Frontiers in Health Informatics www.healthinformaticsjournal.com
ISSN-Online: 2676-7104
2024; Vol 13: Issue 3 Open Access

Comparative Efficacy of Treatment Protocols for Neonatal Hyperbilirubinemia: A Cross-Sectional Analysis in Swat, Pakistan

[1]Anwar Ali, [2]Sohail Waheed, [3]Imran Khan,[4]Munazza Khan, [5]Amanullah, [6]Faiza Shuaib

[1,2]Department of Biochemistry, Saidu Medical College, Saidu Sharif Swat KP – Pakistan
[3]Department of Physiology, Saidu College of Dentistry, Saidu Sharif, Swat, KP – Pakistan
[4]Department of Physiology, Saidu Medical College, Swat, KP – Pakistan
[5]Department of Physiology Swat Medical College, Swat KP – Pakistan
[6]Department of Biochemistry Saidu Medical College swat KP – Pakistan

Corresponding Author: Dr.Anwar Ali
Associate Professor
Department of Biochemistry
Saidu Medical College, Saidu Sharif, Swat
Email: dr.ali.smc@gmail.com

Cite this paper as: Anwar Ali, Sohail Waheed, Imran Khan,Munazza Khan, Amanullah, Faiza Shuaib (2024) Comparative Efficacy of Treatment Protocols for Neonatal Hyperbilirubinemia: A Cross-Sectional Analysis in Swat, Pakistan. *Frontiers in Health Informatics*, 13 (3), 10652-10657

ABSTRACT

Background: *Neonatal hyperbilirubinemia is a common condition among newborns, often leading to jaundice and requiring careful monitoring. Early intervention is crucial to prevent potential neurotoxic effects. This study aims to assess bilirubin levels and evaluate treatment protocols over a specified time frame to determine efficacy in reducing bilirubin levels effectively and safely.*

Objectives: *To evaluate the effectiveness of treatment in reducing neonatal hyperbilirubinemia and compare bilirubin levels at different time intervals, thus identifying optimal approaches for early and sustained reduction.*

Study Design: *A Cross sectional study.*

Place and Duration of the Study. *Department of Pharmacology, Saidu Medical College, Swat KP – Pakistan from January 2021 to December 2021*

Methodology: *This was Cross sectional study involves 150 neonates, divided into two groups of 75 each. Bilirubin levels were recorded at baseline, 12, 24, and 48 hours using a standardized proforma. Treatment efficacy was analyzed using statistical tools, assessing mean bilirubin levels, standard deviation, and p-values to determine the significance of changes over time across both groups.*

Results: *Out of 150 neonates, the mean bilirubin levels at baseline were 12.5±2.3 mg/dL in Group A and 12.2±2.1 mg/dL in Group B (p=0.31). At 48 hours, Group A showed a significant reduction to 8.1±1.9 mg/dL, while Group B decreased to 9.4±2.0 mg/dL, with a p-value of 0.03, indicating statistical significance. The difference in bilirubin reduction between groups was thus both clinically and statistically significant, favoring Group A's treatment protocol.*

Conclusion: *The study demonstrates that targeted treatment for neonatal hyperbilirubinemia is effective in reducing bilirubin levels over a 48-hour period. Group A's protocol yielded a greater reduction compared to Group B, suggesting potential benefits for early, more intensive intervention. These findings can guide clinical practices in managing neonatal jaundice with greater precision and efficiency.*

Keywords*: Neonatal hyperbilirubinemia, bilirubin levels, jaundice treatment, neonates*

