevention. Moving forward, research should focus on combination therapies that address multiple pathophysiological targets, broader inclusion criteria to reflect clinical diversity, and longitudinal studies assessing durability of benefit. Moreover, policy and health system leaders must anticipate the challenges of scaling advanced diagnostic and monitoring tools to meet growing demand.

In sum, donanemab is a meaningful milestone. It offers more than its predecessors and provides hope grounded in science. But it also reminds us that true disease modification in AD will be incremental, iterative, and complex. The road ahead remains long, but the direction is finally clearer.

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Review Article

A BRIEF REVIEW ON 3D PRINTING IN PHARMACY

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ABSTRACT:
3D printing , also known as additive manufacturing has gained significant attention in the pharmaceutical industry due to its potential to revolutionize drug development and delivery. This technology allows for the creation of complex drug formulations , personalized dosage forms , and customized drug release profiles. By priting medications layer by layer , 3D printing offers precision in design , scalability in production , and the possibility for on – specific doses, enhance bioavailability , and improve the convenience and compliance of drug regimens. However , challenges such as regulatory hurdles , material limitations , and the need for standardized quality control processes remain. Despite these obstacles , 3D printing holds great promise for the future of pharmaceutical manufacturing , making it a promising area of research and innovation in personalized medicine.

INTRODUCTION:
3D printing is also known as additive manufacturing, it is a method of creating a three dimensional object layer-by-layer using a computer created design. It was first developed by Charls Haul, in 1984. 3DP has a wide range of applications like tissue design, printing of organ, diagnostics, manufacture of biomedical devices and the design of drug and delivery systems in the medical field. Replacing and repairing the defective organs like kidney, heart, etc or all together creating a new organ that mimics the same functions as that of original are some additional uses of this technology. The application of 3D printing in medicine can provide many benefits, including the customization and personalization of Medical products, drugs and equipment, cost effectiveness, increased productivity, the democratization of design and manufacturing and enhanced collaboration. 3DP has been used in anti-cancer therapy, for the production of stimuli responsive hydrogels, nanogels and drug loaded implants with great flexibility and a wide variety of shapes that allow dose customization and targeted treatment with minimum side effects. Different types of drug delivery systems for instance oral controlled release systems, micro pills, microchip, drug implants, fast dissolving tablets and multiphase release dosage forms have been developed using 3 dimensional printing technology.3D printing is an additive layer manufacturing techniques, where consecutive layers of material are deposited or solidified to form a 3D structure. In this review, the most information was available on different review articles published in different international journals. Several approaches have been taken to ensure a high-quality literature review dissertation of 3D printed oral pharmaceutical formulations, focusing on their mechanical properties. Databases from Research gate and Google Scholar were used for an initial comprehensive and a second in-depth search of the topic. The main keywords used in the search were: 3D printed tablets, 3D printed oral dosage forms, additive manufacturing, 3D printing in personalized drug dosage forms, bioprinting organs for clinical trial. Number of articles analyzed in detail in the Results, websites were also used to obtain reliable information on the guidelines.

LITERATURE SURVEY:
1) Essyrose Mathew, Giulia Pitzanti, Eneko Larraneta and Dimitrios A. Lamprou in 2020 studied 3D Printing of Pharmaceuticals and Drug Delivery Devices which is published by MDPI Journal in 2020. 2) Danae Karalia, Angeliki Siamidi , Vangelis Karalis and Marilena Vlachou in 2021 studied 3D-Printed Oral Dosage Forms: Mechanical Properties, Computational Approaches and Applications which is published in MDPI Journal in 2021. 3) Byeong Ju Park, Ho Jae Choi, Sang Ji Moon, Seong Jun Kim, Rajiv Bajracharya, Jeong Youn Min, Hyo-Kyung Han in 2018 studied Pharmaceutical applications of 3D printing technology: current understanding and future perspectives which is published by Springer an American publishing company in 2018. 4) Nasim Samiei in 2020 studied Recent trends on applications of 3D printing technology on the design and manufacture of pharmaceutical oral formulation which is published by Beni-Suef University Journal of Basic and Applied Sciences in 2020. 5) Witold Jamroz, Joanna Szafraniec, Mateusz Kurek, Renata Jachowicz in 2018 studied 3D Printing in Pharmaceutical and Medical Applications– Recent Achievements and Challenges which is published by Springer an American publishing company in 2018. 6) Asad Ali, Usama Ahmad and Juber Akhtar published 3D Printing in Pharmaceutical Sector: An Overview by intechopen. 7) C. Lee Ventola, MS. in 2014 studied Medical Applications for 3D Printing,

Current and Projected Uses published by P&T publisher in 2014. 8) Ravikumar Tamil Ponni, Mahalingam Swamivelmanickam, Sivagnanam Sivakrishnan in 2020 studied 3D Printing in Pharmaceutical Technology and published an article by research gate in international journal in 2020.

AIM:

The role of 3D printing technology in pharmaceutical industry for production of personalized drug dosage forms and in bioprinting for clinical trials. Importance of 3D manufacturing technique it's advantages and disadvantages. Recent trends in 3d printing and future prospects. Regulatory guidelines for this technology.

OBJECTIVES:

To describe how 3D printing process in formulation of drug delivery is better than conventional manufacturing techniques. Different types of techniques used in 3DP. Working of 3D printing, the steps involved in 3D printing. Advantages and disadvantages of 3DP. Recent trends and 6development in 3D printing technology. Future prospects and limitatregulatory guidelines

HISTORY:

3D Printing was invented by Charles Hull in 1980 which he called "Stereolithography". Year and Major development in the field of 3D printing 1980:- Dr. Hideo Kodama filed firstpatent for RP technology 1984:- Stereo lithography apparatus (SLA) was invented by Charles Hull1986:- Carl Deckard invented apparatus for producing parts by selective sintering 1989:- Patent was granted to Carl Deckard for SLA 1990:- Fused deposition modeling (FDM) 1992:- First SLA machine was produced using 3D system 1993:- 3D printing patent was granted to E.M Sachs 1996:- Clinical application of biomaterials for tissue regeneration 1999:- Luke Massella received first 3D printed bladder which was an amalgamation of 3D. p . rinted biomaterials and his own cells 2000:- MCP technologies introduced the SLM technology 2002:- Miniature functional kidney was fabricated 2003:- Term organ printing was coined 2004:- Dr. Bowyer conceived the RepRap concept of an open-source, self-replicating 3D printer 2005:- First color 3D printer was introduced by Z Corp 2007:- Selective layer customization and on-demand manufacturing of industrial parts 2009:- Organovo, Inc., announced the release of data on the first fully bioprinted blood vessels 2011:- 3D printing was applied in gold and silver World's first 3D printed car, robotic aircarft was introduced 2012:- Extrusion-based bioprinting for an artificial liver 3D printed prosthetic jaw was implanted2013:- SolidConcepts produced a 3D printed metal gun 2014:- Implementation of multi-arm bioprinter to integrate tissue fabrication with printed vasculature 2015:- First 3D printed pill was approved by US FDA Organovo announced the release of data on the first fully bioprinted kidney

MATERIALS AND METHODS:

Tablets are divided manually using hands, knives, or tablet splitters, which leads to uneven weight distribution after division and drug release problems (e.g., premature drug release, breakage of coating system, etc.). 3D printing, on the other hand, can effectively solve these problems by moving away from the "one- size-fits-all" approach and mass production toward personalized pharmacotherapy. Five main techniques have been used to produce pharmaceutical dosage forms: binder jet printing, fused deposition modeling (FDM), semi-solid extrusion (SSE), selective laser sintering (SLS), and stereolithography. 3D screen printing is based on the transfer of API-containing printing paste through specific openings of the printing screen onto a given substrate.

3D PRINTING AND CONVENTIONAL MANUFACTURING:

Conventionally tablets are produced by mass fabrication which involves multiples processes such as blending, mixing, milling, and finally compression into tablets. conventional manufacturing techniques are intended to be a large-scale mass production with a one-dose-fit-all approach which may not necessarily consider the individual needs of a patient. The major disadvantages of the traditional manufacturing process include being time-consuming and costly while also requiring highly skilled technicians.

Parameters	3D printing	Traditional manufacturing
Cost	Upton 70% savings due on Prototyping costs	Higher cost of manufacturing and shipping
Design	Allows for easy yet inexpensive innovation in design	Less innovative designs due to cost constraints
Speed	Lesser time taken due to compressed design cycles	More time to build final product
Quality	Lighter and smaller amount to waste; Higher precision with layer by layer manufacturing	Creates more waste; subtractive process will compromise on precision

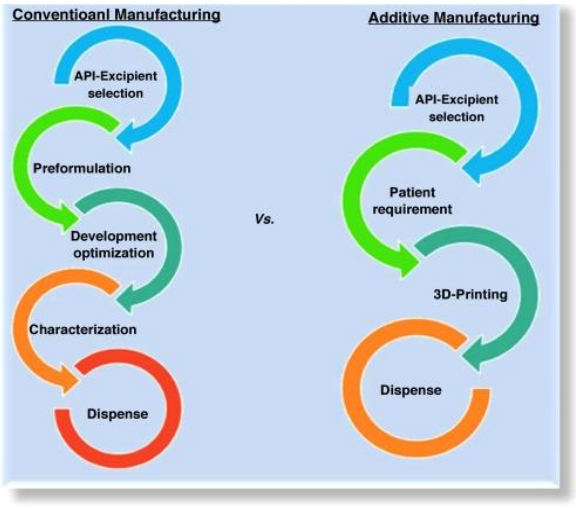


Figure 1 - Conventional tablet manufacturing process (A). 3D printing manufacturing process (additive manufacturing) (B).

Table 1. Difference between 3DP and traditional manufacturing.The 3D printing technology is fundamentally different from the traditional mass production methods. 3D printing in the pharmaceutical industry, it is possible to curtail the process of manufacturing drug products from days to a matter of hours. Speeding up the production process can lead to more rapid release of the drug product into the market. In addition, the ability of 3D printing to rapidly manufacture a drug product causes a substantial cost reduction in the production process, which is highly favorable to the pharmaceutical industry. It promotes creativity, innovation, and customization. The fabrication steps with 3D printing are clean and the material waste is negligible allowing for previously discarded raw materials to be further explored, while also increasing compliance and accessibility of drugs.

PROCEDURE OF 3DP:

Softwares such as onshapes, solidworks, Creo parametric, Autocad, Autodesk, etc. are used for virtual 3D design of objects

The digital design is exported to a readable format for a system which is mainly a stereo lithography (STL) file

Slicer (3D printing software) transfers the STL file into a series of thin layers with the instruction tailored to generate the 3D object.

Preparing pharmaceutical formulation ink such as filament, binder solutions, granules, paste etc. based on technology used.

During the printing, the printer head moves and the formulation ink decomposes onto successive layers on a built tray which will create the basis for the object. The process continues until the desired 3D product is constructed.

Final 3D product may require removal of solvent residues, excess powder, polishing and sintering which occur in the post printing step. Flow chart-Steps involved in 3DP manufacturing process.

TYPES OF 3DP TECHNOLOGY:

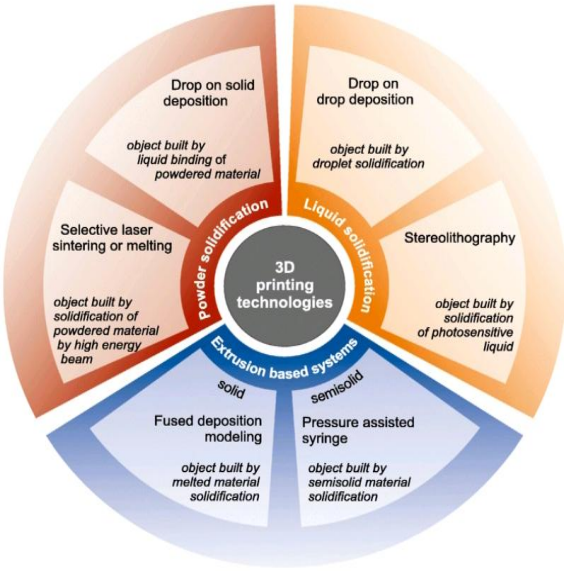


Figure 3 - 3DP methods applied for drug formulation

EXTRUSION BASED SYSTEMS

1. FUSED DEPOSITION MODELING (FDM):
In fused deposition modeling (FDM), drug-loaded thermoplastic polymer filaments are extruded through the print head at a specific temperature in specific directions. The molten filament is then deposited onto the build plate and solidifies in successive layers to form the object. Fused deposition modelling (FDM) is commonly used method in 3D printing, the materials are softer or melt by heat to create objects during printing. Fused deposition modeling 3D printing helps in manufacturing delayed release print lets without an outer enteric coating and also provides personalized medicines doses. This 3D Printing indicates some limitations for system like lack of suitable polymers, slow and often incomplete drug release, because of the drug remain trapped in the polymers, miscibility of drug and additives with the polymers used was not valued. Ethyl cellulose (EC), hydroxypropyl cellulose (HPC), hydroxypropyl methyl cellulose (HPMC), hydroxypropyl methyl cellulose acetate succinate (HPMCAS), ethylated acrylate copolymer (Eudragit® RL and RS), polyethylene glycol (PEG), polyethylene oxide (PEO), polylactic acid (PLA), polyvinyl alcohol (PVA), and polyvinyl pyrrolidone (PVP) are the most commonly used polymers in the FDM 3D printing. Lamichhane et al. used FDM printing technology to develop floating gastro-retentive tablets with controlled release properties.

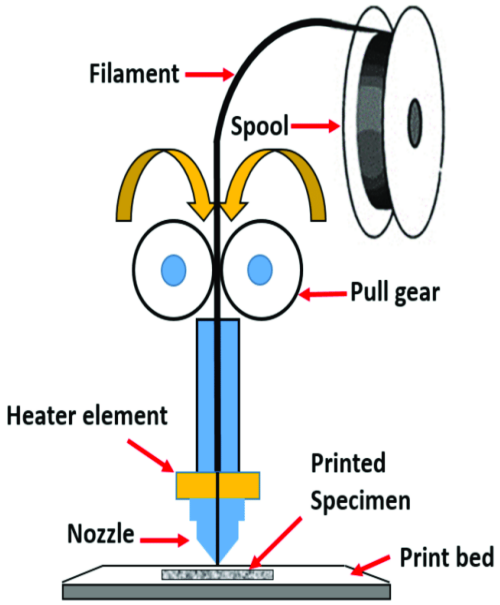


Figure 4 - Fused Deposition Modeling.

2. SEMI-SOLID EXTRUSION:
Semi-solid extrusion (SSE) is a 3D printing technique in which material in semi-solid or semi-molten form is extruded from a syringe-like system in successive layers to form a three-dimensional object. Unlike FDM, which uses solid filaments, SSE prepares the starting material by mixing the ideal ratio of active substances with solvents to form a gel or paste. Moreover, low temperatures are used during the process, therefore, it is suitable for thermolabile active ingredients.

THERMAL INKJET PRINTING (TIJ):
The aqueous ink fluid is transformed to vapours state through heat, expands to push the ink drop out of a nozzle. It is used in the preparation of drug-loaded biodegradable microspheres, drug-loaded liposomes, patterning microelectrode arrays coating, loading drug eluting stents. It is also an effectual and applied method of generating films of biologics without negotiating protein activity.

INKJET PRINTING :
It is also known as ‘mask-less’ or ‘tool-less’ approach for its desired structure formation mainly depends upon the inkjet nozzle movement or substrate movement for an accurate and reproducible formation. The Ink is deposited onto a substrate either in the form of Continuous Inkjet printing / Drop on demand printing. Hence it provides a capability of high-resolution printing. It has a low cost, rate of processing in printing and generation of low level of wastes. It gives CAD information in a ‘direct write’ manner and process material over large areas with minimal contamination.

