

GENERIC DRUGS, PERCEPTION OF THE DOCTORS. CALI, COLOMBIA

Camilo Torres Serna¹, Juan Camilo Ángel Medina², Helen Viviana Klínger Torres^b, Vanessa Márquez Flórez^b, Jean Marcos Micolta Bejarano^b, Jhon Jairo Sánchez Suescún^b.

ABSTRACT

It is common to hear medical mistrust of the effectiveness of generic drugs. The objective of this study is to quantify the acceptance of physicians linked to the General System of Social Security in Health of Colombia to the prescription of generic drugs.

Was performed a cross-sectional, descriptive study. Eighty doctors in clinical practice were interviewed, all doctors who made clinical consultation in the practice sites of a Medical School of Cali-Colombia.

The results show that the physicians consulted are clear about the concept of generic medicine and 89.6% of them consider the generic product essentially similar to the original reference medicine, but at the same time, they tend to think that generic products do not comply with the desired therapeutic effect. It is also stand out that 74.4% of doctors consider that patients value the use of generic products little.

INTRODUCTION

The management and administration of medication use is a determining factor of financial equilibrium of health organization. They have constantly stablish and view bid processes, purchasing, distribution and adequate supplies of medication to users and this area represents a great potential administrative inquiry.

Around the world exist a great controversy about innovative drugs and their analogues also known as generic drugs^{1,2}. Public health entities generally prefer to buy generic products, for the most part unexpensive, but doctors and patients think they are ineffective products^{3,4}.

A generic drug is potentially similar to the first investigational medicine, with a chemical composition called innovative drug^{5,6}. A research laboratory develops an innovative molecule with therapeutic purposes and then, it starts the marketing of brand-name drugs, this molecule has been registered by an intellectual property patent for twenty years, afterwards other laboratories start producing and marketing the same molecule as

International Nonproprietary Name (INN) or other brand-names. These products, with the same composition and mis-named copy drugs, while generic drugs is the right name. In some countries, they are denominated as interchangeable medicines (Mexico). World Health Organization (WHO) recommend using the term Multisource drugs⁷.

The objective of the study was to identify the concept and opinion about generic drugs of doctors of Sistema General de Seguridad Social en Salud (SGSSS) of Colombia, which gives healthcare to 90% of Colombian people⁸. We expect to obtain information in order to target educational campaigns and provide sustained information with figures on bioequivalence for the medicinal products and the importance of reaching a rationalization in drug use from medical staff, pharmacists and patients; moreover, to contribute to expensive pharmacologic substances control and avoid the unnecessary use.

MATERIALS AND METHODS

It was performed a cross-sectional, descriptive study. To pick up information, it was used a mixed questionnaire known as PAMPEFG-01 (Percepción y Actuación de Médicos en la Prescripción de Especialidades Farmacéuti-

cas Genéricas), a valid instrument used by García AJ et al, and adapted for this study.

The universe involves all general practitioners and specialists that accomplished inclusion criteria: working in

Programa de Medicina, Universidad Libre, Cali-Colombia

¹ Médico-Farmacólogo, PhD en Ciencias de la Educación. Investigador del Instituto de Investigaciones Biomédicas de la Universidad Libre y Profesor Titular de Farmacología, Universidad Santiago de Cali, Colombia.

² Estudiante, Programa de Medicina, Universidad Libre, Seccional de Cali, Colombia.

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Correspondence to:
E-mail: catorse@yahoo.com

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direct healthcare services (emergency services and outpatient basis) at clinical practice areas of Faculty of Medicine of Cali-Colombia University, people who didn't work in medical area and develop only administrative work were excluded from the study. This found that seven clinical practice areas of level 1, 2 and 3 with medical complexity. Only 245 general practitioners and specialists from different shifts, via different forms of contract (full-time, half-time or eventual service delivery) accomplished the inclusion criteria. It was applied a sample size calculator software (Rotator Survey®), and obtained a minimum sample of 70 practitioners, which were selected through a probability sampling method the appointed day. We interview each doctor, allocating the time needed and confidentiality to answer the questionnaire.

This research takes part from a large project about social drug use performed by Health Management Group of Health Management Program and the Biomedical Research Institute of Universidad Libre of Cali-Colombia. The participants of the study got information about research purposes and an informed consent that specified voluntary participation of people.

According to the Standards of Health Ministry of Colombia, it was deemed a risk-free research because any biological, physiological, psychological or social intervention of the participants in this study was performed. A survey was carried out, in which the identification of participants weren't revealed due to no personal information or behavior sensitive aspects were requested. The Ethical and Scientific Committee for research involving humans of Universidad Libre de Cali approved, the initiation of this study by means of minutes signed 05, 2016.

