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ORIGINAL RESEARCH

Completion of therapeutic and safety monitoring tests in Lebanese outpatients on chronic medications: a cross-sectional study

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Purpose: To evaluate the appropriateness of laboratory-test monitoring recommended for patients on chronic medication therapies in the Lebanese community setting.

Patients and methods: In October 2011, all outpatients visiting selected community pharmacies in Lebanon were screened by pharmacists to evaluate their use of one or more chronic medications requiring safety and/or therapeutic laboratory tests. The list of medications was elaborated after an extensive review of laboratory-test monitoring recommendations from pertinent up-to-date clinical guidelines, medications that have been issued black box warnings for monitoring, and the most current information from the US Food and Drug Administration website. Patients receiving these medications were subjected to a questionnaire assessing the appropriateness of their laboratory-test monitoring. The study was approved by the Lebanese American University's Institutional Review Board.

Results: A total of 284 outpatients, with almost equal distribution by sex, were identified during the aforementioned period to be on one or more of the specified medications. The majority of the sample (68%) was younger than 65 years of age. Overall, most of the study group (65%) were found to be partially monitored with laboratory tests, while only 27% were fully monitored and 8% were not monitored at all. The study group reported clinic-visit intervals as follows: more than a year (35%), on yearly basis (18%), every 6 months (25%), every 3 months (16%), less than 3 months (6%).

Conclusion: Seventy-three percent (73%) of the study group were receiving incomplete therapeutic/safety laboratory-test monitoring recommended for patients on chronic medication in the Lebanese community. It is concluded from the results that patients need to better understand the importance of recommended test monitoring for the safe and effective use of their medications. Education by physicians may be required to achieve better understanding.

Keywords: laboratory tests, hypertension, statins, diabetes, chronic diseases, drugs, disease management, primary care

Introduction

Therapeutic and safety drug monitoring is an essential element for the effective use of medications and for high-quality medical care. It allows clinicians to use better correlations between drug concentrations and both efficacy and toxicity, and contributes to an ethos of safety. These factors raise standards of medical practice.

In fact, a common cause of therapeutic failures and adverse drug reactions in ambulatory care is related to suboptimal patient monitoring, including inadequate follow-up and insufficient use of laboratory tests to monitor organ function and drug levels.[1]

Studies done on ambulatory patients showed that almost 60% of the reported preventable adverse events occurred at the stage of monitoring.[2,3] A report from two large academic long-term care facilities also confirms that inappropriate monitoring,

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in addition to inappropriate prescribing, are the most common errors in preventable adverse drug events, whereas errors in dispensing and administration are less commonly identified.[4] Additionally, studies have shown a gap between guideline recommendations and actual frequency of baseline medication laboratory-test monitoring.[5]

Furthermore, the Institute of Medicine report, *To Err is Human: Building a Safer Health System,* has categorized medical error based on diagnostic, treatment, prevention, and other types of errors.[6] Specifically, failure to employ indicated tests, to act on their results, or to follow-up were considered to be medical errors.

Total annual costs of medical errors resulting in injury are estimated to be between $17 billion and $29 billion per year.[6] Over one-half of these expenditures are for direct health care costs, such as longer stay or treatment. Thus, the health and economic burden of medication errors, adverse drug reactions, and therapy failures occurring throughout the health care continuum remain significant.[7]

In summary, the indications for carrying out therapeutic/safety drug monitoring are limited not only to avoiding toxicity of chronic medications, but also to monitoring patient compliance, adjusting drug dose to the patients' individual need, assessing the control of the disease, and monitoring and detecting drug interactions.

Aim of the study

There is a dearth of literature that assessed the completion of therapeutic/safety monitoring tests of chronic medications in the Middle East and North Africa region, and particularly in the Lebanese community. Thus, the primary objective of this study was to evaluate the completion of therapeutic/safety monitoring tests recommended for patients on chronic medication therapies in the Lebanese community setting.

Ethical approval

The study was approved by the Lebanese American University's Institutional Review Board. A written informed consent was not needed for this type of protocol approval; however, every participant gave his/her oral informed consent when approached prior to collection of information. The purpose of the study was elucidated to all patients for their approval before participation.