EXTRUSION 3D PRINTING:
In this method the material is extruded from the automated nozzle onto the substrate without any higher support material. It is only utilized to fabricate tablet containing Guaifenesin act as expectorating. The components that can be extruded are molten polymers, suspensions, semisolids, pastes.

HOT MELT EXTRUSION (HME):
Hot melt extrusion (HME) is the method of melting polymer and drug at elevated temperature and the pressure is employed in the instrument sequentially for blending.27 It is a continuous manufacturing technique that involves feeding, heating, mixing and shaping.28 In recent years, it has proved that Hot melt extrusion capable to optimize the solubility and bioavailability of moderately soluble drugs.

LIQUID SOLIDIFICATION:
1. STEREOLITHOGRAPHY:
Stereolithography is the method of computer regulated laser beam is used to make liquid polymer/resin as solid, by this means creating a 3D structure.30 Stereolithography has several advantages over former types of other 3DP, predominantly it's astonishing resolution and dodging of thermal practices can be harmful for specific drug molecules. Healy et al., used SLA as the AM process to create oral dosage forms of 2.5% and 5% concentration of aspirin and paracetamol. The results from release studies showed that there was an increased in release of active drug when drug loading was increased, this highlights the potential for patient specific drugs to be created with the ability to modulate drug release. Overall, this study effectively highlighted the potential for creating solid dosage forms using SLA printing, with the research leading towards the ability to create personalised medication and the ability to modulate drug release from printed products. Robles-Martinez et al., were able to construct a novel SLA printing method that allowed the production of multi-layered tablets (polypills) that had flexible drug content and shape. The drugs chosen for the work were paracetamol, caffeine, naproxen, chloramphenicol, prednisolone and aspirin. This study showed the possibility to uses SLA 3DP for fabricating multi-drugs tablets to improve personalisation for patients.

DROP ON DROP DEPOSITION:
4. DIRECT WISE:
It encompasses a pattern-generating device that moves as per the guidance of computer-controlled translational stage so that layers after layers are put on in order to achieve a 3D microstructure.

POWDER SOLIDIFICATION:
This method customs powder jetting/powder bed to feast thin layers of powder and instantaneously applying liquid binder drops with inkjet printers. The ink (binders and APIs or binder solutions) is sprinkled over a powder bed in two-dimensional (2D) approach to make the decisive product in a layer by layer fashion. The adaption of this approach into pharmaceutical manufacturing is at ease than other approaches as powder and binder solutions are broadly used in the pharmaceutical industry. The own disadvantages of this approach are; to remove solvent residues additional drying is required, during printing excess powder accumulates and contributes to wastage and due to the permeable design of the powder the drug delivery system's mechanical strength may poor.

1. SELECTIVE LASER SINTERING:
Selective laser sintering (SLS) act as a way in the powder bed to bind. The laser is designed to draw a specific pattern on the surface of the powdered bed during the printing process, thus creating a 3D structure. For example, Paracetamol is an Orodispersible tablet prepared by this manner. It is currently used for industrial manufacturing of plastic, metallic and ceramic objects. Awad et al., utilised SLS 3DP, for the first time, to produce small oral dosage forms with modified release properties. They fabricated single miniprintlets using paracetamol as a model drug and dual miniprintlets where paracetamol is combined with ibuprofen. For the single miniprintlets, ethyl cellulose (EC) was employed as the main polymer matrix. In the case of dual miniprintlets one layer contained EC for sustained release whereas the second layer containing Kollicoat IR (a graft copolymer comprised of PEG: PVA, 1:3) for immediate release. In order to assess the effect size has on dissolution properties, miniprintlets of two different diameters, 1 mm and 2 mm, were developed. The single miniprintlets exhibited slow paracetamol release, which was reduced when increasing the diameter. For the dual miniprintlets, the diameter does not affect the paracetamol release profile. This work demonstrates the possibility to use SLS 3D printing to combine multiple Active Pharmaceutical Ingredients (APIs) with distinct release properties in a single dosage form.

2. DROP ON SOLID:
ZIP DOSE:
Zip dose is the world's initial and only FDA-approved, commercial-scale 3DP in current therapeutic areas for pharmaceutical manufacturing areas. It has a distinctive digitally coded layering and zero compression practices, used for tablet formulation with large dosage and prompt disintegration. Hence, it helps in overwhelming a difficulty in swallowing. Spritam-R (Anti-epilepsy drug) is an oral dispersible tablet, marketed by Aprecia Pharmaceuticals based on powder bed fusion by layer-by-layer production system. In

which it consists of the active ingredient, excipients and a binder liquid to produce a matrix tablet.

BINDER JETTING:
Binder jetting (BJ) is a 3D printing technique in which a liquid binder solution is precisely applied to a powder substrate using a printer nozzle. The moistened powder particles are then fused together, solidifying the layer. The first layer is printed onto the build platform, then the plunger lowers to the thickness of the following layer and subsequent layers are printed and bonded together. The process is repeated several times until the 3D object is produced.

3DP Technology	Formulation	API
Fused deposition modeling (FDM)	Caplets Tablets Oral films	Caffeine Hydrochlorothiazide Aripiprazole
Thermal inkjet printing (TIJ)	Solution	Salbutamol suspension
Inkjet printing	Implant Nanosuspension Nanoparticle Tablets	Levofloxacin Folic acid Rifampicin Acetaminophen Chlorpheniramine maleate Chlorpheniramine maleate, diclofenac Levetiracetam

Table 2-Pharmaceutical preparations that were developed by 3DP technology.

EFFECT OF 3D PRINTING TECHNIQUE IN DRUG DELIVERY SYSTEMS:
3D printing most likely corresponds to novel architectural innovation and enables designing and fabricating oral dosage forms with different geometrics, complex features such as tablets with a designed internal structure, porosity gradients, torture channels, and multi-compartment systems such as poly-pills containing multiple API in one dosage forms. These features may enable the control of drug release rate by obtaining specific and complex release patterns in response to the patient's needs, thereby enhancing the drug efficacy. Concerning customized medicine, clinical pharmacists or doctors may need patient's individual information such as age, gender, body mass index, and metabolism in order to develop the optimum medical dose. In this way, the patient can receive accurate personalized treatment regimen matching their particular medical profile

ADVANTAGES:
1) Objects produced by 3D printing are of low cost. It is an advantage for small-scale production units or for companies that produce highly complex products or parts because almost all ingredients are inexpensive. 2) Cost efficient due to less wastage of materials. 3) Suitable drug delivery for difficult to formulate active ingredients like poor water solubility and narrow therapeutic windows drugs.
4) Medication can be tailored to a patient in particular based on age, gender, genetic variations, ethnic differences and environment. 5) Treatment can be customized to improve patient adherence in case of multi-drug therapy with multiple dosing regimen. 6) As immediate and controlled release layers can be incorporated owed to flexible designs, manufacturing method of dosage form and it helps in pick out the best therapeutic regimen for an individual. 7) Evades batch-to-batch variations met in bulk manufacturing of conventional dosage forms. 8) Manufacture of small batch is feasible and the process can be completed in a single run.
9) 3D printers capture minimal space and are affordable.

DISADVANTAGES:
1) The fabrication of 3D products require different types of technologies in particular those used in pharmaceutical production, which are often rarely available in the pharma industry. 2) Hackers making alterations to a drug's recipe or doses within a hospital or pharmacy where it's printed, leading to severe health consequences for patients. 3) Problems related to nozzle are a major challenge as stopping of the print head which affects the final products structure. 4) Powder printing clogging is another hurdle. 5)Possibility of modifying the final structure on to mechanical stress, storage condition adaptions and ink formulations effects. 6) Printer related parameters and these effects on printing quality and printercost. 7) In inkjet printing, proper flow of ink can only be achieved with ink that has precise viscosity. 8) Ink formulation material should have the property of self-binding but should not bind to other printer elements. In some formulation when the ink does not possess adequate self-binding property or it binds with other elements of printer then the resultant formulation does not have required hardness. Rate of drug release may get affected due to binding of ink with other printer materials.

APPLICATIONS:
PERSONALIZED DRUG DOSING: Drugs with narrow therapeutic index can easily be prepared

using 3D printing and, by knowing the patient's pharmacogenetic profile and other characteristics like age, race etc., optimal dosage can be given to the patient. Preparation of entirely new formulation is another vital potential of 3D printing for instance fabrications of pills that have a blend of more than one active pharmaceutical ingredient or dispensed as multi-reservoir printed tablets. Hence patients suffering from more than one disease can get their formulation ready in one multi-dose form at the healthcare point itself, thereby providing personalized and accurate dose to the patient with better or best compliance.

1) COMPLEX DRUG RELEASE PROFILE:

In 3D printed dosage forms, a complex drug release profile that allows fabrication of complex geometries that are porous and loaded with multiple drugs surrounded by barrier layers that modulate release of drug. Example. 3D printing has been used to print antibiotic micropatterns on paper, which have been used as drug implants to eradicate Staphylococcus epidermidis, chlorpheniramine maleate was 3D printed onto a cellulose powder substrate in amounts as small as 10–12 moles to demonstrate that even a minute quantity of drug could be released at a specified time. This study displayed improved accuracy for the release of very small drug doses compared with conventionally manufactured medications.

2) CUSTOMIZED IMPLANTS AND PROSTHESES :

By using MRI, CT scan, and X-ray and its translation into .stl 3D print files, implants and prostheses of any possible shape can be made. By using silver nanoparticles, chondrocytes, and silicon, a prosthetic ear was made out of 3D printing technology that was able to detect electromagnetic frequencies. The impact of this technology is so extensive in the field of hearing aids that today 99% of customized hearing aids are made using 3D printers, because, as everyone's ear canal has a different shape, this technology is able to provide perfect fit for each receiver and, moreover, the devices can be produced efficiently and cost effectively.

3)ANATOMICAL MODELS FOR SURGICAL PREPARATIONS:

Organ transplant surgery is expensive and organ transplantation involves the difficult task of finding a donor who is a tissue match. This problem could likely be eliminated by using cells taken from the organ transplant patient's own body to build a replacement organ. This would minimize the risk of tissue rejection, as well as the need to take lifelong immunosuppressants.

4) INCREASED COST EFFICIENCY:

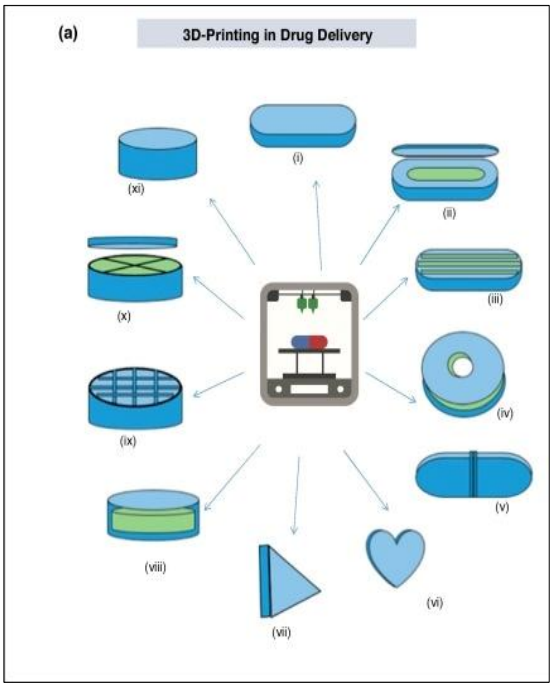
3D printing reduce manufacturing costs by decreasing the use of unnecessary resources. For example, a pharmaceutical tablet weighing 10 mg could potentially be custom fabricated on demand as a 1-mg tablet. Some drugs may also be printed in dosage forms that are easier and more cost-effective to deliver to patients.

5) ENHANCED PRODUCTIVITY:

3D printing works more quickly in contrast to traditional methods especially when it comes to fabrication of items like prosthetics and implants with an additional benefit of better resolution, repeatability, more accuracy, and reliability.

6) DEMOCRATIZATION AND COLLABORATION:

The nature of 3D printing data files also offers an unprecedented opportunity for sharing among researchers. Rather than trying to reproduce parameters that are described in scientific journals, researchers can access downloadable .stl files that are available in open-source databases. By doing so, they can use a 3D printer to create an exact replica of a medical model or device, allowing the precise sharing of designs. Toward this end, the National Institutes of Health established the 3D Print Exchange (3dprint.nih.gov) in 2014 to promote open-source sharing of 3D print files for medical and anatomical models, custom labware, and replicas of proteins, viruses, and bacteria.



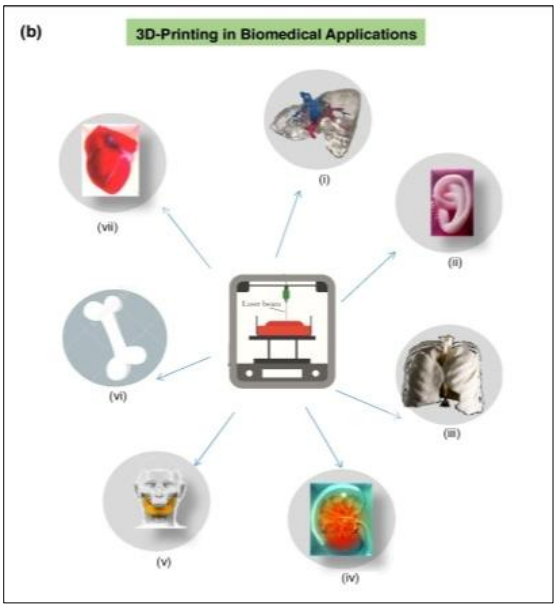


Figure 5 - (a) 3D printing in drug delivery, (b) 3D printing in biomedical applications.

RECENT TRENDS:

PHARMACEUTICAL INDUSTRY:

Spritam (levetiracetam) tablets became the first FDA approved prescription drugs product manufactured using 3D printing technology. Spritam is formulated with Aprecias zip dose technology, which combines the precision of 3D printing and formulation science to produce rapidly disintegrating formulations of medications. An inject printing process produces the water soluble drugs layer by layer by printing aqueous fluid onto layers of powdered medication without compression or traditional molding techniques.

BIOPRINTING COMPANIES:

1) ORGANOVO:

It has been actively developing a line of human tissues for use in medical research and drug discovery. These include both normal tissues and specially designed disease models. They are also working on the development of specific tissues for use in clinical patient care. They successfully printed the liver tissue and kidney tubular tissues.

2) CELLINK:

It develops both bioprinters and bioprinting materials for providing ready-to-print or use models for researchers and healthcare providers. This technology is used to print tissues such as liver, cartilage, skin, and even fully functional cancer tumors that can then be used to develop new cancer treatments.

3) ASPECT BIOSYSTEMS:

Currently the company has been cooperating with the Frampton Lab to create synthetic skin tissue and recently formed a partnership with Johnson & Johnson to develop 3D-printed knee meniscus tissue the thin, fibrous cartilage between some of your joints.

4) CYFUSE BIOMEDICAL:

The researchers created 3D printed human liver tissue which stably maintained metabolic functions and thus it might be used for toxicity testing in drugs.

5) TEVIDO BIODEVICES:

They use 3D printers for various reconstructive and cosmetic surgeries and gives hope to breast cancer survivors not to lose their sense of femininity even after serious surgeries. They apply the patients own pigment-producing cells (melanocytes) and tissues during the printing process to lower the chance of rejection and allow patients to have a high quality of life.

6) DIGILAB:

It offers the Cell Jet 3D printer, which has the unique capacity to print cells with 95 percent viability. The 3D-printed cells can be used for stem cell research, cancer biology, automated cell arrays, cell-cell or cell-drug interaction studies, tissue engineering or regenerative medicine.

7) ADVANCED SOLUTIONS LIFE SCIENCES:

Advanced Solutions produces robotic arms for bioprinters, which can print out cell systems and arrays, experimental tissue models, organ models, microfluidic platforms or implant systems. The company offers visualization software, with which medical professionals can create visualizations based on patient data from medical images and print out 3D models with the help of its robotic arm.

