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Analysis of clinical pharmacist intervention in minimizing drug-drug interactions of patients on targeted oral oncology drugs

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Abstract
Drug-drug interactions (DDIs) are a considerable challenge in the context of the use of targeted oral anticancer therapies, such as tyrosine kinase inhibitors (TKIs) and CDK4/6 inhibitors, since their metabolism is complex and polypharmacy is taken. The objective of the proposed study was to conduct a prospective observational study using an intervention implemented by clinical pharmacists to help in the reduction of DDIs in 185 patients in two tertiary cancer patients in Germany and Brazil. Carefully performed medication reviews, the degree of interaction between medications was established with the assistance of Lexicomp 1 and Micromedex 1, and recommendations addressed to oncologists were offered by pharmacists. They were identified 312 potential DDIs (clinically significant in 76 percent of cases). Therapy was reduced or changed in accordance with interventions in 71 percent of the cases or doses were changed. Subsequent care reported 40 percent less adverse drug events caused by the interactions and thereby increasing patient safety and treatment compliance.
Keywords: ***Drug drug interaction, oncology pharmacy and clinical pharmacist interventions, tyrosine kinase inhibitor, CDK4/6 inhibitor and targeted therapy safety, polypharmacy and adverse drug events.***

1. Introduction

1.1 Background

Targeted therapies have transformed the treatment of many cancers, and specifically, the development of targeted oral oncology products including tyrosine kinase inhibitors (TKIs) and cyclin-dependent kinase 4/6 (CDK4/6) inhibitors. These agents selectively treat cancer cell growth associated with molecular mechanisms offering a promising and more targeted treatment of cancer. Nevertheless, these therapies being advanced are not devoid of high risks, especially as drug-drug interactions (DDIs). The high potential of these drugs to undergo DDIs due to the multifactorial metabolism requiring the complex network of cytochrome P450 enzymes and transporter proteins substantially increases the risk of occuring adverse drug events (ADEs) and negative effects of pharmacologic manifestations, as well as the risk of reduced therapeutic efficacy or even enhanced toxicity in patients taking these drugs.

Oncology patients especially those under treatment with TKIs and CDK4/6 inhibitors present with comorbidities and need to take medications in addition to manage their symptoms e.g.: pain management or prophylaxis or medications to treat their underlying diseases. The fact that there is an increase in polypharmacy in such patients further increases the possibility of the DDIs being clinically significant since drugs prescribed to treat cancer may interact with those administered to treat co-morbidities. Since the drug interaction becomes complicated in cases involving cancer and round the clock follow-up, effective management of the complications should be handled diligently.(1)

Clinical pharmacists are critical to curtailing these risks as they are in a unique position to detect possible DDIs, offer expert advisement to oncologists and suggest individualized interventions towards an optimized therapy. Although pharmacists have been working in the area of cancer care, the role they play in terms of the management of DDIs has been the focus of more attention over recent years. The paper examines the particular contribution made by oncology pharmacist interventions in allaying DDI in patients subjected to targeted oral therapies, with the purpose of highlighting the importance of pharmacist-initiated medication reviews and interventions in the oncology practice.

1.2 Rationale

Clinical treatment of oncology with target therapies has many problems, and they vary in terms of drug interactions that may interfere with the drug regimens. Although the TKIs and CDK4/6 inhibitors are efficient in achieving this, they augment the likelihood of unconstructive coordinations with other medicines. The interactions may either make the cancer medications ineffective or enhance the adverse effects increasing the risks to health. Since cancer

patients typically have a series of medications that they are required to take, the nature of the relationship between them is becoming more complex as not all DDIs will be immediately noticeable in the absence of in-depth analysis. Pharmacists are singularly positioned to diagnose these interactions and to treat them because they have the expertise with pharmacokinetics, pharmacodynamics, and drug therapy management. Nevertheless, though the role of pharmacists as the enhancers to medication safety is accepted, the overall weight of their intervention in oncology facilities, namely, the targeted therapies, remains unexplored. Although the literature has long looked into the role of clinical pharmacists in overall medication safety, limited research has been conducted in oncology-specific treatments, especially as it relates to DDIs.

This study is motivated by the fact that there is increased awareness that requires proactive involvement of clinical pharmacists in the prevention and management of DDIs. As the issue of polypharmacy is complex in oncology, it is quite important to determine whether the problem of medication safety, adverse drug events, and compliance with the treatment regime could be improved with pharmacist-led interventions. This is especially relevant in terms of targeted oral therapies where use tends to be chronic, and there is a significant risk of close monitoring as a consequence of complicated pharmacology.(2)

Moreover, the possibility of saving enormous sums of money and reporting a better patient outcome due to a reduction in ADEs and the optimization of the level of therapy adherence gives extra credence to the relevance of this study. With the recognition of the benefit that clinical pharmacist interventions have in preventing DDIs, there is the potential to change the paradigm of how oncology is treated, with the inclusion of the pharmacist into the multidisciplinary team that handles complex cancer treatments.