RESULTS

We interviewed 80 clinically active faculty physicians, of which 59 were men and 21 women, from emergency services and outpatient basis. Fifty-three were >31 years old (see table 1), 41 were general practitioners and 39 had a specialty. Half of the physicians had 10 years of work experience and only three had less than one year (see Table 2).

All the questions on the form were analyzed by knowledge of physicians in relation to generic drug concept (see Table 3) and physician confidence in generic drugs (see Table 4). The answers show good knowledge of generic drug concept, 69% recognize the difference between an essen-

Table 1
Age and Gender distribution of participant physicians in the study about generic drug perception

Age (years)	Men	Women	Total
30 or less	14	13	27
31-40	8	5	13
41-50	12	3	15
51-60	22	0	22
Less than 61	3	0	3
Total	59	21	80

tial drug (WHO defined, as those that satisfy the priority health care needs of the population) and a generic drug; 73% considers not to confuse a generic drug with a counterfeit drug. The 89,6% accounts generic are similar to original drugs and 69% doesn't believe the generic drug use can limit pharmacological research.

In respect of questions regarding confidence physician of generic drugs (see Table 4), 71,8% use generic drugs, 62,3% didn't find treatment failure and 67,1% doesn't consider an increase of adverse effects. A crucial result is interviewed physicians perceive patients undervalued generic drugs use.

The following Table 4 summarizes the knowledge of generic drug concept of interviewed physicians, it compares agreement and disagreement answers, and uncertain responses were ruled out.

Table 2
Years of professional experience of physicians in the study about generic drugs perception

Years of experience	Men	Women	Total
Less than 1	2	1	3
1-5	13	13	26
5-10	5	5	10
More than 1	39	2	41
Total	59	21	80

DISCUSSION

It's important for health system actors to have clear concepts about myths and facts of generic drugs¹¹. The term generic, doesn't mean a pharmaceutical product put on the market under the name of the active molecule, as many people believe, this term refers to a drug, which isn't originally develop by a pharmaceutical company, but made by others¹², there is overwhelming evidence of chemical, pharmaceutical and clinical bioequivalence between original and generic products^{13,14}.

The results of this study present interviewees have a clear concept of generic drug (see table 3), 89,6% consider a generic product must be essentially similar to original drug, at the same time, 62,3% think generic products comply with the desired, therapeutic effect. We emphasized 74,4% consider patients underestimate generic drugs use.

Despite generic drugs are as effective as brand-name drugs and cheaper, the study's results and others show a significant proportion of doctors (around 40% in this study), that prefer original products and think patients do, too. Dr. Óscar Andía, Director of Monitoring Drug of Colombian Medical Federation (Observamed), present Colombia

Table 3.
Knowledge about generic drug concept of the survey participants

Question	Knowledge about generic drug	Disagreement with the statement (%)	Agreement with the statement (%)
6	Essential meds and Generic Drugs are the same thing	69,33	21,33
7	Drugs provided by Health system can only be generics	68,83	27,27
12	Generic drugs should be essentially similar to original drugs.	9,09	89,61
14	The prescription of generic drugs reduces pharmaceutical costs of Health system	19,23	73,08
15	Generic drugs should be used as the substitution for patent meds due to low cost	53,95	32,89
17	Commercial drugs are prioritized in my service delivery Institution	16,88	75,32
19	Physicians tend to obtain gifts and rewards to prescribe commercial drugs	43,59	51,28
21	Most generic drugs that exist on the Market are counterfeit products (pirating)	73,69	15,79
22	The use of generic drugs limits creation and research centres of new drugs	69,23	21,79

Table 4.
Confidence of generic drugs of survey participants

Question	Confidence of generic drug	Disagreement with the statement (%)	Agreement with the statement (%)
8	Medicaments are as bioequivalence and available as nongeneric	52,63	35,53
9	Generic drugs have have a clinical effect similar to nongeneric	48,05	37,66
10	Generic drugs generally don't fulfill the therapeutic effect (failed treatment)	62,34	22,08
11	The Generic drugs use increase the risk of adverse effects	67,1	23,7
13	Generic drugs offer the same quality guarantees for the production of a registered trademark	51,3	35,9
16	Usually, I/they prescribe generic drugs	19,2	71,8
18	The Generic Drug use reduces physician's choice to prescribe medicaments	45,5	49,4
20	It hesitates about the quality of laboratories that produce generic drugs	37,2	44,9
23	Patients undervalue generic drugs	16,7	74,4

has a fake and deep-rooted thought about generic drugs are worst, low quality cited by Silva S¹⁵. Including doctors prefer to recommend this option.

