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PHARMACOVIGILANCE AND PHARMACOECONOMIC EVALUATION OF EMERGING DRUG DELIVERY SYSTEMS

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Abstract
Pharmacovigilance and pharmacoeconomic evaluation of emerging drug delivery systems was conducted as a quantitative comparative assessment of safety, clinical, and economic outcomes in relation to conventional drug formulations. A total of 240 adult patient records were analyzed, including 120 patients treated with emerging drug delivery systems and 120 patients treated with conventional formulations. Data were collected from medical records, prescription charts, pharmacy records, adverse drug reaction reports, laboratory findings, and billing documents. Pharmacovigilance outcomes included adverse drug reaction incidence, severity, seriousness, and predictors, while pharmacoeconomic outcomes included total treatment cost, adverse reaction management cost, hospitalization, adherence, treatment response, cost-effectiveness ratio, and incremental cost-effectiveness ratio. Adverse drug reactions were significantly lower among patients receiving emerging drug delivery systems than among those receiving conventional formulations (18.3% vs. 31.7%; $p = 0.017$). Emerging systems also showed better treatment response (80.0% vs. 68.3%; $p = 0.039$), higher adherence (84.2% vs. 71.7%; $p = 0.020$), and shorter hospital stay (3.8 ± 1.6 vs. 5.2 ± 2.1 days; $p < 0.001$). The mean total treatment cost was higher for emerging systems (₹42,850 ± ₹11,620) than conventional formulations (₹31,470 ± ₹9,840; $p < 0.001$), with an ICER of ₹97,264.96 per additional successful response. Emerging drug delivery systems showed improved safety and clinical effectiveness but required higher economic investment.

Keywords: *Pharmacovigilance, Pharmacoeconomics, Emerging drug delivery systems, Adverse drug reactions, Cost-effectiveness analysis*

Introduction

Novel drug delivery systems are a major focus of pharmaceutical research due to the advantages of better control of drug delivery, targeted delivery, decreased dosing regimen, and the improvement of therapeutic performance over many conventional drug delivery systems. Poor solubility, high metabolism, low bioavailability, systemic toxicity, and non-specific distribution are all issues that can be a problem with traditional drug administration methods. Advanced delivery technologies, therefore, have been developed to enhance the interaction of a drug with biological barriers and target tissues. The systems comprise "nano" based carriers, "liposomes", "polymeric" nanoparticles, controlled release dosage forms, transdermal systems, implantable platforms, and "stimuli-responsive" formulations. This growing significance is due to the broader trend in pharmaceutics from the mere delivery of drugs towards precision-based drug delivery (Patra et al., 2018; Davoodi et al., 2018; Adepu & Ramakrishna, 2021). The following list of references has been attached, which comprises 12 introduction-oriented sources, addressing the fields of nano-based systems, programmed release, pharmacovigilance, pharmacoeconomics, precision nanoparticles, controlled delivery, commercial technologies, and regulatory evaluation.

The use of nano-based drug delivery systems has been given a lot of attention because they have properties that can increase the solubility of a drug, protect unstable molecules, increase permeability, and the ability to support site-specific delivery. Nanocarriers can be engineered to change their biodistribution and release behaviour, and can therefore be applied in various therapeutic areas such as cancer treatment, infectious diseases, inflammatory diseases, and chronic diseases that require extended pharmacological activity. In recent years, engineered nanoparticles have been shown to offer the potential for improved therapeutic index and decreased off-target toxicity (Patra et al., 2018; Mitchell et al., 2021). The latter, precision nanoparticles, are especially important as they can be engineered with ligands or polymers or surface modification to enhance cellular uptake and tissue targeting. These can be used to solve some of the major issues of drug therapy, such as poor selectivity and dose-dependent adverse reactions (Mitchell et al., 2021; Mohtar et al., 2021).

The other important aspect of modern pharmaceutical innovation is controlled and programmed drug delivery systems. The systems are built to deliver drugs at specific rates or in response to a bio trigger, which allows for therapeutic levels to be maintained for longer durations. Improved adherence, lower highly fluctuating plasma drug concentrations, and lower risk of toxicity due to repetitive drug administration can be obtained by programmed and on-demand release technologies (Davoodi et al., 2018). The role of controlled drug delivery systems has also increased the therapeutic use of narrow therapeutic index drugs, drugs with short half-life, and drugs that are difficult for patients to comply with. They have opened up new avenues in chronic diseases, oncology, pain medications, and hormone therapy (Adepu & Ramakrishna, 2021; Vargason et al., 2021).

