Biomedical Registry of Follow-up to Clinical Outcomes (RBDC) of a Cohort of Patients with Chronic and Acute Pathologies in Primary Care in 12 Colombian Cities Results of a Real-Life Study

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Abstract

Introduction: Biomedical records are a tool for the generation of evidence. These databases store a large amount of information, which makes it possible to identify the distribution of a pathology and to determine the heterogeneity in the management of patients and to generate investigations based on real-life data that suggest the efficacy of a drug.

Objective: To design, implement and evaluate a biomedical registry of follow-up to medical care and clinical outcomes of patients with general acute and chronic diseases of high frequency among the Colombian population.

Methods: A biomedical record was built (descriptive cohort), in patients diagnosed with chronic and acute pathologies (arterial hypertension, dyslipidemia, osteoarthritis, gastroesophageal reflux disease, venous insufficiency, asthma, pain, rhinitis, vertigo, vaginal discharge syndrome, osteoporosis, intestinal parasitosis, pneumonia and sinusitis) in 12 Colombian cities.

Results: We analyzed 3555 patients. The records included the information filled out on the platform. The median age was 49 years (IQR: 33-63), and sex was distributed as follows: 2,232 women (62.8%) and 1,323 men (37.2%). Regarding adherence to medical follow-up, of the total records (n=6186), 3555 corresponded to associations and 2631 to follow-up appointments, which led us to determine that adherence to medical control was (73.9%).

Conclusion: The findings of this study contribute to strengthening the need for biomedical records, as a source of real-life information. It is relevant to be rigorous in the construction of biomedical records for the generation of evidence, since the quality of the information is associated with the presence and control of biases.

Keywords: • Records •Chronic diseases• Real-life studies• Primary Health Care

Introduction

The medical record is a document where the patient's information is recorded after an interview and evaluation with a health professional, which can be directly linked to a systematized clinical history or an information collection system [1]. Currently, these records are evolving into electronic repositories to guarantee permanent and immediate availability while having remote access, which allows their consultation and analysis for research, auditing, and, in many cases, evaluation of administrative aspects. All of the above aim to improve the processes involved in the health service delivery system [2]. As a result of the implementation of these electronic records during the last decade, the databases of the health systems have become sources of information that allow the follow-up in real life or Real-Life Information (RLI) of the patients, giving step to immediate knowledge that can contribute to decision-making, to improve the health service [3]. The information obtained has allowed for the creation of a close relationship with research since, from these records, hypotheses related to the treatment, clinical outcomes, and prognosis of a patient arise.

At the same time, access to this information must be linked to a series of regulations that guarantee the privacy of clinical information, which is related to ethical considerations aiming to protect the patient from any risk regarding the use of their personal information. For this reason, different international organizations have developed recommendations for these scenarios, as described in the Declaration of Helsinki, the Belmont Report, and the local policies of each country, among others. The World Medical Association (WMA) reaffirmed in 2016 the considerations regarding the management of databases, making explicit the obligation of those responsible for biomedical records and within those that are: authorization of the use of information, confidentiality of data, providing information to the patient about the purpose of the registration or study, the scope of the registration and knowledge of the results. In the same way, it is recommended that before implementing a registry, it be evaluated by an ethics committee to allow its execution following national regulations and international positions [4-7],[8-10]. These databases store a large amount of information that offers different approaches to diagnosis, treatment, and follow-up, which makes it possible to identify heterogeneity in patient management, which at the same time reflects actual clinical practice, in complete contrast to control of clinical trials [11]. This suggests that routine clinical practice sometimes does not resemble the ideal scenarios presented by controlled studies and that it has been widely discussed, since it confronts the distrust on the part of some researchers towards this type of registry-based research with the presence of biases, uncontrolled evidence, and unrealistic settings from real-life studies [12]. Worldwide, medical follow-up records have focused on chronic, orphan, and high-cost pathologies since the interest in evaluating their behavior and the impact on the health system has become an incentive to learn more about these diseases' characteristics [13]. This has not been different in Colombia, given that these registries have been extended to developing countries to identify these patients actively. Many of them are financed by the national government to control medical costs in service provision [14,15].