Methods

Study setting

The study was conducted in two community pharmacies affiliated with the School of Pharmacy at the Lebanese American University, located in the Beirut area. Pharmacies were selected on the basis of their ability to attract sufficient numbers and variety of patients, a good record of professionalism and care toward patients, and their ability to protect patient privacy and confidentiality.

Medication selection

The study group developed a list of chronic medications requiring therapeutic/safety monitoring parameters (Table 1). This list of medications was expanded after an extensive review of monitoring recommendations from respective up-to-date clinical guidelines, lists of medications that have been issued black box warnings for monitoring, and the most current information, at the time, from the US Food and Drug Administration (FDA) website.[8–26]

The medications that required therapeutic/safety monitoring tests included: acenocoumarol, amiodarone, antiepileptics (carbamazepine, phenytoin, and valproic acid), oral antidiabetics, oral antifungals, antihypertensives, bisphosphonates, digoxin, immunosuppressants, isotretinoin, lithium, statins, and thyroid replacement therapy.

In a few cases where the frequency of therapeutic/safety monitoring recommendations was not consistent for a specific medication/class among different authorities, we adopted the longer time interval to assess completion of monitoring tests. For example, the American Society of Hypertension recommends self-monitoring of blood pressure (SMBP) on several days per week for patients in whom antihypertensive medication has been recently started or changed, and less frequently for more-stable patients.[14] The New York City Department of Health and Mental Hygiene recommends adjusting monitoring-test frequency to complement patient self-management goals, varying from once a day to once a week.[15] Hence, patients were considered completely monitored if they tested their blood pressure (BP) at least once weekly. It is of interest to highlight that warfarin is not available on the Lebanese market. Its use is substituted with acenocoumarol. The monitoring requirement for both is the same.[8,9]

Our study design included only the most commonly prescribed anticonvulsant agents in our community setting and did not expand to all antiepileptics. Along the same lines, the study design did not include antipsychotic medications except for lithium, considering that the majority of patients on such therapy benefit from the Lebanese Ministry of Public Health – National programs and therefore complete all therapeutic/safety monitoring tests recommended. Lithium is not covered under the provision of this program.

Table 1 Drugs and laboratory tests monitoring recommendations

Drug class	Monitoring laboratory parameter	Frequency	Comments
Acenocoumarol	INR	48 hours after initial dose	Agence Nationale de Sécurité du Médicament et des Produits de Santé[8]
		Every 2–4 days until stabilization	
		Every 1 month after stabilization	Hirsh et al[9]
Amiodarone	Chest radiograph	Baseline	Siddoway[10]
	Ophthalmologic examinations	Baseline	Goldschlager et al[11]
	Pulmonary function tests	Baseline	
	LFT	Baseline	
		Every 6 months	
	TSH	Baseline	
		Every 6 months	
Antidiabetics, oral	HbA_{1c}	Baseline	American Diabetes Association[12]
		Every 3 months for patients not at goal	Glucophage® package insert[13]
		Every 6 months for patients at goal	
	Renal function[a]	Baseline	
	SMBG	Recommended but not required	
Antihypertensives	SMBP	Once weekly, or more frequently	Pickering[14]
			Bloomberg and Frieden[15]
Bisphosphonates	DXA score	Baseline	Watts et al[16]
		1–2-year interval	
Carbamazepine	LFT	Baseline	National Institute for Health and Clinical Excellence[17]
		Every 6 months	
	CBC	Baseline	Tegretol® package insert[18]
		Every 6 months	
	Urea and electrolytes	Every 6 months	
	Serum drug level	Every 6 months	
Cyclosporine	Renal function	Baseline	Epocrates[19]
		Periodic	Sandimmune® package insert[20]
	Serum drug level	Periodic	
Digoxin	Electrolytes	Periodic (especially if concurrent diuretic)	National Institute for Health and Clinical Excellence[21]
Insulin	SMBG	≥3 times daily	American Diabetes Association[12]
	HbA_{1c}	Baseline	
		Every 3 months for patients not at goal	
		Every 6 months for patients at goal	
Isotretinoin	LFT	Baseline	Goldsmith et al[22]
		Periodic	
	Lipid panel	Baseline	
		Periodic	
	Pregnancy test	For patients of childbearing potential	
Itraconazole	CBC	Baseline	Rodgers and Bassler[23]
		Every 4–6 weeks	
	LFT	Baseline	
		Every 4–6 weeks	
Lithium	Lithium level	Every 3 months	National Institute for Health and Clinical Excellence[17]
	Thyroid function	Every 6 months	
	Renal function	Every 6 months	
	CBC	Only when clinically indicated	
Phenytoin	CBC	Baseline	Dilantin® package insert[24]
		Periodic	
	LFT	Baseline	
		Periodic	
	Serum drug level	If evidence of ineffectiveness, poor adherence, or toxicity	