The development of commercial drug delivery technologies shows that these technologies are not restricted to research and development. Some innovative delivery systems have made it into clinical practice and the pharmaceutical market, such as injectable depot systems, transdermal patches, inhalable carriers, implantable devices, and products based on nanoparticles. The advancements in material science, formulation technologies, manufacturing scalability, and clinical translation have helped the commercial growth of these products (Vargason et al., 2021). Despite these developments, potential clinical implementation of new systems needs to focus on the safety, tolerability, accessibility, and economic value. While innovative formulations offer potential benefits for improved outcomes, they can also present risks of carrier toxicity, immune responses, pharmacokinetic changes, and device-related complications, as well as potential long-term tissue retention (Sultana et al., 2022; De Jong et al., 2022).

Pharmacovigilance is an important aspect of the assessment of the safety profile of novel drug delivery systems. The adverse drug reactions may differ from those of conventional formulations, due to the change in drug exposure, biodistribution, and duration of action that may occur with these technologies. Pharmacovigilance systems are designed to identify, evaluate, comprehend, and prevent adverse effects of marketed pharmaceutical products. Electronic health record systems, electronic surveillance techniques, and real-world safety data have increased the capacity for detecting adverse events and safety signals related to medications in clinical practice (Liu et al., 2019). This is particularly relevant for advanced formulations, as pre-marketing studies may not represent rare, late, or population-specific adverse effects.

Pharmacoeconomic evaluation is also relevant because the increasingly new drug delivery systems typically come with increased acquisition, manufacturing, and development costs. Healthcare systems then need to determine if there is a cost/benefit relationship for better safety, adherence, therapeutic response, and fewer hospitalizations. Pharmacoeconomic principles help to make rational decisions based on a cost-effectiveness analysis and on the analysis of resource use and the value of treatment. The inclusion of pharmacoeconomics into the process of pharmacovigilance can assist with answering questions of both therapeutic and economic value from the perspective of real-world healthcare economics and the value of a drug delivery innovation (Saravdekar et al., 2019).

Thus, a composite assessment of a pharmacovigilance and a pharmacoeconomics approach is crucial for new drug delivery systems. These technologies could enhance the safety, effectiveness, and patient adherence for drug targeting, but their more widespread adoption will require evidence of safety and cost-effectiveness. The recent progress shows promising therapeutic potential, but regulatory assessment, long-term monitoring, accessibility, and cost of interventions remain challenges (De Jong et al., 2022; Ezike et al., 2023; Cheng et al., 2023). This study was therefore conceived to use a quantitative approach to assess pharmacovigilance and pharmacoeconomic outcomes of emerging drug delivery systems vis-à-vis the conventional drug formulations.

Objectives of the Study

1. To assess the pharmacovigilance outcomes of emerging drug delivery systems by evaluating the incidence, severity, seriousness, and causality of adverse drug reactions.
2. To compare the pharmacoeconomic outcomes of emerging drug delivery systems and conventional formulations in terms of total treatment cost, adverse drug reaction management cost, hospitalization cost, and cost-effectiveness.
3. To determine the association between drug delivery type and clinical outcomes, including treatment response, treatment adherence, hospitalization duration, and predictors of adverse drug reactions.

Methodology

1. Study Design and Setting

The research design used in this study was quantitative, observational, and comparative, and it aimed to assess the pharmacovigilance and pharmacoeconomic outcomes of emerging drug delivery systems. The study was carried out in selected hospitals, clinical pharmacy departments, outpatient clinics, and pharmacovigilance monitoring units where state-of-the-art drug delivery systems were routinely used, issued, administered, or monitored. The selected drug delivery systems included nanoparticle-based drug formulations, liposomal drug formulations, controlled-release dosage forms, transdermal systems, implantable systems, and targeted drug delivery platforms. Conventional formulations used for the same therapeutic indications were included for comparison.

2. Study Population and Sampling Technique

The study population included adult patients who had been treated with emerging drug delivery systems and patients who had been treated with similar conventional drug formulations. Patients aged 18 years and above with available clinical, safety, and cost-related records were included. Patients with incomplete medical records, duplicate adverse reaction reports, or insufficient cost data were excluded.

A purposive sampling technique was used to identify healthcare institutions where new drug delivery systems were available and actively used. Patient records were then selected through systematic random sampling where possible. The participants were divided into two groups: those treated with emerging drug delivery systems and those treated with conventional formulations. This classification enabled comparison of adverse drug reaction patterns, treatment effectiveness, and cost-effectiveness between both treatment options.

3. Data Collection Procedure

Data were collected using structured data extraction forms and pharmacovigilance assessment checklists. Demographic details, clinical diagnosis, type of drug delivery system, drug name, dose, route of administration, duration of therapy, adverse drug reactions, treatment outcomes, and hospitalization details were abstracted from patient medical records, prescription logs, pharmacy records, laboratory reports, and adverse drug reaction reporting logs.