In this context, it is important to mention that biomedical registries and research based on real-life data have been gaining strength in the face of clinical decision-making, monitoring of drugs on the market, identification of adverse events, drug interactions, unusual presentations of pathologies, diagnosis of rare diseases and the identification of access barriers in medical care that are sometimes not considered in a clinical trial, therefore, the records become a complement that allows knowing in detail the behavior of a disease and its treatment, taking into account the multifactorial aspects related to them [11,16,17].

Due to the above, and to describe the experience of structuring and executing a Biomedical Registry for Clinical Outcomes (RBDC from its initials in Spanish), this project aimed to design, implement and evaluate a biomedical registry for monitoring medical care and clinical outcomes of patients with acute and chronic general diseases of high frequency among

the Colombian population, and who have been treated with drugs from the portfolio of a pharmaceutical company in Colombia.

Materials and Methods

A biomedical record was built (descriptive cohort), in patients diagnosed with chronic and acute pathologies, among which were: arterial hypertension, dyslipidemia, osteoarthritis, gastroesophageal reflux disease, venous insufficiency, asthma, pain, rhinitis, vertigo, vaginal discharge syndrome, osteoporosis, intestinal parasitosis, pneumonia and sinusitis who attended the private consultation of a group of 21 general practitioners, in 12 Colombian cities (Bogotá, San Juan del Cesar, Manizales, Floridablanca, Bucaramanga, Medellín, Florida, Palmira, Cali, Santa Marta, Barranquilla, and Cartagena).

Construction and execution of the biomedical record

This biomedical record was built to know the real-life conditions, in which a group of primary care physicians carried out their daily practice using medications for the pathologies above. The following diagram describes the phases of the construction of the registry Figure 1.

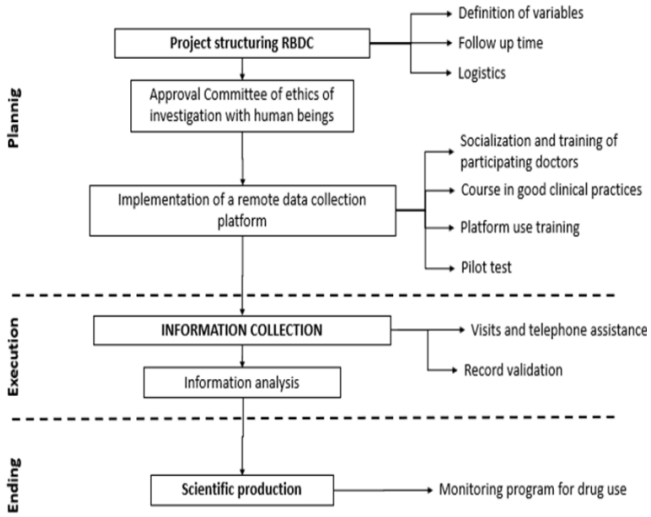

Figure 1. Execution of the biomedical record.

Information collection

The information was collected by filling out an electronic format available on the platform (web page) of the group responsible for data collection, which had remote access from any device within the Biomedical Registry of Clinical Outcomes (RBDC) framework. These registries were part of a clinical outcome monitoring program where each patient, according to their clinical condition and medical criteria, received a pharmacological prescription and made a follow-up appointment to review medical progress as part of regular clinical practice. It is important to mention that the information recorded resulted from daily medical care, and no other activities or interventions were performed.

Sociodemographic, clinical, and diagnostic variables were documented according to the pathology resulting from the physician's assessment. In the same way, variables associated with pharmacological management were analyzed, where the active principle of the medication and its presentation were described. Finally, the relevant clinical outcomes were evaluated in the patients who attended medical check-ups after the start of outpatient treatment.

These variables were evaluated at the enrollment or first consultation and at the control or follow-up after treatment. Adherence to medical control was defined as attendance at medical control for the same reason for the consultation and with the same health professional who prescribed the medication according to medical recommendations. Enrollment was defined as the record of a patient who had been evaluated by the primary care physician for the first time, meeting selection criteria. Similarly, follow-up was defined as when the patient attended the second appointment to evaluate the symptoms presented in the enrollment.

These variables were considered taking into account the characteristics of the RBDC as a follow-up program and hoping to observe the changes concerning what was presented at the time of enrollment Table 1.

Table 1. Pathologies and clinical variables.