(*Continued*)

Table 1 (*Continued*)

Drug class	Monitoring laboratory parameter	Frequency	Comments
Statins	CPK	Baseline	Pasternak et al[25]
	LFT	Baseline	
		At 12 weeks[b]	
		Yearly[b]	
	Lipid panel	Baseline	
		Periodic	
Terbinafine	CBC	Baseline	Rodgers and Bassler[23]
		Every 4–6 weeks	
	LFT	Baseline	
		Every 4–6 weeks	
Thyroid replacement therapy (levothyroxine, triiodothyronine)	TSH/T4	Baseline	Demers and Spencer[26]
		6–8 weeks after initiation of therapy and change of dose	
		Yearly when stabilized	
Valproic acid	CBC	Baseline	National Institute for Health and Clinical Excellence[17]
		Every 6 months	
	LFT	Baseline	
		Every 6 months	
	Serum drug level	If evidence of ineffectiveness, poor adherence, or toxicity	

Notes: [a]Renal function monitoring is only required with metformin therapy and not with all oral antidiabetics. [b]The US Food and Drug Administration revised its labeling information on statins in February 2012 to recommend liver function testing only prior to initiation of statin therapy and to repeat such testing only when clinically indicated, rather than periodically thereafter.

Abbreviations: CBC, complete blood count; CPK, creatine phosphokinase; DXA, dual-energy X-ray absorptiometry; HbA_{1C}, glycosylated hemoglobin; INR, international normalized ratio; LFT, liver function tests; SMBG, self-monitoring of blood glucose; SMBP, self-monitoring of blood pressure; T4, thyroxine; TSH, thyroid stimulating hormone.

For reporting purposes, we defined 1) a patient with "Complete Monitoring Tests" (CoMT) as a patient who completed all recommended therapeutic/safety monitoring tests specific to their drug therapy, 2) a patient with "Partial Monitoring Tests" (PaMT) as a patient who completed some, but not all, of the recommended therapeutic/safety monitoring tests, and 3) a patient with "No Monitoring Tests" (NoMT) as a patient who did not complete any of the recommended therapeutic/safety monitoring tests. Those three terminologies have been used throughout to identify the completion rate of tests within a single disease condition, and per patient overall. Classification of the patients was completed and verified by two researchers to ensure its accuracy and transparency. These data were double checked and validated by an external reviewer.

Selection of participants

Participants were selected from all patients aged 18 years or older who visited the study site(s) from October 1–31, 2012. Participants were chosen if they received one or more of the chronic medications mentioned previously and agreed to participate in the study.

Questionnaire administration

Eligible patients were voluntarily subjected to a questionnaire designed to evaluate the completion rates of the therapeutic/safety monitoring tests indicated. The questionnaire collected information related to patient demographics, physician specialty, frequency of patient clinic visits, dates and frequency of monitoring tests, and time of treatment initiation. Licensed pharmacists were trained to interview the patients and collect the data.

Statistics

Data were collected and then entered into Microsoft Office Excel spreadsheet, and descriptive statistics were used to calculate and report the frequency distribution of patients maintained on each medication/medication class, frequency of patients' clinic visits, and percentage of CoMT, PaMT, and NoMT.

Results

Study medications

The detailed list of the study medications, as well as their recommended therapeutic/safety monitoring parameters and respective frequencies, are listed in Table 1.

Patient demographics

Of 468 patients approached, 72 patients rejected participation due to time constraints and 112 patients did not meet

the inclusion criteria (younger than 18 years of age; not receiving one or more of the chronic medications mentioned previously), giving a total response rate of 61%. Accordingly, a total of 284 outpatients were included in the analysis, and the majority (n=193; 68%) were of age below 65 years. Such age distribution is aligned with the US Central Intelligence Agency's world factbook data.[27]

Patients surveyed were using antihypertensives (n=179; 63%), statins (n=106; 37%), oral antidiabetics (n=72; 25%), thyroid replacement therapy and bisphosphonates (n=24; 9% each), insulin (n=19; 7%), antiepileptics, oral antifungals, and acenocoumarol (n=12; 4% each), and other medications (n=9; 3%). Among those, 139 patients (49%) were recorded to be on two or more medication classes, while no patient was reported to be on digoxin, fibrates, and phenytoin therapy. Detailed results are shown in Table 2.

