From ISET to InDRE. V. Institute of Epidemiological Diagnosis and Reference. Global strategic position, 2012-2019

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Abstract

This document describes the changes at the Institute of Epidemiological Diagnosis and Reference (InDRE) from 2012 to 2019, the administrative and equipment modifications, the new headquarters and the National System of Epidemiological Surveillance legal modifications. The process of relocation is mentioned, especially the careful transfer of the biological material protected by the Institute, and the new way of studying epidemic outbreaks, endemic diseases and the negative network is analyzed. At the international level, the promotion of links with global networks of the Pan American Health Organization, the World Health Organization (WHO) and other international organizations is described. The assignment to InDRE of four WHO collaborating centres is also mentioned. The Global Health Security Initiative Laboratory Network acknowledged InDRE's leadership, which co-chaired the working group during the study period.

KEY WORDS: Institute of Epidemiological Diagnosis and Reference. History of medicine. Public health.

Del ISET al InDRE. V. Instituto de Diagnóstico y Referencia Epidemiológicos. Posición estratégica global, 2012-2019

Resumen

En este documento se describen los cambios en el Instituto de Diagnóstico y Referencia Epidemiológicos (InDRE) de 2012 a 2019, las modificaciones administrativas y de equipamiento, la nueva sede y las modificaciones jurídicas al Sistema Nacional de Vigilancia Epidemiológica. Se menciona el proceso de mudanza, en especial el cuidadoso traslado del material biológico que resguarda el Instituto y se analiza la nueva forma de estudiar los brotes epidémicos, los padecimientos endémicos y la red negativa. Respecto al ámbito internacional, se describe el fomento de la vinculación con redes globales de la Organización Panamericana de la Salud, la Organización Mundial de la Salud (OMS) y otros organismos internacionales. También se menciona la designación en el InDRE de cuatro centros colaboradores de la OMS. La Red de Laboratorios de la Iniciativa Global para la Seguridad en Salud reconoció el liderazgo del InDRE, cuyo director ocupó la copresidencia del grupo de trabajo en el periodo de estudio.

PALABRAS CLAVE: Instituto de Diagnóstico y Referencia Epidemiológicos. Historia de la medicina. Salud pública.

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... that which on the tree is flowering,
lives from that which it has buried in the ground.

FRANCISCO LUIS BERNÁRDEZ

Introduction

This article gives continuity to number IV of the “From ISET to InDRE” series,¹ where the complex operation of the National Network of Public Health Laboratories (RNLSP – *Red Nacional de Laboratorios de Salud Pública*) was described.

The changes at InDRE in the 2012-2019 period had repercussions on the entire structure of the National System of Epidemiological Surveillance (SINAVE – *Sistema Nacional de Vigilancia Epidemiológica*), which was organized according to the Official Mexican Standard NOM-017-SSA2-2012, for epidemiological surveillance (Fig. 1). On one hand, there are the National Committee of Epidemiological Surveillance, the General Directorate of Epidemiology, InDRE and the epidemiological surveillance units; and, on the other, the flows of information and samples, whose entrance door are the epidemiological surveillance units of all institutions of the health sector.² The entire process is regulated by the National Committee of Epidemiological Surveillance and the General Directorate of Epidemiology. When SINAVE requires confirmation of cases, RNLSP and InDRE are incorporated.¹

In 2013, InDRE changed its headquarters, although preparations had started since the previous year. It took three months for the institution’s teams and working groups stepwise mobilization. On April 7, 2014, the new facilities were formally opened.

Regarding the change of institutional headquarters

Administrative and work modifications

As part of the strategy for the management of the change towards the modernization and systematization of InDRE’s attributions, the Quality Management System was implemented in 2012, with a focus on processes and a risk-based approach. The incorporation of the biological risk management standard for laboratories, the CWA15793:2011 standard, consolidated the Institute’s comprehensive management model, so far the only one in the world for national reference laboratories.

The imminence of the change of institutional headquarters generated more commitment and a sense of

belonging among the personnel and, at the same time, uncertainty and concern. By means of tripartite dialogue tables, with the participation of workers, union and institutional authorities, adapting the profiles of the positions in the job profile diagram was agreed, the staff members who were under contract were work-wise institutionalized and the change of assignment of 59 workers (who represented around 10 % of the workforce) was allowed.³ At the same time, 67 newly-created positions were obtained, which triggered more than a hundred hierarchical movements.

