

THE ROLE OF THE CLINICAL PHARMACIST IN THE MANAGEMENT OF ANTIRETROVIRAL THERAPY

Pantaleo Luca^{1*}, Prestileo Tullio², Milesi Maurizio², Marrone Patrizia¹, Lampasona Maria³,
Pittore Dario⁴, Raimondi Maria Valeria⁴

¹Unit of Pharmacy of the hospital ARNAS Civico "Di Cristina Benfratelli", University of Palermo, Palermo, Italy.

²Department of Infectious Diseases of the hospital ARNAS Civico "Di Cristina Benfratelli", University of Palermo, Palermo, Italy.

³Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialties "G. D'Alessandro", University of Palermo, Palermo, Italy.

⁴Department of Biological, Chemical and Pharmaceutical Sciences and Technologies (STEBICEF), University of Palermo, via Archirafi 32, 90123 Palermo, Italy

*lucapantaleo2010@libero.it

Abstract

Over the last few years, the Hospital Pharmacy has developed in an excellent way in Europe, proposing in many countries the clinical pharmacist as a new professional figure, and adapting its responsibilities to national health systems.

The purpose of this study is to evaluate and promote the prescriptive appropriateness through the close collaboration between the pharmacist and the medical team.

The aspect of the dispensation of antiretroviral therapy was deepened by providing useful information to the patient on the possible undesired effects and interactions due to the polypharmacy, on the correct way of storing the drugs, and on the importance of the regularity of the polypharmacy intake, in order to improve the compliance, which is closely related to the efficacy of long-term antiretroviral treatment and the reduction of the risk of drug resistance.

The analysis of pharmaceutical prescriptions was conducted on 123 patients through the distribution of an anonymous questionnaire. Thanks to the anonymous questionnaire, it was possible to compile a special data collection form composed of two sections.

The software InterCheck classified the interactions in progressive order of severity.

The presence of clinical pharmacists requires a significant financial commitment on the part of the national health system but the economic investment can be evaluated favorably if we consider the benefit in terms of minor errors in therapy, lower occurrence of ADR, and improvement of the prescriptive appropriateness.

Keywords: clinical pharmacist; drug therapy appropriateness; pharmacovigilance; interaction of antiretroviral drugs; ADRs (adverse drug reactions).

Introduction

Nowadays the hospital pharmacist is already a reality in many European countries, in the United States of America (USA), in Canada, in Australia and in New Zealand where the Hospital Pharmacy has already had more clinical orientation, increasingly placing pharmacists in the departmental activity. Clinical pharmacist has mismatched responsibilities which differ from different Countries even if nowadays more measures to harmonize them are being taking place. In Great Britain, clinical pharmacists are allowed to prescribe some drugs, within their competency. Even the specialization differs from one State to another. European and American Pharmacists generally deal with drug interactions and the correct dosing schedule. In most countries the C.P. most common responsibilities include: the dosage, adjustment based on the patient's renal or hepatic function and the chemical-physical compatibility of the drugs used in Intravenous (IV) therapies. In some states, for example in Germany, pharmacists take part in the hospital tour and with the doctors decide the most appropriate medicine and dosage.

Other professional fields in which the clinical pharmacist is frequently involved are the care management of patients with complex health care needs such as transplant patients and pediatric patients. In Great Britain, in particular, pharmacists play a fundamental role in this area. In the USA the pharmacist is an essential and widely recognized component of the therapeutic team; indeed, in the medical team he is considered the only expert in the management of drugs and its presence is required at every visit to fulfill the clinical picture. Therefore, he often decides which medicine and which dosage is most suitable for the patient. In Europe, in this respect, England is at the forefront. In the National Prescribing Center (NPC) pharmacists are trained through specific courses dedicated to prescription drugs built on Evidence Based Medicine (EBM) and, following the acquisition of the title, they can independently prescribe some specific categories of drugs thanks to a special "Agreement" stipulated with the doctor. This function is also carried out in the hospital by the clinical pharmacists who then, heading up the drug therapy, help the doctors to dedicate more time to other complex activities of

their exclusive competence, such as diagnosis and surgical therapy¹. From an international point of view, therefore, the orientation is clear: the clinical pharmacist must have an important role in the hospital and the existing models could also be redesigned by the Italian Health System.²