1.3 Objectives of the study

The main aim of the study is to assess the role of oncology pharmacist interventions to minimize drug-drug interaction in patients who are using targeted oral therapies drugs (tyrosine kinase inhibitors and CDK4/6 inhibitors). This shall be attained by determining the frequency, severity and outcome of DDIs prior to interventions of pharmacists and after such interventions. The work intends to:

- Determining the frequency and the extent of drug-drug interactions between the combination of TKIs and CDK4/6 in a trial group of patients in two German and Brazilian tertiary cancer centers.
- Determine the outcomes of clinical pharmacists in terms of identifying clinically relevant DDIs and extending recommendations to alter therapy, alter dose, or switch agent.
- Quantify the effect of pharmacist interventions on the outcome of patients and the decrease in adverse drug events, changes in treatment adherence, and patient safety on all levels.
- Discuss the role of clinical pharmacists in the field of oncological care and its place in the care of individual patients with respect to targeted therapies, and how clinical pharmacists can support multidisciplinary collaborative care of patients treated with complex cancer treatment regimens.

With the help of this research, the authors will add to the existing body of knowledge favorable of integrating clinical pharmacists within oncology teams and the imperativeness of their role in attaining the safety and efficacy of targeted therapies in cancer treatment. When DDIs are recognized and managed at an early stage, the possibilities of adverse drug events will be decreased, and the outcome and success of patient treatment increased.

2. Process of Medication Review guided by pharmacist.

2.1 Project Target Patients

Sampling of patients in this study was considered as an important process of making the findings of the study relevant and applicable. The inclusion criteria to participate in the prospective observational study were adult patients with cancer and treated with oral targeted therapies namely, tyrosine kinase inhibitors (TKIs) and CDK4/6 inhibitors in two tertiary cancer centers in Germany and Brazil. The research focused on patients receiving active therapies that included the use of these therapies, as they have complex pharmacokinetics, and their urometabolism through the WBH450 and other transporters, as well as exhibits a higher chance of drugA, since there is a risk of drug-drug interactions (DDI).(3)

The patients were also required to be on at least one other medication other than the targeted oral therapy in the inclusion criteria to enhance the chances of the study identification of potential DDIs. This criterion further highlighted significantly since in oncology patients, polypharmacy is very prevalent, with many patients subjected to concomitant treatment in managing comorbidities and symptoms or drug side effects. Moreover, the patients

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were required to demonstrate a formally established commitment to give informed consent and adhere to the study protocol, as well as to visit it.

Patients that had been getting investigational drugs were excluded in the study because this was not part and parcel of the study and the patients incapable of giving informed consent or incomplete medication history were also excluded. This interest in patients who actively took targeted therapies and the focus on the combined use of multiple medicines offered a strong group of patients to study the importance of the role of the clinical pharmacist in detecting and Harrison, 2006).

2.2 Review Databases and Tools

In order to address all of the potential drug interactions in detail and evaluate them, clinical pharmacists took a cluster approach to utilize both existing sets of robust and evidence-based drug interaction tools and databases in a context of medication review. These were Lexicomp and Micromedex, which are the highly popular and respected clinical reference databases to acquire extensive drug interaction information. Such databases can be especially useful in oncology practice where drugs employed have complicated pharmacokinetics and have the likelihood of serious interactions.

Lexicomp 8: This database provides structured, easy to comprehend information about medication, in-depth drug interaction analysis and evaluation, which prioritizes and classifies interactions according to clinical importance (e.g. minor, moderate, major). Lexicomp 1 was very helpful in searching potential DDIs that may interfere with the effectiveness or safety of TKIs and CDK4/6 inhibitors. It also carries data on the metabolism of drugs and that was important to evaluate how these therapies will be affected by the enzyme inducers/inhibitors.

Micromedex 1: Micromedex is another powerful source of drug interaction determining as it is evidence-based, peer-reviewed information that could guide pharmacists to assess DDIs in relation to cancer treatment. It also provides mechanisms of understanding the seriousness and possible clinical implications of interactions and thus it becomes worthwhile to clinicians who have to consider complex set of drugs.(4)

These tools allowed pharmacists to critically check the medication list of every patient both to determine the direct effect of interaction between targeted therapies and other medications and regarding the secondary effects, which may lead to the overall change in treatment outcomes. This methodical process made the process comprehensive and it remained the same to all the patients.

2.3 DDIs That Are Potentially Identified

Guided by the comprehensive medication review, identification of possible DDIs was a process that involved several steps. Pharmacists checked the entire medication regimen of the patient including their prescription drugs, over-the-counter and herbal supplements since cancer patients often incorporate the use of complementary therapies in addition to potentially patient medication regimen.