Legal modifications

In 2013, the Official Mexican Standard NOM-017-SSA2-2012, for epidemiological surveillance, was updated,² with InDRE acquiring legal support as a national reference laboratory. The previous year, the Institute had joined the General Directorate of Epidemiology, in accordance with the new Internal Regulations of the Ministry of Health.⁴ The NOM-017-SSA2-2012 standard established the protocols to update InDRE’s operational criteria and technical guidelines. These documents have incorporated new methodological developments in the diagnostic algorithms and express RNLSP technological innovation.⁵

Also in 2013, owing to its “high national importance”, the new property was designated as a triple A strategic facility, in terms of the General Statute of the National System of Public Security, and as a National Security Agency, in accordance with the collaboration bases signed between the Ministry of Health and the Ministry of the Interior.⁶

Relocation

During the relocation process, InDRE had to retain the capacity to carry out “critical” diagnostic algorithms and continue operating should any epidemiological contingency occur in the country. Activities were maintained at the *Santo Tomás* facilities and the RNLSP members supported while all the diagnostic phases were transferred to the new headquarters. Technical and administrative processes were carefully planned and executed, including the chain of custody and biosafety.

The most important challenge in the relocation process was the transfer of the biological material stored in the Institute’s facilities. It was a national security event in terms of biological risk management.⁷

Figure 1. Diagram of the National System of Epidemiological Surveillance, where the role of the national reference laboratory (InDRE) is shown. Mexico, 2019.

After performing an exhaustive inventory of the biological material that had to be transported from the old facilities to the new ones, the Pan American Health Organization/World Health Organization (PAHO/WHO) regional office was informed. Hours before the transfer, InDRE staff packed the material, in accordance with international criteria. The transfer of all the material was carried out on Saturday, November 16, 2013, around midnight, in a single trip, with a caravan of trucks escorted by members of the Federal Police.

Due to its relevance, the operation was planned and coordinated by CISEN officials (Center for Investigation and National Security, now the National Intelligence Center) and the InDRE, with participation of members of the legal cabinet staff: Ministry of the Interior, Ministry of National Defense, Ministry of Communications and Transportation, in addition to the Federal Police. The High Level Specialized Committee on Disarmament, Terrorism and International Security Matters coordinated the compliance with international agreements on the subject. The WHO shipping pass was signed at the former facilities, and the mobilization process was notified to PAHO/WHO, the United

Nations Office for Disarmament Affairs and the Biological Weapons Convention.

Work continued until dawn for InDRE staff. As the areas were vacated and the laboratories, laboratory animal facilities, insectariums, cold rooms, etc. were dismantled, bio-decontamination and disinfection (environmental biosafety) was carried out to ensure the safety of the furniture, materials, equipment and buildings at the time the old property was delivered.

After having been settled for 78 years in the *Santo Tomás* neighborhood, InDRE moved to the new property that had belonged to the grounds of an old hacienda, then to *La Castañeda* General Insane Asylum (1910-1968) and to the National Institute of Human Communication (1968-2002).⁸

Opening

Finally, on April 7, 2014, the World Health Day, that year dedicated to vector-borne diseases, the official opening ceremony of the new facilities was celebrated in presence of the President of the Republic, Enrique Peña Nieto; the Secretary of Health, Mercedes Juan López; and the representative of the PAHO/WHO

Table 1. National Network of Public Health Laboratories. Integration of specific laboratory networks. 2019⁵

Network	Public health state laboratories	Laboratories of epidemiological surveillance support (LAVE)*	Jurisdictional/local laboratories
1 Malaria	32	—	116
2 Influenza and other respiratory viruses	32	8	—
3 Tuberculosis	31	-	737
4 Dengue and other arboviroses	31	1	3
5 Acute bacterial diarrheic disease	31	1	—
6 Febrile exanthematous illness	31	1	—
7 Brucellosis	31	—	—
8 Sexually-transmitted infections	31	—	—
9 Hepatitis	30	—	—
10 HIV-AIDS	30	—	—
11 Chagas disease	29	—	—
12 Acute bacterial respiratory infections	28	—	—
13 Pertussis	28	—	—
14 Leishmaniasis	28	—	116
15 Rotavirus and other enteroviruses	27	—	—
16 Entomology	27	—	1
17 Rabies	25	—	—
18 Cervical cytology	21	—	74
19 Leptospira	21	—	—
20 Rickettsiosis	4	—	—

*Participating institutions: Mexican Institute of Social Security (with four LAVEs), Institute of Social Security and Services of State Workers, National Institute of Respiratory Diseases, National Institute of Medical Sciences and Nutrition, General Hospital of Mexico.

office in Mexico, Maureen Birmingham. This event was reported in all national circulation newspapers, on eight front pages (*El Universal*, *Reforma*, *Excelsior*, *El Sol de México*, *Impacto Diario*, *Diariolmagen*, *Opciones*, *Unomásuno*) and on inside pages in the rest of the written press. The Secretary of referred to InDRE as follows:⁹

... main point of support for the national epidemiological surveillance system... (it) is part of the national security strategy to respond to highly dangerous biological emergencies.