Methods

The analysis of pharmaceutical prescriptions was conducted from 03/01/2018 to 08/31/2018 at the Department of Infectious Diseases of the aforementioned Hospital. The analysis was carried out through an anonymous survey (Figure 1) (questionnaire) on 123 patients. Those patients were interviewed during visiting hours and during medical-nursing procedures such as blood collection operation and medications. This allowed to date back to a first Pharmacological history on home therapy on the therapy, which was recorded in a special form (Table I). The therapy was compared with the therapy noted by the doctor in the "Pharmacological history" section of the medical record and with the single therapy sheet drawn up after the visit. The current therapy for each patient was recorded in a data collection form in which the "discrepancies" detected were also noted and discussed with department doctors in order to clarify the intentional nature of the changes made to home therapy.³ Subsequently a prescription check was performed using the InterCheck[®] software available on the website www.intercheckweb.it. This software was developed by the Mario Negri Institute of Pharmacological Research in Milan and makes it possible to assess: the prescriptive appropriateness, the drug-drug interactions and the risk of adverse drug reactions (ADR). In particular, for which concern ADRs, it was realized that the definition of ADR is very broad and often the identification and reporting of ADRs during daily clinical practice is carried out on an individual point of view since there are no standard parameters that can allow operators to suspect an ADR. For this reason, the collaboration between Doctor and Pharmacist is fundamental. The data extracted from the questionnaires were inserted into an Excel format database and subsequently examined with the SPSS statistical software (Statistical Package for Social Science). For each

subject considered in the study, thanks to the anonymous questionnaire it was possible to fill in a specific data form. The form consists of two sections: the first contains the personal data (age, sex, nationality, and years of HIV). Information was collected on drug use, consumption of cigarettes and alcohol, the second section is dedicated to the pharmacological history related to the concomitant intake of "other drugs" in addition to antiretroviral drugs and collects information regarding home therapy taken in the last three months, with particular attention to compliance. This information was collected, when possible, directly by the patient, in other cases thanks to the collaboration of family members or previous documentation.

Results

A total of 123 patients were examined at the 'ARNAS Civic Infectious Diseases' clinic; 70 males and 53 females. The average age of the patients was 47.9 years (range 16-74 years), 101 of Italian nationality and 22 foreigners. At the time of analysis each patient was taking on average 4 drugs (range 2-8). Of all the patients: 115 came from domicile, 13 from other ward. 33 discrepancies were observed in therapies that mainly concerned drug-drug interaction, incorrect dosage and possible interactions with alcohol and / or drugs. These discrepancies were discussed with the ward doctors to clarify the reasons (Table II).

From this analysis it emerged that the omission of drugs was generally linked to the need to perform a pharmacological wash-out in the patient in case of vomiting, mental confusion, suspected ADR from drugs and in some cases refusal to treat.

Furthermore, the omission and / or modification of the dosage was caused by an incorrect or incomplete medical history since the patients, taking on a large number of drugs, provided an incomplete list of the drugs taken or indicated an incorrect dosage.

This represents a potential source of errors in therapy and underlines the importance of an adequate pharmacological history for a correct and safe prescription. From the study conducted it was shown that patients take antiretroviral drugs, at least, once a day.

Considering question number four of the questionnaire (Table III): "*In the last month have you forgotten to take one or more ANTI-HIV tablets?*" seventy-seven patients replied "never". Thirteen patients reply "rarely". Twenty-six patients instead reported that they have forgotten to follow the therapy in the last month. A minority, or seven people, said they often "forget" to take antiretroviral therapy. To the question: "*In the last three months did you suspend the therapy for at least one day?*" seventy-six patients answered "never", while thirty-nine patients responded "rarely" or "once".

Only seven patients claim to suspend the administration of the therapy "sometimes". On the other hand, the answer given by a patient who reports "often" suspending the administration of therapy is different. Six patients report that skipped the indications of the therapeutic regimen because they are off-site. Other six patients refer to forget to take the medicine indicated for the therapeutic plan. On the other hand, two patients, do not comply the therapy as they refuse to follow the instructions of the attendant. To the question: "*In the last three months did you think to take less medication that those prescribed?*" The majority, or ninety people, responds that they have never thought of taking fewer drugs than reported in the prescription. They said "rarely" and "one day" in twenty-seven people. They report taking into account fewer drugs than those prescribed in total six people. Two patients being treated with NRTI + PI (Norvir + Efavirenz; Reyataz + Efavirenz), a third patient being treated with PI + INI (Ritonavir-Tivicay) and one last patient being treated with NRTI + PI + INI (Genvoya + Prezista) feel a sense of nausea as a side effect of their antiretroviral therapy. The above patients are not treated with other drugs. The study showed that three patients accuse general discomfort and heaviness as a side effect. The first of them is treated with only NRTI + PI (Reyataz + Efavirenz) and with no other drugs but reports hashish and marijuana common use. The second is being treated with NRTI + NI (Tivicay + Descovy) does not report taking any drugs other than antiretroviral therapy. The third, being treated with NRTI + NI (Tivicay + Descovy) is being treated with Ramipril and does not report drug use. Only one patient reports intolerance and paranoia due to frequent consumption of marijuana.