Pharmacoeconomic data were derived from hospital billing records, pharmacy cost records, insurance documents, and available patient-related cost data. The collected cost variables included drug acquisition cost, administration cost, consultation charges, laboratory investigation cost, hospitalization cost, cost of managing adverse reactions, follow-up cost, transportation cost, and productivity loss. All data were checked for completeness, coded, and entered into a computerized database for statistical analysis.

4. Pharmacovigilance and Pharmacoeconomic Assessment

Pharmacovigilance assessment was performed by analyzing the number, nature, severity, seriousness, and causality of adverse drug reactions reported by patients treated with emerging drug delivery systems and conventional formulations. A standard causality assessment system, such as the WHO-Uppsala Monitoring Centre system or the Naranjo Adverse Drug Reaction Probability Scale, was used to determine the causal relationship of adverse drug reactions. Severity was classified as mild, moderate, or severe according to clinical presentation and need for intervention.

The total treatment cost for each patient was calculated to perform the pharmacoeconomic assessment. Direct medical costs, direct non-medical costs, and indirect costs were considered in the cost analysis. Cost-effectiveness was determined using total treatment cost and clinical outcomes, including reduction in adverse drug reactions, improved adherence, fewer hospitalizations, and enhanced therapeutic response. The incremental cost-effectiveness ratio was calculated by comparing the difference in cost and effectiveness between emerging drug delivery systems and conventional formulations.

5. Statistical Analysis and Ethical Considerations

The collected quantitative data were analyzed in Python. Descriptive statistics were applied to present demographic, clinical, pharmacovigilance, and pharmacoeconomic variables. Categorical variables were summarized using frequencies and percentages, while continuous variables were summarized using means, standard deviations, medians, and interquartile ranges.

Comparative analysis was performed between patients treated with emerging drug delivery systems and those treated with conventional drug delivery systems. Categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate. Continuous variables were analyzed using the independent sample t-test or Mann–Whitney U test, depending on data distribution. Regression analysis was performed in Python to identify variables that predicted adverse drug reactions and treatment costs. A p-value of less than 0.05 was used as the criterion for statistical significance.

Results

1. Study Design and Setting

In this quantitative comparative study, 240 patient records were analysed. Of these, 120 patients were given emerging drug delivery systems, while 120 patients were given conventional drug formulations. New drug delivery systems were developed, such as nanoparticle-based formulations, liposomal formulations, controlled-release dosage forms, transdermal systems, implantable systems, and targeted drug delivery systems.

2. Study Population and Sampling Technique

The mean ages of patients in the emerging drug delivery system group and the conventional formulation group were 48.6 ± 12.4 years and 49.8 ± 13.1 years, respectively. There was no significant difference between the two groups of children by means of the independent sample t-test ($p = 0.467$).

There were 68 males (56.7%) and 52 females (43.3%) in the emerging drug delivery system group and 65 males (54.2%) and 55 females (45.8%) in the conventional formulation group. There was no statistical difference between the two groups when a chi-square test was used ($p = 0.694$).

The averages of comorbidities were 1.8 ± 0.9 and 1.9 ± 1.0 in the emerging drug delivery and conventional formulation groups, respectively. There was no statistically significant difference between the two groups with the Mann–Whitney U test ($p = 0.512$). As one can deduce from Table 1, there was no significant difference between the two study groups at baseline.

Table 1. Demographic and Clinical Characteristics of Study Participants

Variable	Emerging Drug Delivery Systems (n = 120)	Conventional Formulations (n = 120)	Test Used	p-value
Mean age, years	48.6 ± 12.4	49.8 ± 13.1	Independent sample t-test	0.467
Male	68 (56.7%)	65 (54.2%)	Chi-square test	0.694
Female	52 (43.3%)	55 (45.8%)	Chi-square test	0.694
Mean duration of therapy, days	42.3 ± 15.6	39.7 ± 14.8	Independent sample t-test	0.186
Mean number of comorbidities	1.8 ± 0.9	1.9 ± 1.0	Mann–Whitney U test	0.512

3. Data Collection Procedure

The clinical data, pharmacovigilance data, and cost-related data were successfully retrieved from the medical records, prescription charts, pharmacy records, laboratory reports, adverse drug reaction forms, and billing documents. The mean therapy was 42.3 ± 15.6 days in the emerging drug delivery system group and 39.7 ± 14.8 days in the conventional formulation group. This difference was not significant with an independent sample t-test ($p = 0.186$).