FUTURE PROSPECTS:

1) In the medical field bioprinting could be an excellent, fast and life saving solution for creating various tissue structures such as kidney tissue, skin tissue, liver, bone, etc. 2) Bioprinting help to shape the future of healthcare and eliminate animal testing, bioprinting can play a vital role in personalized healthcare for curing diseases, bioprinting organs to eliminate the need to wait, creating skin for burn victims and cosmetic companies for testing. 3) At present, however, the impact of 3D printing in medicine remains small. 3D printing is currently a $700 million industry, with only $11 million (1.6%) invested in medical applications. In the next 10 years, however, 3D printing is expected to grow into an $8.9 billion industry, with $1.9 billion (21%) projected to be spent on medical applications. 4) 3D printing is expected to be especially common in pharmacy settings. The manufacturing and distribution of drugs by pharmaceutical companies could conceivably be replaced by emailing databases of medication formulations to pharmacies for on-demand drug printing. This would cause

existing drug manufacturing and distribution methods to change drastically and become more cost-effective. 5) However, more research does need to be conducted in the field before the production of 3D-printed products on demand can become a reality within a clinical setting, such as the effect of process parameters on the print quality and how reproducibility in 3DP can be improved. FDM is also limited to the number of drugs that can be loaded into filaments, as they need to withstand the high temperatures of the process. However, if research continues to rise in the area of 3DP, due to the versatility of 3D printed products and the number of manufacturing advantages that 3DP offers there is potential for more 3DP to leave the proof-of-concept stage and be developed into a widely used manufacturing tool. 6) Multiple regulatory questions should be addressed. One of the main unanswered questions is the quality assurance if the dosage form/medical device is created on demand for each patient. In order to accelerate the acceptance of this technology, the US FDA published guideline documents for medical devices manufacturing using 3DP technology. Accordingly, we anticipate that more 3D printed pharmaceutical/medical products will reach to the market within the next few years.

REGULATORY LIMITATIONS:

In 2017, the FDA released guidelines for the manufacturing of medical devices and implants; however, there are currently no regulatory guidelines on the 3D printing of other products.The patentability process, especially with regard to intellectual property rights involving 3D printed drug products, should be granted to innovative processes or products. The patent owner has exclusivity on the product or process until the concession expires; in the meantime, other manufactures may not produce, use, or sell without the owner's authorization. Despite this patent right, extemporaneous formulations produced at compounding pharmacies prescribed by professionals to a specific patient are exempted and do not configure patent violation, according to the intellectual property law of several countries, such as UK and Brazil. If the market for compounding pharmacies is not a threat to large pharmaceutical corporations, this technological leap by digital pharmacies can change the global market scenario.

CONCLUSION:

3D printing has become a useful and potentially transformative tool in a number of different fields, including medicine. It is a valuable and potential tool for the pharmaceutical sector, leading to personalized medicine focused on the patients' needs. The regulatory modifcations and considerations may also need to be defned for the approval of pharmaceutical products made by 3DP methods. The number of manuscripts published in this Special Issue focused on 3DP of oral dosage suggests an increasing interest in personalised medicine. Additionally, this Special Issue included several works describing the use of 3DP for other applications such as medical devices. Therefore, 3DP can be applied in a wide variety of fields within biomedical sciences.

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Review Article

SURGICAL MANAGEMENT OF BHAGANDARA BY IFTAK TECHNIQUE ALONG WITH ARAGWADHADI VARTI - A CASE STUDY

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ABSTRACT:

FISTULA is a condition in which two epithelial surfaces communicate abnormally. When a communication is established between anal canal and perineal region that condition is called as FISTULA-IN-ANO. The track is typically lined with unsightly granulation tissues. The primary cause of this condition is improperly treated crypto glandular infection.[1] Over the advancement of time the Ksharasutra is still the best choice among treatment modalities available for Fistula-in-ano because of lesser complications like recurrence and incontinence.[2] Despite all these advantages, there are still certain drawbacks such as discomfort, prolonged periods of anxiety, increased hospital visits, extended treatment duration, and significant post-operative scarring, among others. IFTAK (Interception of Fistulous tract with application of Ksharasutra) is a novel advanced ksharasutra technique thus making it more convenient to patient as well as to exclude the drawbacks of conventional method. Further using Aragwadhadi varti along with the above said technique lead to better healing of the leftover portion of the track.[3] Here in this case , IFTAK is done under Local anaesthesia. Kshara sutra was changed upto 4 weeks and aragwadhadi varti applied for 8 times . The fistula healed completely in 2 months . This study revealed an early complete remission of the fistulous tracts by IFTAK method and Aragwadhadi varti,When compared with the conventional kshara sutra method . According to the length , the conventional method takes 15-20 weeks whereas in this study it took much less time . And during followup no recurrence was noted. Therefore, the IFTAK technique combined with Aragwadhadi varti was deemed highly effective due to its time-saving properties and reduced scar and fibrosis.

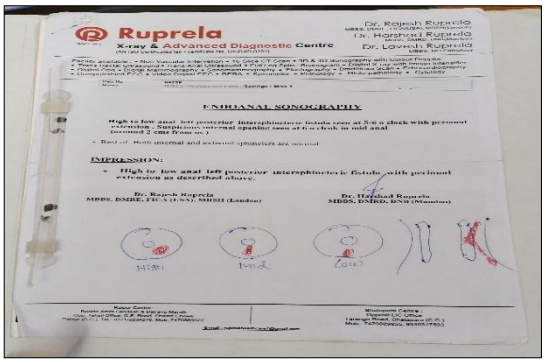
1.INTRODUCTION:

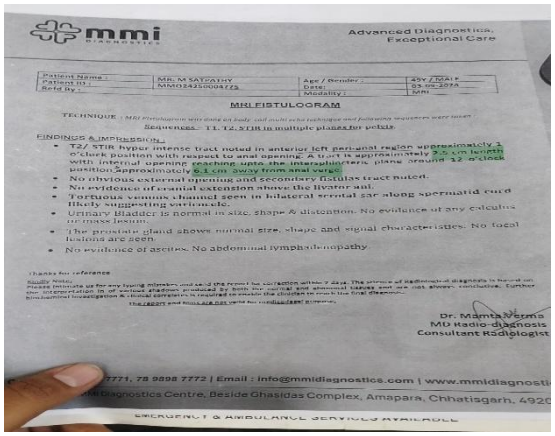
The untreated or improperly treated cryptoglandular infection is the most common cause of fistula in ano or Bhagandara .[4] In this case study administration of IFTAK (Interception of Fistulous track with application of ksharsutra) technique was done along with application of Aragwadhadi Varti in treating a complex intersphincteric fistula in Ano successfully Although the disease is not that much life threatening but produces severe inconvenience in routine life because of pus discharge and pain. By looking into the severity and chronicity of disease The Father of surgery Acharya Sushruta included Bhagandara in Asta Mahagada.[5] There are numbers of treatment modalities available for the management of fistula in ano. Modern surgical management includes fistulotomy, fistulectomy, Seton placing, ligation of intersphincteric fistula tract (LIFT), fibrin glues, advancement flaps, and expanded adipose derived stem cells (ASCs).[6] Acharya Sushruta has also described different therapeutic measures for the management

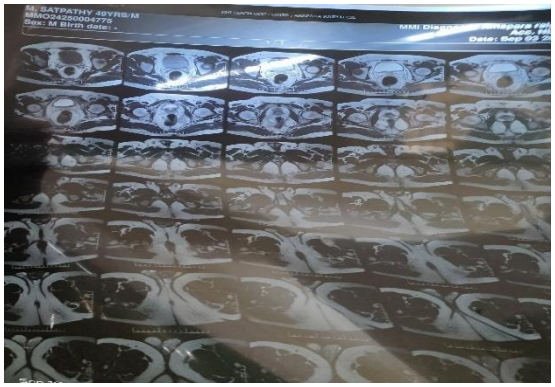
Bhagandara asin terms of various oral medications, local applications, surgical procedures and para-surgical intervention.Acharya Charaka has mentioned it under swayathu chikitsa adhyaya and kshara sutra ligation as its treatment.[7] Presently Ksharasutra therapy is found most approaching and attractive treatment modality among para-surgical procedure for fistula- in-ano. Over the advancement of time the Ksharasutra is still the best choice among treatment modalities available for Fistula-in-ano because of lesser complications like recurrence and incontinence. But with all these benefits, still there are some consequences suffered by practitioners while practicing Ksharasutratherapy in relation to patients i.e. it causes discomfort , long anxiety period, number of hospital visits and longer duration of treatment, big post-operative scar etc. IFTAK (Interception of Fistulous tract with application of Ksharasutra) is an innovative ksharasutra technique rooted in this concept, thereby enhancing convenience for patients and avoiding the limitations of traditional methods.[8] There are a number of choices in Ksharasutra like Apamarga based, papaya based, guggulu based or palasha based. But in this case we need to use Apamarga Ksharasutra because it has terrific result in cutting and healing the fistulous track.[9] Thus, cases of fistula treated with this method can produce positive results. Additionally, utilizing Aragwadhadi varti alongside the aforementioned technique might enhance the healing of the remaining track portion and reduce the likelihood of subsequent sinus recurrences. Because the indurated portion of the fistulous tract also needs to be healed properly along with the area near anal verge. Aragwadhadi varti, as mentioned by Acharya Sushruta in the Bhagandara roga adhikara, may offer improved outcomes in reducing fibrosis of the fistulous tract and facilitate quicker healing compared to the standard treatment.

2. PRESENTING COMPLAINTS AND MEDICAL HISTORY:

A 44 year old male patient came to Shalya OPD of Shri Narayan Prasad Awasthi Govt. Ayurveda College , Raipur having Complaints of Intermittent pus discharge from perianal region along with Intermittent pain and itching since last 3 years . Patient was not having any Comorbidities . Patient got treated under various Doctors but did not get any satisfactory results . Endoanal Sonography and MRI fistulogram reports are attached below.







3.CLINICAL FINDINGS:

On examination perianal skin was normal . An external opening was present at 6 O'clock approximately 5 cm away from anal verge . On digital rectal examination , sphincter tone was normal tender dimpling or buttonhole-like opening noted at 6 O' clock at a distance of 2 cm inner to OS . On probing it was found that the probe goes upwards towards anal verge in a curvilinear manner. A single complete fistulous tract of about 6.5cm in length was found . A sinus of about 4.5 cm in length, perpendicular to the above tract was also found having a common external opening . Rest of the examinations were found to be normal and laboratory investigations were also found within normal limits .

4. TREATMENT:

After obtaining written consent and completing necessary pre operative procedures , the patient was placed in lithotomy position . After painting and draping , under Local anaesthesia probing was done to ascertain the finding . After confirming the diagnosis , a small vertical incision was made at 6 O'clock position at a distance of 1 cm near from anal verge and Interception of fistulous tract was done . Then a metallic probe was introduced through the window and taken out from the internal opening and kshara sutra ligation was done in the proximal tract .The kshara sutra was ligated loosely on initial days in order to facilitate proper drainage of pus . The residual distal tract was also ligated with ksharasutra inorder to keep the tract patent (Fig.10). After achieving haemostasis dressing and packing done with Jatyadi taila and patient then shifted to male surgical ward . Patient was advised for regular hot sitz bath from post operative day 2. Patient was prescribed with Triphala guggulu 2 tab BD after food , Syp Abhayarista 15 ml BD with equal amount of water after food , Triphala churna 5 gm HS with luke warm water after food . On dressing from post operative day 2 , ksharasutra was removed from distal tract and antiseptic dressing done with Jatyadi Taila and Aragwadhadi varti inserted in distal tract as well as in sinus(Fig 11) on every alternate days till the signs of Shuddha vrana appeared .

4.1. ARAGWADHADI VARTI:

In Sushruta Samhita, Aragwadhadi varti is described in Treatment of Bhagandara.[10] Aragwadhadi varti has properties of Shodhana i.e Cleanses the tissue by scraping out unhealthy tissue and Ropana i.e Accelerates healing process by clearing debris tissue.[11] Powdered Haridra (*Curcuma longa*) and Tagara(*Valeriana wallichii*) taken in equal quantities and mixed in a well-balanced manner, followed by addition of Aragwadha(*Cassia fistula*) Majja, ghrita, and honey, all in equal quantities (Fig.4). The wicks were then prepared by hand, measuring 2 to 3 inches in length, and dried in the sun(Fig.5). Once the wicks dried and hardened, they were sterilised in UV chambers and then placed in air-tight containers. Aragwadhadi varti was prepared in the Department of Rasa Shastra and Bhaishajya kalpana Of Shri N.P.A. Govt. Ayurveda College Raipur (C.G) according to classical reference. The ingredients of formulation Aragwadhadi varti were collected from local fields and purchased from the market (Fig.2 & 3) and were authenticated by help of the Department of Dravya guna , Govt. Ayurveda college Raipur (C.G) . Moreover, further authentication was done from the Central research facility, KLE Academy of higher Education and Research , Karnataka (Fig. 1). Aragwadhadi varti was sent to the Drug Testing Laboratory and Research Centre, Raipur (C.G) / NABL accredited lab for analysis of phytochemical and physiochemical constituents . Drug Authentication Report, DTL report are attached hereby (Fig.6) .

SHRI B.M.K. AYURVEDA MAHAVIDYALAYA
A constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University
Central Research Facility
DRUG AUTHENTICATION REPORT

Outward: - BMK/CRF/rtr/2024-25

Submitted By: Dr.Piyusha R. Parhi
Submitted Date :02/05/2024

Date of Issue: 08/05/2024

Sl. No	Common Name	Scientific Name	Family	Part submitted	CRF Code	Authenticated as			
						Sample Name	Scientific Name	Family	Part Authenticated
1.	Aragvada Majja	*Cassia fistula* Linn.	Caesalpiniaceae	Fruit Pulp	CRF/Auth/177/2024	Aragvada Majja	*Cassia fistula* Linn.	Caesalpiniaceae	Fruit Pulp
2.	Tagar	*Valeriana wallichii* DC.	Valerianaceae	Rhizome	CRF/Auth/178/2024	Tagar	*Valeriana wallichii* DC.	Valerianaceae	Rhizome
3.	Haridra	*Curcuma longa* Linn.	Zingiberaceae	Rhizome	CRF/Auth/179/2024	Haridra	*Curcuma longa* Linn.	Zingiberaceae	Rhizome
4.	Apamarga	*Achyranthes aspera* Linn.	Amaranthaceae	Whole Plant	CRF/Auth/180/2024	Apamarga	*Achyranthes aspera* Linn.	Amaranthaceae	Whole Plant

Signature:
Authentication Expert Name: DrAjit Lingayat.
Date : 08/05/2024

CRF

Signature of Coordinator
ASU Drug Testing Laboratory

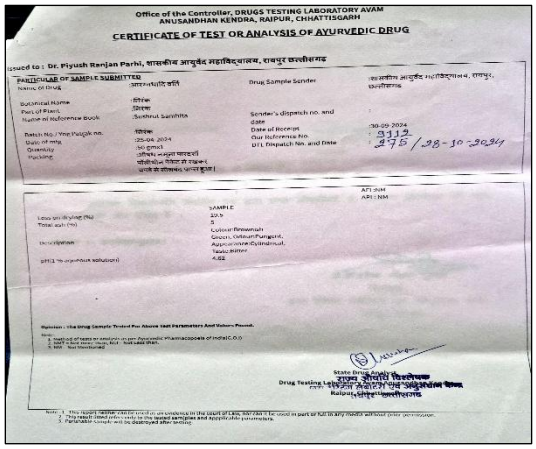
Fig.1

Fig.2

Fig.3

Fig.4

Fig.5


Office of the Controller, DRUGS TESTING LABORATORY AVAM ANUSANDHAN KENDRA, RAIPUR, CHHATTISGARH

CERTIFICATE OF TEST OR ANALYSIS OF AYURVEDIC DRUG

Fig.6

5.FOLLOWUP AND OUTCOMES:

Weekly follow up advised for Ksharsutra changing. Ksharsutra was changed three times after the first Ksharsutra was placed. The pus discharge was fluent in the first week from the artificially made window, gradually reduced and completely disappeared after two weeks(Fig 9). Pain was also moderate in the first week and later on gradually relieved. Pus discharge also diminished from the sinus tract after two weeks. The discharge from the external opening was also reduced gradually in 6-7 days and totally dried up in two weeks. (Fig 10) Then the ksharasutra was ligated tightly and Cut through was done (Fig 11) when discharge completely diminished from the artificial made window i.e. after three weeks of first Ksharsutra placed and complete healing was achieved in 15 days after cut through of proximal tract. Patient was advised for application of Jatyadi taila. The fistulous tract as well as the sinus healed simultaneously by 4th week with minimal scar and without any fibrosis (Fig 12). There was no complication seen during and after treatment and patient got free from all the symptoms. After 3 months of follow up, no recurrence is noted, the patient was cured completely .