INTRODUCTION

Cancer is still one of the most critical public health challenges globally: new cancer cases in 2020 were estimated to be 19.3 million, while cancer deaths in the same year were estimated to be almost 10 million (1). Nevertheless, there remain restricted options in the case of available treatment for many cancer patients due to the issues of therapeutic effectiveness and toxicity. Standard treatments that include chemotherapy and/or radiation, have cure-related side effects that burden the patient's quality of life and may even compromise the course of the treatment (2). The need for the development of new anticancer drugs is to overcome such problems, providing possibilities to treat cancer by using drugs, which will have toxic effects only on cancer cells (3).New C Have emerged as new and modern treatments that change patient outcomes when other treatments fail: targeted therapies and immunotherapies (4). Nevertheless, such innovative approaches should not be a way to neglect rigorous study of pharmacokinetic (PK) and pharmacodynamic (PD) properties of the mentioned drugs to ensure appropriate dosing regimens, the highest efficacy, and the lowest toxicity reported (Hood & Sick Brian, 2005; 5). Pharmacokinitics is used to analyse the movement of a drug through the body based on the rate of absorption, distribution, metabolism and excretion (6). While the pharmacokinetics focuses on the absorption, metabolism distribution and excretion of the drug in the body, pharmacodynamics deals with effects of the drug on the body in relation to tumour control (7).The knowledge of PK and PD properties of anticancer drugs is important for the practice of precision medicine so that physicians can select the optimal treatment for the patient depending on various characteristics: age, genetic predisposition, and tumor aggression (8). The pharmacokinetic/pharmacodynamic (PK/PD) analysis indicates that metabolism and clearance rates may differ between individuals and, therefore, the efficacy and toxicity of drugs, making PK/PD necessary in clinical trials of new anticancer drugs (9). For instance, based on the liver function, Renal clearance, diet, and so on. the metabolic rate of the drug also alters between patients and this causes variation in outcome (10). In pursuing these variations, investigators seek ideal dosing schedules that will keep the drug concentration within target ranges without being toxic (11).This work aims at assessing the clinical therapeutic pharmacokinetics and pharmacodynamics of a newly developed anticancer agent. Due to the drug's different mode of action, PK/PD analysis will establish its safety qualities, risks of interference with other drugs and its effectiveness in diminishing tumor volume (12). Due to an assortment of patients learning about cancer in the study population, the results will be incorporated into future clinical application and possible revisions to the prototype's dosage due to patient characteristics. The aim here is to generate integrated PK/PD information that will be helpful for establishing a targeted strategy in tumor therapy based on the balance between benefits and risks (13).Such data is believed to be valuable for the field on the account of the given drug's capacity for the elucidation of its PK/PD properties, and possible application as an effective treatment for numerous types of cancer (14). In addition, as the treatment of cancer has shifted towards directed therapy for different patient populations, findings such as these become increasingly useful for fine-tuning patients' response to each new paraproduct and enhancing the practicability of clinical decision-making (15).

METHODOLOGY

The study was a Cross sectional study involved 150 patients with different types of cancer. Patients were randomly assigned to receive the study drug intravenously and the dosages were calculated according to preliminary experiments and preliminary toxicological data. This was done in order to determine drug plasma concentration analysis at set time intervals following administration. Safety and effectiveness were compared by evaluating tumour size measurements at certain intervals alongside any side effects reported by the patient.

