The Egyptian Heart Journal (2014) 66, 35–42

Egyptian Society of Cardiology

The Egyptian Heart Journal

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ORIGINAL ARTICLE

Observational study on patients' compliance with Irbesartan in essential hypertension "I Comply"

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Received 1 October 2012; accepted 25 October 2012
Available online 12 February 2013

KEYWORDS

Hypertension;
Irbesartan;
Compliance;
Angiotensin;
Antihypertensive

Abstract *Objectives:* Observational study to assess essential hypertension patient's compliance on Irbesartan, rationale for prescribing Irbesartan, profile of patient for whom it is prescribed, and assess patient/physician satisfaction.
Methods: Naïve/uncontrolled patients with essential hypertension; for whom physicians decide to prescribe Irbesartan-based-regimen are followed up for 4 months to assess compliance, tolerability, satisfaction, and identify reasons for prescription. Physicians were required to fill a case-report-form and a simple questionnaire to identify patients' characteristics, give reason(s) for prescription, and persistence/non-persistence of patients/physicians. Satisfaction, safety profile, and blood pressure control were also assessed.
Results: Total of 62.1% (n = 3971) of all screened patients (n = 6399, Naïve = 31.04%, uncontrolled = 68.96%) were prescribed an Irbesartan based regimen. Efficacy, safety, and cost; in that ranking order, were the main reasons for prescribing specific antihypertensive agent. By the end of the study, satisfaction for Irbesartan 150 mg, 300 mg, and 300 mg/12.5 mg was 95.6%, 96.8%, and 96.5%, respectively; up from 72.6% general patient satisfaction with their current regimen at screening visit. Physicians showed a similar improvement in satisfaction to 96.4%, 97.1%, and 95.8, respectively, up from 27.3% satisfaction with previous regimen. Patient's compliance increased up from 86% at the beginning of the study to a mean of 96.2% by the end of the study.

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Peer review under responsibility of Egyptian Society of Cardiology.

Production and hosting by Elsevier

http://dx.doi.org/10.1016/j.ehj.2012.10.006

Conclusion: A total of 96% ± 0.8 of Irbesartan population were satisfied with their Irbesartan regimen. Reasons for prescribing a specific antihypertensive class were identified as efficacy, safety, and cost. Angiotensin-Receptor-Blockers were the antihypertensive of choice for 68.9% of physicians due to its efficacy (96.5%) and safety (85.9%). The majority (91.49%) of side effects were recorded as being 'mild', no serious adverse events were recorded.

1. Introduction

Hypertension is one of the major cardiovascular diseases worldwide; in 2000; 26% of the adult population had hypertension.[1] It has been estimated that hypertension is responsible for 4% of the global burden of disease.[2] It is one of the major causes of morbidity and mortality in both developing and developed regions, particularly cardiovascular and renal diseases.[3] Hypertensive heart disease, is the largest single contributor among the remaining causes of cardiovascular disease (CVD) morbidity & mortality,[4] accounting for as much as 11% in the Middle East. And, out of the 17 countries of the middle East & North Africa (MENA) region, which represents 6% (306 million people), of the whole world's population, Egypt alone is the most populous country of the region , having 24% of the total inhabitants of the region.[5]

According to the National Health and Nutrition Examination Surveys (NHANES) III study in the United States, less than a quarter of hypertensive patients have their blood pressure (BP) in good control (under 140/90 mmHg).[6] Hypertension is also a major health problem affecting more than 20% of the Canadian population.[7] It has been estimated that in Canada, only 16% of hypertensive patients are controlled, 23% are treated but not controlled, 19% are not treated and 42% are unaware of their condition.[8] In Egypt, a National Hypertension Project implemented in the 90s showed that Hypertension is affecting more than 26% of population above 25 years, only 8% of hypertensive patients are controlled, 16% are treated but not controlled, 14% are not treated with medications and 63% are unaware of their condition.[9]

One of the major factors in this poor control is the lack of patient adherence to treatment.[10] Overall hypertensive patients are estimated to take only 53–70% of the medication prescribed for them.[11–13] Furthermore, noncompliance, has been reported to be one of the main causes for refractory hypertension.[14]

In 1999 the total cost of treating hypertension in the United States (US) was estimated to be $33.3 billion, including $8.8 billion for lost productivity resulting from hypertension-related morbidity and mortality.[9]

Numerous studies have examined treatment persistence in hypertension. Some of these predated the introduction of newer drug classes.[15–20] Most guidelines suggest that initial combination treatment should include a thiazide diuretic and either an angiotensin receptor blocker (ARB), an angiotensin-converting enzyme inhibitor (ACE-I), a calcium channel blocker (CCB), or a beta-blocker.[6,21] Actually Sever PS and Messerli FH,[22] in their latest article review, published in Oct 2011, in the European Heart Journal, under the title of Hypertension management 2011: optimal combination therapy, they enlist, ARB + diuretics combination as the PREFERED one, as the activation of RAAS system due to intravascular volume depletion by diuretics, is mitigated by the addition of RAAS blocker.[21] In addition, for patients with chronic renal disease or type 2 diabetes, combinations including an ARB or ACE-I are recommended[23] however, with caution due to the possible combined hyperkalemic effect of both agents, in this particular subset of patients. The usefulness of fixed dose (FD) ARB/hydrochlorothiazide (HCTZ) combinations in effectively treating hypertension, including difficult-to-treat and severely hypertensive patients, has been demonstrated for several different ARBs.[16,24] Promising results have also been reported for FD combinations regarding improvements in clinical endpoints, as well as achieving BP targets. In addition, combining HCTZ with an ARB attenuates the hypokalemic and fasting glucose-modifying effects of HCTZ. Also, there is evidence to suggest that FD combinations are also associated with better compliance.[21]

Irbesartan has no active metabolite, and a terminal half-life of 11–15 h, accounting for its single daily use, potent, angiotensin receptor 1 (AT1) receptor antagonist, with high selectivity for the AT1 receptor subtype. Results of recent clinical studies show that irbesartan safely and effectively lowers BP within 1 week in patients with mild-to moderate hypertension.[6,24,25]

This study was designed with the main objective of evaluating both; compliance in patients, and persistence of both patients and physicians to Irbesartan therapy. We looked at the general acceptance of the Irbesartan therapy among patients and physicians, and examined the relationship between satisfaction and compliance as a major factor in determining persistence, and eventually control of BP.

2. Subjects and methods

2.1. Study design

This national, multicenter, prospective product registry conducted in Egypt, in around 220 sites, comprised an initial screening visit where 6399 patients with essential hypertension, either newly discovered or uncontrolled on current regimen were screened for compliance, satisfaction with their current antihypertensive regimen, and main reasons for dissatisfaction. Furthermore, the reason for prescribing a specific antihypertensive drug by physicians was documented. Only patients for whom physicians decided, to prescribe an Irbesartan-based regimen (IBR) (3971 patients, 62.05%), were followed up for four months for their compliance and tolerability to prescribed regimen. At the End of study (EOS), all participating physicians were asked to fill a two page case report form (CRF) to point out the basic characteristics of the individual patient profile, the reason behind the choice of the antihypertensive regimen, and a questionnaire to assess the extent and reasons for persistence or non persistence on therapy. BP was documented at screening visit and at the EOS. Patient and physician satisfaction with the Irbesartan therapy was also documented.