PROBABLE MODE OF ACTION OF ARAGWADHADI VARTI:

Traditional treatments for wound healing include honey, Curcuma longa, Valerian wallichii, and Cassia fistula. Cassia fistula's anti-inflammatory, antibacterial, antifungal, and antioxidant qualities aid in wound closure, tissue regeneration, and enhanced healing.[12] Curcuma longa contains antibacterial, antioxidant, and anti-inflammatory qualities[13], while Valerian wallichii possesses analgesic and anti-inflammatory qualities.[14] As a natural antimicrobial, honey promotes quicker healing and reduced scarring by lowering inflammation, encouraging tissue development, and aiding autolytic debridement.[15] Ghrita is a traditional Ayurvedic medication that decreases inflammation and speeds up wound contraction. Also it has been found that Aragwadhadi varti has a pH of 4.62, which is slightly acidic. Because it encourages quicker re-epithelialization, collagen deposition, and wound closure, a slightly acidic environment is optimal for wound healing.[16] It also prevents the formation of dangerous microorganisms. Acidification promotes the migration of epithelial cells, increases oxygen release, and activates fibroblasts. By preventing the development of fibroblasts into myofibroblasts, which are in charge of collagen deposition and scarring, it may be able to lessen fibrosis.[17] Collagen synthesis and fibrosis development can be inhibited by lowering pH levels in cell culture conditions.[18]

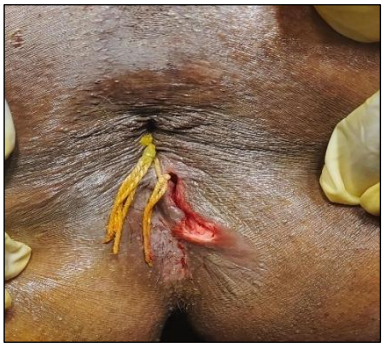


Fig.7

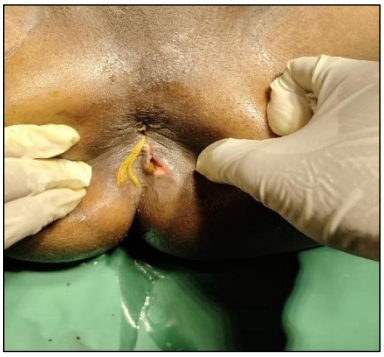


Fig.8

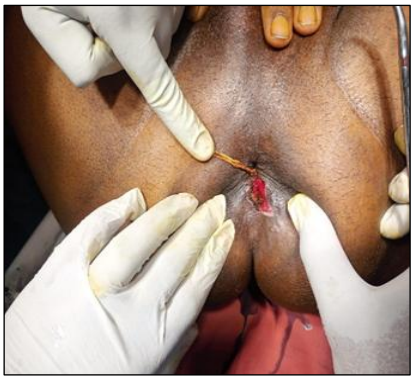


Fig.9

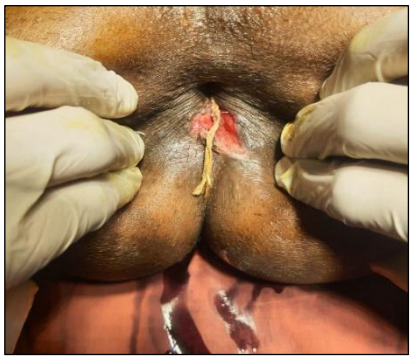


Fig.10

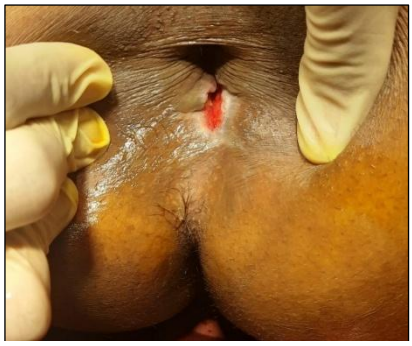


Fig.11

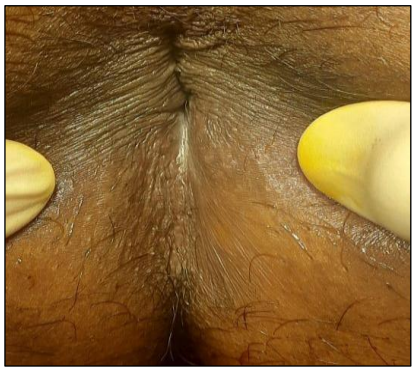


Fig.12

DISCUSSION :

Ksharasutra therapy is the most successful treatment modality for fistula in ano. Ksharasutra therapy has high success rate[19] and least recurrence rate (3.33%) [20]. It is a highly simple day care option and an affordable treatment with a lower complication rate compared to traditional treatment methods that involve hospitalization, regional or general anesthesia, and frequent post-operative care. These surgical procedures carry a notable risk of recurrence (0.7–26.5%) and a considerable risk of reduced continence (5–40%) .[21] While Ksharasutra therapy is a preferred treatment for fistula in ano due to its various benefits, it does come with certain drawbacks, including discomfort, pain after the procedure, multiple hospital visits, extended treatment duration, significant post-operative scarring, and post-treatment fibrosis, resulting in low compliance and reduced acceptability among many patients. IFTAK (Interception of Fistulous tract and application of Ksharsutra) technique seems to overcome the limitations and consequences of conventional methods. Duration of therapy was less by shortening the length of the track and taking care of crypto glandular infection where there was no need to treat residual curved track. Pain was significantly reduced because of less exposure of tissues after interception which is from internal opening where as in conventional method whole track was exposed along the axis during the Ksharsutra change which increases the pain and burning sensation because of more tissue exposure.

In this case study, the external opening was approximately 6.5 cm from the anal verge at the 6 o'clock position, and interception occurred at the 6 o'clock position about 1.0 cm from the anal verge, thus decreasing the length of the tract. Consequently, the IFTAK technique shortened the total healing time and significantly decreased pain while leaving minimal scarring.[22] Aragwadhadi varti purified the leftover tract and the sinus tract due to its Shodhana and Ropana properties. The patient was fully healed within two months, and no recurrence was observed during the three-month follow-up. Tablet Triphala Guggulu were used to counter inflammation, pain and to prevent infection. Triphala Guggulu tablets were utilized to alleviate inflammation, relieve pain, and guard against infection. Triphala guggulu has demonstrated antimicrobial properties. [23] Thus, it may be useful in prevention of infection and promote wound healing also. Triphala has antibacterial action against a variety of Gram-positive and Gram-negative bacteria and immunomodulatory effect .[24] And as per Ayurveda, Triphala exhibits Anulomana properties, which helps balance Apana Vata and promotes smooth bowel movements.The local use of Jatyadi Taila is said to notably enhance the levels of protein, hydroxyproline, and hexosamine in granulation tissue, facilitating quicker healing. [25] So, IFTAK is a sophisticated and efficient method in the area of fistula that features significant innovation and numerous advantages. Additionally,

Aragwadhadi varti functions like the cherry atop a cake when it comes to cleaning the fistulous tract, enhancing wound healing, and preventing fibrosis following complete recovery.

7. CONCLUSION:

Therefore, the research concluded that IFTAK, in conjunction with the use of Aragwadhadi Varti, is a secure, efficient, and progressive method that reduces post-operative duration while improving mild post-procedural pain and minimizing scar marks.

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Review Article

SYSTEMATIC REVIEW ON MICRONEEDLES DRUG DELIVERY IN THE MANAGEMENT OF VARIOUS DISORDERS

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ABSTRACT:
Microneedle transdermal distribution is a method of providing medicinal substances to specific organs or tissues that involves inserting very small needles into the stratum corneum, the skin's outermost layer. Many people feel that this procedure could eventually replace the more common practice of administering medication to patients by injection. Microneedles (MNs) are a revolutionary form of drug administration that allows for the least invasive entry of medicinal substances into a variety of tissues, including skin. This review delves deeply into the use of microneedles in the diagnosis and treatment of a variety of medical conditions, including cancer, diabetes, obesity, neuropathic pain, neurological disorders, respiratory problems, wounds, acne, ophthalmic illnesses, and wound healing.

KEYWORDS:
Microneedles, Transdermal drug delivery, Targeted therapy, Drug delivery systems, Biomedical applications

1.INTRODUCTION:

MICRONEEDLES IN OBESITY MANAGEMENT

Obesity, a chronic illness that can cause a variety of health concerns, is defined by an excessive buildup of fat [1]. Traditional treatments to obesity therapy, such as dietary changes, medication, and bariatric surgery, have limited success and frequently result in unpleasant side effects [2].

MICRONEEDLES AND THEIR USES:

- Local Drug Delivery: Microneedles can be used to deliver anti-obesity medications such as phentermine or liraglutide to the dermal or subcutaneous layers, ensuring localised action with less systemic side effects [3].
- Leptin Therapy: In this treatment, the hormone leptin is delivered by microneedles. Leptin regulates appetite and
- can modulate hunger signals, which may lead to better weight management.
- Fat Metabolism: Microneedle-delivered gene therapy aimed at fat metabolism pathways may improve fat breakdown and reduce obesity [4].

BENEFITS:

Compared to oral treatments, there are less gastrointestinal side effects, and weight loss medications can be delivered more accurately, resulting in fewer unpleasant effects overall.

MICRONEEDLES IN DIABETES MANAGEMENT:

Diabetes is a metabolic condition marked by consistently elevated blood sugar levels due to insulin resistance or insufficient insulin synthesis. Microneedles are a promising method for administering insulin and non-insulin medicines to regulate blood glucose levels [5].

MICRONEEDLE APPLICATIONS:

- Transdermal Insulin Delivery: Microneedles improve patient compliance by administering insulin without the need for several injections.
- Microneedle injection of GLP-1 agonists, such as liganduide, can increase insulin production and sensitivity in type 2 diabetes [6].

Insulin that responds to changes in blood glucose levels: Microneedles can be used to create smart insulin systems that release insulin in response to blood glucose fluctuations.

BENEFITS:

The benefits include improved insulin

administration without the need for regular blood tests, as well as a less intrusive and uncomfortable alternative to injections [7].

MICRONEEDLES IN CANCER MANAGEMENT:

Cancer is defined by the unregulated proliferation of aberrant cells. Radiation, chemotherapy, and surgery are common therapies, but each has its own set of hazards. Microneedles provide a fresh approach to cancer treatment by enabling targeted drug delivery [8].

MICRONEEDLE APPLICATIONS:

- Chemotherapy Delivery: Two chemotherapy medications, paclitaxel and cisplatin, can be delivered locally using microneedles to reduce systemic toxicity.
- Immunotherapy: Cancer vaccines and immunomodulatory drugs can be delivered directly to the skin or tumour microenvironment using microneedles, boosting the immune response.
- The use of microneedles to administer gene editing tools such as CRISPR/Cas9 has the potential to transform gene therapy by increasing immune surveillance and detecting cancer-specific mutations [9].

BENEFITS:

Reduced systemic toxicity and improved cancer cell targeting are two advantages, while less intrusive administration increases the likelihood that patients would report feeling comfortable throughout therapy.

MICRONEEDLES IN VACCINE DELIVERY:

Traditional vaccination procedures requiring needles can be uncomfortable and require educated medical experts, but they are vital to prevent the spread of hazardous diseases. Microneedles offer a viable method for administering vaccines [10].

MICRONEEDLE APPLICATIONS:

- Microneedles allow vaccines (such as the COVID-19 and flu vaccines) to be delivered intradermally or transdermally with minimum discomfort.
- Microneedles can be used to deliver adjuvants and immunisations simultaneously, which can boost immune response.
- Self-administration: Microneedles enable self-administration of vaccines, making them more accessible to impoverished and rural communities [11].

BENEFITS:

It is cost-effective and appropriate for large-scale immunisation efforts; Patients find it simple to use; and It is non-invasive.

MICRONEEDLES IN NEUROLOGICAL DISORDERS:

The blood-brain barrier (BBB) blocks many therapeutic drugs from reaching the brain, making it difficult to treat neurological illnesses such as MS, PD, and Alzheimer's [12].

MICRONEEDLE APPLICATIONS:

- Microneedles can deliver neuroprotective drugs or dopamine agonists straight to the brain, bypassing the blood-brain barrier.
- Gene therapy: Microneedles can administer gene-editing tools to treat hereditary neurological illnesses by repairing mutations at the molecular level.
- Transdermal microneedle injection can alter brain activity and reduce symptoms in Parkinson's disease[13].

BENEFITS:

Minimal invasiveness, reducing the requirement for brain surgery. Direct and targeted delivery of neuroactive medications.

MICRONEEDLES IN RESPIRATORY DISORDERS:

Inhalers are used to treat a variety of respiratory illnesses, including asthma, COPD, and pulmonary fibrosis. However, the difficulty of properly targeting the lungs limits their efficacy [12].

MICRONEEDLE APPLICATIONS:

- Microneedles can administer bronchodilators and anti-inflammatory medications directly to lung tissue through the skin, a technique known as pulmonary drug administration.
- Microneedles containing gene editing tools can be utilised to treat genetic respiratory illnesses such cystic fibrosis as part of gene therapy [14].

BENEFITS:

One advantage is the potential for increased drug absorption and effectiveness, as well as the ease of delivery to the lungs or other specific parts of the respiratory system.

MICRONEEDLES IN NEUROPATHIC PAIN MANAGEMENT:

Because it involves both the central and peripheral neural systems, neuropathic pain produced by nerve injury can be difficult to treat [15].

MICRONEEDLE APPLICATIONS:

- Local Anaesthetics (e.g., lidocaine) or Anti-Inflammatory Medications: Microneedles can deliver local anaesthetics or anti-inflammatory medications directly to the affected area, alleviating pain.
- Neurostimulation: Microneedles can be used to provide capsaicin or other neurostimulatory drugs, which desensitise pain receptors and relieve chronic pain [16].

BENEFITS:
One of the advantages is that it relieves pain quickly and specifically. Systemic side effects are less common than with oral painkillers[17].

MICRONEEDLES IN DIAGNOSIS AND TREATMENT:
Microneedles have a wide range of medicinal uses due to their ability to detect biomarkers or infections [18].

MICRONEEDLE APPLICATIONS:
- Microneedles and their uses: Microneedles can be used to collect interstitial fluid for biomarker sensing, which is the process of identifying biomarkers associated with inflammation, infection, or diabetes.
- Diagnostic instruments: Adding microneedles to diagnostic tools can aid in illness detection at an early stage [19].

BENEFITS:
Being non-invasive and enabling for real-time monitoring; minimising the need for invasive diagnostic procedures and blood draws. [20].

MICRONEEDLES IN ACNE MANAGEMENT:
Acne is a common inflammatory skin illness that typically responds to topical therapies, oral medicines, or laser therapy [21].

MICRONEEDLE APPLICATIONS:
- Microneedles can be used for topical drug delivery, which entails delivering antibiotics (such as benzoyl peroxide), retinoids, or anti-inflammatory pharmaceuticals directly to the acne-affected skin layers.
- Gene therapy: Microneedles can carry gene-editing tools that can regulate skin cell turnover or prevent excessive sebum production, which is the primary cause of acne [22].