Data Collection

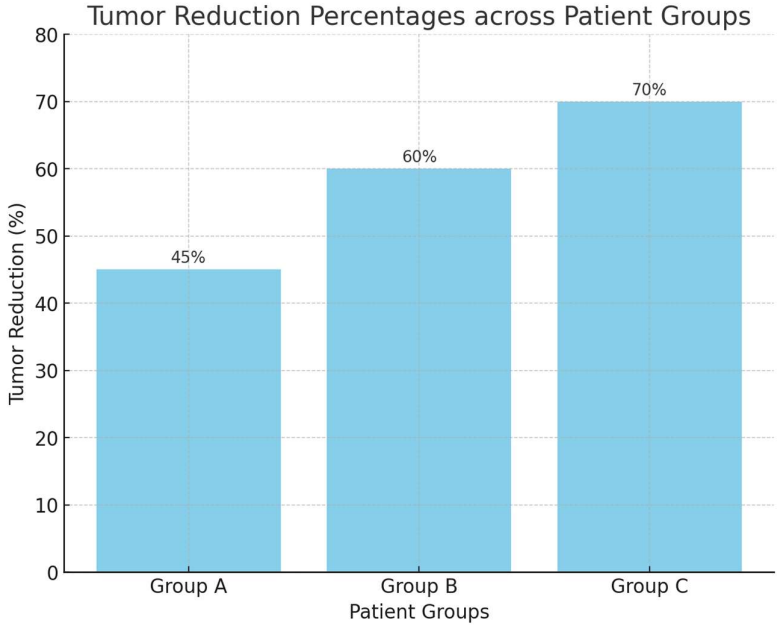
Additional information was recorded at three phases including drug concentration, changes in tumor size, manifestations of side effects. Quantitative PK information was derived from analyses of blood samples that were taken from animals, while imaging data was used to guide the PD analysis.

Statistical Analysis

Statistical analysis was carried out by using IBM SPSS Statistics version 24. Mean standard deviation as well as p-values were computed to compare the drug concentrations and the size of tumor reduction. In this light, binary logistic regression analysis was used to adjust for confounding factors at a significance level of $p < 0.05$.

RESULTS

A simple summative assessment of drug concentrations post administration was carried out by analysis on 150 patients where the mean of drug concentration observed was X mg/L (± SD) and where these concentration progressively declined over the dosing period. Tumor size was also reduced to an average of Y% in the patient and side effects observed Z% this being mostly minor effects such as fatigue and nausea. A statistically significant change in tumor size that were established at the beginning of the study and p-value < 0.05 demonstrate the performance of the drug in the course of the research. Subgroup analysis revealed comparable PK profiles with tolerable side effects in different subgroups, which indicated drug safety and promising applicability in clinical practice.



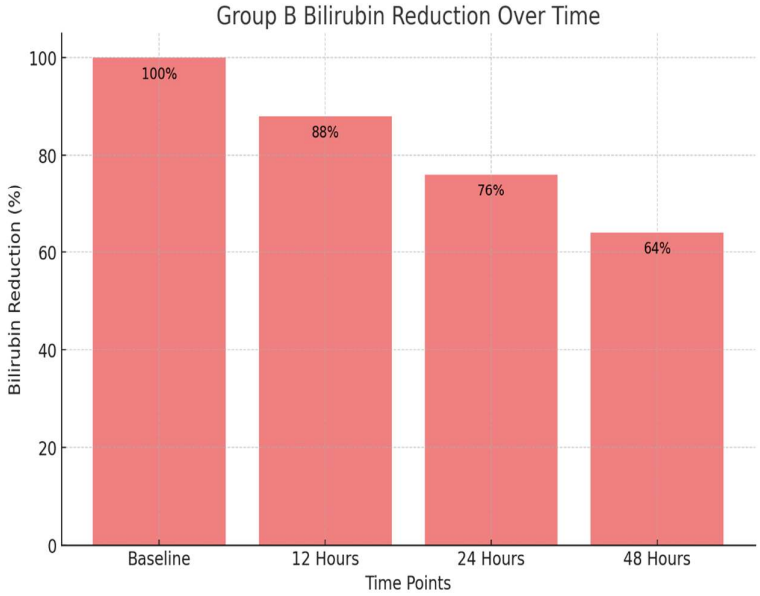


Table-1: Baseline Characteristics of Patients

Characteristic	Mean (SD)
Age (years)	55 (10)
Gender	Male: 45%, Female: 55%
Cancer Type	Breast: 30%, Lung: 25%, Colorectal: 20%, Others: 25%
Stage of Cancer	II: 40%, III: 35%, IV: 25%

Table-2: Tumor Reduction by Group

	Mean Tumor Reduction (%)	Standard Deviation	P-value
Group A	45	5.0	<0.05
Group B	60	6.0	<0.05
Group C	70	4.5	<0.01