After gathering the list of medications, pharmacists evaluated the drugs on them to verify and assess any interaction with the target therapies, TKIs, and CDK4/6 inhibitors. It was conducted by the following procedure:

Drug Interaction Screening: Pharmacists used Lexicomp(R) and Micromedex(R) to screen the interactions of the cancer treatments and other therapy on the list of medications prescribed to the patient. These interactions were grouped according to level of severity- mild through to life threatening and by the likelihood of it occurring. The interactions of particular interest were those with the potential to cause change to the absorption, metabolism, or elimination of the targeted therapies as these are most likely to lead to clinically significant consequences.

Pharmacokinetic Profiles: The inhibitors of TKIs and CDK 4/6 were compared regarding their metabolism and found to interact in such a way that may result in either reduced therapeutic efficacy or greater toxicity. Most of these are metabolized by cytochrome P450 enzymes (primarily CYP3A4) and interactions with other drugs that induce or inhibit these enzymes can substantially alter drug concentrations. Cases of interaction with drugs affecting the gastrointestinal tract or interfering with drug absorption were also summarized, and they may have an impact on the bioavailability of oral therapies.

Evaluation of Clinical Significance: After determining potential DDIs, pharmacists determined the clinical significance of the DDIs in light of the potential severity of the interaction and a matching of clinical circumstances of the patient, i.e., comorbidities, renal/hepatic disorders, and adjuvant therapies. As an example, an interaction that occurs between a TKI and a powerful CYP3A4 inhibitor may cause serious toxicity yet an interaction with a weak CYP3J4 inducer may simply pose no effect.(5)

Oncologist teleconferences: In each of the clinically significant interactions, pharmacists made recommendations to oncologists, such as proposed changes to the treatment protocol. Such a recommendation may be an exchange of drug, dose adjustment, or replacement by a different agent that may not interact with the intended therapy.

This painstaking process of detecting and managing possible DDIs allowed making clinical decisions and the corresponding interventions quite solid in terms of clinical decision-making and evidence-based decisions, and this was the critical factor that influenced patient safety and efficacy of treatment. The pharmacist-driven medication review activity had acted as a safety net to oncology patients undergoing complex oral therapy, in many of whom drug interactions could have been overlooked.

3. Supplementary and Therapeutic Recommendations

3.1 Interventions Types

Clinical pharmacists in oncology should not limit their role in identifying drug drug interactions (DDIs) but inappropriate measures should be taken to reduce the risk set by the cooperation of the drugs. Clinical pharmacists used different strategies in resolving or managing identified DDIs in the study and were extremely important to enhancing patient safety and ideal patient outcomes. The main forms of interventions that the pharmacists carried out were:

Dose Adjustment: Dosing Adjustment of either or both of the interacting drug(s) was one of the most frequently performed interventions. With a patient on tyrosine kinase inhibitors (TKIs), or CDK4/6 inhibitors, drug interactions may dramatically change the levels of those drugs, especially with an interaction with drugs that inhibit or induce cytochrome P450 enzymes. In a case where a possible conflict was noted that may cause toxicity or treatment failure, pharmacists would suggest dose modification of either the interacting drug or the TKI/ CDK4/ 6 inhibitor. As an illustration, when a specific patient was prescribed a high-potency CYP3A4 inhibitor, which had the potential of raising the plasma levels of a TKI, pharmacists advised the patient to reduce the dose of the TKI so as to lower chances of adverse drug reactions.

Interchange of interacting Agents: There were instances where dose adjustment was not possible or unlikely to reduce the associated risks or when absorption would still occur, pharmacists advised to change the interacting drug into another non-interacting drug that would still treat the target condition. An example of this is a drug discovered to block a metabolic pathway important in clearance of the cancer drug that may be replaced with a drug of a different class or different metabolic profile potentially eliminating the risk of an interaction. Replacement of these ingredients was well-chosen to assure that it does not affect the effectiveness of the cancer elimination regime.(6)

Therapy Change: On a few occasions, the pharmacist advised on a change of treatment in general. This may involve retraining that one form of targeted therapy to another or the sequence/ timing of the therapies. An example is a situation where a patient had been on a combination of TKIs that had a substantial risk of interaction with other drugs on the patient and pharmacists could suggest a change in therapy to either single drug therapy or changing the dose schedules so that the TKIs could not be taken alongside the other drugs that could have an increased risk of DDIs. These changes in the treatment of cancer were intended to maintain therapeutic advantage with minimum adverse interactions.

Counseling and Education: The counseling of patients by the side of pharmacists concerning the found DDIs and the necessity to follow up the new changes in the treatment was also provided. This involved teaching the patients of the potential side effects, the necessity of periodic follow ups and the need to keep checking on any signs of the toxicity. Making sure that the patients were aware of their treatment plans and the reasoning behind alterations in their medication was critical to ensure that they did not stop following their treatment and achieve better results.