The majority of drug prescribers were cardiologists (n=144; 51%), followed by endocrinologists (n=94; 33%) and general practitioners (n=29; 10%). It is interesting to note that 14% (n=41) of patients had multiple prescribers, with 11% (n=31) having had two specialist prescribers and 4% (n=10) having had both a specialist and general practitioner. Around 3% (n=9) of patients reported to have had their drug dispensed by pharmacists without physician consultation.

Thirty-two percent of the patients (n=90) did not visit their physician for more than a year, whereas 16% (n=45) visited their physician every 3 months. The clinic visit interval was reported as "not applicable" for patients whose medications were dispensed by pharmacists without physician consultation (n=9; 3%).

Table 2 Patient characteristics

Characteristics	n (%)
Age	
20–29 years	17 (6)
30–39 years	7 (3)
40–49 years	29 (11)
50–59 years	89 (31)
60–65 years	51 (18)
>65 years	91 (32)
Sex	
Male	143 (50)
Female	141 (50)
Medications[a]	
Antihypertensives	179 (63)
Statins	106 (37)
Oral antidiabetics	72 (25)
Thyroid replacement therapy	24 (9)
Bisphosphonates	24 (9)
Insulin	19 (7)
Carbamazepine and valproic acid	12 (4)
Oral antifungals	12 (4)
Acenocoumarol	12 (4)
Other drugs (immunosuppressants, lithium, and isotretinoin)	9 (3)
Prescribers' specialty[b]	
Cardiologists	144 (51)
Endocrinologists	94 (33)
General practitioners	29 (10)
Orthopedists	16 (6)
Neurologists	13 (5)
Pharmacists	9 (3)
Oncologists	6 (2)
Residents/interns	4 (1)
Others (eg, psychiatry, dermatology)	11 (4)
Clinic visit frequency	
More frequently than every 3 months	17 (6)
Every 3 months	45 (16)
Every 6 months	72 (25)
Every 1 year	51 (18)
Less frequently than every year	90 (32)
Not applicable	9 (3)

Notes: [a]139 patients (48.9%) were recorded to be on two or more drug classes. [b]14.4% of patients have multiple prescribers.

Chronic medications monitoring results

The majority of patients (65%; n=185) were found to be PaMT for all the medications they were taking, while 27% (n=76) were CoMT and 8% (n=23) did not complete any of the recommended monitoring tests (NoMT) (Tables 3 and 4).

Among patients with incomplete therapeutic/safety monitoring (PaMT and NoMT combined; n=208), 57% (n=119) had two or more medical conditions, 47% (n=97) visited their physicians on a yearly basis or less frequently, and 31% (n=64) received prescriptions and follow-ups from nonspecialist prescribers. Indeed, incomplete monitoring was reported by 80% (n=64) of the patients who had received their prescriptions and follow-ups from nonspecialist prescribers. Around 42.5% of patients (n=76) taking antihypertensive medications were classified as CoMT, as their BP was monitored at a once-weekly interval or more frequently (Table 2). Another 42.5% (n=76) were found to be PaMT since they monitored their BP less frequently than every week and the remaining 15% (n=27) did not complete any SMBP (NoMT).

In contrast, 17% (n=18) of patients on statin therapy were reported to be CoMT, while 61% (n=65) and 22% (n=23) were PaMT and NoMT, respectively.