Pathology	Clinical variables
Venous insufficiency	Telangiectasias, varicose veins, edema, pigmentation, healed ulcers, and active ulcers
GERD †	Heartburn, reflux, epigastralgia, dysphonia, and nausea
Arterial hypertension	Blood pressure, creatinine, urea nitrogen
Vertigo	Rotational motion sensation, loss of balance, nystagmus, double vision
Vaginal discharge	Presence of vaginal discharge on physical examination, unpleasant odor, itching, irritation, and pain
Asthma	Cough, wheezing, secretions, admission to the emergency room, and number of crises
Rhinitis	Rhinorrhea, nasal itching, sneezing, and nasal obstruction
Dyslipidemia	Total cholesterol, triglycerides, HDL and LDL
Pain	Location, intensity (analog pain scale), edema, erythema, and history of trauma
Osteoarthritis	Location, joint pain, joint edema, stiffness, and pain analog scale
Sinusitis	Rhinorrhea, headache, nasal itching, facial pain, and subsequent discharge
Intestinal parasitosis	Abdominal pain, bloating, and anal itching
Pneumonia	Cough, hoarseness, wheezing, expectoration, chest pain, dyspnea, and fever
Osteoporosis	Densitometry and fragility fracture
GERD † = Gastro Esophageal Reflux Disease	

During the collection, the development group considered the validation of the information relevant for data quality purposes, for which a nursing professional visited all the RBDC doctors to validate the information completed on the remote platform. On this visit, they randomly selected 10% of the records, which were contrasted against the clinical history, which allowed for a reliable record for patient follow-up.

Statistical analysis

From the construction of the database, the result of the consolidation of the completion of the information from the collection platform, a descriptive analysis was carried out. Absolute and relative frequencies were used for the qualitative and nominal variables, and for the quantitative variables, central tendency and dispersion measures according to the data distribution. The analysis of the information was carried out in STATA 15 ®.

As it appeared, the collection was carried out in the context of the usual practice of primary care physicians, according to the methodology, variables outside of daily life were not measured, therefore informed consent was not required. However, the patient was presented with a form for the use of personal data (clinical history) in accordance with the Personal Data Protection Law or Law 1581 of 2012 of Colombia.

This project took into account the international ethical guidelines considered in the Belmont Report and the Declaration of Helsinki, as well as Colombian legislation according to Resolution 8430 of 1993, where this study was classified as "No risk." This project was presented and approved by a human research ethics committee (Hospital San José - FUCS. CEISH 018-2015).

Results

We analyzed 3555 patients who were included in the RBDC. The records included the information filled out on the platform and included the link or

first consultation and follow-up one or first control. As mentioned, some patients had two or three follow-ups or control appointments, depending on the pathology. The median age was 49 (IQR: 33-63), ranging from 18 to 99 years. Sex was distributed as follows: 2,232 women (62.8%) and 1,323 men (37.2%), and age by sex showed the following results: the median age in women was 52 years (IQR: 34-66), and for men, the median was 49 years (IQR: 33-53). Regarding the pathological history, (2545/3555) 71.5% reported having comorbidities. The details of the distribution of sex and age by pathology are presented in Table 2.

Table 2. Distribution of age and sex, according to pathology.