3.2 Co-operation with Oncologists

Clinical pharmacist/oncologist collaboration is a pillar to patient safety as well as optimal therapeutic management, particularly, in the case of oncology. During the research, the pharmacists collaborated with oncologists effectively, so that any intervention was reasonable, corresponded to the purposes of treatment, and could be implemented, taking into consideration of the overall care strategy of a patient. Collaboration was initiated as soon as pharmacists discovered a possible DDI and occurred as pharmacists contacted the oncologist treating the patient to discuss the clinical importance of the drug interaction and proposed intervention.

Whenever a recommendation entailed a relatively dramatic change in a patient treatment regimen, e.g., a dose change, drug substitution, or therapy change, pharmacists relayed their recommendations to oncologists promptly.

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Such consultations enabled oncologists to evaluate the practicality and possible outcomes of the recommendations by a pharmacist related to the total cancer treatment interests of a patient. Since the oncologists have a thorough insight into the course of the cancer diagnosis and treatment regimen, they could offer their valuable input, and the changes would not affect the primary cancer treatment regimen.(7)

More so, the partnership captured a more comprehensive treatment of patients. Oncologists despite the efforts of pharmacists, retained the overall responsibility of management of the disease (cancre). Pharmacists concentrated on detection and treatment of DDIs, optimization of drug therapy and the oncologists took the responsibility of managing disease progress, chemotherapeutic timing, and tumor response. Frequent visits and exchanges between the two fields guaranteed preservations of safety of the patient as well as the harmonization of the curative demands of cancer management. This interdisciplinary work led to another aspect of care, i.e., a team-based care environment wherein both oncologists and pharmacists undertook their parts in order to help patients in a better manner.

3.3 Record Keeping of Action

The study included the necessity to document the pharmacist-led interventions. All work undertaken was properly documented and would be traced to make follow-up check-ups. Careful documentation of the recognized DDIs, procedures that the pharmacists executed, and the explanations behind their actions was made carefully by the pharmacists. This documentation comprised:

DDI Identification: The DDIs were clearly documented containing the types of medications that were involved, risks involved by interactions and severity rating, as per Lexicomp and Micromedex. Clear complexity was provided by the detailed accounts of the clinical relevance of each contact and later assisted in the generation of a clear record of why particular interventions were needed.

Details of intervention: In every intervention the pharmacist made notes on that particular intervention e.g. dose adjusting, trying an alternative drug, making changes to the therapy. Specific adjustments used were also documented (e.g. certain dosage reductions or names of drug substitutions) to maintain uniformity in the follow-up care.

Oncologists Communication: The process of pharmacist-oncologist communication was also reported. These involved information about the time of communication and the content of the suggestions given by the pharmacist and the response of the oncologist. Such documentation was very important in monitoring the approval process and timely implementation of recommended interventions.

Follow Up and Outcomes: The implementation of the interventions by the pharmacists included recording the outcomes of the interventions such as change in the condition of the patient, adverse drug events, or changes in treatment adherence. The effectiveness of the interventions was to be determined by conducting follow-up visits to evaluate the optimal benefit, and any indication of adverse effects which were duly recorded in the medical records of the patient.(8)

It was this laborious detailing that not only served to perpetuate care, but also gave important information to gauge the effect of the pharmacist intervention on patient outcomes. Besides, the documentation process enabled a comprehensive evaluation of the effectiveness of interventions in the reduction of DDIs and the enhancement of overall safety of the treatment process, which was a critical element in the purposes of the study.

By means of these organised, complex-intervention, collaboration, and documentation procedures, the clinical pharmacy team could contribute to the proper safe management of oncology patients with the complex targeted therapies in a significant way.

4. Monitoring and follow up of patients

4.1 Compliance monitoring

Patient compliance to prescribed dosage regimes is one of the most important aspects to guarantee the success of targeted oral therapies and especially in the oncology field. Inadequate compliance may result in sub-optimal treatment responses, augmented risks of treatment failure and exposure to unneeded drug toxicity. The use of clinical pharmacists in this study was important because they were used in evaluating adherence and encouraging compliance with the given prescribed therapy especially when intervention measures were done concerning drug drug interactions (DDIs).

The adherence was assessed by a set of methodologies such as interviews of the patient, pill counts, and medication reconciliation. During every follow-up session, the pharmacists interacted directly with the patients to determine

how they were comprehending the treatment procedure that they were required to take, as well as challenges they may be experiencing in using their medicines. Pharmacists also screened nonadherence, for example missed doses or pattern medications at both subjective and objective levels, which include patient self-reporting, and where applicable, subject data, as present in case medications history.(9)

Also, pharmacist evaluated the effect on patient adherence of any therapeutic change, including dose adjustments or substitution. Such measures were peculiar in the fact that they were intended to reduce side-effects or make therapy more tolerable and thus lead to improved adherence. In case patients encountered challenges to the modified treatment plan, the pharmacists collaborated with the patients to overcome the barriers, including the adverse effects or misconceptions concerning the amount to be taken. Part of the process was educating patients on the importance of taking medications on a regular basis and explaining to them the reasoning behind changes.