Thirty-five percent of patients (n=25) taking oral antidiabetics were classified as CoMT as they reported completing a baseline and periodic glycosylated hemoglobin (HbA_{1c}) test every 6 months or more frequently. Around 63% (n=45) were

Table 3 Therapeutic and safety monitoring test rates

	CoMT n (%)	PaMT n (%)	NoMT n (%)
Antihypertensives	76 (43)	76 (42)	27 (15)
Statins	18 (17)	65 (61)	23 (22)
Oral antidiabetics	25 (35)	45 (63)	2 (3)
Thyroid replacement therapy	22 (92)	2 (8)	0
Bisphosphonates	11 (46)	12 (50)	1 (4)
Insulin	12 (63)	7 (37)	0
Oral antifungals	3 (25)	3 (25)	6 (50)
Acenocoumarol	12 (100)	0	0
Carbamazepine	0	8 (89)	1 (11)
Immunosuppressants	1 (25)	3 (75)	0
Lithium	0	4 (100)	0
Valproic acid	3 (100)	0	0
Isotretinoin	0	1 (100)	0

Abbreviations: CoMT, patient with complete monitoring test; NoMT, patient with no monitoring test; PaMT, patient with partial monitoring test.

considered PaMT because they missed the baseline HbA_{1c} test or performed it less frequently than recommended, while only two patients were NoMT.

Interestingly, insulin therapy patients had higher rates of monitoring-test completion overall, as 63% (n=12) were CoMT. These patients reported completing a baseline and periodic HbA_{1c} test at least every 6 months, and self-monitoring of blood glucose (SMBG) at least three times daily. A proportion of insulin therapy patients (37%; n=7) were PaMT because they either missed the periodic HbA_{1c} test or completed the SMBG less frequently than recommended.

On the contrary, the majority of patients taking thyroid supplement (92%; n=22) were CoMT, as they reported completing a thyroid stimulating hormone/thyroxine test at baseline and yearly thereafter, while only 8% (n=2) were PaMT because they performed the test less frequently.

Forty-six percent (n=11) of patients on bisphosphonate therapy were classified as CoMT as they reported completing a dual-energy X-ray absorptiometry test at baseline and at least every 2 years thereafter. Fifty percent (n=12) were reported as PaMT because they missed the periodic dual-energy X-ray absorptiometry test or performed it less frequently, while only one patient did not undergo any monitoring tests at all (NoMT). It is noteworthy to mention that, among those who had incomplete monitoring tests (PaMT and NoMT), 62% (8 out of 13 patients) were visiting their physicians less frequently than once a year.

Among patients taking oral antifungal therapy, 25% (n=3) were reported to be CoMT, 25% (n=3) were PaMT, and 50% (n=6) did not complete any monitoring tests at all (NoMT). Fifty percent (n=6) of patients who took antifungal therapy were dispensed the medication from the pharmacist without a physician's prescription.

Interestingly, all patients taking acenocoumarol (n=12) were CoMT, as they completed the international normalized ratio test 48 hours after the initial dose, every 2–4 days until stabilization, and monthly thereafter.

Discussion

In our study, 185 patients partially completed their monitoring tests, whereas only 76 patients were fully monitored. The present results were compared to those from other

Table 4 Therapeutic and safety monitoring tests completion

Drug class	Monitoring parameter	Frequency	Test done n (%)	Test not done n (%)
Antidiabetics, oral	HbA_{1c}	Baseline	64 (89)	8 (11)
		Every 6 months, or more frequently	46 (64)	26 (36)
	Renal function[a]	Baseline	42 (58)	30 (42)
	SMBG	Recommended but not required	60 (83)	12 (17)
Antihypertensives	SMBP	Once weekly, or more frequently	76 (42)	103 (57)
Bisphosphonates	DXA score	Baseline	23 (96)	1 (4)
		1–2-year interval	11 (46)	12 (54)
Insulin	SMBG	≥3 times daily	15 (79)	4 (21)
	HbA_{1c}	Baseline	16 (84)	3 (16)
		Every 6 months, or more frequently	16 (84)	3 (16)
Statins	CPK	Baseline	27 (25)	79 (75)
	LFT	Baseline	68 (64)	38 (36)
		Yearly	69 (65)	37 (35)
Thyroid replacement therapy (levothyroxine, triiodothyronine)	TSH/T4	Baseline	24 (100)	0
		Yearly when stabilized	23 (96)	1 (4)

Note: [a]Renal function monitoring is only required with metformin therapy and not with all oral antidiabetics.
Abbreviations: CPK, creatine phosphokinase; DXA, dual-energy X-ray absorptiometry; HbA_{1c}, glycosylated hemoglobin; LFT, liver function tests; SMBG, self-monitoring of blood glucose; SMBP, self-monitoring of blood pressure; T4, thyroxine; TSH, thyroid stimulating hormone.

studies[28–32] that assessed completion of recommended monitoring tests.