Pathology	Sex		Age group				*Med (IQR)* ‡	*Subtotal*
	Female	*Male*	*≤ 18*	*19- 30*	*31- 60*	*≥ 61*		
Venous insufficiency	251 (79.9)	63 (20.1)	60 (19.1)	95 (30.2)	112 (35.7)	47 (15)	60 (49- 71)	314 (8.8)
GERD †	169 (56.9)	128 (43.1)	36 (12.1)	133 (44.8)	56 (18.9)	72 (24.2)	47 (33- 58)	297 (8.4)
Arterial hypertension	177 (60.4)	116 (39.6)	6 (2)	96 (32.8)	1 (0.6)	190 (64.9)	60 (51- 69)	293 (8.2)
Vertigo	90 (79.6)	23 (20.3)	2 (1.7)	75 (66.3)	0 (0)	36 (31.9)	57 (44-72)	113 (3.2)
Vaginal discharge	176 (100)	-	11 (6.2)	45 (25.6)	118 (67)	2 (1.1)	35(26.5-42.5)	176 (5)
Asthma	75 (59.5)	51 (40.5)	16 (12.7)	44 (34.9)	37 (29.3)	29 (23)	37.5 (16-58)	126 (3.5)
Rhinitis	247 (60.2)	163 (39.7)	41 (10)	166 (40.5)	105 (26.6)	98 (23.9)	26 (9-47)	410 (11.5)
Dyslipidemia	312 (62.3)	189 (37.7)	104 (20.7)	314 (62.7)	4 (0.8)	79 (15.7)	56 (48-67)	501 (14.1)
Pain	354 (46.3)	410 (53.6)	59 (7.7)	401 (52.5)	5 (0.5)	299 (39.1)	45 (33-55)	764 (21.5)
Osteoarthritis	86 (73.5)	31 (26.5)	16 (13.7)	69 (59)	3 (2.5)	29 (24.8)	68 (62-76)	117 (3.3)
Sinusitis	27 (62.8)	16 (37.2)	2 (4.6)	19 (44.2)	1 (2.3)	21 (48.8)	41 (26-55)	43 (1.2)
Intestinal parasitosis	192 (64.8)	104 (35.1)	64 (21.6)	192 (64.8)	17 (5.7)	23 (7.7)	23 (10.5-43)	296 (8.3)
Pneumonia	14 (53.9)	12 (46.1)	4 (15.4)	14 (53.8)	6 (23)	2 (7.7)	62.5 (38-80)	26 (0.7)
Osteoporosis	71 (89.8)	8 (1.1)	14 (17.7)	46 (58.2)	3 (3.8)	16 (20.2)	68 (62-77)	79 (2.2)
Total	2232 (62.8)	1323 (37.2)	350 (9.8)	1009 (28.3)	431 (12.1)	1765 (49.6)	49 (33-63)	3555 (100)

GERD † = Gastro Esophageal Reflux Disease , IQR = Inter Quartile Range

Regarding adherence to medical follow-up, of the total records (n=6186), 3555 corresponded to associations and 2631 to follow-up appointments, for which it was determined that adherence to medical control was (73.9%). The detail by pathology is presented in Figure 2.

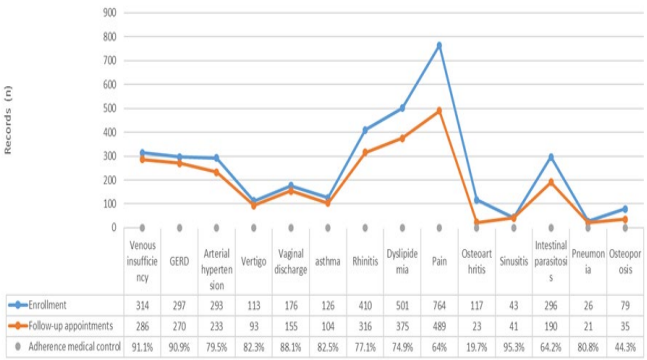

Figure 2. Records (enrollment - follow-up appointments) and adherence to medical control.

In the case of osteoarthritis and osteoporosis, compliance with the follow-up appointments was considered when the patient attended the third control after starting the treatment (enrollment).

Geographical distribution

Enrollments of patients from 18 doctors from 12 cities were included, consolidated into nine departments detailed in Figure 3.

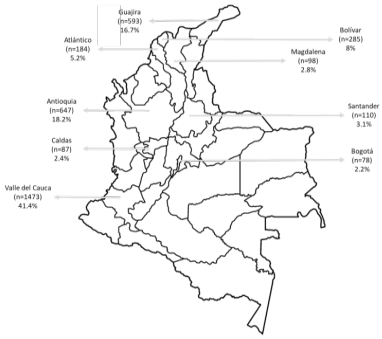

Figure 3. Geographical distribution of enrollments.

Medications included within the RBDC

According to the pathologies included in the RBDC, the drugs used Table 3 were molecules that are available in the Colombian market and are usually easily accessible to the patients to whom they are prescribed. Additionally, it was possible to observe that 100% of the patients who attended the control appointments, regardless of the pathology, stated that they had acquired or received the medication without specifying if they had received it from their insurer or if they had needed to buy it with their own resources.

Table 3. Prescribed medications.