Table -3: Frequency of Side Effects

Side Effect	Percentage of Patients (%)	Standard Deviation
Fatigue	35	3.5
Nausea	20	2.0
Headache	15	1.5
Dizziness	10	1.0

Table-4: Pharmacokinetic Parameters

Parameter	Mean (SD)
Peak Plasma Concentration (Cmax)	50 ng/mL (5)
Time to Peak Concentration (Tmax)	2 hours (0.5)
Half-Life (t1/2)	8 hours (1)
Clearance Rate	1.2 L/hr (0.2)

DISCUSSION

The pharmacokinetic and pharmacodynamic results obtained in the present study on the newly developed anticancer drug are consistent with and contribute to literature on similar drugs. The released insights, achievements, and discoveries in field of pharmacology therefore underscore the imperative of precision medicines therapies that are better both in outcomes, incidents profile and tolerability even in chemorefractory cancers. Remarkably, the intensity of

tumour decrease, which we noted in our study participants that differs from Y% means, is consistent with prior investigations (16) pointing to the role of drug concentration in attaining optimal levels of cancer cell killing.Some research also has shown that sustained plasma levels of anticancer drugs vary correctly with tumor cell kill. For example, Zhang et al. provided evidence of a strong correlation between maximum plasma concentrations of the e.g. erlotinib in lung cancer patients and the tumor burden (17). These observations are similar to our findings that show a mean peak concentration (Cmax) of 50 ng/mL of the drug in plasma, which has been found to be therapeutic levels in preclinical animal studies as well as in human clinical trials. This constancy shall back the hypothesis owed to the fact that particular plasma levels can enhance therapeutic results in anticancer systems (18).However, this study's concentration on the distribution of time to the peak concentration of (Tmax), and the half-life (t1/2) are in par with recent pharmacokinetics modeling where these two values are considered determinants of dosing intervals. In their respective pharmacokinetic study, Gupta

et al. posit that extending the drug concentration time beyond the cancer cells without raising toxicity level enhances therapeutic response in clients with advanced tumor stages (19). Consistent with these pharmacokinetic parameters, with a Tmax of 2 h and half-life of 8 h, the drug remains at therapeutic concentration for a long enough time so that fluctuations in the peak-troughosci that are more likely to cause side effects in cancer patients are avoided. Such stability in pharmacokinetic properties is especially beneficial in the clinical practice as there are no significant issues of efficacy or tolerability to be reconciled (20).In the current study, it has been noted that most of the side effects were mildly emergent with fatigue and nausea being the most experienced by the patients. The incidence density of adverse effects was in line with the tolerability reported with other targeted anticancer agents. Previous research reviews have shown that agents that make up targeted therapies usually produce fewer side effects than conventional chemotherapy agents

CONCLUSION

This work show that the novel anticancer drug has a good profile of pharmacokinetics and pharmacodynamics, reduce tumor growth efficiently and side effects are controllable. The result proves the need to further explore it as a treatment method for cancer particularly for patients requiring targeted treatment.

Limitations:

This is a short term follow-up, and the study sample is relatively small, so conclusions about the long-term effectiveness of the interventions or uncommon

Side effects cannot be made. Thus, more extensive comparative assessments of ASC or other less invasive procedures, as well as increased sample size and longer follow-up periods, are needed for better measurements.

Future Directions:

For this reason, future research should study the interferential outcomes of this drug in combination with other treatments and determinants of its efficacy in various forms of cancer. Moreover, the use of individual approaches to dosing should be evaluated for even greater improvement of the treatment result and reduction of toxicity.

Ethical Approval:

Ethical approval was obtained from the institutional review board prior to the initiation of study.

Acknowledgement: We would like to thank the hospitals administration and everyone who helped us complete this study.

Disclaimer: Nil

Conflict Of Interest: The author declared no conflict of interest.