In fact, 85% (n=152) of the hypertensive patients in our study group reported SMBP, 42% (n=76) did it at least once weekly, and 49% (n=88) did self-monitoring at least once monthly. These results are similar to those obtained in a telephone survey among patients with hypertension, where 70% of patients were found to practice self-measurement.[28] Furthermore, in a multicenter survey from six outpatient hypertension clinics in Italy, 75% of the participants performed home SMBP measurements at least once monthly.[29] However, this is in contrast to another cross-sectional survey, where only 31% of patients with hypertension registered with primary care practices in the United Kingdom reported SMBP; of these, 60% self-monitored at least monthly and 13% at least weekly.[30]

Numerous recent guidelines and reviews highlight the importance of SMBP as a means to evaluate therapy, and as a key prognostic factor for cardiovascular risk.[33–38] However, none of these references, and none of the recent guidelines for the management of hypertension,[39–43] have recommended a determined frequency for the SMBP. Twice-daily SMBP has been strongly recommended for patients with resistant hypertension.[35,44] Duplicate twice-daily SMBP has also been recommended only for 7 consecutive days for confirmation of hypertension diagnosis, as complementary to ambulatory BP monitoring. Both of the aforementioned conditions are beyond the scope of this study.[36,37,43]

In our study groups, 35% (n=25) of the diabetic patients on oral medications adhered to the American Diabetes Association guidelines on frequency of HbA_{1c} monitoring tests. These findings are lower than those reported in a study of 193 Type II diabetic patients in a rural family, where 51% of the study population adhered to these guidelines.[31] This could be primarily due to the fact that 62% (n=29) of the diabetic patients who had incomplete monitoring tests (PaMT and NoMT combined) in our study visited their physician once yearly or less frequently.

Similarly, 64% (n=68) and 25% (n=27) of our patient population receiving statins completed their baseline liver function tests and creatine phosphokinase tests, respectively. From a different perspective, 65% (n=69) of patients who received statin therapy had periodic liver function tests measured at least once during the follow-up. These results closely align with those reported by Tragni et al[32] where the prevalence of safety laboratory-monitoring tests necessary for statin therapy, prescribed by Italian general practitioners, was 8.5% and 37.8% for the creatine phosphokinase test, 50.9% and 60.3% for the aspartate aminotransferase test, and 53.9% and 64.4% for the alanine aminotransferase test at baseline and during follow-up, respectively.

It is noteworthy to mention that in our study, completed in 2011, a patient on statin therapy must monitor baseline and yearly liver function tests and baseline creatine phosphokinase to be considered CoMT as per the American College of Cardiology/American Heart Association/National Heart, Lung and Blood Institute 2002 clinical advisory on use and safety of statins.[25] However, the US FDA issued revised labels and new safety warnings for statins in February 2012.[45] The new labels only recommend baseline liver function testing, and to only repeat such testing for clinical indications, rather than periodically thereafter. Hence, routine/periodic monitoring of liver enzymes for statin users is no longer needed.[45] Accordingly, the percentages of CoMT, PaMT, and NoMT participants in our study were recalculated under these new guidelines as follows: 25%, 52% and 22%, respectively.

Our data collected for patients on antiepileptics, immunosuppressants, lithium, and isotretinoin did not have enough power to generate any relevant conclusion or recommendation. Moreover, our results indicate that 3% of patients have had their antifungal drugs dispensed by pharmacists without physician consultation, and for these patients, the clinic-visit interval was reported to be not applicable. Unfortunately, patients in the Lebanese community can acquire most prescription medications, excluding psychotropic drugs, narcotics, cocaine, and other highly addictive substances, without a physician's prescription. This is mainly due to the absence of law application and reinforcement. Although the number of individuals surveyed in this category was small, lack of monitoring of these patients could potentially lead to rare but serious liver toxicity.