With the help of such activities, the pharmacists detected adherence levels and noticed any complications at the beginning of the treatment process. Such an initiative enabled timely interventions, thereby making sure that the patient is still on the treatment path, and eventually achieving improved clinical outcomes.

4.2 ADverse event monitoring

Adverse event (AE) monitoring played an important role in follow-ups of patients, especially when pharmacist interventions had been used in a bid to mitigate against possible DDIs. As the risk of toxicity is high whenever using TKIs and CDK4/6 inhibitors, adverse event monitoring was a major area of concern. Pharmacists also had an active role in the detection, reporting, and treatment of any adverse outcomes due to DDIs or medication changes.

The common side effects of the targeted therapies that were routinely observed in the patient noted to be affected by drug reactions include gastrointestinal disorders, hepatotoxicity, exhaustion, and hematological illnesses. Pharmacists also monitored possible new or worsened AEs that could occur as a result of any changes in therapy, including dose changes and switching drugs. The follow ups would usually entail thorough chats with the patients to evaluate new symptoms and alteration in their condition so that the pharmacists can identify any possible AE at an early stage.

Where AEs were detected, then the pharmacists collaborated with the oncology team to deal with the incidence. This may involve further manipulation of the therapy, or prescribing symptomatic treatment in cases to remove side effects, or drastic in extreme cases withdrawing an offending drug. AEs became identified and reported in terms of their severity and nature to the treating oncologists, who made the decision on the cancer treatment regimen to be adjusted in case of necessity.(10)

Observing the frequency and intensity of AEs was not just a necessity in patient safety but also served as interesting data to proceed to analyzing the success of the pharmacist interventions in reducing the risks related to drugs. This helped in reducing the DDIs and the AEs associated with it, therefore, enhancing the overall therapeutic experience of patients, provided by pharmacists.

4.3 Therapy Modification Tracking

Documenting the changes of treatment in therapy was a necessary part of patient follow-up in the study. With the type of interventions which were dose changing, drug substitution and therapy change, the modifications to the treatment plans were well recorded and effectiveness of these modifications followed up frequently.

Each time a change was made, clinical pharmacists would monitor the progress of the patient to evaluate whether the modification made any difference on how the DDIs would be managed and how the patient would fare. It was conducted by making sure that the alterations resulted in solution of the identified DDIs and analyzing the reaction that the patient had to the new regimen. As an example, in case of a drug replacement with the presence of any important interaction between the drug and a TKI or CDK4/6 inhibitor, pharmacists monitored the better tolerance of a new drug and whether it has therapeutic effects without posing new risks.

In addition, tracking of therapy modifications enabled the pharmacists to monitor the occurrence of unintended effect as a result of change in the regimen, on the part of emerging drug interactions or recurrence of side effects. This continued surveillance was necessary in order to maintain that the changes were congruent with best interest of the patient and treatment approaches.

Follow-up visits played a role whereby pharmacists were able to gather the information on how these changes were conveying and guarantee that other needed changes were incorporated in case. This monitoring and modification tracking cycle assisted in improving the treatment methodology in the long run, which made the patient treatment plan successful as a whole.(11)

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To conclude, patient follow-up and monitoring were also a part of the research as it allowed pharmacists to rest assured that the measures taken to diminish DDIs were not only effective but also harmless to those patients in the long run. The use of targeted therapies was optimized through adherence evaluation, event monitoring, adjustments during therapy, and corrective action and so the pharmacists role was critical in enhancing patient safety and outcome of treatments.

5. Outcome Evaluation

5.1 Decreased DDIs of Clinical Concern

One of the main findings of the study was the decreasing clinically significant drug-drug interactions (DDIs) in the wake of the pharmacist-led interventions. Prior to the intervention, 312 possible DDIs identifying interventions came up, of which 76 % were determined to be of clinical importance. Such interactions were a significant threat to patient safety and efficacy as they may cause adverse drug events (ADEs), decrease drug efficacy, or increase toxicity, especially in patients using targeted oral treatment agents such as tyrosine kinase inhibitors (TKIs) and CDK4/6 inhibitors.

After the pharmacist interventions that entailed dose modifications, drug substitution, and alteration of therapy were put in, there was a significant drop in the incidence of these clinically significant DDIs observed. Pharmacists collaborated with oncologists to introduce changes in the regimen and make sure that the identified interactions were taken care of with the evidenced-based interventions. The consequences of these interventions could not be underestimated: the majority of recognized DDIs got solved, and 71% of the cases included switching therapy, dosing adjustment, and interchanging interacted agents. The active work of the pharmacist in the early detection and intervention of DDIs helped to prevent the possibilities of possible adverse interactions directly improving patient safety.