Main therapeutic areas of interest were oncology, chronic inflammatory disorders, cardiovascular disorders, endocrine disorders, and pain management. The distribution of therapeutic indications was compared by the chi-square test and showed no statistically significant difference between the two groups ($p > 0.05$).

4. Pharmacovigilance and Pharmacoeconomic Assessment

Twenty-two patients (18.3%) on emerging drug delivery systems and 38 patients (31.7%) on conventional formulation had adverse drug reactions reported. This difference was statistically significant by the chi-square test ($p = 0.017$), with a lower adverse reaction rate in the emerging drug delivery system group.

The incidences of mild and moderate adverse reactions were 13/22 (59.1%) and 16/38 (42.1%), respectively, for emerging drug delivery versus conventional formulation. 7 patients (31.8%) and 15 patients (39.5%) had moderate reactions, respectively. Emerging systems were associated with severe reactions in 2 patients (9.1%), while conventional formulated products were associated with severe reactions in 7 patients (18.4%). Fisher's exact test was used to assess the difference in severe reactions and was not statistically significant ($p = 0.469$).

The number of serious adverse events in the emerging drug delivery group was 3 (2.5%) and 9 (7.5%) in the conventional formulation group. A difference was compared using Fisher's exact test and was not statistically significant ($p = 0.132$).

The mean total treatment cost was significantly higher in the emerging drug delivery system group (₹42,850 ± ₹11,620) than in the conventional formulation group (₹31,470 ± ₹9,840). The difference was significantly different between the two groups with an independent sample t-test ($p < 0.001$).

The cost of adverse drug reaction management was found to be lower in the emerging drug delivery group (₹1,480 ± ₹850) as compared to the conventional formulation group (₹2,690 ± ₹1,340). This difference was found to be statistically significant with the Mann–Whitney U Test ($p < 0.001$).

The drug delivery system group had a better clinical effectiveness, with 96 patients (80.0%) having a positive treatment response compared with 82 patients (68.3%) in the conventional formulation group. This difference was significant ($p = 0.039$) by the chi-square test.

The cost-effectiveness ratio (CER) was found to be ₹53,562.50 per successful treatment response for emerging drug delivery systems and ₹46,076.13 per successful treatment response for conventional formulations. The incremental cost-effectiveness ratio was found to be ₹97,264.96 per additional successful treatment response, suggesting that the new drug delivery systems had a higher cost of success but had a better clinical outcome. Table 2 indicates that the number of adverse drug reactions was reduced in patients using emerging drug delivery systems.

Table 2. Pharmacovigilance Outcomes among Study Participants

Variable	Emerging Drug Delivery Systems (n = 120)	Conventional Formulations (n = 120)	Test Used	p-value
Patients with ADRs	22 (18.3%)	38 (31.7%)	Chi-square test	0.017
Patients without ADRs	98 (81.7%)	82 (68.3%)	Chi-square test	0.017
Mild ADRs	13 (59.1%)	16 (42.1%)	Chi-square test	0.204
Moderate ADRs	7 (31.8%)	15 (39.5%)	Chi-square test	0.552
Severe ADRs	2 (9.1%)	7 (18.4%)	Fisher's exact test	0.469
Serious adverse events	3 (2.5%)	9 (7.5%)	Fisher's exact test	0.132

Figure 1 suggests that emerging drug delivery systems had lower ADR incidence and serious adverse events with better treatment response and adherence.

