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Economic Impact of Rheumatic Diseases

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1. Introduction

The prevalence and incidence of rheumatic diseases (RD) have been growing over the last two decades, related to the timely and accurate diagnosis, affecting in two ways the Health Systems (HS) and society, on one hand to early detection can prevent further functional compromise and sequels; and second, a greater cost in detection, approach, monitoring and treatment that ultimately impact on the prevention of functional decline of patients who suffer it.

The substantial increase in costs of health care service, the growing demand of these services, the increase of users without contributing to its financing and the latest technological advances in medical science have strong implications for the maintenance and provision of services, as well as increase the costs in this sector, creating changes in demand; it makes imperative the economic evaluation of interventions carried out in this social service.

Moreover, the approach to health has evolved significantly and nowadays, not only is essential to consider the evaluation of the patient to describe their evolution but also analyze which health technologies have the best cost/effect in order to achieve that decision makers to choose the most optimal according to the HS and typical econometric conditions of each nation.

In this chapter, will be presented a current view of how to measure the economic and functional impact of RD, the main results in the field and how these concepts are applied from Colombian perspective. Obviously given the relevance of these health technologies, we will approach very much to biological therapies and diseases in which are often used, predominantly Rheumatoid Arthritis (RA)

2. Basic concepts of economic evaluation

The pharmacoeconomics is defined as the description and analysis of how much the drug therapy costs to healthcare systems and society (1). It covers all areas considered like aspects of drugs such as the impact on society, the pharmaceutical industry, pharmacies, national budgets, and so on. It starts with the economic evaluation of health technologies, whose aim is the selection of options with a more positive health impact for appropriate decision-making. This evaluation process is done through comparisons of different alternatives to determine which of them offer the best cost-effect relation; but sometimes this comparison is

not necessarily performed against other drugs, but rather against alternative therapies (surgical or prophylactic).
Additionally, the ethical component is a factor to consider when making decisions, because frequently, the fact of paying more for more effective therapy is not necessary, since in the future, these resources will be able to used for the benefit of many patients and perhaps, more favourable conditions that guarantee the success of treatment (fair distribution of scant resources). In this respect, the physician's role is critical because it must balance between the effectiveness of treatment and its cost associated, to decide the best treatment option that is given to the patient, without neglecting the economic concepts that derive from their decision.
Health authorities are also actors, they have to guarantee a standard approach in the economic evaluation process; an unified evaluation ensures reliable outcomes and therefore their proper utilization and optimal use of resources, always based on the ratio of total healthcare costs (not just the drug itself). Likewise, it should develop a critical and systematic evaluation of these research results to ensure transparency and comparability (audit system).
The pharmaceutical industry also plays a important role, it discovers new products also carries out maintenance or exit of drugs already known, but new drugs must ensure at least a better effectiveness in terms of variables more objective, that truly justifying its use and additional payment; likewise, it has to be interested in promote standard strategies for economic evaluations of drug and integrate them into their research processes, a situation that would help the results of the other components (governments, insurance companies and health authorities).

3. Methods of drug evaluation

This method follows the footsteps of any clinical research in the medical field that is to create a strategic plan for attaining the goals of the study, the proper patient selection, the patients' assessment which they will be submitted, and obviously the objects of measurement.
Measuring the effects of compared options should be clearly established and to it should be led ideally by research with the aim of getting a suitable and clear conclusion, as well as obtaining a high-quality research.
The measurement and identification of costs is made through prospective and / or retrospective studies. The most frequently used are the direct costs (medical and non medical), and indirect costs, which are related to disabilities generated by illness itself, and the intangible costs given by sensations in the patients, it derivated from disease and that are hardly measurable, mainly chronic diseases and psychiatric disorders.
The types of economic evaluation depend on the manner how to measure the effects of a particular drug: cost-benefit; where costs and effects are measured by monetary units and they are compared between different alternatives. In cost-effectiveness, the effects are measured by typical clinical units: (deaths prevented, reduced levels, etc). In cost-utility, the effects are measured through a component that integrates life quality and quantity of life years (quality-adjusted life year -QUALYs). Finally, the cost-minimization compares directly the costs, and it prefers the lower value, but care must be taken when interpreting its results.
The QALY is an indicator that combines survival with quality of life. The measure of quality of life is not standardized and often varies from study to study depending on the disease

and the author preferences about treatment and evaluation. To calculate a QALY, it has to multiply the length of the state of health (in years) by a factor representing the quality ("utility") of this condition. The value of quality (utility) for the economic evaluation usually derived from an index of health, whose scale value 1 equals perfect health and a value of 0 to death (it is also possible to quantify health states with a negative value ("worse than death").