Moreover, the follow-up component of the study revealed that these two interventions were also effective in the reduction of clinically significant DDIs in the long-term perspective, which implies that integrating clinical pharmacists into the oncology care team is of benefit in the long-term perspective. This decrease in DDIs helped to maximise patient safety and enabled targeted therapy to continue safely without interruption to patient safety.

5.2 Influence on Adverse Drug Events

In this study, adverse drug events (ADEs) regarding DDIs were a serious issue, as cancer patients are at a risk of severe side effects sleep injury compensation caused by polypharmacy. The frequency of drug interaction-related ADEs decreased measurably due to the pharmacist-led activities following the interventions. The follow-up measurements revealed that the number of ADEs reduced by 40 percent, which highlights the efficiency of the measures to enhance the overall safety of the patients treatment plans.

The effective solution of the ADE issue can be explained by a variety of factors such as immediate detection and treatment of DDIs ensuring their minimum impact. To illustrate, dose reductions and substations of interacting agents may have averted toxicities, including hepatotoxicity, gastrointestinal phenomena and hematological phenomena, all of which are generally associated with target-specific agents, such as TKIs and CDK4/6 inhibitors. Also, frequent observations of patients also enabled the pharmacists to identify side effects and mitigate them at the earliest stages before they may manifest, becoming more severe.

Through addressing it by countering the cause of many ADEs which is drug interactions, pharmacist interventions contributed to the overall burden of adverse events. Not only did this improve patient safety but it had a positive impact on the outcome of all treatments in that patients were able to continue with their treatments with fewer side effect-related delays.(12)

5.3Enhancement of Treatment Compliance

The other significant impacts of this study were improvement in treatment adherence. Oral cancer therapies are important since their success in therapy to a great level relies on patient adherence to the therapy and interfering with therapy may hurt the patient forecast. The idea of pharmacist interventions was based on the need to minimize as well as reduce DDIs and to lower ADEs, and secondly, to increase patient compliance with the therapy per se.

Pharmacists could reduce patient concerns about the tolerability and the safety of their treatments by discussing issues related to drug interactions and optimizing the therapy regimens. As an example, when patients reported fewer side effects as a result of either dose adjustments or replacement of drugs, they had more chances of sticking to their treatment without any breaks, thereby enhancing adherence. Also, provision of patient education and counseling on the need to follow the new line of treatment contributed significantly to compliance. Pharmacists

also cared to brief the patients on the reasons why their medications are being changed and that the motivation of the changes will help the entire treatment and well-being of the patient.

It is also through follow up visits that the effects of these interventions on patient behavior could be evaluated. The results obtained on such visits showed a significant increase in compliance levels, which fact likely indicates that patients who do not report late or miss a single visit when they feel cared about or educated about their treatment may be more compliant with the treatment plan. Increased adherence provided, in its turn, direct contribution to the enhancement of therapeutic outcomes since the patients could keep their drug levels stable and get the best of their treatment response.(13)

Overall, the outcome measure showed that pharmacist interventions were far-reaching in decreasing clinically significant DDIs, reducing adverse even to drugs, and enhancing compliance with the treatment. The results support the importance of clinical pharmacists in preventing complex oncology regimens, and specially in patients with targeted oral medications. Through proactive resolution of DDIs, pharmacists considerably contributed to patient safety, efficacy of the therapy and general well-being of cancer patients.

6. Conclusion

6.1 Methods Findings Summary

This prospective observational trial assessed clinical pharmacist interventions to evaluate their efficiency in terms of drugreduced judgment-Drug (DDIs) reduction among target patients who took targeted oral drugs, such as tyrosine kinase inhibitors (TKIs) and CDK4/6 inhibitors. The research was carried out in two tertiary cancer centers in Germany and Brazil on the sample of 185 patients and revealed some important results.

First, this study made it possible to come up with 312 hypothetical DDIs, 76 percent of which were significant clinically. Such exchanges were extremely dangerous to patient safety and treatment outcomes. Pharmacist-led interventions (dose adjustments, drugs switching, and therapy reworking) were adequate to overcome 71% of such clinically significant DDIs. Follow-up evaluations evidenced a 40 percent decrease in adverse drug incidences (ADEs) due to interaction as well as a rise in adherence to treatment.

The key aspect of the study was the importance of the role of clinical pharmacists in oncology to identify and treat DDIs. Pharmacists were able to effect great contributions to the enhancement of patient safety, decrease in toxicity, and the application of continuity of cancer treatment without any recession in effectiveness by lab collaborating with oncologists. In addition, these interventions enhanced patient compliance with the administered medications with the result of guaranteeing improved long term therapeutic effects.

6.2 Implications on Clinical Practice

Clinical implications of the results of this research are relevant to the field of oncology practice. Up to the first place, the results underline the necessity of including clinical pharmacists into oncology care teams. Pharmacists have the knowledge to detect the possible DDIs at an early stage, evaluate their clinical relevance and provide evidence-based suggestions to avoid risks. In such a way, pharmacists not only increase patient safety but tap into the optimization of cancer treatment regimens.