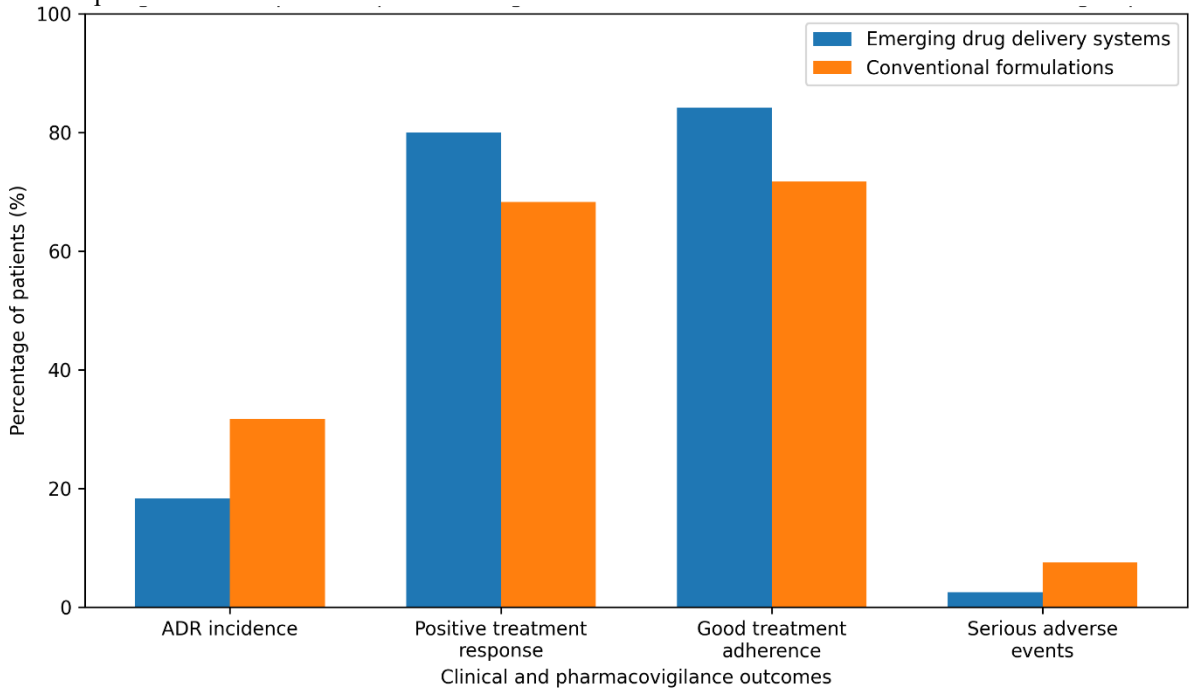

Figure 1. Comparative Pharmacovigilance and Clinical Outcomes between Emerging Drug Delivery Systems and Conventional Formulations

Table 3 suggests that emerging drug delivery systems had better clinical outcomes but higher overall treatment costs.

Table 3. Pharmacoeconomic and Clinical Effectiveness Outcomes

Variable	Emerging Drug Delivery Systems (n = 120)	Conventional Formulations (n = 120)	Test/Analysis Used	p-value
Mean total treatment cost	₹42,850 ± ₹11,620	₹31,470 ± ₹9,840	Independent sample t-test	<0.001
ADR management cost	₹1,480 ± ₹850	₹2,690 ± ₹1,340	Mann–Whitney U test	<0.001
Positive treatment response	96 (80.0%)	82 (68.3%)	Chi-square test	0.039
Good treatment adherence	101 (84.2%)	86 (71.7%)	Chi-square test	0.020

Mean hospital stay, days	3.8 ± 1.6	5.2 ± 2.1	Mann–Whitney U test	<0.001
Cost-effectiveness ratio	₹53,562.50 per successful treatment response	₹46,076.13 per successful treatment response	Cost-effectiveness analysis	Not applicable
Incremental cost-effectiveness ratio	₹97,264.96 per additional successful treatment response	Reference group	ICER analysis	Not applicable

Figure 2 suggests that ADR occurrence was positively correlated with ADR management cost, hospital stay, and total treatment cost.