BENEFITS:
Advantages include targeted therapy for acne-prone areas and reduced systemic negative effects from oral acne medicines [23].

MICRONEEDLES IN OCULAR DISEASES:
Specialized treatment for eye disorders such as glaucoma, diabetic retinopathy, and macular degeneration is difficult due to limited medication absorption across ocular barriers [24].

MICRONEEDLE APPLICATIONS:
- One potential application for microneedles is ocular drug delivery, which entails increasing the bioavailability of growth hormones or anti-glaucoma medications by delivering them directly to eye tissues.
- Microneedles enable the delivery of gene therapies, which have the potential to treat retinal degenerative disorders [25].

BENEFITS:
In addition to having a larger concentration of medicine in ocular tissues, this treatment is non-invasive, which means patients feel less pain than with invasive procedures such as injections or surgery [26].

MICRONEEDLES IN WOUND HEALING:
Because illnesses such as diabetes or persistent wounds can impede the healing process, it is vital to discover innovative techniques to stimulate tissue regeneration [27].

MICRONEEDLE APPLICATIONS:
- One proposed application for microneedles is to distribute growth factors such as vascular endothelial growth factor (VEFG), which can aid in tissue repair and regeneration [28].
- Antimicrobial Treatment: Microneedles can be used to provide antibiotics or antiseptics to help manage infections in chronic wounds [29].

BENEFITS:
The benefits of localized drug delivery include a lower risk of infection, faster wound healing and tissue regeneration, and better overall health [30].

CONCLUSION:
Microneedles, as a versatile and potentially successful pharmaceutical delivery method, hold considerable promise for treating a wide range of ailments. The ability to precisely and minimally inject medications into specified regions has transformed therapeutic methods. Microneedles may increase pharmaceutical efficacy, patient adherence to treatment programs, and overall care results for a variety of conditions, including diabetes, obesity, cancer, and neurological disorders. As technology progresses, microneedles are poised to play an increasingly essential role in focused and customised treatment across a wide range of medical sectors.

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Review Article

COMPARATIVE STUDY OF CREAM AND OINTMENT CONTAINING THYMOQUINONE OIL FOR ANTIBACTERIAL ACTIVITY

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ABSTRACT:
Thymoquinone, a bioactive compound derived from *Nigella sativa* (black seed oil), has demonstrated significant antibacterial properties. This study investigates the comparative efficacy of cream and ointment formulations containing thymoquinone oil in inhibiting bacterial growth. Creams and ointments are widely used as topical applications, with different physical properties influencing the delivery and potency of active ingredients. The study assess the antibacterial activity of both formulations against common pathogenic bacteria, such as *P. aeruginosa, S. aureus* and *E. coli*, through in-vitro testing. By comparing the physical test, pH, spread ability, zone of inhibition, test for content uniformity and overall effectiveness. The findings of this study suggest that the cream formulation containing thymoquinone oil is a promising topical antimicrobial agent with potential applications in various dermatological conditions.
Key words: Thymoquinone, *P. aeruginosa, S. aureus, E. coli,* physical test, pH, spread ability, zone of inhibition, test for content uniformity.

INTRODUCTION:
Nowadays the topical formulation has been gained the more attention of people for various benefits. By highlighting this we are going to formulate the cream and ointment using thymoquinone oil. Thymoquinone is a phytochemical compound found in the plant *Nigella sativa Linn*. *Nigella sativa* (N. Sativa) belongs to the family of Ranunculaceae. It is commonly known as kalonji, black caraway, black seed, black cumin. Chemical constituents of Nigella sativa plant includes: Nigellone, Thymoquinone (TQ), Thymohydroquinone (THQ), Dithymoquinone, thymol, carvacrol, α and β-pinene, d-limonene, d-citronellol.Thymoquinone has various health benefits like anti-fungal, anti-oxidant, anti-inflammatory, antimicrobial, and anticancer properties. Thymoquinone may also use for asthma, diabetes, cardiovascular diseases, and certain types of cancer. Nigella Sativa is native to eastern Europe (Bulgaria and Romania) and western Asia (Cyprus, turkey, Iran and Iraq), but naturalized over a much Wider area. including parts of Europe, Northern Africa and east to Myanmar. The main moto of our study is to formulate cream and ointment using thymoquinone oil.

MATERIALS AND METHODOLOGY:
OINTMENT:

INGREDIENTS	PERCENTAGE	PROPERTIES
Thymoquinone oil	2%	Medicament
Wool fat	20%	Absorption base
Liquid paraffin	45%	Hydrocarbon base
White soft paraffin	8%	Hydrocarbon base
Cetyl alcohol	24%	Emulsifying agent and vehicle
Propyl paraben	1%	Preservative

METHODOLOGY:

Wool fat, white soft paraffin was melted in a beaker on the water bath at 90°C and then add liquid paraffin and thymoquinone oil. The above solution was filtered through coarse filter paper which was placed in a heated funnel (ointment base).

↓

Add medicament with ointment base. The medicament was dissolved in organic solvents like ethanol and was diluted with aqueous buffer of choice.

↓

The mixture was then incorporated with the remaining melted base. Then the formulation was poured into a suitable container.

EVALUATION TEST:

1. **PHYSICAL TEST:** The colour, consistency, odour was evaluated.
2. **pH MEASUREMENT:** The pH of the ointment was depicted by using digital pH meter.
3. **SPREADABILITY TEST:** The spreadability of ointment was determined by placing 10gm of ointment between 2 glass slides.
4. **MICROBIAL LIMIT TEST:** Zone of inhibition was conducted to study the antibacterial activity of the ointment.
5. **TEST FOR CONTENT UNIFORMITY:** The content uniformity of ointment was determined by using appropriate analytical technique such as UV-Visible spectrophotometry.

6. **CREAM:**

INGREDIENTS	PERCENTAGE	PROPERTIES
Thymoquinone	5%	Medicament
Wool fat	4%	Emollient
Tween 80	20%	Emulsifying agent
Cetyl alcohol	5%	Stabilizer or Thickener
Glycerine	5%	Humectant
Propylparaben	1%	Preservative
Water	60%	Primary solvent

METHODOLOGY:

Tween 80, cetyl alcohol and wool fat was melted in a beaker A on the water bath at 70°C (oily phase). Water and glycerine was then heated in another beaker B upto 70°C (aqueous phase).

↓

Aqueous phase was slowly added to melted oily phase with continuous stirring. Add thymoquinone (medicament), propyl paraben and stir.

↓

The above formulation was poured into a suitable container.

EVALUATION TEST:

1. **PHYSICAL TEST:** The colour, consistency, odour was evaluated.
2. **pH MEASUREMENT:** The pH of the cream was depicted by using digital pH meter.
3. **SPREADABILITY TEST:** The spreadability of cream was determined by placing 10gm of cream between 2 glass slides.
4. **MICROBIAL LIMIT TEST:** Zone of inhibition was conducted to study the antibacterial activity of the cream.
5. **TEST FOR CONTENT UNIFORMITY:** The content uniformity of ointment was determined by using appropriate analytical technique such as UV-Visible spectrophotometry.

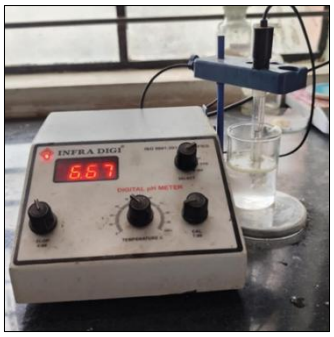
RESULTS AND DISCUSSION:

OINTMENT:

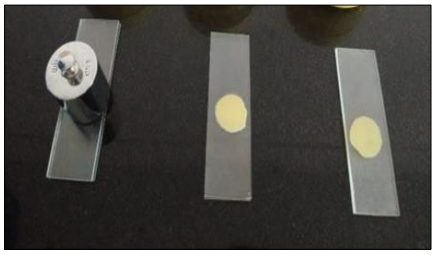
PHYSICAL PROPERTIES:

The organoleptic evaluation like general colour, consistency and odour of ointment was evaluated. It was found that ointment had persistent in odour, greasy in Consistency and yellowish in colour

PHYSICAL PROPERTIES OF OINTMENT
TEST FOR PH:
Three trails was performed. The pH of ointment in trials was found to be: I trail – 6.62, II trail – 6.52 and III trail – 6.67. The ideal pH of ointment on skin is 5.6-6.9.
The obtained result 6.59 matches the ideal pH of ointment.



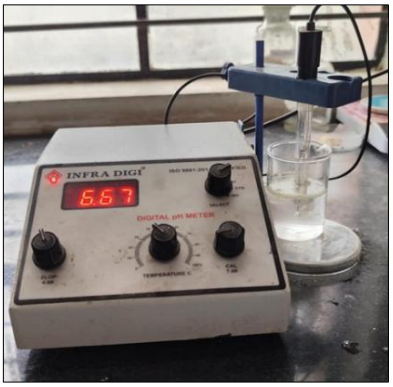
PH TEST FOR OINTMENT
SPREADABILITY TEST:
The spreadability of three formulations was determined and it was observed that formulation F3 has greater spreadability as compared to other formulations.The spreadability of the ointment (F3) was found to be 15.02cm^2 /sec.



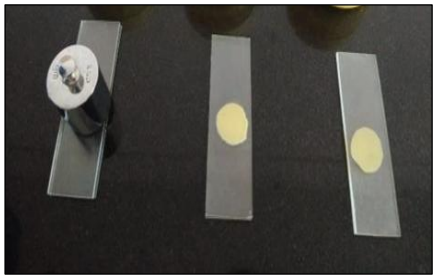
SPREADABILITY TEST OF OINTMENT
MICROBIAL TEST:
Microbial test was conducted to evaluate the antibacterial efficacy against a range of bacterial strains like *E. coil, S. aureus, P. aeruginosa*. The zone of inhibition was not shown in the ointment.

CREAM:
PHYSICAL PROPERTIES:
The organoleptic evaluation like general colour, consistency and odour of cream was evaluated. It was found that cream had persistent in odour, creamy in Consistency and pale yellow in colour.

PHYSICAL PROPERTIES OF CREAM
TEST FOR PH:
Three trails was performed. The pH of cream in trials was found to be: I trail – 6.24, II trail – 6.31 and III trail – 6.24. The ideal pH of cream on skin is 5.8-6.3.
The obtained result 6.26 matches the ideal pH of ointment.



PH TEST FOR CREAM
SPREADABILITY TEST:
The spreadability of three formulations was determined and it was observed that formulation C1 has greater spreadability as compared to other formulations. The spreadability of cream (C1) was found to be 18.03cm^2 /sec.



SPREADABILITY TEST OF CREAM
MICROBIAL TEST:
Microbial test was conducted to evaluate the antibacterial efficacy against a range of bacterial strains like *E. coil, S. aureus, P. aeruginosa*. The zone of inhibition was shown in the cream.

SUMMARY:
In this work, an attempt was made to design an antibacterial cream and ointment containing Thymoquinone oil. The ultimate objective of present research work is to incorporate Thymoquinone oil into cream and ointment, which has various topical applications. Cream and ointment formulations were developed incorporating thymoquinone oil, a bioactive compound known for its antimicrobial properties. Both formulations were evaluated for their antibacterial efficacy against a range of bacterial strains like *E. coil, S. aureus, P. aeruginosa*. A comparative study was conducted to assess the relative effectiveness of the cream and ointment formulations. The cream formulation demonstrated superior antibacterial activity compared to the ointment formulation. The enhanced efficacy of the

cream may be attributed to factors such as better drug penetration, improved drug release, and enhanced skin contact time. The findings of this study suggest that the cream formulation containing thymoquinone oil is a promising topical antimicrobial agent with potential applications in various dermatological conditions.

CONCLUSION:

This study compared the antibacterial efficacy of thymoquinone oil in cream and ointment formulations against E. coli, S. aureus and P. aeruginosa. Both formulations showed significant activity, but the cream was found to be more effective. This superior efficacy of the cream was likely due to better drug delivery and skin compatibility. These findings suggest the potential of thymoquinone oil-based creams for treating skin infections. Further research is needed to optimize formulation and dosage for clinical use.

ACKNOWLEDGEMENET:

Thankful for faculty of department of pharmaceutics, Sarada vilas college of pharmacy, Mysuru for providing all the facilities and guidance required for carrying out the project. Special thanks to Dr. P K Kulkarni Professor, Department of Pharmaceutics and Mr. Salman M, Assistant professor, Department of Pharmaceutics, Sarada vilas college of pharmacy, Mysuru.

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Review Article

A Comparative Review of mRNA, Viral Vector, Inactivated, and Protein Subunit COVID-19 Vaccines

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ABSTRACT:
The COVID-19 pandemic prompted an unprecedented global response in vaccine development. Multiple platforms, including mRNA, viral vector, inactivated, and protein subunit vaccines, were rapidly developed to curb the spread of SARS-CoV-2. This review provides a comparative analysis of these vaccine types, focusing on their mechanisms of action, efficacy, safety profiles, storage requirements, and global distribution. mRNA vaccines such as Pfizer-BioNTech and Moderna demonstrated high efficacy, while viral vector vaccines like AstraZeneca and Johnson & Johnson offered logistical advantages. Inactivated vaccines such as Covaxin and Sinopharm are based on traditional methods and showed good safety profiles. Protein subunit vaccines like Novavax are emerging as a promising alternative with minimal side effects. Understanding these differences is essential for informed public health decisions, vaccine acceptance, and future pandemic preparedness.

KEY-WORDS:
COVID-19 vaccines, mRNA vaccines, viral vector vaccines, inactivated vaccines, protein subunit vaccines, SARS-CoV-2, vaccine efficacy, vaccine safety, immunogenicity, vaccine platforms

INTRODUCTION:
The outbreak of coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2, led to a global health emergency, necessitating rapid development of effective vaccines. Several vaccine technologies, some novel and others traditional, were explored to deliver safe and effective protection against the virus. This review focuses on four main types of COVID-19 vaccines—mRNA, viral vector, inactivated, and protein subunit—highlighting their mechanisms, clinical performance, advantages, and limitations. A comparative understanding of these platforms can support public confidence, guide healthcare decisions, and enhance preparedness for future pandemics. COVID-19 vaccines are safe and effective, and benefits outweigh the noks as vaccine help in protecting adults and children aged 12 years and sider against getting severe illness, hospitalization, and death with COVID-10 infection. However, some COVID-19 vaccinated people (who is vaccinated with either a primary series or a primary series plus a booster dose can still have a vaccine breakthrough infection because none of the available vaccine is 100% effective.Currently vaccines which have been given emergency use authorization are:

- ❖ mRNA vaccines (Pfizer-BioNTech and Modernal)
- ❖ Protein subunit vaccine (Novavax, Corbevac)
- ❖ Viral vector vaccine (Johnson & Johnson's Janssen
- ❖ Inactivated coronaviruses (Covaxin, CoviShield

MECHANISM OF ACTION OF COVID-19 VACCINE TYPES:

1) MRNA VACCINES:
mRNA vaccines work by delivering messenger RNA encoding the SARS-CoV-2 spike protein into host cells. The mRNA is translated into the spike protein, which is recognized as a foreign antigen, triggering both humoral and cellular immune responses. Examples: Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273) Advantages: High efficacy, fast production Challenges: Requires cold-chain storage, initial concerns about long-term effect.