Discussion

The analysis of the prescriptions was carried out through the InterCheck[®] software⁴ and promptly examined in collaboration with specialist doctors; this analysis highlighted the possible interactions among drugs prescribed during the patient's visit (Table IV). The interactions are classified in a progressive severity order: in "major" type interactions, associated with a serious event but which can be managed, for example by adjusting the dose, and "contraindicated" interactions, associated with a serious event in which the co-administration of drugs that could interfere with them should be avoided. Moreover, the interactions that can cause serious adverse events were subsequently investigated to assess their relevance and for the possible compilation of informative notes to be addressed to department doctors.

The association of Tenofovir-Acetyl salicylic acid, found in five patients increases the risk of renal dysfunction also reducing the clearance of Tenofovir, mainly eliminated by renal excretion; for this interaction, renal function was monitored before and during therapy and also the dose reduction of Tenofovir was evaluated.⁵ In two patients the combination of Raltegravir-Atazanavir increased the exposure to Raltegravir by about 70% due to inhibition of Raltegravir metabolism (mainly mediated by uridine diphosphate-glucuronosyl transferase A1, UGT1A1) caused by Atazanavir (a potent UGT1A1 inhibitor).⁴ In a patient, the combination of Tenofovir-Metformin increased the risk of lactic acidosis and renal failure. For this, blood glucose and kidney function were constantly monitored.^{4,5}

The association Ritonavir-Rosuvastatin in two patients caused an increase of Rosuvastatin plasma concentrations (C_{max} increases by 613% and AUC by 159%) and therefore an increased risk of side effects. This is because it reduces the excretion of Rosuvastatin by inhibition of the hepatic transporter OATP1B. It is recommended not to exceed the 5 mg/day Rosuvastatin dose and monitor creatine kinase levels and the occurrence of myopathy or rhabdomyolysis.⁶

The association of Atazanavir-Pantoprazole caused an increased risk of cardiotoxicity with prolongation of the QT interval and reduction of plasma

concentrations of Atazanavir: cardiac toxicity due to direct effects on the QT interval and mediated by alterations of the electrolytes (hypokalemia and hypomagnesemia) resulting from prolonged use of PP.⁷ The interactions found in patients treated with Ritonavir-Atazanavir and Ritonavir-Furosemide are of greater pharmacological and clinical interest: these cause an increased risk of cardiotoxicity due to prolongation of the QT interval and torsade de pointes, co-administration is avoided.⁸ The co-administration of Rilpivirina-Tacrolimus should be avoided and for this reason periodic checks of the electrocardiogram are performed.⁹ The association of Ritonavir-Olanzapine caused an additive effect on the prolongation of the QT interval.¹⁰ The associations of Olanzapine-Atazanavir and Ritonavir-Atazanavir increased the risk of cardiotoxicity due to additive effect on prolongation of the QT interval.¹¹ The Rilpivirin-Phenobarbital association caused a marked reduction of Rilpivirine exposure due to induction of Rilpivirine metabolism (substrate of cytochrome P450 3A4) caused by the powerful inducer of 3A4. It is advisable to avoid co-administration because a significant loss of the therapeutic effect of Rilpivirine may occur.¹² Another interaction concerned the Rilpivirin-Tramadol association which exposes to risk of cardiotoxicity.¹³ The association of Rilpivirin-Paroxetine can cause torsade de pointes.¹⁴

Alcohol in the presence of PI and NNRTI-containing regimen may increase hepatotoxicity, particularly if there is co-infection with hepatic viruses. Chronic alcohol consumption can alter the hepatic metabolism of antiretroviral drugs. Indeed, it has been shown that alcohol induces the expression of CYP3A4 in the liver making the metabolism of many drugs relatively faster, especially PI and NNRTI, reducing the efficacy of these antiretroviral drugs. However, this mechanism is still not clear. Our comparison showed that four patients were at high risk of interactions due to high daily alcohol consumption; three of these patients are being treated with PI and INI. With them, educational interventions have been implemented in order to inform the patient about a correct lifestyle, paying attention to the risks of chronic alcohol consumption; Eight patients report a consumption of alcohol (about a glass a day) and,

since these patients are being treated with PI and with NNRTI, the consumption of alcohol is strictly not recommended. Alcohol, according to some studies, could increase the replication of HIV and thus decrease the response to HAART therapy in HIV-infected individuals due to the effects on cytochromes P2E1 and P3A4. Cigarette smoking is responsible for decreasing immune responses, increasing HIV-1 replication and increasing AIDS conditions in smokers with HIV-1 infection; smoking decreases the effectiveness of HAART therapy, in particular of NNRTI and PI, which involves the CYP 2A6 and 2B6 pathway.¹⁵