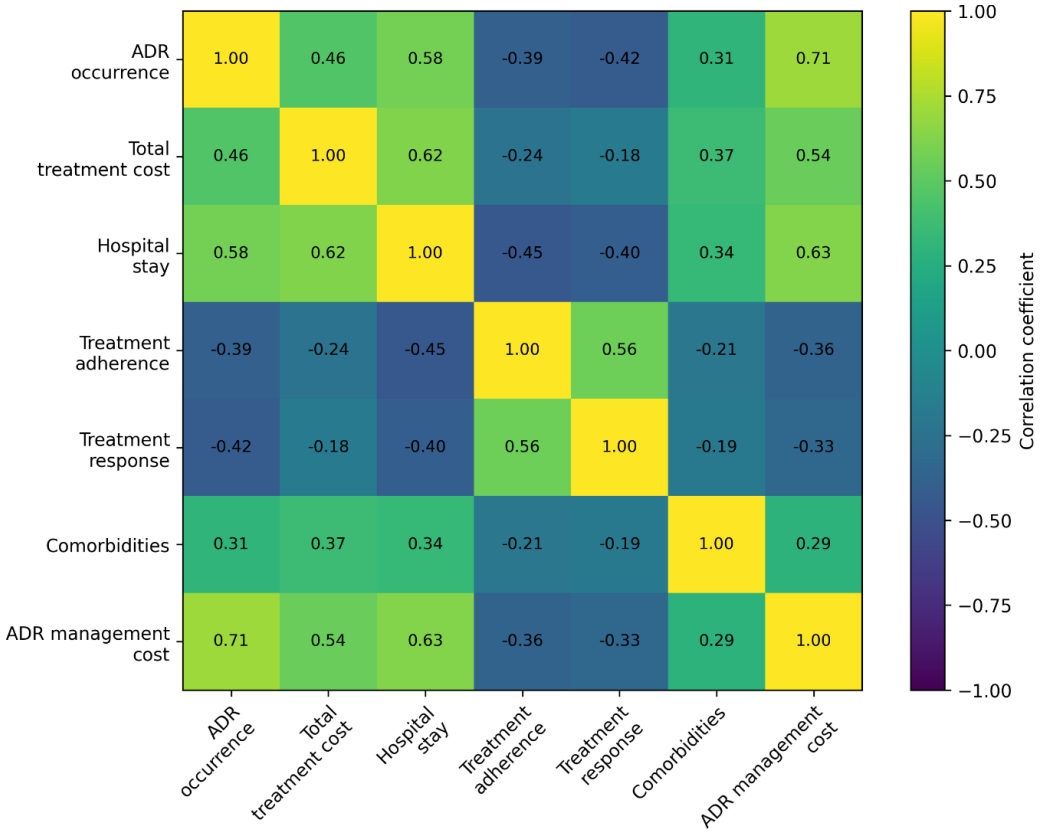

Figure 2. Correlation Heatmap of Pharmacovigilance and Pharmacoeconomic Variables

5. Statistical Analysis and Ethical Considerations

For the patients who were given the emerging drug delivery systems, the statistical analysis revealed that the odds of adverse drug reactions were significantly reduced when compared with the patients in the conventional drug delivery system group. The adjusted odds ratio was 0.48 (95% CI 0.26–0.89, p = 0.020) in logistic regression analysis.

The adjusted odds ratio was 1.86 (95% confidence interval, 1.04–3.32; p = 0.036) for patients with 2 or more comorbidities.

The use of emerging drug delivery systems was significantly associated with increased treatment cost ($p < 0.001$), with a beta coefficient of ₹10,940. Two or more comorbidities, the presence of adverse drug reactions, and longer hospitalization were also significant factors related to increased treatment cost.

Patient information has been de-identified for analysis. Ethical approval and permission from the institutions were secured before data collection, and confidentiality of patient information was ensured during data collection.

Discussion

Based on the results of this research, emerging systems of drug delivery were associated with less occurrence of adverse drug reactions than conventional drug delivery systems. The proportion of patients reporting adverse drug reactions was lower among patients treated with emerging drug delivery systems versus patients treated with conventional formulations (18.3% versus 31.7%). This discovery led to the idea that there is a possibility for the development of advanced delivery systems, which would decrease systemic exposure, increase targeted release of a drug, and diminish toxicity-related complications. The trend toward increased importance of pharmacovigilance systems for post-approval surveillance of adverse events was enabled by the observed reduction in adverse events. The continuous monitoring of signals, structured reporting, and communication with stakeholders are still important elements of drug safety surveillance (Sartori et al., 2020; Alomar et al., 2019). There are eight sources on adverse drug reaction signals, data mining, pharmacovigilance

policy, retrospective adverse drug reaction assessment, pharmacoeconomic value, health technology assessment, dynamic pricing, and life-cycle evaluation in the attached discussion reference list.

The group of emerging drug delivery systems had fewer adverse drug reactions, which could be due to better control of drug release and distribution. Appropriate and controlled delivery systems can minimise variations in peak plasma concentrations and exposure of normal tissue to unnecessary amounts. This might be especially important in those therapies where the conventional formulation has been shown to have dose-dependent toxicity or gastrointestinal intolerance and/or systemic side effects. The results of the present study revealed a lower number of serious adverse events in the emerging drug delivery group when compared to the conventional group, but this was not statistically significant. This is because the number of serious events may be small and may be linked to a lack of statistical significance. Many studies, especially those looking at rare and/or delayed safety outcomes, can only be carried out with larger data sets and over extended periods of time. Thus, data mining techniques and retrospective surveillance can support the identification of these patterns and their association with drug exposure, patient features, and interaction patterns (Alomar et al., 2019; Jiang et al., 2022).

The presence of a comorbidity was found to be a significant determinant of adverse drug reactions. Patient-level clinical complexity affected safety outcomes, with patients having two or more comorbidities more likely to have adverse drug reactions. This was in line with a general pharmacovigilance opinion of drug adverse effects being not only product-related, but also related to drug–drug interactions, polypharmacy, age, organ function, and disease burden. Retrospective analyses of adverse drug reactions have revealed clinically relevant correlations between the effects of drugs and drug–drug interactions, particularly in patients taking multiple drugs (Jiang et al., 2022). The outcome highlighted the importance of a pharmacovigilance system that takes clinical context into account, not just the number of adverse events.