The analysis of results is the last step before making conclusions. There are two types of them: the incremental analysis, where the costs of alternatives (difference) are divided by the differences in effectiveness; and sensitivity analysis, which speculates some assumptions on the values of the most relevant variables, hoping that it does not change the results strikingly.

4. Evaluation of rheumatic diseases

In a series of research from the 1960s, Dorothy Rice et al (2-5) have provided estimates of the economic impact of musculoskeletal diseases, including all forms of arthritis. These estimates were made using constant methods based on the system of national health accounts. The economic burden of musculoskeletal disorders has increased slightly more than half of 1% of Gross Domestic Product (GDP) in the 1960s to just under 3% in 1995 (3% corresponds to $ 215.000). The national data Arthritis Working Group has concluded that about half of this increase was result of an increase in the prevalence of musculoskeletal diseases, due to aging population and higher costs per case, while the other half is due to better accounting methods in each data sources used by Rice and colleagues in their studies.

5. Costs of specific conditions

There have been made many studies on the costs of RA and the results are highly consistent in showing that the direct costs in the U.S. are between $ 4,000 and $ 6,000 a year (average: $5,425), but with the use of biological therapy increases these costs up to $ 19,000 and $ 25,000 / year, while the indirect costs associated with lost wages in the U.S. are between $ 9,000 and $ 24,000 one year (average U.S. $ 9,744) (6.7). In Colombia was made recently a case assessment to calculate the direct costs of early RA during attention first-year and categorized by the severity of the disease, being the average of $1,689, $ 1,805 and $ 23,441 to mild, moderate and severe forms of this disease respectively, and with well differential ranges, especially in the severe form, which allowed the use of anti-TNF therapy (costs in U.S. dollars for 2007) (8).

Hospital admissions represent between 40 and 60% of total direct costs in one year, although only 10% of hospital admissions for people with RA reported their hospital status (9).

Under similar conditions of other variables, the indirect costs of RA are likely to increase in coming decades as women continue to make progress in achieving equality in the labour market. Nowadays, women still have the lowest labour force participation, work fewer hours and lower wages per hour, even after better training and work experience. Moreover, the introduction of biological agents and cyclooxygenase-2 inhibitors has resulted in a dramatic increase of RA direct cost.

Therefore, increasing equality between genders is likely to result in an increase of RA indirect costs, while the development of new agents has led to this increase in direct cost

side. On the other hand, while indirect costs are likely to increase in the short term, the advent of biological agents can reduce both direct and indirect costs in the longer term. Randomized clinical trials provide evidence that these agents reduce functional decline (10-13).

The evidence regarding the costs of specific rheumatic diseases is limited. Sutcliffe et al (14) reviewed the literature on the costs of Systemic Lupus Erythematosus (SLE) and reported that the direct costs of this disease were £ 2,613, while indirect costs were £ 5,299, roughly the same proportion as in the AR, it would not surprise, considering that both conditions exist in similar age.

For Colombia, Quintana et al (15) conducted a research to determine the health care costs for the first year of treatment for lupus nephritis (LN). They found a cost of U.S. $ 1,160 for the LN type I and II, the type III and V share the same costs of U.S. $ 3,498 using EURO-LUPUS protocol for induction and maintenance with azathioprine (AZA). In case of use of mycophenolate (MMF), the costs rise to U.S. $ 13,646 for LN type III and U.S. $ 14,161 for the LN type V. In type IV, the cost is U.S. $ 3,499 when using EURO-LUPUS protocol and maintenance with AZA; if it uses MMF for induction and maintenance, the costs amount to U.S. $ 14,163.

In studies of the costs of Ankylosing Spondylitis (AS), the direct costs range from € 1,309 and € 2,686, while indirect costs ranged from € 2,517 up to € 8,862. Maetzel et al (16) summarized the literature on the costs of back pain and they concluded that the costs of this disease were comparable to those associated with heart disease, depression, diabetes, and headaches; most them due to indirect costs. By contrast, in studies of osteoarthritis (OA), this usually affects those who are near or beyond retirement age. Gabriel et al (17, 18) reported that direct costs in USA are $ 1,388, and were 3 times higher than indirect costs ($ 824). Similarly, despite juvenile rheumatoid arthritis has a much higher cost because it affects the population that is not in working age, the direct costs in USA are $ 7,905, nearly 4 times higher than other costs of the same disease (primarily lost wages for parents) (19).

6. Economic evaluations of the rheumatic diseases

As it was mentioned at the beginning of the chapter, it will examine practical aspects of economic evaluations related to RD; therefore it reviews Cost-Effectiveness Analysis (CEA) associated with these diseases, in order to know what the current position and parallel, the situation in our environment.