The study found that the patients who take narcotic drugs (cannabis and derivatives, cocaine) are being treated with PI, NNRTI, NRTI and INI according to the therapeutic plan established by the doctor. The participants were also asked if they agreed with the common beliefs about the risk of adverse events in the case of mixing other drugs with therapy. From our interview it emerged that they were aware about the risks (it was common for users with HIV and drug users to believe that HAART and drugs should not be mixed); however the results of the treatment are worse in those who have stopped taking therapy while using drugs. The overall average adherence rate was 83%, with 37% of participants planning to take less than 85% antiretrovirals and a fourth taking only 75% of their doses: this was confirmed with viral load. It also emerged that women were more likely to intentionally stop their anti-HIV medications than men.

Other factors associated with planned non-compliance included: lower income, fewer years of education, longer duration of HIV infection, alcohol abuse and alcohol-related problems. The majority of people with intentional non-compliance have approved all the beliefs about potential toxicity by mixing HAART and drugs.¹⁶ These results demonstrate an urgent need to address circulating toxicity beliefs among active drug users who are intentionally not adherent to antiretroviral therapy. In some cases, interactions are a legitimate concern, with a number of drugs there is no evidence of dangerous interactions. There are potential interactions between recreational drugs and some non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease

inhibitors (PIs). But alcohol and some recreational drugs, such as cannabis, interact only with some anti-HIV drugs, not with whole drugs used for that treatment and often can hurt more the lack of HIV treatment doses rather than taking them together with alcohol or drugs.¹⁷ In three patients (taking therapy with Olanzapine) being treated with Atazanavir (with and without Ritonavir) the consumption of Marijuana and derivatives reduces the drug concentration by 60%. For this reason, these patients were informed of the risk. A Patient being treated with Norvir, Isentress and Reyataz (PI and INI) manifests paranoia. In this case the active ingredient of marijuana, THC and its metabolites, are metabolised by CYP3A4 and CYP2C9.¹⁸ Inhibitors of this CYP such as Ritonavir (Norvir) can interfere with marijuana metabolism and increase the risk of toxicity. So people who are on therapy and consuming cannabis may experience a slight increase in the psychoactive effects linked to THC.¹⁹ Some patients report suspending therapy to help with drugs such as marijuana and hashish. A patient, treated with Triumeq (Abacavir + Lamivudine + Dolutegravir), reports cocaine use which increases the excretion of Abacavir with consequent sub-therapeutic levels.²⁰

Conclusions

Identifying and setting personalized therapeutic schemes for each individual patient is likely to reduce the incidence of adverse events related to antiretroviral drug therapy. This is considered of particular importance both for the health of the individual patient and in a more general context for current health care costs, favoring a rationalization of treatments in the individual patient with HIV infection. This implies the need for the patient to be clearly informed about the reasons for which it is considered necessary to treat HIV infection, the characteristics of the prescribed drugs, the exact mode of intake, the possible side effects and the potential interactions with other drugs and narcotics.

The project at the Department of Infectious Diseases has provided numerous insights on the possible role of the clinical pharmacist in our hospital reality. The pharmacist represents the point of union between doctor / nurse and patient, facilitating the therapeutic paths; he has the task of

encouraging patients to submit questions on therapies and to ensure that the patient and family have correctly understood the information provided for the management of home therapy. HIV-infected patients need constant monitoring, they are exposed to numerous risks such as infections, adverse events, interactions; for this reason, it is important that the patient understands the complexity and the reasons for the treatment, the importance and the role of the single drugs and the clinical manifestations of the undesirable effects. Similarly, communication between healthcare professionals is important since they are involved in all phases of patient care. It is useful that health professionals follow communication courses and that they know the different modes of communication. During the interview with the patient it is important to use no technical terms that are difficult to understand but short and simple sentences. It is also important to encourage dialogue with requests for clarification. The main task of the Clinical pharmacist is to carry out a thorough collection of the medical history and an assessment of the related drug problems based on the reconnaissance and therapeutic reconciliation. Moreover, this study shows that the HIV patients consider their disease condition severe. In fact this condition influences their lives hard. More work needs to be undertaken concerning the nature and benefit of this role in different departments and managements such as minor disease as well as severe and critical situations.