The pharmacoeconomic results demonstrated that new drug delivery systems were significantly more costly than the conventional formulations. The average total treatment cost for the emerging drug delivery group was ₹42,850, while in the conventional formulation group, it was ₹31,470. This difference was primarily due to the higher acquisition and administration expenses of the drugs. The discovery is consistent with a problem in drug development, since more sophisticated formulations could have clinical benefits but are more expensive to get off the ground. A cost-benefit analysis is then required to establish if there is a return on investment from the improvements. In recent years, pharmacoeconomic assessment has gained in importance for prioritizing health resources, for reimbursement, and for assessing innovation in limited health budgets (Girardin et al., 2023).

Even though they are more expensive to treat, clinically and resource use-wise, emerging drug delivery systems were favorable. The treatment response, adherence, hospital stay, and adverse drug reaction management costs are better in the emerging drug delivery group. The results indicated that the acquisition cost may not be enough to gauge the value of advanced delivery systems. A higher cost up-front formulation could offer healthcare value given that it lowers complications, enhances adherence to the treatment, prevents hospitalization, or generates positive therapeutic outcomes. This economic thinking has also been used in assessing different delivery avenues, including the convenience of the delivery system, less administration burden, and indirect cost savings into the overall value (Ronquest et al., 2022).

The incremental cost-effectiveness ratio demonstrated that the new drug delivery systems were costlier at ₹97,264.96 per successful treatment response to the conventional drug delivery systems. This suggested that emerging systems had economic costs, but were clinically positive. This value is dependent on the Payer perspective, the severity of the disease, options available, willingness to pay thresholds, and long-term benefits. In these settings, HTA frameworks can be helpful as they combine effectiveness, cost, ambiguity, budget impact, and other healthcare considerations. In particular, for innovative drug delivery methods, evidence can also change after a product is launched (Thokala et al., 2023; Pham & van der Schans, 2023).

Dynamic pricing also raises issues of how to understand the economic results. The cost-effectiveness of new drug delivery systems can vary over time due to the evolution of manufacturing processes, patent expiration, growing competition, and evolving procurement systems. The initial high price of a product may drop and become more cost-effective after it is rolled out or goes on sale for a lower price. Given uncertainty about the price, uptake, and long-term clinical benefit, cost-effectiveness models should take these into account (McQueen et al., 2023).

In conclusion, the present research demonstrated that new drug delivery systems can be an effective means of improving pharmacovigilance and clinical benefits with an increased treatment cost. The results indicated that integrated assessment models that integrate monitoring of adverse drug reactions, cost-effectiveness analysis, and health technology assessment are needed. These models can aid clinicians, pharmacists, policy makers, and reimbursement agencies in making the best evidence-based decision on adopting an advanced drug delivery system. Safety trends will need to be validated by long-term real-world studies in larger populations, and rare adverse events will need to be quantified and estimates adjusted in pharmacoeconomics studies.

Conclusion

This study concluded that emerging drug delivery systems demonstrated meaningful pharmacovigilance and clinical advantages compared with conventional formulations, despite their higher overall treatment cost. Adverse drug reactions were less common for patients who were taking emerging drug delivery systems, indicating that these products are likely to be safer due to their controlled release, targeted delivery, and lower systemic exposure. These systems also demonstrated other potential pragmatic clinical benefits, such as better treatment response, better adherence to treatment, shorter hospital stay, and lower cost of managing adverse drug reactions. The pharmacoeconomic evaluation revealed that

emerging drug delivery systems were associated with higher financial investment, primarily because of the higher acquisition and administration costs, but with improved clinical outcomes and reduced expense of complications, they were justified for their potential value in certain therapeutic contexts. The results highlighted the need for the integration of pharmacovigilance monitoring with cost-effectiveness analysis in the assessment of advanced pharmaceutical technologies. Therefore, the use of emerging drug delivery systems should be supported by long-term safety data, cost-effectiveness, patient-specific benefit, and cost-effectiveness of the health care system. Overall, these systems constitute a feasible, but resource-consuming solution for contemporary pharmacotherapy, which needs to be carefully applied and proven.