2) VIRAL VECTOR VACCINES:
These vaccines use a harmless adenovirus as a vector to deliver DNA encoding the spike protein into human cells. The host cells produce the spike protein and stimulate an immune response. Examples: Oxford-AstraZeneca (ChAdOx1 nCoV-19), Johnson & Johnson (Ad26.COV2.S), Sputnik V Advantages: Stable at 2–8°C, single-dose options available Challenges : Pre-existing immunity to vector may reduce efficacy

3) INACTIVATED VACCINES:
These contain whole virus particles that have been killed or inactivated. They cannot replicate but can still stimulate an immune response.Examples: Covaxin (Bharat Biotech), Sinopharm, Sinovac Advantages: Traditional method, safe and well-established .Challenges: Require adjuvants, multiple doses, lower efficacy than mRNA

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4) PROTEIN SUBUNIT VACCINES:
These vaccines contain purified fragments of the virus, typically the spike protein or its receptor-binding domain (RBD), along with adjuvants to enhance the immune response. Examples: Novavax (NVX-CoV2373), Covovax Advantages: Good safety profile, minimal side effects Challenges: Newer platform, may need boosters

COMMON SIDE EFFECTS (USUALLY MILD AND TEMPORARY) :

- Pain, redness or swelling at the injection site
- Fever , Fatigue , Headache
- Muscle or joint pain

These typically resolve within a few days.

LESS COMMON / RARE SIDE EFFECTS

1. **MYOCARDITIS/PERICARDITIS**
   (Inflammation of the Heart or surrounding tissue) Mostly seen in younger males (usually under 30) after mRNA vaccines (Pfizer, Moderna)Usually mild and resolved with treatment

2. **THROMBOSIS**

- Rare blood clotting disorder
- Seen with viral vector vaccines like Astra Zeneca and Johnson & Johnson
- Occurred mostly in younger women
- Very rare : a few cases per million doses

3. **ANAPHYLAXIS**

- Severe allergic reaction
- Occurs shortly after vaccination , very rare
- Vaccination sites are equipped to treat it immediately

4. **GUILLAIN – BARRE SYNDROME (GBS)**

- Rare neurological condition
- Reported after J & J vaccine, but also occurs after infections , including COVID itself

5. **MENSTRUAL CYCLE CHANGES**

- Some women reported irregularities
- No long – term fertility effects found

TYPES OF COVID-19 VACCINES AVAILABLE

Vaccines	Dose schedule	Dose, route, site	Common adverse effect	Contraindication	Precaution
BCG (Freeze-dried)	At birth	0.1 ml intradermal left deltoid	Axillary lymph adenitis	Immunodeficiency	Instruct patient to not to squeeze or scratch, rub or massage the site or use ointments, oils, or herbs on the site or put a sticking plaster over the site.

DTwP (whole cell vaccine) DTaP	6.10.14 week booster 16 to 18 month 2 booster 4 to 6 years: 3rd booster10 to 12years (T dap/Td)	0.5 ml IM anterolateral aspect of thigh	Fever, local pain induration, incessant crying, rarely encephalo pathy	Progressive neurological disease, severe reaction to first dose Severe allergic reaction (eg, ana-phylaxis after a previous dose or to a vaccine component Encephalopath y (eg, coma decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP or DTaP	
IPV	610, 14 weeks: booster 16 to 10 months: 2nd booster 4 to 6 year s	Infants and small children, anterolateral aspect of the thigh Older children and adults: deltoid muscle for Mor the posterior aspect of the upper arm for SC Injection	Local itching, skin rash, soreness, hard lump, tenderness or pain, fever, crying persistentl y, Irritability, less of appetite. ti redness.	Severe allergic reaction (eg, ana-phylaxis) after a previous dose or to a vaccine compo nent	Pregnancy Moderate or severe acute illness with or without fever
OPV	At birth	2 drops orally	Vaccine-associated paralytic poliomyeli tis rarely	Immunodeficie ncy, HIV disease	

MMR (lyophilized)	9 months. 15 months booster 4 to 6 years	0.5 ml SC deltoid thigh	Mild fever, mild rash after 7 days	Severe allergic reaction (e.g., ana-phylaxis) after a previous dose or to a vaccine component Pregnancy Known severe immunodeficiency Family history of altered immunocompetence. Systemic hypersensitivity to neomycin	Recent (≤11 months) receipt of antibody-containing blood product (specific interval depending on the product) History of thrombocytopenia or thrombocytopenic purpura Need for tuberculin skin testing or interferongamma release assay (IGRA) testing. Moderate or severe acute illness with or without fever
Hepatitis B 10 mcg of purified HBsAg	At birth, 6,14 weeks	0.5 ml IM anterolateral aspect of thigh	Local pain, erythema	Severe allergic reaction (e.g., ana-phylaxis) after a previous dose or to a vaccine component Hypersensitivity to yeast	Moderate or severe acute illness with or without fever
Hepatitis A ln activated)	12 months, 18 months 2 dose 6 to 18 months apart	0.5 ml IM Thigh	Local pain, erythema: fever, and headache are cases of severe side effects like the elevation of liver enzymes, ITP (idiopathic thrombocytopenic purpura), and Guillain-Barré syndrome (GBS)	Severe allergic reaction leg, ana -phylaxis) after a previous dose or to a vaccine component, safety in pregnancy remains undetermined	Moderate or severe acute illness with or without fever

Varicella (lyophilized)	15 months: 4 to 6 years	0.5ml SC Deltoid	Milder varicella type rash	Severe allergic reaction (e.g., ana-phylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy. congenital immunodeficiency, long term immunosuppressive therapy or w patients with HIV infection who are severely immunocompromised) Pregnancy Family history of altered Immuno-competence	Recent (<11 months) receipt of antibody-con-taining blood product (specific interval depends on product) Moderate or severe acute illness with or without fever Receipt of specific anti viral drugs (acyclovir, famciclovir, or valacy clavir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vacci nation) Use of aspirin or aspirin-containing products
Typhoid Vi antigen vaccine 30 mcg of inactivated Vi capsular poly sacch aride	9 to 12 months: booster 2 years	0.5 ml IM Deltoid	Mild local reaction and pain, fever and headache, and general dis comfort	Allergic reaction after a previous dose of typhoid vaccine, or history of severe, life-threatening allergies: immunosuppressed; pregnant or breastfeeding; on antibiotics or anti-malarial drugs	Acute febrile illness or acute Gl illness
Meningoccal lyophilized) 50 mcg each sero type of inactivated capsular polysaccharide (Men ACWY)	11 to 12 years: booster at 16 years, no booster if 1 dose given after 16 years	0.5 ml IM or SC deltoid/thigh	Mild fever, local reaction	Severe allergic reaction (eg: ana-phylaxis) after a pervious dose or to a vaccine component	Moderate or severe acute illness with or without fever Preterm birth (MenACWY-CRM)

Serogroup meningococcal (MenB)	16 to 18 years (10 year or older in high-risk group) two or three doses	IM: 2 doses at least 1 month apart	Local pain, redness or swelling, tiredness, fatigue, headache, muscle/joint pain, fever, chills, nausea or diarrhea	Severe allergic reaction(e.g., anaphylaxis after a previous dose or to a vaccine component	Moderate or severe acute illness with or without fever Pregnancy Latex sensitivity (MenB-4c)
Japanese encephalitis (lyophilized)	9 months, 15 months: Travelers two-dose series spaced 28 days apart and at least 1week before travel. A 3d booster if a person has received the two-dose primary vaccination series one year or more previously and there is a continued risk for JE virus infection	2 months 1 years: 0.25 ml 1 to 3 years: 0.5 ml >3 years: 1.0 ml SC deltoid	Local pain, tenderness, headaches, myalgia, and low-grade levers, rarely encephalitis	Allergic reaction after a previous dose (allergy to Protamine component) or any severe, life threateing allergies, pregnancy	Moderate or severe acute illness with or without fever
Rotavirus	6,10,14 weeks for infants upto 24 weeks of age	Oral	Irritability or mild. temporary diarrhea or vomiting ear ache fever headache irritability muscle pain or cramping in the abdomen	Severe allergic reaction (eg. anaphylaxis) after a previous dose or to a vaccine component history of Intussusception	Altered Immunocompetence other than SCID Chronic gastrointestinal disease Spina bifida or bladder exstrophy Moderate or severe acute illness with or without fever

			or stomach, sore throat, stuffy of runny nose, unusual tiredness o r weakness		
***Recom binant Zoster Vaccine (RZV) Zoster vaccine liv e (ZVL)	Two doses of RZV (0,2 to 6 months) one dose of ZVL for 60 years and older (allergic to RZV)	0.5 ml in the deltoid region of the upper arm, reconstitute using adjuvant suspension component; use it within 6 hours of reconstitution	Diarrhea, difficulty in moving, fever, headache, muscle aches, cramps, pains, or stiffness nausea pain, redness, and swelling at the Injection site shivering stomach pain, unusual tiredness or weakness, vomiting	Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine compo nent	Moderate or severe acute illness with or without fever, may Increase the risk for nervous system prob lems, including Guillain-Barré syndrome.
PCV 13 (pneumoc occal conjugate vaccine)	Infants to 5 years: 4 doses at 2, 4, 6 and 12-15 months. 6-18 years age with certain medical conditions single dose if not already rec eived	0.5 ml, IM antero lateral aspect of the thigh deltoid muscle in Toddlers/childr en/adults: Do not administer in the gluteal area or near major nerve trunks or blood vessels Do not mix with other vaccines/produc ts in the same syring e	Fever common, rarely chest pain, chills coughing, difficult breathing and swallowin g, tachycardi a, seizures skin itching, rash, or redness, a naphylaxis	Severe allergic reaction (e.g anaphylaxis) after a previous dose of PCV13 or any diphtheria-tux-old-containing vaccine or to a component of a vaccine (PCV13 or any diphtheria-toxoid-containing vaccines, inclu ding yeast	Moderate or severe acute illness with or without fever
PPSV23 Pneumoco ccal polysaccha ride vaccin e	6 weeks	0.5 ml IM or SC anterolateral aspect of thigh/deltoid	Local reaction	Severe allergic reaction (e.g, anaphylaxis) after a previous dose or to a	Moderate or severe acute illness with or without fever

				vaccine compo nent	
Haemophil us influenzae B 10 mcg of capsular polysaccha ride	6, 10, 14 weeks: 12 months, booster 16 to 18 mont hs	0.5 ml IM antero lateral aspect of thigh	Local pain, erythema, mild fever	Severe allergic reaction (eg, ana phylaxis) after a previous dose or to a vaccine component Ag e 5 weeks	Moderate or severe acute illness with or without fever
Live attendu- ated influenza vaccine (LAIV) quadrivale nt Seasonal I nfluenza	Every year to 2 through 49 years of ag e	0.2-ml prefilled single-use intranasal spray er	Fever, malaise, myalgia, and other systemic s ymptoms	Severe allergic reaction (eg, ana phylaxis) after a previous dose or to a vaccine component. Pregnant, immunocompr omised persons. Concomitant use of aspirin or salicylate containing medication in children and adolescents. LAIV4 should not be administered to persons who have taken oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days Children aged 2 through 4 years with diagnosis of asthma or wheezing: episode has occurred during the preceding 12 months Persons with active cerebrospinal fluid/orophary	GBS <6 weeks after a previous dose of influenza vaccine Asthma in persons aged 5 years old or older Medical conditions which might predispose to higher risk of complications attributable to influenza. Moderate or severe acute illness with or without fever

				ngeal communica tions/leaks Close contacts and caregivers of severely Immunosuppre ssed persons who require a protected environment. Persons with cochlear implants (dur to the potential for CSF lesk, which might exist for some period of time after implantation, Providers might consider consultation with a spe cialist concerning risk of persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used. Altered immunocompe tence Anatomic or functional asplenia (eg, sickle cell disease)	
RIV (Recombin ant influenza vaccine) egg free Quadrivale nt inactivated influenza vaccine [IIV4] egg protein	every year to 18 years and older Every year to 6 months of age and older ever y year	0.5-ml prefilled syringe (PFS) 15 µg/0.5 ml IM	Fever, malaise, myal-gia, and other systemic symptoms Pain, redness at the injection site, head-ache, muscle aches, and malaise.	Severe allergic reaction (eg:, ana-phylaxis) to any component of the vaccine, egg free	GBS <6weeks after a previous dose of influenza vaccine Moderate or severs acute illness with or without fever

CONCLUSION

COVID-19 vaccine development marked a significant milestone in medical science, showcasing rapid innovation across various platforms. While mRNA vaccines offered high efficacy, viral vector vaccines brought logistical convenience. Inactivated vaccines provided a familiar and safe approach, and protein subunit vaccines offered a well-tolerated alternative with strong immunogenicity. Each platform has contributed uniquely to controlling the pandemic, and understanding their differences is essential for guiding policy, public trust, and future vaccine innovation.

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Article

PRESCRIPTION LABELLING

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ABSTARCT:
The International Standard of Community Pharmacy Practice starts with prescription labeling. DATA COLLECTION begins here.It is essential to underscore the pivotal role of data collection in community pharmacies. Data serves as the cornerstone of informed decision-making in healthcare, and this knowledge empowers us as healthcare professionals to make the best decisions for our patients.The dream does not come in sleep, but the dream is what gives sleepless nights. Avoiding the data collection process at the community pharmacy is like kicking the can down the street to prevent the management of a nation's health care. It's not just about managing the nation's health care, but also about ensuring patient safety and well-being.The quality of the Global Standards is not just an expectation; they are our identity.Every prescription we dispense in healthcare promises life, trust, and healing.It is a fact, not a DREAM, that India is the world's major medicine supplier. BUT WHY DO INDIAN COMMUNITY PHARMACIES NOT FOLLOW THE WORLD STANDARD OF DISPENSING MEDICINE TO THE CONSUMER AT THE DISPENSING LEVEL?On a lighter note, when one buys a packet of idlis, sambhar, or dhokla mix, they get instructions on how to make them, heat them, or what setting the microwave is.Strangely, the medicine man does not have to do this when they hand the consumer a strip of medication!! Providing a clear and comprehensive prescription label is not just a task; it's a responsibility for pharmacists. It reassures consumers, helping them understand their medication and feel confident in their treatment plan. This commitment to patient care sets us apart in the healthcare system. India is the major supplier of generic (sometimes brand) medicines to many countries. Most of these countries require Prescriptions, labeling, and auxiliary labels before the medication is handed over to the consumer at the dispensing, say, a pharmacy.INDIA HAS BECOME & IS NOW KNOWN AS “THE PHARMACY HUB OF THE WORLD.” Congratulations to all the members of the INDIAN ACADEMIA.

WHY SHOULD PHARMACISTS DO THIS?

Prescribers write to the pharmacy instructing them to dispense medicine according to the consumer's name, the proper medicine name, the correct dose, the right directions for consumption, and the correct route of administration for their patients.On-demand Pharmacists usually pick up medicine strips from the pharmacy shelves and give oral instructions to consumers on how to use them. Just imagine how someone can remember all that if they are taking four or more medications. Sometimes, the person who takes the medication does not pick up the order. So now there is one more variation: a middleman who will transmit the information you gave orally.

FOR A MINUTE, IS IT BETTER TO GIVE THE MEDICATION INSTRUCTIONS IN WRITING?

*To a layman, antibiotics, blood pressure, diabetes, or pain medication mean nothing by their name.*A layman knows medicines by color, shape, or form (liquid or cream). Blue, white & yellow color tablets or capsules. It could be a round, triangular, or elongated product. *Consumers need to learn what it is for. *A consumer can have more than one health condition. The same person can have pain, blood pressure, diabetes, arthritis, a cough, or a cold. How will consumers remember all these instructions if they are not given in writing? Pharmacovigilance (PV) applies to all aspects of pharmacy practices

THE FOLLOWING ARE A FEW EXAMPLES

*Data collection is an opportunity that should be noticed at the dispensing level. *How about double-checking by writing the label to ensure you have given the right medicine? *How will you trace back or contact consumers during a product recall? *How will you perform ADR if you don't have an individual's medicine profile? *How will you perform the drug interaction function without medicine profile data? I have always wondered how one can prevent the occurrence of ADR or ADE without the data! Are consumers supposed to end up at a hospital whenever there is an ADR or ADE?
Prescription labeling, a written, printed, or graphic representation of information about a drug or its container, is crucial to drug safety. It includes

instructions for use, storage, and disposal, as well as warnings about the drug. The FDA, a leading authority in drug regulation, mandates that all approved prescription drugs have labeling that communicates information to patients, caregivers, and healthcare professionals.