Independently of the disease, comparing the results of the CEA is difficult due to differences in lifetime horizons, outcomes measurement, treatment sequences, and the perspective taken in estimating costs. Another limitation is that any of the clinical trials used in the CEA included an instrument based on utility to calculate the QALY. Thus, it is necessary new standards to make disease-specific functional scales or measures of Health-Related Quality of life (HRQL), with the purpose of obtaining utility scales. In addition, each CEA uses different utility scores, which has shown an influence on outcomes RA studies from CEA (20). Regardless of this, when is used the monotherapy with Infliximab (INF), Etanercept (ETN) and Adalimumab (ADA), even when some of these are used together with Metotrexate (MTX), they are well tolerated and lead to improvements in HRQL. However, caution is needed because the treatment with biologics can result in adverse effects such as

infections (especially tuberculosis reactivation, although a proper examination can reduce this risk).

For synthetic DMARDs in early RA, it is assumed they are profitable because of its low cost, although published data are limited. There are some CEA that have been carried out to Methotrexate (MTX) (21, 22), Sulfasalazine (SSZ) (21) and Leflunomide (LEF) (23). LEF appears to be cost-effective compared to SSZ (24).

Comparing the efficacy of LEF and MTX, the results of randomized controlled trials (RCTs) (25, 26) are not consistent, which consequently is reflected in the models of this CEA (24). For biological therapy in early RA as the first line of treatment has not been proven to be cost-effectiveness (22).

For ETN monotherapy, during an Indefinite Time Horizon (ITH), Brennan (27) reported an improvement of 1.66 QALY; Jobanputra et al (28) reported an improvement in 0.214; and Tanno et al (29) reported a gain of 2.56 QALY. For combined therapy, ETN + MTX results in a greater increase of 0.37 QALY (5 years) (30). The INF plus MTX increased QALY in 0.34 (ITH) (31), 0.26 (ITH) (32) and 2.98 (10 years) (33). The ADA plus MTX resulted in 2.3 QALY gained (ITH) (34). In terms of incremental cost-effectiveness ratio (ICER), Kobelt (35) found that ETN or INF produced a ratio of $ 96,166 per QALY gained. Studies with long time horizons provide better results. The ICER for the ETN monotherapy ranged between $ 21,000 to $ 32,000 for ITH per QALY (27, 29). Combined therapy with INF plus MTX resulted in an ICER of $ 30,500 to $ 46,000 (31, 33). From the Canadian perspective, Coyle et al (36), reported an ICER of $ 99,305 per QALY (5 years, in a directly way) acquired for therapy with INF combined.

In a recent Colombian study, Quintana et al (37) conducted a CEA where they found that in a time horizon of 2 years, the effectiveness of ETN, ADA and INF is 1.4689, 1.4627 and 1.4340 QALY respectively, versus net costs in Colombian Pesos (COP) of $ 77'938.000, $ 81’975.000 and $ 89'598.000, respectively. ETN dominates over ADA or INF with a cost-effectiveness rate of $ 53'056.723/QALY versus ADA: $ 56'042.654/QALY and INF: $ 62'479.625/QALY. The univariate sensitivity analysis, showed sensitivity of outcomes, mainly to the reduction in the cost / month for the drugs tested.

The Abatacept (ABA) has recently been investigated, this results suggested that is cost-effective for moderate to severe RA after failure to MTX; based on data from the AIM study (38), resulting in $ 47,910 per QALY gained over 10 years and $ 43,041 to ITH.

When failures after one or more anti-TNF are analyzed, Rituximab (RTX) has been profitable (39), this based on data modeling of the REFLEX study. The RTX resulted in QALY gained of 0.526 years. The ICER based on total direct medical cost was £ 11,601, and the addition of RTX, without sequential use of biologics, it generates an ICER of £ 14,690. In this onset, the ABA has also been profitable (40) (the models were based on data from ATTAIN trials); although initially have been rejected by the National Institute for Clinical Excellence (NICE), because it exceeded the threshold of £ 30,000. So far, there are not comparative randomized data head to head of RTX and ABA available. In a summary report, ABA is postulated to be more profitable than RTX (40) in a model derived from AIM and REFLEX.

The cost-effectiveness of anti-TNF therapy on health resources depends on two factors. First, research reviewed, (only those with long time horizons (ITH)) they found that treatments have ICER lower than $ 50,000. However, by definition, a long-term analysis is based on hypotheses for extrapolating the effect of treatment, making it less reliable and

uncertain. Second, reimbursement for treatment with an ICER less than $ 50,000 is only economically viable as long as financial resources do not be diverted into more effectiveness treatments.