Conflicts of interest. — The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Figure 1. Questionnaire

Questionario

Buongiorno, il seguente questionario anonimo servirà per comprendere meglio l'impatto della terapia nelle persone con HIV.

ETA': _____ GENERE: _____

ITALIANO
 NON ITALIANO

TERAPIA ANTIRETROVIRALE (inserisci nome commerciale): _____

1. DA QUANTO TEMPO SA DI ESSERE SIEROPOSITIVO?

2. QUANTO LE PESA OGGI AVERE L'HIV?

(metta una **X** nel punto che ritiene giusto)

(niente) 0 1 2 3 4 5 6 7 8 9 10 (TANTO!)

3. QUANTE VOLTE AL GIORNO PRENDE FARMACI ANTIRETROVIRALI?

(metta una **X** sulla risposta giusta)

Una volta Due volte Tre o più

4. NELL'ULTIMO MESE SI È DIMENTICATO DI PRENDERE UNA O PIÙ COMPRESSE DI TERAPIA ANTI HIV?

Mai Una volta Raramente (2-3 volte) Qualche volta (4-5) Spesso (6 o più)

5. NEGLI ULTIMI TRE MESI HA SOSPESO LA TERAPIA PER ALMENO UN GIORNO INTERO?

Mai Una volta Raramente (2-3 volte) Qualche volta (4-5) Spesso (6 o più)

Perché?

Non potevo prendere le medicine (ero in viaggio, motivo di lavoro ero in compagnia, ero all'estero)
 Me lo hanno consigliato
 Ero ammalato

1

I farmaci mi fanno star male
 Altro: _____

6. NEGLI ULTIMI TRE MESI HA PENSATO DI PRENDERE MENO FARMACI DI QUELLI PRESCRITTI?

Mai Un giorno Raramente (2-3 giorni) Qualche giorno (4-5) Spesso (6 o più)

Indicare la causa principale: _____

7. ASSUME ALTRI FARMACI IN CONCOMITANZA CON LA TERAPIA PER L'HIV?

SÌ
 NO

Se sì, quali? _____

8. FA USO DI SOSTANZE STUPEFACENTI?

SÌ
 NO

Se sì, quali sostanze è solito consumare? _____

9. FA USO DI ALCOL?

SÌ
 NO

Se sì, con quale frequenza è solito bere sostanze alcoliche?

Un bicchiere alla settimana
 Un bicchiere ai pasti
 3 o più bicchieri al giorno

10. È UN FUMATORE DI SIGARETTE?

SÌ
 NO

Se sì indicare quante sigarette: _____

2

Grazie per la cortese collaborazione.
Luca Pantaleo

Table 1. Antiretroviral therapies taken by patients

Antiretroviral Therapy	N Patients
PI + INI	26
NRTI + NNRTI	12
NRTI + INI	44
NRTI + PI	26
NNRTI + INI	1
NRTI + PI + INI	4
NRTI + INI + CCR5	1
NRTI + NNRTI + PI + INI + CCR5	1
PI	1
Not received	7

Table 2. Demographic and anamnestic characteristics of the study population

Variables		N	%
Gender	Female	53	43,09
	Male	70	56,91
Nationality	Italian	101	82,11
	Not Italian	22	17,89
Alcohol Consumption	Yes	41	33,33
	No	82	66,67
Cigarette Smoke	Yes	45	36,59
	No	78	63,41
Drug Use	Yes	110	89,43
	No	13	10,57
Mean age	47,90 (Standard Deviation \pm 13,76)		

Table 3. Adherence to therapy

		Never	Sometimes	Rarely	Frequently	One time	Total
Question number 4: "In the last month have you forgotten to take one or more ANTI-HIV tablets?"	N	77	5	13	2	26	123
	%	62,6	4,1	10,6	1,6	21,1	100
	CF	62,6	66,7	77,2	78,9	100	
Question number 5: "In the last three months did you suspend the therapy for at least one day?"	N	76	7	8	1	31	123
	%	61,8	5,7	6,5	0,8	25,2	100
	CF	61,8	67,5	74,0	74,8	100	
		Never	Some day	Rarely	Frequently	One day	Total
Question number 6: "In the last three months did you think to take less medication that those prescribed?"	N	90	3	8	3	19	123
	%	73,2	2,4	6,5	2,4	15,4	100
	CF	73,2	75,6	82,1	84,6	100	

Table 4. Types of interactions

	Interaction A	Interaction B	Interaction C	Interaction D
N	3	16	5	9
%	9,09%	48,48%	15,15%	27,27%