HERE ARE SOME THINGS THAT PRESCRIPTION LABELS INCLUDE

- Patient information: The patient's name, the drug's name and strength, and clear instructions for use.
- Highlights: A concise summary of the label's information.
- Prescribing information: Information for healthcare professionals.
- Warnings and precautions: Information about potential adverse reactions and drug interactions.
- Dosage and administration: Instructions for how to take the drug.
- Patient labeling: Information for patients and caregivers, such as Medication Guides, Patient Package Inserts, or Instructions for Use.

The FDA's goal is to help patients use drugs safely and effectively by providing patient labeling in lay language.

WHAT ARE THE LEGAL REQUIREMENTS FOR DRUG LABELING?

There is a legal requirement for the following to appear on the label of any prescribed medicine:

- Name of the patient;
- Name and address of the supplying pharmacy;
- Date of dispensing;
- Name of the medicine;
- Directions for the use of the medicine;
- Precautions relating to the use of the medicine.

WHAT ARE THE STANDARDS FOR DISPENSED MEDICINE LABELS?

All medicines dispensed are legally required to have a label before being provided to the consumer. Although mandated requirements vary between states and territories, they include the consumer's name, the medicine's name, the strength and dose form, the date of dispensing, and the name and address of the dispensing pharmacy.

WHAT MUST THE DISPENSING LABEL ON PRESCRIPTION MEDICATION INCLUDE?

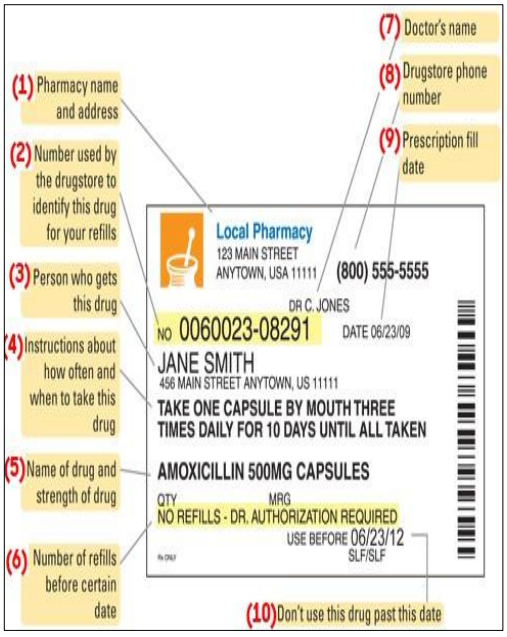
The name and address of the pharmacy / medical practitioner. The trade name or common name of the medicine. The dosage per unit. The method and dosage of administration.

WHAT INFORMATION IS ALWAYS GIVEN ON PRESCRIPTION LABELS?

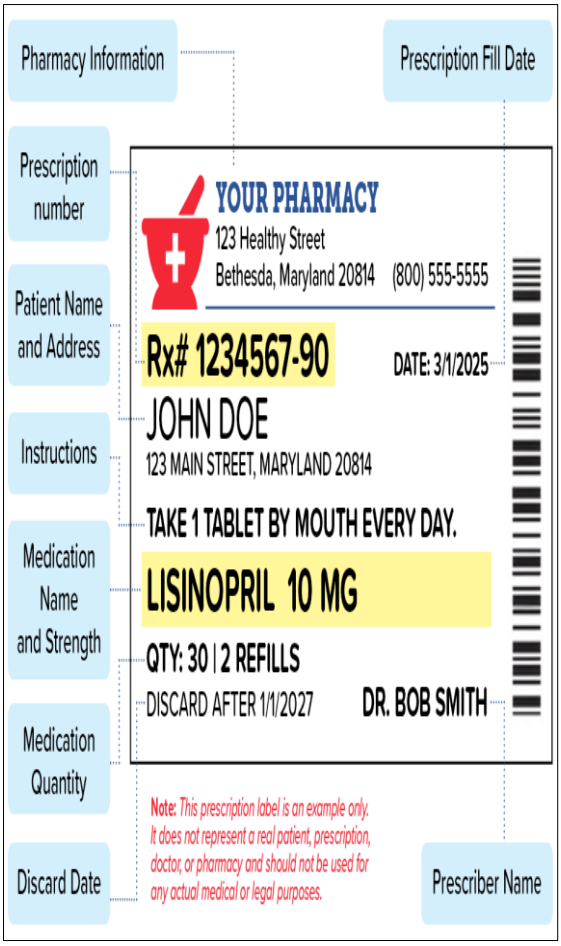
All prescription medicine containers have information on the label, including the patient's name, the name of the medicine, the dosage, and instructions on how often to take it. The pharmacy usually provides more detailed printed information about the medication when dispensing the prescription. Prescription label requirements vary by state but generally include the following information: Patient and prescriber information The patient's name, the prescriber's name, and the dispensing pharmacy's name and address Medication information The name and strength of the medication, the expiration date, and the date of dispensing Directions. The prescriber's directions for the patient to use the medication. Quantity. The number of dosage units or the number of millimeters dispensed if the medication is liquid. Some states also require that the label include the condition or purpose for which the drug was prescribed. In addition to state requirements, the FDA has issued guidelines that require prescription labels to be easier to understand and include information about the dangers of abuse. These guidelines include:

- Using clear, commonly understood terms
- Including abuse-deterrent information
- Providing better patient instructions, including visual elements Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order: (A) Name of the patient, (B) Name of the drug, and strength of the drug.

EXAMPLE #1 OF RX LABEL



EXAMPLE#2 RX LABEL



REFERENCES TO READ FURTHER

- Prescription Label Information, Translations, and Sample Labels - California State Board of Pharmacy
- Frequently Asked Questions about Labeling for Prescription Medicines | FDA Prescription Drug Container Labels
- Discussion of Pharmacy Prescription Labeling

AUXILIARY LABELS

Why are auxiliary labels needed when dispensing medications?

Auxiliary labels provide additional information about medication use and potential side effects, enhancing patient understanding and safety. They are a crucial part of patient education to be included.

WHAT IS THE AUXILIARY LABEL?

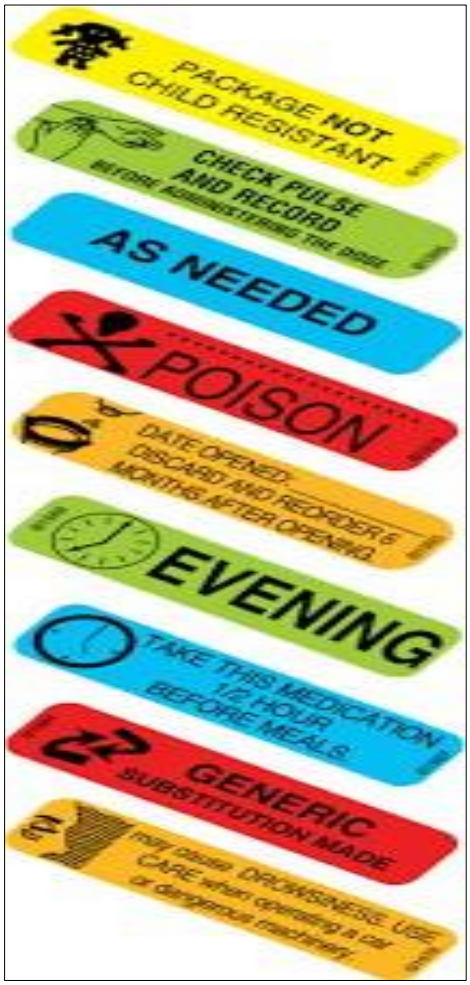
An auxiliary label (also called a cautionary, advisory, or prescription drug warning label) is a label added to a dispensed medication package by a pharmacist in addition to the usual prescription label.

WHAT INFORMATION DOES AN AUXILIARY LABEL PROVIDE?

Patients must also know how to safely use, administer, and store their medicines. Auxiliary labels are medication labels that display various information, such as warnings, dietary information, administration instructions, or cautionary details.

HERE ARE A FEW EXAMPLES OF COMMON TYPES OF AUXILIARY LABELS

- Do Not Chew or Crush
- Swallow Whole
- May Cause Urine Discoloration
- May Cause Drowsiness
- Take With Food or Milk
- Take on an Empty Stomach
- Keep Refrigerated
- Shake Well Before Use
- Protect From Sunlight
- For External Use Only
- For the Eye (or Ear) Only
- For Rectal Use Only



REFERECES TO EXPLORE

- https://ptcbtestprep.com/auxiliary-labels/
- https://pubmed.ncbi.nlm.nih.gov/6839952/ https://nevsink.com/what-are-auxiliary-labels/
- https://en.wikipedia.org/wiki/Auxiliary_label\

Review Article

NARRATIVE REVIEW OF CLINICAL PHARMACIST CONTRIBUTIONS TO CANCER PAIN CONTROL: INTEGRATION OF WHO GUIDELINES AND PAIN ASSESSMENT TOOL

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ABSTRACT:

Pain is a prevalent and distressing symptom in cancer patients, affecting up to 90% depending on cancer type and stage. It arises from multiple sources including the tumor, treatments, and comorbidities, significantly impairing quality of life, psychological well-being, and treatment adherence. Despite advances in pharmacologic therapies and evidence-based guidelines like the WHO's three-step analgesic ladder, cancer pain remains under-assessed and inadequately managed globally. Barriers include clinician knowledge gaps, opioid-related concerns, limited medication access, and fragmented care, especially in resource-limited settings. Emerging clinical pharmacist-led analgesic stewardship programs offer innovative solutions to these challenges by optimizing pain assessment, individualized treatment, opioid management, and patient education. Pharmacists bring specialized pharmacotherapeutic expertise, playing a vital role in tailoring analgesic regimens, monitoring efficacy and adverse effects, and fostering interdisciplinary collaboration. Studies demonstrate that pharmacist involvement improves pain control, medication adherence, and patient satisfaction while reducing medication-related complications and healthcare costs. Opioid stewardship is critical due to risks of misuse and regulatory scrutiny. Pharmacists contribute by applying guideline recommendations, individualizing therapy based on pharmacokinetics and pharmacogenomics, and implementing risk mitigation strategies consistent with CDC and international guidelines. Accurate pain assessment using validated tools—Visual Analogue Scale (VAS), Numerical Rating Scale (NRS), and Verbal Rating Scale (VRS)—is foundational to effective management. Pharmacists enhance guideline implementation by training healthcare teams, ensuring consistent assessment, and integrating pain evaluation into clinical workflows.Overall, clinical pharmacist-led interventions align with global best practices and are integral to comprehensive, patient-centered oncology pain management. Their involvement bridges the gap between guidelines and clinical practice, promoting safer, more effective analgesic use and improving outcomes in cancer patients experiencing pain.

1.INTRODUCTION:

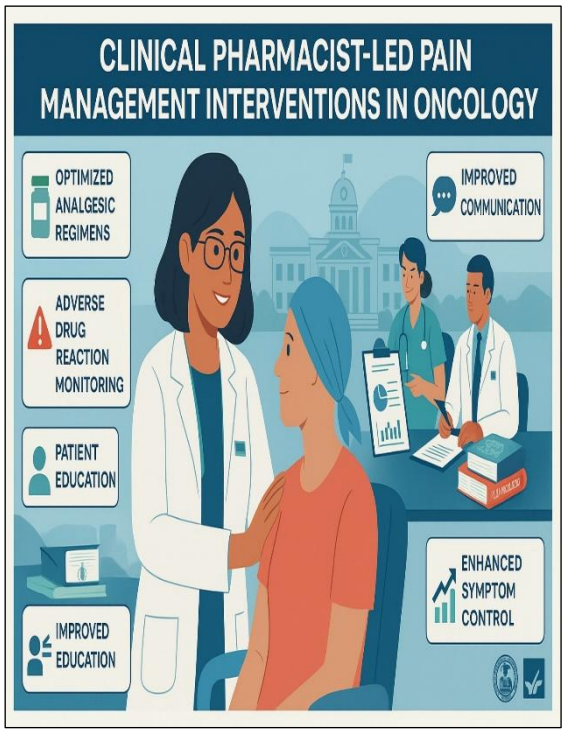
Pain is a ubiquitous and debilitating symptom among cancer patients, with prevalence rates ranging from 30% to 90%, depending on cancer type and stage [1]. It can manifest as acute, chronic, or breakthrough pain, and may arise from the tumor itself, treatment modalities such as chemotherapy, radiotherapy, or surgery, or from comorbid conditions. Poorly managed pain not only deteriorates the overall quality of life but also significantly impairs functional status, psychological well-being, and treatment adherence [2,3]. Patients suffering from uncontrolled pain often experience anxiety, depression, sleep disturbances, and social withdrawal, which further compounds the burden of illness and diminishes therapeutic outcomes. Despite advancements in pharmacological interventions, including the availability of opioids, adjuvants, and novel delivery systems, and the existence of evidence-based guidelines, pain remains under-assessed and inadequately managed in many oncology settings [4]. A range of factors contributes to this gap, such as clinicians' lack of training in pain assessment, fear of opioid addiction or adverse effects, limited

availability of medications, and inadequate communication between patients and healthcare providers. To address this, the World Health Organization (WHO) introduced its three-step analgesic ladder in 1986 as a foundational framework for cancer pain management, emphasizing the use of non-opioids, mild opioids, and strong opioids in a stepwise manner based on pain severity [5]. However, translating these guidelines into clinical practice remains a challenge, particularly in resource-limited settings where access to medications and palliative care services is constrained and where interdisciplinary collaboration is often lacking [6]. Fragmented care and inconsistent application of guidelines can lead to both undertreatment and overtreatment of pain, undermining patient outcomes. Recently, clinical pharmacist-led analgesic stewardship programs have emerged as innovative and effective strategies for optimizing pain control in cancer patients [7]. By leveraging their pharmacotherapeutic expertise, clinical pharmacists play a pivotal role in assessing pain, recommending individualized treatment plans, adjusting opioid dosages, and monitoring for efficacy and adverse effects. These programs not only enhance the safe and effective use of analgesics but also address critical aspects such as patient education, adherence support, and prevention of medication misuse [8]. Furthermore, such pharmacist-led interventions align with international best practices, being guided by WHO-recommended pain assessment tools and supported by authoritative global guidelines from organizations including the Centers for Disease Control and Prevention (CDC), the European Society for Medical Oncology (ESMO), and the European Association for Palliative Care (EAPC) [9–11]. These collaborative, multidisciplinary approaches are increasingly recognized as integral to delivering comprehensive, patient-centered oncology care.