Interventions to increase awareness and improve adherence of physicians and patients to the recommended therapeutic/safety monitoring tests are also needed. In fact, adherence to the required monitoring tests is a multifaceted issue that requires cooperation between the patient and health care providers involved. Patients need the knowledge, attitudes, and means to appropriately complete all recommended therapeutic/safety monitoring tests and to sequentially have the behavior to intentionally or nonintentionally adhere to pharmacotherapy.[46] In a study aiming to explore the barriers and facilitators to SMBG in type 2 diabetes patients using insulin, barriers identified included the perception that SMBG was only for insulin titration, fear of needles and pain, cost of test strips and needles, as well as lack of knowledge and self-efficacy.[47]

Similarly, physicians, particularly nonspecialists, need to follow updated and current guidelines in recommending therapeutic/safety monitoring tests, particularly its indicated frequency. They also need to ensure that patients understand the reason and importance for therapeutic/safety drug monitoring.[48] In fact, a study assessing the perception of laboratory monitoring by physicians in practice suggested varying opinions among practitioners for its necessity, especially for medications perceived to be low-risk for adverse effects. They also expressed their inability to track the progress of laboratory tests that they had ordered and recommended for patients.[49]

Several approaches can be adopted to increase patient completion rates for monitoring tests, such as attending patient education programs. In a cross-sectional study carried out in 15,000 patients with diabetes, diabetes education center attendance was associated with improved SMBG (adjusted odds ratio =6.45 [95% confidence interval =5.61–7.42], $P<0.0001$).[50]

Technology developments, such as the use of point-of-care testing medical devices, present increasing opportunities for monitoring to occur outside hospitals or clinics.[51] The use of widely available communications technologies, such as electronic medical record reminders to the prescribing health care professional and automated voice messages to the patient, were also effective in increasing laboratory monitoring when initiating new medications in primary care.[52,53]

Study limitations

This study has the following potential limitations that should be considered.

Firstly, we could not identify whether tests have not been ordered by physicians or whether they were ordered but not performed. Hence, it was not possible to separate physicians' inadequate follow-up from patient nonadherence with recommended tests, nor to identify possible reasons behind the incomplete monitoring tests, such as patients' socioeconomic status.

Many of the patients who were admitted in our study presented with their laboratory tests' results or prescriptions for the next scheduled follow-up visit; however, data collection may still be subject to recall bias, as the study relied on patient recall to determine the completion of some of the therapeutic/safety monitoring tests.

Moreover, it was beyond the scope of our study to assess clinical conditions such as recent initiation of medications, dose adjustments, or achievement of therapeutic goals as judged by clinician's discretion; hence, these situations were not addressed in our questionnaire. This might have implications in the results of some drug classes, particularly antihypertensives and antidiabetics. Consequently, this study assessed monitoring of all antihypertensives, as a class, by the completion of SMBP alone, in an attempt to maintain the objectivity of the data and minimize complexity of the parameters' condition.

To the best knowledge of the authors, the present study is the first to address such a topic in the Lebanese community and in the (Middle East) region. In the absence of national consensus clinical guidelines, the evaluation of the therapeutic/safety monitoring tests in our study participants was benchmarked to international evidence-based guidelines that are recognized in Lebanese practice. This may help to strengthen the external validity of this study.

The authors also believe that this study identified potential risk factors behind incomplete monitoring, which included patients with two or more medical conditions, patients visiting their physicians on a yearly basis or less frequently, and patients receiving their prescriptions from nonspecialist prescribers. Future studies may be needed to identify characteristics associated with patient monitoring rates, and to further examine these risk factors in terms of achieving guideline-recommended monitoring. Furthermore, future studies can also assess the economic and health burden of incomplete therapeutic/safety test monitoring results and its potential impact on health care costs.

Conclusion

Seventy-three percent of the study group were receiving incomplete therapeutic and safety monitoring tests recommended for patients on chronic medications in the Lebanese community. Patients were categorized into completely monitored (27%), partially monitored (65%) or not monitored at all (8%).

While the completion rates of monitoring tests in our study were similar to those obtained from other reports, the present results identified the various types of medications that require therapeutic/safety monitoring tests and their completion rates for each class or type of medication. Patients need to better understand the importance of recommended test monitoring for the safe and effective use of their medications.

Further research is needed to determine the consequent clinical implications. Measures should also be taken to further educate prescribers about medication-safety updates and the importance of completion of the recommended therapeutic and safety monitoring tests.

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Author contributions

Elsy Ramia and Rony Zeenny have equal contribution in this work, and this is based on:

1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content;
3. Final approval of the version to be published; and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Disclosure

The authors report no conflicts of interest in this work. The ideas expressed in this manuscript are those of the authors and in no way represent the position of the Lebanese American University or the School of Pharmacy, Byblos, Lebanon. No sources of funding were used to assist in the preparation of this study.

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