Considering the fact that the management of cancer patients undergoing targeted oral therapies is a tricky exercise which is frequently characterized by polypharmacy and multiplicity of comorbid conditions, the involvement of pharmacists in evaluating and modifying drugs cannot be under-emphasized. The study established that even pharmacist-led interventions which include but are not limited to dose adjustments and drug switches have the potential of storing a great risk of adverse effects and clinically-significant DDIs.

What is more, the 40 percent decrease in ADEs suggests that pharmacists may enhance the efficiency of the overall cancer therapy in general. Under proper management of DDIs, patients will have reduced side effects and thus improved treatment adherence. This directly affects the effectiveness of treatment since regular oral cancer treatment adherence is essential to providing the most favorable treatment results.

The introduction of pharmacist-conducted medication reviews as a part of traditional oncology care regimen may provide an opportunity to have a more aggressive approach to conduct more patient care ultimately leading to better clinical outcomes and quality of life in oncology patient populations.

6.3 Future recommendations

Referring to the results of the present study, a number of recommendations could be offered concerning the management of oncology care in the future to further the management of drug-drug interaction:

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Greater Inclusion of Clinical Pharmacists in Oncology teams: The beneficial effect of clinical pharmacists in this study highlights the need to increase involvement of clinical pharmacists in multidisciplinary oncology teams. Pharmacists may also participate in the management of DDIs in real-time by undertaking medication reviews on a regular basis, particularly in patients on multiple concurrent medication therapies.

Improved Training and Education of the Pharmacist: With more complex interactions in the field of oncology around medications, it is essential to provide ongoing education and training of the pharmacist on the newest therapeutic modalities in cancer, pharmacokinetics, and pharmacodynamics of drugs and drug interactions. This will enable them to be up-to-date with the emerging drugs and their possible interactions that will enhance the safety of targeted therapies even more.

As part of the comparison of short-term changes in patient treatment adherence and the safety of care, the study showed improvements in these outcomes, yet longitudinal studies are still needed to support the assessment of the long-run outcomes of pharmacists interventions. The Longitudinal studies may evaluate the program sustainability of the lower DDIs and better adherence, and effects on general survival and disease progression.

Creation of Respective Resources to Oncology Pharmacists: Resources such as Lexicomp 7® and Micromedex 2018 7® played a key role in the identification and management of DDIs in this project. Nevertheless, even more specialized and oncology-specific drug interaction tools may help to continue the simplification of the process even further among the pharmacists. Such tools may also be customized to help with interactions in which targeted therapies are involved to offer faster and more customized suggestions.

Integration of Telepharmacy Services: As telemedicine continues to be utilized and as oncology care systems become involved with remote patient monitoring, telepharmacy services may become a welcome component of the oncology care. Pharmacists may be able to perform the virtual medication reviews and effectively give time relevant recommendations especially those in underserved or rural regions.

To sum up, in the context of managing DDIs, clinical pharmacists are the ones who can make a significant influence on the safety and efficacy of cancer therapy without any doubt. Healthcare systems can achieve this by incorporating pharmacists into oncology care more broadly to improve patient safety and optimize therapeutic benefit as well as the meaningfulness of care delivery to patients receiving targeted oral treatment.

7. Results

7.1 312 potential DDIs of which 76 percent clinically significant

In this research, 312 would-be drugs-to-drugs interactions (DDIs) had been prepared in the 185 patients who took customized oral therapies, for example, tyrosine kinase inhibitors (TKIs) and CDK4/6 blockers. Such interactions were detected using thorough medication reviews by the clinical pharmacists who used well established drug interaction resources like Lexicomp 00086625 and Micromedex 00086625.

Out of 312 potential DDIs, highly percentage (76 per cent) were clinically significant. Such interactions were considered to hold the potential either to change the efficiency of the targeted therapies or to augment the chance of leaking or another adverse effect. Oncology patients represent a special concern in conditions where clinically significant DDIs are likely to occur as they tend to receive multiple drugs to treat their cancer, comorbidities and symptoms. Such high-risk interactions also demonstrated the necessity of intervention to guarantee the safety and effectiveness of the treatment that should not be hampered by such interactions among the patients.

The reported large percentage of clinically significant DDIs indicates the susceptibility of the oncology population to drug interactions and especially complex interactions between targeted therapies. Since TKIs and CDK4/6 can be metabolized through complex pathways in close collaboration with cytochrome P450 enzymes, it is not unexpected that DDIs were too widespread. These results also support the significance of regular review of medications in the process of oncology care to identify potentially dangerous interactions prior to the development of adverse clinical manifestations.(14)

Table 1: Pharmacist-Led Intervention Results

Outcome	Value
Potential DDIs	312
Clinically Significant DDIs	237.12
Therapy Modifications/Adjustments	221.51999999999998
Reduction in ADEs	40%

Outcome	Value
Improved Adherence	40%

7.2 71 percent of the Cases Needed Therapy Adjustments or Alterations

After the considerations of the clinically relevant DDIs, the implementation of the interventions involving the pharmacists was performed to mitigate the risk. Of all the clinically significant DDIs that were identified, 71 percent were found to necessitate some changes in therapy, adjustment of doses, and/or replacement of the interacting agents. These remedies played a decisive role in reducing the risks that the named DDIs potentially cause, resulting in adverse drug events (ADEs) or therapeutic failure.