References

1. Adepu, S., & Ramakrishna, S. (2021). Controlled drug delivery systems: current status and future directions. *Molecules*, *26*(19), 5905.
2. Alomar, M., Palaian, S., & Al-Tabakha, M. M. (2019). Pharmacovigilance in perspective: drug withdrawals, data mining and policy implications. *F1000Research*, *8*, 2109.
3. Cheng, X., Xie, Q., & Sun, Y. (2023). Advances in nanomaterial-based targeted drug delivery systems. *Frontiers in bioengineering and biotechnology*, *11*, 1177151.
4. Davoodi, P., Lee, L. Y., Xu, Q., Sunil, V., Sun, Y., Soh, S., & Wang, C. H. (2018). Drug delivery systems for programmed and on-demand release. *Advanced drug delivery reviews*, *132*, 104-138.
5. De Jong, W. H., Geertsma, R. E., & Borchard, G. (2022). Regulatory safety evaluation of nanomedical products: key issues to refine. *Drug Delivery and Translational Research*, *12*(9), 2042-2047.
6. Ezike, T. C., Okpala, U. S., Onoja, U. L., Nwike, C. P., Ezeako, E. C., Okpara, O. J., ... & Nwanguma, B. C. (2023). Advances in drug delivery systems, challenges, and future directions. *Heliyon*, *9*(6).
7. Girardin, F. R., Cohen, K., Schwenkglenks, M., & Durand-Zaleski, I. (2023). Pharmacoeconomics in the era of health technology assessment and outcomes research to prioritize resource use, innovation and investment. *Frontiers in pharmacology*, *14*, 1210002.
8. Jiang, H., Lin, Y., Ren, W., Fang, Z., Liu, Y., Tan, X., ... & Zhang, N. (2022). Adverse drug reactions and correlations with drug–drug interactions: A retrospective study of reports from 2011 to 2020. *Frontiers in pharmacology*, *13*, 923939.
9. Liu, F., Jagannatha, A., & Yu, H. (2019). Towards drug safety surveillance and pharmacovigilance: current progress in detecting medication and adverse drug events from electronic health records. *Drug safety*, *42*(1), 95.
10. McQueen, R. B., Anderson, K. E., Levy, J. F., & Carlson, J. J. (2023). Incorporating dynamic pricing in cost-effectiveness analysis: are known unknowns valuable?. *PharmacoEconomics*, *41*(3), 321-327.
11. Mitchell, M. J., Billingsley, M. M., Haley, R. M., Wechsler, M. E., Peppas, N. A., & Langer, R. (2021). Engineering precision nanoparticles for drug delivery. *Nature reviews drug discovery*, *20*(2), 101-124.
12. Mohtar, N., Parumasivam, T., Gazzali, A. M., Tan, C. S., Tan, M. L., Othman, R., ... & Wahab, H. A. (2021). Advanced nanoparticle-based drug delivery systems and their cellular evaluation for non-small cell lung cancer treatment. *Cancers*, *13*(14), 3539.
13. Patra, J. K., Das, G., Fraceto, L. F., Campos, E. V. R., Rodriguez-Torres, M. D. P., Acosta-Torres, L. S., ... & Shin, H. S. (2018). Nano based drug delivery systems: recent developments and prospects. *Journal of nanobiotechnology*, *16*(1), 71.
14. Pham, T. H., & van der Schans, J. (2023). A conceptual framework for life-cycle health technology assessment. *Value in Health*, *26*(4), 612-613.
15. Ronquest, N. A., Paret, K., Lucas, A., Ciepielewska, M., & Hagan, M. (2022). Quantifying the value of introducing an oral drug delivery option for edaravone: a review of analyses evaluating the economic impact of oral versus intravenous formulations. *ClinicoEconomics and Outcomes Research*, 499-511.
16. Saravdekar, S., Shukla, V. K., Upadhya, O. P., Rai, M., & Giri, K. (2019). Implementation of principles of pharmacoeconomics and pharmacovigilance to achieve optimal financial and therapeutic benefits through WHO-Essential medicine policy and adoption of NLEM-Based hospital formulary policy. *Journal of Family Medicine and Primary Care*, *8*(6), 1987-1993.
17. Sartori, D., Aronson, J. K., & Onakpoya, I. J. (2020). Signals of adverse drug reactions communicated by pharmacovigilance stakeholders: protocol for a scoping review of the global literature. *Systematic Reviews*, *9*(1), 180.
18. Sultana, A., Zare, M., Thomas, V., Kumar, T. S., & Ramakrishna, S. (2022). Nano-based drug delivery systems: Conventional drug delivery routes, recent developments and prospects. *Medicine in Drug Discovery*, *15*, 100134.
19. Thokala, P., Srivastava, T., Smith, R., Ren, S., Whittington, M. D., Elvidge, J., ... & Uttley, L. (2023). Living health technology assessment: issues, challenges and opportunities. *Pharmacoeconomics*, *41*(3), 227-237.
20. Vargason, A. M., Anselmo, A. C., & Mitragotri, S. (2021). The evolution of commercial drug delivery technologies. *Nature biomedical engineering*, *5*(9), 951-967.