Pathology	Medication	n	%
Venous insufficiency (n= 314)	Pycnogenol	138	43.9
	Diosmin + Hesperidin	176	56.1
GERD	Mosapride	84	28.3

(n= 297)	Esomeprazole	213	71.7
Arterial hypertension (n= 293)	Amlodipine + valsartan	92	31.4
	Amlodipine + valsartan + hydrochlorothiazide	31	10.6
	Candesartan + amlodipine	8	2.7
	Candesartan + Amlodipine + Hydrochlorothiazide	14	4.8
	Valsartan	83	28.3
	Valsartan + hydrochlorothiazide	65	22.2
Vertigo	Betahistine	113	100
Vaginal discharge (n= 176)	Fluconazole + secnidazole	130	73.9
	Terconazole + clindamycin	46	26.1
Asthma	Montelukast	126	100
Rhinitis (n= 410)	Mometasone Furoate	55	13.4
	Ciclesonide	25	6.1
	Levocetirizine	192	46.8
	Cetirizine	138	33.7
Dyslipidemia (n= 501)	Rosuvastatin	153	30.5
	Rosuvastatin + ezetimibe	77	15.4
	Atorvastatin + ezetimibe	104	20.8
	Rosuvastatin + fenofibrate	68	13.6
	Fenofibric acid	99	19.8
Sinusitis	Moxifloxacin	43	100
Pain (n= 764)	Naproxen + ezomeprazole	302	39.5
	Diclofenac + codeine	130	17
	Meloxicam	332	43.5
Pneumonia	Moxifloxacin	26	100
Osteoporosis (n= 79)	Ibandronic acid + Vitamin D	67	84.8
	Ibandronic acid	12	15.2
Intestinal Parasitosis	Nitazoxanide	296	100
Osteoarthritis	Persea oil + Glycine	117	100

Serious adverse events

No serious/non-serious adverse events were recorded in any of the treatment groups, and treatment suspension was not documented in any case due to any adverse event.

Discussion

Biomedical records are systematized strategies that offer detailed knowledge of diagnosis, treatment, follow-up, and prognosis[17]. This information arises from observing and describing a series of variables that aim to evaluate results for clinical, scientific, and public health purposes, hoping to improve and impact patients' quality of life, health research, and the costs of providing health services [2]. In coherence, the different methodological alternatives generated from the research to solve health problems have allowed health professionals to know different epidemiological designs as fundamental tools, guaranteeing the systematicity and validity of the information; for this reason, today, real-life evidence and clinical trials, generate advantages and disadvantages ranging from methodological rigor as synonymous with the presence of biases, such as controlled scenarios that are not similar to reality. Worldwide, official and private organizations have created biomedical registries to follow patients with pathologies and health technologies, this being the only way to know their performance, their advantages, and disadvantages, hoping to verify what was explored in early experimental phases, as well as new aspects that had not been known, which implies the possibility of generating clinical behaviors in favor of the patient [18].

In the RBDC experience, the primary objective was to find out how a group of drugs behaved in actual practice, which generally showed similar results to the pivotal experimental studies of each molecule versus their clinical performance [19,20], though given the methodological characteristics of this registry, this hypothesis could not be assumed; however, and as mentioned by Blumenthal and Ramagopalan, the planning of these registries must be thought out in consistency with the objectives of the project, because if we are talking about knowing only how a condition or medicine is being distributed in the market, the variables collected should be focused for this purpose, which is far from interests related to research, since the complexity would be directly related to the initial questions and the need to corroborate or refute the hypotheses, forcing the inclusion of variables that could impact logistics, viability and the complexity in the collection of registry information [21].

Worldwide, there are scenarios where chronic, high-cost, and infectious diseases generate many research questions to characterize these diseases, which motivates researchers to gather information to closely estimate what can actually happen in clinical practice. These efforts arise from local observational studies, which, according to interests, can evolve or grow to other countries where multicenter information is collected, generating products that can be useful both for health systems and to support pedagogical aspects in implementing health interventions. These experiences have given way to the modernization of collection strategies, from structuring physical instruments to using remote interfaces based on the Internet, which has improved access to information and the participation of information collectors in everyone [22].