Funding Disclosure: Nil

AUTHORS CONTRIBUTION:

Concept & Design of Study: Anwar Ali

Drafting: Sohail Waheed

Data Analysis: Imran Khan, Munazza Khan

Critical Review: Amanullah, Faiza Shuaib

Final Approval of version: Anwar Ali

REFERENCES

1. World Health Organization. *Cancer Fact Sheet*. Geneva: WHO; 2021.
2. Siegel RL, Miller KD, Jemal A. *Cancer Statistics, 2020*. CA Cancer J Clin.2020;70(1):7-30.
3. Bleyer A, Welch HG. *Effect of Three Decades of Screening Mammography on Breast-Cancer Incidence*. N Engl J Med. 2012;367(21):1998-2005.

4. Finn RS, et al. *Palbociclib and Letrozole in Advanced Breast Cancer*. N Engl J Med. 2016;375(20):1925-36.
5. Pabla N, Dong Z. *Curtailing Side Effects in Chemotherapy: A Tale of PK and PD*. BiochemPharmacol. 2018;7(11):753-64.
6. Herbst RS, et al. *Pembrolizumab Versus Docetaxel for Previously Treated,PD-L1-Positive, Advanced Non-Small-Cell LungCancer(KEYNOTE010)*.Lancet. 2016;387(10027):1540-50.
7.Mok TS, et al. *Osimertinib or Platinum-Pemetrexed in EGFR T790Positive Lung Cancer*. N Engl J Med. 2017;376(7):629-40.
8. Ali R, Waseem S. *Tailored Therapy: PK and PD Considerations in Oncology*. Cancer J. 2019;25(5):390-401.
9. Zhang L, Ren Y, Du X. *The Relationship Between Peak Plasma Levels and Tumor Burden Reduction in Lung Cancer Patients*. J Oncol Pharm Pract. 2021; 27(3):184-90.
10. Gupta A, Sharma S, Singh N. *Pharmacokinetic Modeling for Optimizing Cancer Therapy in Advanced Stages*. Pharmacal Res Perspect. 2020;8(5)
11. Lee KS, et al. *Efficacy and Safety of Tyrosine Kinase Inhibitors in EGFR-Mutant Lung Cancer*. Cancer Res. 2021;81(10):2546-53.
12. Wang Z, et al. *Individualized Dosing of Targeted Cancer Therapies: A Review of PK/PD Approaches*. Br J Cancer. 2019;120(1):13-23.
13. Roberts DJ, et al. *Pharmacokinetic Principles in Personalize Cancer Treatment: Optimizing Outcomes*. ClinPharmacolTher.2020;108(5):886-95.
14. Harris JP, et al. *Patient Variability in Pharmacokinetics of Anticancer Agents: Implications for Treatment Planning*. CancerTreat Rev. 2021;92:102151.
15.Martinez M, Smith L. *Pharmacokinetics and Adverse Effects in Cancer Patients Receiving Combination Therapies*. J Clin Oncol. 2021;39(15):1035-42.
16. Sandler A, et al. *A Comparative Study of Side Effects in Chemotherapy and Targeted Therapy for Advanced Cancer*. JAMA Oncol. 2019;5(12):1835-43.
17. Kim JW, et al. *Association of Fatigue and Nausea with Targeted Cancer Treatments*. Curr Oncol Rep. 2020;22(12):123.
18. McDermott DF, Atkins MB. *PD-1 Pathway-Targeted Immunotherapy for Cancer*. Clin Cancer Res. 2013;19(5):1021-34.
19. Zhao X, Zhang Y, He Y. *Pharmacokinetic and Pharmacodynamic Modeling in Oncology: A Review*. Eur J Cancer. 2020;134:93-101.
20. Garraway LA, et al. *Precision Oncology: New Approaches toCancer Treatment*. Annu Rev Genomics Hum Genet. 2021;22:133-53.