A limiting factor common to all CEA of TNF antagonists in RA is the lack of data from long-term randomized studies. As such, researchers must combine data from short-term efficacy with the cohort of long-term observation. This raises many problems such as how to combine data from different sources, to predict the long-term results and alteration of the model after discontinuation of treatment in a biological DMARD. This also influences the lack of standardization of schemes for the use of biologics in relation to the start time and its indications at certain stages of the natural history of disease. It is accepted that treatment for RA is likely to be a sequence of treatments. However, treatment may vary among individuals, clinicians and countries.

Despite of most studies have found that ETN and INF have clinical effects on AS, the study of Boonen et al (41) suggests that high costs from these biological therapies may limit their use in patients who have a BASDAI greater than 4. In fact, an ICER of € 118,022 and 189,564 for ETN and INF provides preliminary evidence that biologics will not be a cost-effectiveness option for individuals with AS, unless a longer-term perspective is adopted. The long-term outcome by Kobelt et al (42) (£ 9,600 per QALY; 30 years) and Kobelt et al (43) ($ 37,491 per QALY, 30 years) it would be a poor indicator, since the clinical outcomes short-term of this trial were extrapolated using epidemiological modeling techniques. The update of the results with data records of longitudinal databases will be needed to verify these findings.

The analysis of TNF antagonists in Psoriatic Arthritis found that the ETN in patients who have previously failed other treatments DMARD was encouraging; but limitations in available data make it difficult to draw definitive conclusions (44). The results on short-term cost-effectiveness of ETN compared with cyclosporine or LEF are not worthwhile. It showed an improvement in the ICER after the first year, but this hypothesis was based on the disease progression founded from poor quality databases. Moreover, the estimations of HRQL from the analysis may not reflect true benefits, since these estimates were based single on HAQ-DI and the EQ-5D (function and quality of life scores).

7. Conclusions

Economic evidence suggests that biologics are not cost-effective compared with DMARDs for RA in adults, with a threshold of cost-effectiveness $ 50,000 per QALY. There is mixed evidence of effectiveness in selected populations about their willingness to pay $ 100,000 per QALY. Definitive conclusions are difficult to make, because there is a lack of consistent studies and high quality. Economic evaluations of biological products are hampered by the lack of data on long-term responses and consequences of responses on health in relation to their utilization and productivity of people.

Likewise, economic analyses support the concept of an early onset with traditional DMARD and rapid progress to the next step when there is an inadequate response. In these specific circumstances, the strategy of incorporating biological treatment, considerably more expensive, seems to provide enough effectiveness. Most current guidelines related to the treatment of RA are consistent with the careful use of social and financial resources.

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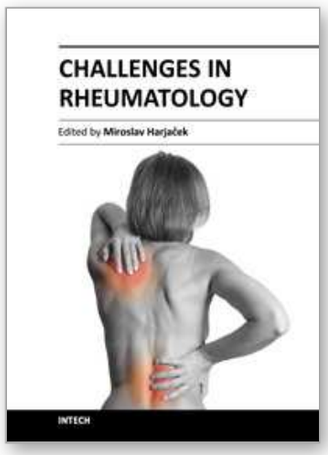

Challenges in Rheumatology

Edited by Dr. Miroslav Harjacek

ISBN 978-953-307-848-9
Hard cover, 190 pages
Publisher InTech
Published online 22, December, 2011
Published in print edition December, 2011

Rheumatology is a subspecialty of medicine that focuses on the biology, cause, diagnosis and the treatment of a variety of musculoskeletal and other systemic diseases. The field of rheumatology is expanding rapidly and several very exciting developments have occurred during the recent years. Firstly, there has been a new dramatic understanding of the nature of inflammation and the possibility of specifically regulating the aberrant immune inflammatory response. Secondly, an understanding of pathogenesis has lead to the development of new, more targeted therapies. Challenges in Rheumatology has assembled an impressive group of international experts who have studied specific aspects of certain rheumatic diseases and have extensive experience either in pathophysiology, or with the in-depth diagnosis and/or management of rheumatic patients. They communicate their knowledge and experience to the reader in chapters that are conveniently organized as pathophysiology, clinical manifestations and diagnosis of selected rheumatic diseases, medical and perioperative orthopedic management, and the economic impact of rheumatic diseases. We hope that this book will help trainees become better physicians and scientists, and that it will help practicing rheumatologists to provide better care, and ultimately, improve the quality of life of our patients.

How to reference

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Gerardo Quintana L. and Paola Coral-Alvarado (2011). Economic Impact of Rheumatic Diseases, Challenges in Rheumatology, Dr. Miroslav Harjacek (Ed.), ISBN: 978-953-307-848-9, InTech, Available from: http://www.intechopen.com/books/challenges-in-rheumatology/economic-impact-of-rheumatic-diseases

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