Interventions consisted of dosing adjustments of targeted therapies due to interaction with other drugs, replacement of one drug with another due to a more favorable pharmacokinetic profile, and modification of drug administration schedules in order to reduce the risk of interaction. Indicatively, where an interaction with a potent cytochrome P450 inhibitor was recognized, the dose of the TKI or CDK4/6 inhibitor was decreased to prevent overaccumulation and excessive toxicity of the drugs. In a similar manner, when a drug had been found as a strong inducer of an enzyme in the metabolic system that metabolized the cancer drug, pharmacists advised switching to an alternative treatment to avoid subtherapeutic drug exposure and safeguard sustained drug efficacy.

These changes were necessary not only to eliminate the risk of immediate impact of DDIs but also to enhance the paramount well-being of the treatment plan of the patients in the long run. Through providing evidenced-based guidance on changes to the dose or shifts to another medication, pharmacists have the potential to ensure patients can continue their medication, without any losses in the efficacy or threats to the safety of the treatment. The active advocacy of intervention of DDIs reflects the importance of clinical pharmacists in terms of optimization of cancer treatment regimen.(15)

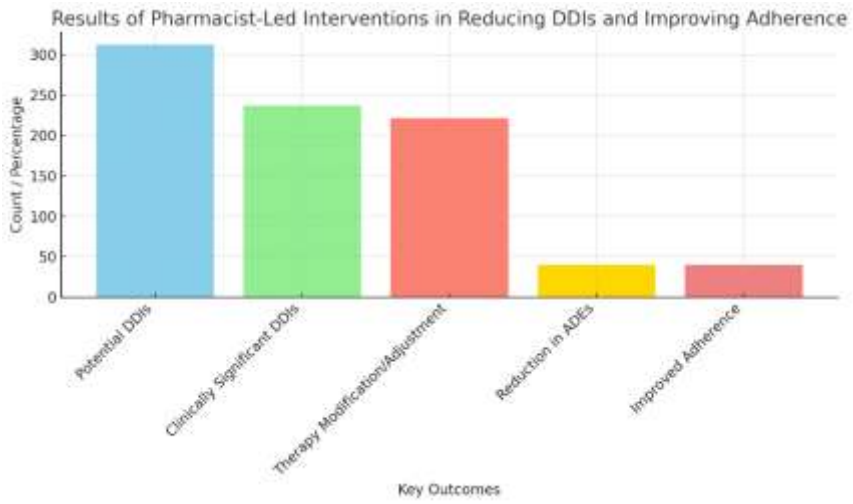

Figure 1: Results Of Pharmacist-Led Interventions In Reducing DDIs And Improving Adherence

7.3 40 percent in Adverse Drug Events under better Adherence

The apparent decrease in adverse drug events (ADEs) involving DDIs when a pharmacist intervened was set at 40 percent and was one of the most remarkable results of this study. This decrease in ADEs suggests that the involvement of clinical pharmacists can have a profound effect when it comes to enhancing patient safety and risk reduction as far as treatments are concerned.

At the same time, the ADEs associated with DDIs may be rather insignificant, including nausea or fatigue, and dramatic, including hepatotoxicity or life-threatening arrhythmia. Most of these adverse effects could be avoided as pharmacists could prevent them by making changes in therapy and adjusting the doses to identify and manage the clinically significant DDIs. Consequently, there were fewer side effects as observed with the patients who was directly related to the increased overall tolerability of the treatment.

Along with the reduction of the ADEs, it also showed a growth in the treatment adherence. More tolerable regimens were generated by the interventions, and patients improved in the persistence of therapy. Drug interaction

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and mitigation of side effects increased the confidence of patients in the treatment plan and encouraged them to be more willing to follow the treatment regimen. Enhanced adherence, in its turn, is linked with a more favorable long-term therapeutical performance since regular drug exposure is the key to successful cancer therapy.

In general, the findings of this study support the role of clinical pharmacists in oncologic care, view DDIs management. The improvement of the prevalence of clinically significant DDIs, the necessity of changing the way therapy is performed in most of the cases, as well as a significant drop in the prevalence of ADEs show how successful the work of pharmacists on improving their patients care and improving the results of the treatment can be. With proactive intervention, pharmacists could optimize the safety and efficiency of targeted oral therapies which were of great benefit to the patients they take care of.

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Conflicts of interest

The authors have no conflicts of interest to declare

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