On the other hand, Anglemeyer et al. carried out a systematic review, comparing clinical trials with observational studies, finding contradictory results when answering the same research question, suggesting multiple biases, where it was determined that the main problem was confounding factors [23]. This approach is coherent given the limitations that were identified in the RBDC, since when analyzing the characteristics of each pathology and its respective medication in the enrollment and the follow-up appointments, there may be variables that were not measured and could generate confusion regarding outcomes such as therapeutic failure or abandonment of treatment, which finally suggests that if a registry or observational study intends to explain clinical performance, it must consider the presence of confounding variables to have an explanation of the effect associated with the use of any intervention in health. On the other hand, the Association of the British Pharmaceutical Industry refers that even though clinical trials are the ideal methodological design to confer efficacy or effectiveness of an intervention, they are also carried out in strictly controlled conditions that could be far from real practice, where observational studies have gained space that could support decision-making in health. Thus, there is currently one of the largest records in the world called "The Clinical Practice Research Datalink (CPRD)," which comes from the UK National Health System (NHS), which to date has 4.4 million active patients, which represents 6.9% of the population. This registry has integrated the collection of information from follow-up biomedical records with the generation of research products to generate descriptions of local populations [24]. From the RBDC, it has been possible to generate scientific publications, establishing a tool that seeks to mix research, safety, and commercialization interests, keeping the parameters against independence in scientific production and the use of information for corporate purposes.

Accordingly, it is important to note that registries are also linked to disease surveillance systems, which has led to structuring notification and reporting models at both the private and public levels, generating statistical data that can impact public policy at the local and international levels, which argues the use and implementation of this type of information tools. For this case and as part of the national guidelines for research with health technologies in Colombia, research studies must include within the collection system the report of adverse events as part of the objectives of the studies; this is a variable that must be considered within the registries for subsequent

analysis, both in clinical trials and in observational studies or registries. In the RBDC, this variable was considered observing that no serious and non-serious adverse events were reported, although studies usually report them; this could be explained by the ignorance of those responsible for evaluating and collecting the information, Faced with the association of symptoms with the use of the drug, the lack of knowledge of the adverse event reporting system that governs in Colombia or due to lack of information from the professional in the presentation of adverse events, Although within the initial parameters of the RBDC, doctors were trained on good clinical practices and registration of adverse events related to the use of drugs. This forces us to be emphatic in training on information records even though it is part of the clinical practice of any professional who prescribes drugs, which alerts us to a possible under-registration of adverse events. In the same way, it was observed that adherence to medical control was around 70%, which suggests a commitment of the patient to the continuity of his treatment and the medical evaluation of control; however, concerning the remaining 30%, it was not possible to determine if there was no improvement or if the patient resolved or controlled his pathology, since there was no different contact than those reported by doctors in his usual clinical practice.

Other relevant aspects are those related to the costs of the disease for the health system, private care providers (clinics and hospitals), and pharmaceutical providers [23,24]. From the analysis of the variables included in the RBDC, some hypotheses can arise about the behavior of clinical outcomes, adherence to medical controls, and the characterization of prescriptions, which has allowed a periodic diagnosis of the expenditure of the different pathologies, as well as the identification of underreporting of adverse events. These strengths and weaknesses of biomedical records are the reality of real-time monitoring that has continuously been formalized, managing to include relevant information with relevant impacts for the patient, health professionals, and the health system [25].

Conclusion

The findings of this study contribute to strengthening the need to complement health research, not only from controlled clinical studies but also from observational studies, biomedical records, and collection strategies, using remote technological tools that allow the recording of information and its concentration as part of databases. In the same way, it is relevant to be rigorous in the construction of the records as a source for the generation of evidence since the scope and quality of the information are closely linked to the presence and control of biases. On the other hand, and according to what has been stated in the literature, the RBDC agrees with the objectives that are usually sought in a biomedical registry since it takes into account not only the collection and analysis of information but also ethical considerations regarding the use of personal and clinical information of patients as a source of information. Finally, we consider that this experience of the RBDC allowed us to know the behavior of a series of drugs in real-life practice in a group of primary care physicians, resulting in the generation of arguments to make decisions in the commercial area, in the follow-up from the pharmaco-epidemiological area, as well as in the production of evidence for publication purposes.

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Declaration of Conflicts of Interest

None of the authors declare conflicts of interest.

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