2.CLINICAL PHARMACIST-LED PAIN MANAGEMENT INTERVENTIONS:

The integration of clinical pharmacists into oncology care teams is increasingly recognized for its substantial contributions to improving clinical outcomes in cancer pain management. These healthcare professionals bring pharmacotherapeutic expertise that complements the roles of physicians and nurses, enhancing individualized patient care and ensuring evidence-based treatment decisions. Li et al. conducted a prospective, multicenter, randomized controlled trial to assess the impact of a clinical pharmacist-led guidance team on cancer pain management. The study included a substantial number of patients from multiple centers and reported significant improvements in pain control in the intervention group compared to the control group. Clinical pharmacists were actively involved in optimizing analgesic regimens, monitoring for adverse drug reactions, maintaining detailed documentation of pain assessments, and conducting educational sessions for both patients and other healthcare providers—underscoring the multifaceted nature of their contribution to oncology pain care [12]. Similarly, Koshy et al. highlighted the added value of incorporating oncology pharmacists into multidisciplinary care teams. Their research demonstrated notable improvements in symptom control, medication adherence, and overall patient satisfaction. Importantly, pharmacists served as crucial liaisons in facilitating effective communication between physicians, patients, and other care team members—an aspect particularly vital for managing complex and persistent symptoms such as cancer-related pain [22]. In China, Zhang et al. evaluated the physician-pharmacist collaborative care model, demonstrating that such interprofessional partnerships significantly enhanced clinical outcomes and provided greater economic efficiency in cancer pain management. Patients receiving co-managed care experienced improved pain relief, a reduction in medication-related complications, and overall lower healthcare expenditures compared to those managed by physicians alone. This model not only reflects a scalable strategy for optimized care but also exemplifies the global relevance of pharmacist-led interventions in oncology [20]. Collectively, these studies reinforce the role of clinical pharmacists as essential contributors to standardized, safe, and effective cancer pain management, bridging the gap between guidelines and clinical practice. [Figure 1]

Figure 1 Clinical Pharmacist-Led pain management interventions in oncology



3.OPIOID STEWARDSHIP AND PRESCRIBING GUIDELINES:

Opioids remain the cornerstone in the pharmacologic treatment of moderate to severe cancer pain, but their use poses several clinical and regulatory challenges. These include issues related to dependence, tolerance, risk of misuse, and scrutiny over prescribing practices. To address these challenges, the Centers for Disease Control and Prevention (CDC) released a comprehensive clinical practice guideline in 2022 focusing on the rational and responsible prescribing of opioids. The guideline emphasizes patient-centered care, advocating for individualized pain therapy, prudent opioid initiation and titration, and ongoing risk monitoring. It supports integrating non-opioid and non-pharmacologic therapies when feasible, aligning well with the principles of pharmacist-led opioid stewardship programs [13]. An earlier 2016 guideline by Dowell et al. laid the foundational principles for opioid safety, including patient selection criteria, dosage thresholds, and the need for continual risk-benefit assessment. These recommendations have guided many institutions in formulating opioid stewardship policies aimed at minimizing harm while preserving access to essential pain relief for those in need [21]. Further supporting this need, Chou et al. conducted a systematic review for the NIH, which concluded that long-term opioid therapy carries limited evidence for sustained efficacy and considerable evidence for harm, such as overdose risk, opioid use disorder, and endocrine dysfunctions [17]. These findings underscore the importance of involving clinical pharmacists in opioid stewardship initiatives. Their expertise allows them to identify at-risk patients through medication reviews, tailor opioid regimens based on pharmacokinetics, monitor therapy using validated tools, and flag potential drug interactions. Smith's comprehensive analysis of opioid metabolism further highlights the importance of individualized therapy; genetic polymorphisms in metabolizing enzymes like CYP2D6 and CYP3A4 can dramatically influence both the efficacy and toxicity of opioids. Pharmacists, equipped with knowledge in pharmacogenomics and drug metabolism, are uniquely qualified to adjust doses, prevent adverse effects, and ensure optimal therapeutic outcomes in cancer pain management [19].[Figure 2].

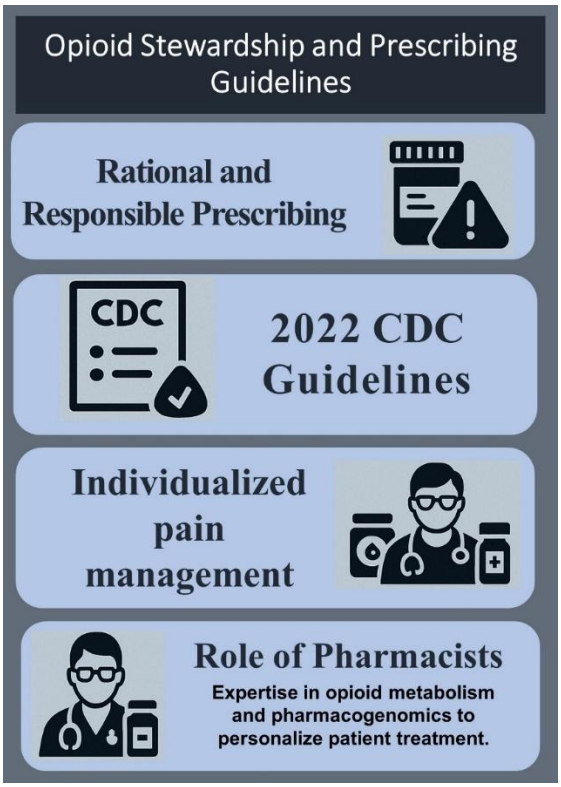


Figure 2 Opioid Stewardship and Prescribing Guidelines

4. PAIN ASSESSMENT AND WHO GUIDELINES:

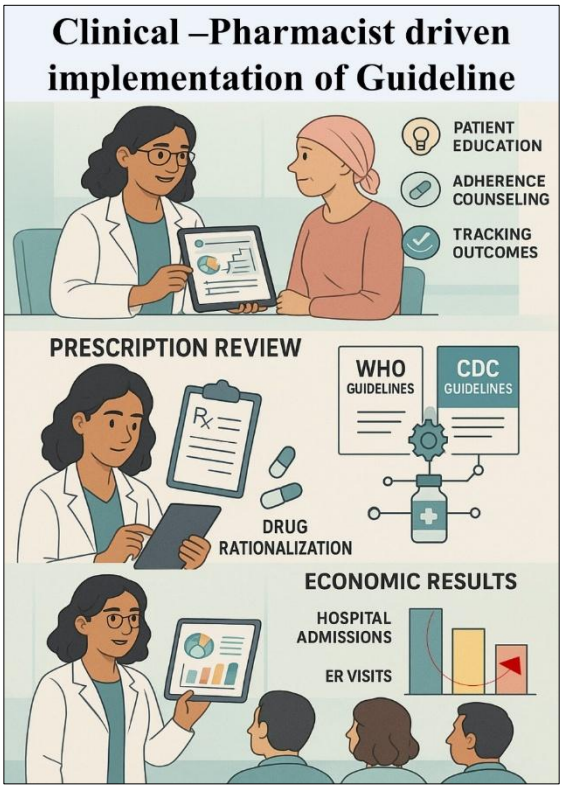
Effective pain management begins with accurate and consistent pain assessment. The WHO guidelines for the pharmacological and radiotherapeutic management of cancer pain underscore the importance of using validated pain assessment tools regularly and tailoring interventions to individual patient needs. Among these tools, the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS), and the Verbal Rating Scale (VRS) are widely used in clinical settings. The VAS, validated by Price et al., is particularly sensitive to subtle changes in pain intensity and generates ratio-level data, making it a valuable tool for clinical trials and therapeutic evaluations [14]. Caraceni et al. provided a detailed review of the methodologies and tools used in palliative care research, emphasizing that pain measurement must be reliable, easy to administer, and applicable across various clinical environments. Inadequate or inconsistent assessment practices, they noted, often result in suboptimal treatment strategies and increased patient dissatisfaction [16]. Paice and Ferrell offered a multidimensional framework for evaluating cancer pain, stressing that effective assessment should consider intensity, character, duration, and impact on functional capacity and daily living. They

reinforced the importance of WHO's stepwise analgesic strategy while also advocating for the integration of non-pharmacological and adjuvant interventions in comprehensive pain care plans [15]. The WHO's three-step analgesic ladder serves as a foundational guideline for cancer pain management. It recommends starting with non-opioid analgesics like acetaminophen or NSAIDs for mild pain, escalating to weak opioids such as tramadol or codeine for moderate pain, and utilizing strong opioids like morphine or fentanyl for severe pain. The model promotes scheduled rather than as-needed dosing and supports the oral route of administration as the most convenient and preferred method. It also encourages the use of adjuvants at all steps to address neuropathic components or enhance analgesia [9].

5.PHARMACIST-DRIVEN IMPLEMENTATION OF PAIN GUIDELINES:

Clinical pharmacists play a critical role in ensuring the effective implementation of clinical guidelines in day-to-day practice. Their role extends beyond dispensing to encompass patient education, therapeutic drug monitoring, and quality assurance. Pereira et al. conducted a systematic review demonstrating that pharmacist-led interventions significantly improved adherence to antidepressant therapy—a finding that holds relevance for cancer pain management, where patient adherence to complex, long-term analgesic regimens often poses a challenge [18]. By tracking adherence, addressing barriers, and providing tailored counseling, pharmacists enhance treatment continuity and patient outcomes. Pharmacists are also instrumental in auditing prescription patterns, minimizing medication errors, and promoting rational drug use through formulary management and policy development. Their involvement ensures that WHO and CDC guidelines are not merely theoretical frameworks but are actively applied in clinical settings. Pharmacists also act as educators, equipping healthcare teams with up-to-date knowledge on evolving guidelines, evidence-based practices, and pharmacovigilance principles. Zhang et al.'s economic analysis provides strong evidence supporting the sustainability of pharmacist-driven models. The study showed that the integration of pharmacists into cancer pain management significantly reduced healthcare costs related to hospital admissions, emergency department visits, and management of medication-related complications, while simultaneously improving patient outcomes [20]. [Figure 3].

Figure 3 Pharmacist-Driven Implementation of Pain Guidelines



6. COMPARATIVE EVALUATION OF WHO RECOMMENDED PAIN ASSESSMENT SCALES:

The success of any pain management strategy is inherently dependent on the accuracy and reliability of the assessment tools employed. The WHO supports standardized tools such as the VAS, NRS, and VRS, each tailored to different clinical scenarios. The VAS, while highly sensitive and suitable for detecting subtle changes in pain levels, may be difficult for certain populations—including elderly patients or those with cognitive impairments—to comprehend and utilize effectively. The NRS is a more user-friendly alternative, allowing patients to rate their pain on a numerical scale from 0 to 10, but it may lack the statistical robustness of VAS. The VRS, which uses descriptors like “mild,” “moderate,” and “severe,” offers simplicity at the cost of quantitative precision. Caraceni et al. emphasized that the choice of assessment tool should be informed by patient characteristics, clinical context, and the specific goals of treatment. In this respect, clinical pharmacists can provide valuable guidance by

training healthcare professionals in the appropriate use of these tools, ensuring consistent implementation, and integrating assessments into electronic health records for ongoing monitoring and quality improvement [16]. Furthermore, pharmacists can contribute to the development and validation of novel pain assessment tools tailored to specific populations such as pediatric, geriatric, or palliative care patients. Their involvement ensures that tools are not only selected appropriately but are also administered correctly and interpreted accurately, leading to more effective pain control and enhanced patient care outcomes.

7. CONCLUSION:

Cancer pain remains a significant burden on patients and healthcare systems alike. While global guidelines provide a robust framework for management, implementation gaps persist. Clinical pharmacist-led analgesic stewardship programs have demonstrated substantial benefits in optimizing pain control, improving adherence to guidelines, reducing opioid-related risks, and enhancing overall patient quality of life. Pharmacists contribute at every level—from drug selection and dose adjustment to patient education and policy development. Their integration into multidisciplinary care teams has shown to improve outcomes, reduce healthcare costs, and ensure safe and effective pain management practices. As the complexity of cancer care increases, so does the need for specialized roles like that of clinical pharmacists. Their expertise in pharmacotherapy, combined with patient-centered care principles, positions them uniquely to lead analgesic stewardship initiatives. Future research should focus on expanding these roles, developing standardized implementation frameworks, and evaluating long-term impacts on patient outcomes and healthcare resource utilization. In conclusion, clinical pharmacist-led analgesic stewardship represents a transformative approach in cancer pain management. By adhering to WHO-recommended pain assessment tools and incorporating evidence-based guidelines, these programs promise to set a new standard in oncologic care.

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Authors should submit two hard copies of manuscripts and electronic version of the manuscript in a Compact Disc to the Editor. Authors also encouraged submitting a copy of manuscript to the Editor by electronic mail. Accepted papers will be processed further, if the papers are rejected, the decision will be communicated to the corresponding author but the manuscripts will not be returned.

PREPARING A MANUSCRIPT

Authors should keep their manuscripts as short as they reasonably can. Manuscripts should be typed double spaced on one side of good quality A4 size paper. Page number should appear in the upper right-hand corner of each page, beginning with the title page.

The language of manuscript must be simple and explicit.

Author's/Co-author's name or any other identification should not appear anywhere in the body of the manuscript to facilitate blind review.

Articles were accepted under following headings:

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h. Events.

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- Abstract and Key words,
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- Materials and
- Methods,
- Results,
- Discussion,
- Acknowle
- gement,
- References,
- Tables,
- Figures.
- The total number of words should not exceed 3200. 2

TITLE PAGE: It should be paginated as page 1 of the paper. It should carry the title, authors' names and their affiliations, running title, address for correspondence including e-mail address.

TITLE: Must be informative, specific and short and not exceed 100 characters.

AUTHORS AND AFFILIATIONS: The names of authors and their appropriate addresses should be given. It should be made clear which address relates to which author.

RUNNING TITLE: It is a short title printed in the journal at the right top corner of right-hand page of the article (except the lead page). A short running title of not more than 50 characters should be given.

ADDRESS FOR CORRESPONDENCE: The corresponding author's address should be given in the title page. The e-mail ID of the corresponding author or the contact e-mail ID must also be provided.

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It must start on a new page carrying the following information: (a) Title (without authors' names or affiliations), (b) Abstract, (c) Key words, (d) Running title. It should not exceed 200 words excluding the title and the key words. The abstract must be concise, clear and informative rather than indicative. The abstract must be in a structured form consisting of OBJECTIVES, METHODS, RESULTS and CONCLUSIONS briefly explaining what was intended, done, observed and concluded. Authors should state the main conclusions clearly and not in vague statements. The conclusions and recommendations not found in the text of the article should not be given in the abstract.

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MATERIAL AND METHODS

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The details of statistical tests used and the level of significance should be stated. If more than one test is used it is important to indicate which groups and parameters have been subjected to which test.

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This section should deal with the interpretation, rather than recapitulation of results. It is important to discuss the new and significant observations in the light of previous work. Discuss also the weaknesses or pitfalls in the study. New hypotheses or recommendations can be put forth.

ACKNOWLEDGEMENTS

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International Journal of Community Pharmacy

The Official Publication of ACPI

OBJECTIVES

- To organize into an association of all persons engaged in, interested in or connected with community pharmacy.
- To elevate and establish a standard of competence for community pharmacy.
- To develop and promote standards of education and training for community pharmacy.
- To develop and promote short term informal training programs for individuals interested in community pharmacy.
- To educate hospital trustees, Board of Directors, Board of Visitors and the public to understand that the practice of community pharmacy calls for special training and experience.
- To serve as a forum for exchange of ideas and experiences, and collection and dissemination of information in general community pharmacy.
- To spread the knowledge on the principles, practices, techniques and methods concerning community pharmacy.
- To promote and safeguard the status and the interest of community pharmacy and the interests of those engaged in it.
- To promote sponsor, submit, memorandums, petitions and representations to local, state, union and other authorities for better laws, and influence legislation which affect hospitals and other community pharmacy organizations.
- To organize conferences, seminars, meetings and discussions for the promotion and furtherance of the aims and objects of the ACPI.
- To undertake and bring out, publish, sell, distribute free or otherwise, edit, print and exhibit for sale, magazines publication, bulletins, books pamphlets and the like, in furtherance of the objects of the ACPI and in any event not for the purpose of carrying a trade there from but only for the purpose of furthering the objects of the ACPI.
- To raise any monies for the purpose of the ACPI by way of special subscriptions, membership or entrance fees, donations, special fees, loans or in any other manner on such terms and conditions as may be determined.
- To purchase, take on lease or in exchange, or otherwise acquire, any movable or immovable property, rights or privileges, which may be deemed necessary, expedient or desirable for any of the objects of the ACPI.
- To accept from the Government, organizations, institutions and individuals, grants, donations, subscriptions, gifts bequests, endowments, special fees, etc. for the furtherance of the objects of the ACPI.
- To make from time to time, regulation and bye-laws for the control, conduct and regulation of the affairs of the ACPI.
- To confer Fellowships in community pharmacy on those who have done or are doing noteworthy service in the field of community pharmacy.
- To generally do all such other things as are incidental or conducive to the attainment of any or all of the above-mentioned objects.

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