Similar to the note “Finally, it will be founded”, published in 1936 by *El Universal* on the occasion of the foundation of the Sanitary and Tropical Diseases Institute (ISET – *Instituto de Salubridad y Enfermedades Tropicales*), the newspaper *Reforma*, 78 years later, titled its note “Finally, InDRE’s headquarters are opened”.

A new way to approach epidemiological surveillance

Currently, the country has 20 specific diagnostic networks under the stewardship of InDRE as National Reference Laboratory (Table 1). In addition to the new infrastructure, practically all laboratory, computing and communication equipment was replaced. The laboratory equipment changed from monocular microscopes with external lamps to optical microscopes with LED illumination and digitized documentation; from classical bacteriology to gene sequencing; from agglutination tests, to automated chemiluminescence, to real-time quantitative PCR, to next-generation sequencing, and to bioinformatics. Together, these transformations constitute the most important technological renewal of the Institute since its foundation.

As a result, there were modifications in the Institute's participation in epidemiological surveillance. Below, some aspects are described.

Epidemic outbreaks

In the reviewed period, the Institute participated by characterizing epidemic outbreaks using a more expedite strategy with higher predictive value, based on the identification and analysis of nucleic acids by real-time PCR and whole-genome sequencing. A clear example of InDRE's contribution was the characterization of a highly pathogenic avian A influenza strain (H7N3) in poultry farm workers from Jalisco.¹⁰ The transmission of the chikungunya¹¹, Zika¹², and dengue¹³ viruses in our country was also studied, the circulation of non-polio D68 enterovirus was identified in respiratory conditions and the diagnosis of influenza in children was ruled out at the Institute.¹⁴

Detection of the *Aedes* mosquito in Mexico City¹⁵ triggered focused monitoring and surveillance activities.¹⁶ As a consequence, all state public health laboratories (LESP – *Laboratorios Estatales de Salud Pública*) have had, since then, molecular methodologies available for these diagnoses, which facilitated national response.

During the cholera outbreak in Mexico in the 2013-2014 period, diagnosis was obtained with conventional methods, and with molecular methods, the origin of the strain (Haiti) that caused the re-emergence of this disease was established. With a mobile field laboratory, the time of response for the care of affected individuals was reduced, which facilitated decision-making. The outbreak was controlled by SINAVE and inter-sectoral participation in only 13 weeks.¹⁷

Given the possible introduction in Mexico of highly infectious unknown pathogens such as Ebola, and the reintroduction of others, such as the yellow fever virus, InDRE strengthened the capacity to receive them at its new facilities and to contain them in level 3 biological safety laboratories; it also reinforced the communication networks with computer systems.

Endemics

The Mexican experience in malaria eradication facilitated WHO certification of all microscopists at InDRE Malaria Laboratory, which allowed the creation of the WHO Collaborating Center for Malaria. This certified personnel maintains its high level throughout the country and also carries out parasitological diagnoses for leishmaniasis and Chagas disease (Juan Manuel Serena-Velázquez, personal communication).

Chagas disease serological diagnosis is essential for strategies to control the transmission of this parasite. To that end, InDRE developed a national reference algorithm and a solid performance evaluation program where RNLSP members and the National Center for Blood Transfusion participate, to ensure diagnostic reliability.

The Tuberculosis Network started operating since the decade of 1970; currently, it has 768 laboratories of different levels of complexity throughout the country. Bacteriological tests are the basis of this network.⁷

The establishment of the Rickettsiosis Epidemiological Surveillance program allowed the creation of the Institute's most recent diagnostic network.

In November 2019, the WHO granted Mexico the first certification in the world as a country free of dog-transmitted human rabies, based on scientific evidence provided by InDRE and RNLSP.

Surveillance of eliminated or eradicated diseases (negative network)

The negative network includes diseases without autochthonous cases in Mexico² (Table 2). As a relevant example, InDRE has participated in the polio eradication process, with the diagnosis of probable cases in outbreak studies and through environmental surveillance; in addition, it is the only agency that generates laboratory information for epidemiological surveillance of acute flaccid paralysis in Mexico.

Recognitions, academic activity and scientific production

The Institute received the ISO 15189:2012 accreditation, ISO 9001:2015 certification and the 2015 National Health Quality Award. That year, InDRE was granted the Funsalud-GSK Award in the category of epidemiological research; in 2017, a recognition with the CANIFARMA Award and was a finalist in the Carlos Slim Award to the Exceptional Institution. In 2019, it was finalist for the National Quality Award granted by the Ministry of Economy.