According to Instituto Colombiano de Vigilancia de Medicamentos y Alimentos (Invima), generic drugs are produced with high standards of quality and cost less because they aren't included patent, development and research costs, moreover, manufacturers spend less in advertising stuff⁶.

A meta-synthesis study compared the use of generic medicine and non-generic (innovative or original products) in key medical situations, they are mentioned below.

In Universidad Del Valle, Cali, Colombia, compared the bioavailability of two high engagement products, original cyclosporine immunosuppressant with a generic drug¹⁷ and between low molecular weight heparin (original enoxaparin) and a generic drug. Both of either them, didn't present significant differences in measured pharmacokinetic parameters, or area under the curve (AUC), or maximum concentration (Cmax), or time required to achieve maximum concentration (Tmax)¹⁸.

Kesselheim, Misono et al, performed a systematic search of publications in MEDLINE, EMBASE and International Pharmaceutical Abstracts, there were 47 scientific papers about detailed knowledge that covered nine different subclasses of cardiovascular drugs, 81% represented randomized clinical trials.

The clinic equivalent was tested in seven encountered beta-blockers trials, in 10 of the 11 reviewed about diuretics trials, in five of seven calcium antagonists, in three about antiplatelet agents, in two reviews of statins, in one of ACE inhibitors and other about alpha-blockers. This meta-analysis also analyzed 53 publishers and opinions, in which expressed a negative point of view about generic drugs compared with 28% that encourage innovative to generic drugs replacement.

The substitution of generic drugs of antihypertensive medication doesn't lead to less compliance instead of, increases cardiovascular hospital admissions compared with innovative drugs therapy. When a generic antihypertensive

is available, it must be considered the original drug replacement in order to achieve economic benefits and ensure chronic treatment²¹.

In other medical specialties, there are studies as Vlahiotis y Devine²² with similar results, it describes major depressive episode patients, in which didn't observed high treatment abandon rate between the ones that start with generic therapy and the ones with original meds.

One of the biggest controversies reported in literature, is the substitution of brand name for generic drugs, in people with epilepsy. Polard et al, studied the association between generic therapy replacement and the loss of crisis control, a total of 8 379 patients were analyzed along with sensitivity analysis yielded similar results. Authors concluded that the substitution of anticonvulsants for generic drugs are not associated with high risk of seizures.

Pereira et al, made the comparison of the blood-thinning effect of oral warfarin based on International Normalized Ratio effect, there weren't differences between original and generic meds that forced to a dose setting. Neither they also found difference biological variation of INR based on warfarin formulation ($p > 0,69$), nor interaction between warfarin and patient ($p > 0,81$). The conclusion of this studies is that patients can change from original warfarin for generic with security and effectiveness.

As Duerden and Hughes raised, despite the substitution of innovative products for their generic can affect some individual patients, specially the reduction of adherence and high potential medication errors, it might be a price worth paying due to a huge opportunity for money savings, associated with drugs use clinically no better compared with the cheap alternatives.

The insurance companies and pharmaceutical policy makers promote generic drugs use in order to reduce costs, but they continue currently underused. Physicians and patients agree generic drugs are as safe and cheaper.

The 74,4% of physicians consider patients rarely value generic drugs, which has been particularly significant. This finding tally with other studies^{27,28}, as Shrank found that 56% of Americans think, they should use more generic drugs, only 37,6% prefer to take them²⁹. There are actions of health officials, in attempting to change people thought, around

the world. According to WHO, it's described that pharmaceutical industry has made great efforts in order to discredit generic drugs. "The usual is to stigmatize generic drugs showing them as an alternative for 'poor people' and low quality"³⁰, States must do the same with this practices.

In conclusion, many studies^{31,32} consider generic drugs are as effectiveness and safe as original meds, and their introduction and marketing assume pharmaceutical money savings, which make them a necessary step to Health System sustainability^{33,34}.

It's important to take into account counterfeit products, which aren't subject of study in this research. Under no circumstances, these products comply with conditions to be a generic drug, therefore it has to identify the origin of generic drug for ensuring its bioequivalence^{35,36}.

In order to reduce patients and physicians susceptibility about generic drug use, it should spend time by giving information of medicament rational use to patients and prescribers. It's essential that physicians and pharmacists understand correctly the substitution of original meds for generic drugs approved by local authorities, and inform accurately to patients³⁷.

Results from this and other researches appear to show, more efforts are necessary in order to Colombians trust in generic drugs and save a huge amount of resources to Health System.

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Conflict of interests:

All authors are involved actively in the elaboration of this manuscript, data collecting, analysis and drafting, and certify that they have NO affiliations with or involvement in any pharmaceutical industry, organization or entity with any financial interest.

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