In 2014, the National Council of Science and Technology distinguished Dr. Clara Gorodezky as emeritus researcher, and she was also named "Person of the Year 2019" at Forbes Health Forum, due to her contributions to the benefit of health.¹⁸

In the 2012-2019 period, 179 articles were published in peer-reviewed indexed journals, 2972

Table 2. InDRE participation in the surveillance of conditions with no autochthonous cases recorded in the national territory

Condition	Year the last cases were recorded	Origin
Polio	1990	Jalisco
Diphtheria	1991	Michoacán
Measles*	1996	Federal District
Onchocerciasis	1998	Oaxaca
Dog or cat-transmitted human rabies	2004	Sinaloa
Blindness caused by trachoma	2007	Chiapas
Congenital rubella syndrome*	2008	Nuevo León
Malaria caused by <i>Plasmodium falciparum</i> *	2009	Sonora
Rubella*	2010	Distrito Federal and Nuevo León
<i>Rhodnius prolixus</i> -transmitted Chagas disease	2012	Chiapas
Cholera*	2018	Sinaloa

*The diagnosis is made by the entire RNLS.

genetic sequences and complete genomes were deposited in public or restricted databases, and the number of members at the National System of Researchers increased by 143 %, due to the training and incorporation of young professionals with post-graduate degrees.

All these achievements illustrate the expertise, commitment and human talent that InDRE has developed and offered to the field of public health.

InDRE international participation

According to the WHO, among the top 10 health problems in 2019, six are related to infectious diseases: influenza as a pandemic event, antimicrobial resistance, the threat of spread of the Ebola virus and other pathogens (including X disease, which represents the need for preparedness for an unknown pathogen that might cause a serious epidemic), vaccine hesitancy, dengue and human immunodeficiency virus.

In addition to intensive technical meetings, InDRE has participated in many other on national laboratory policies, planning, regulation, biological risk management, and financing. It has also maintained collaboration with global networks and has joined other new ones (Table 3). The InDRE National Influenza Center has been maintained since 1951¹⁹ and was re-designated in 2016. The InDRE Tuberculosis Laboratory has been a supranational laboratory for Central America since 2005; in 2016, it was accredited as member of the Network of Supranational Reference Laboratories

for Tuberculosis by the WHO Global Tuberculosis Program.^{20,21}

Through the United States Northern Command, in 2017, InDRE received a next-generation sequencer to decrease response times in epidemic events, such as Zika, influenza, and foodborne diseases.²²

InDRE is part of the Global Health Security Initiative Laboratory Network (Table 3), where only the seven most industrialized countries and Mexico participate;²³ the InDRE director was unanimously elected co-chair for the 2012-2019 period. Mexico hosted the meetings of that body in 2014 and 2017.

WHO collaborating centres at InDRE

Between 2012 and 2019, the Institute received important designations from PAHO/WHO (Table 4). A WHO Collaborating Centre (WHOCC) is an institution designated to carry out activities in support of WHO's public health programs. InDRE received four designations as WHOCC:

- WHO Collaborating Centre for Training on Malaria Microscopy Diagnosis.²⁴
- WHO Collaborating Centre on Laboratory Biosafety.²⁵
- WHO Collaborating Centre for Arboviruses.²⁶
- WHO Collaborating Centre on Laboratory Quality Management.²⁷

With these designations, 28 % of the WHOCCs established in the country are under the care of InDRE.²⁸

Table 3. InDRE participation in global and multinational diagnostic networks

Program	Coordinating body	Objective
PAHO/WHO global networks		
The Global Polio Laboratory Network	WHO	To differentiate polioviruses from other causes of acute flaccid paralysis
Global Influenza Surveillance and Response System (GISRS)	WHO	Global network for influenza epidemiology and virology surveillance
WHO External Quality Assessment Project for the detection of influenza viruses	WHO/Centre for Health Protection, (Hong Kong)	To assure quality and improve the capacity of laboratories at the global level for the detection and sub-typing of the influenza virus (support to GISRS)
Global Measles and Rubella Laboratory Network	PAHO	To monitor and verify viral transmission and monitoring the susceptibility profile of a population
System of Networks for the Surveillance of Agents Responsible for Bacterial Pneumonias and Meningitis	PAHO	Epidemiological surveillance of bacterial pneumonias and meningitis
Latin American Network for Antimicrobial Resistance Surveillance	PAHO	Surveillance of resistance in nosocomial and community-acquired pathogens
Pan American Cytology Network	PAHO	To improve the quality of the Papanicolaou test
Global Salm-Surv	WHO	To strengthen surveillance of foodborne diseases. Alert and response in case of outbreaks
Laboratory Network for Arbovirus Diagnosis	PAHO	To strengthen diagnosis in order to ensure a timely response to outbreaks and epidemics
Genomic Surveillance of Dengue in the Americas	WHO/PAHO	To promote genomic surveillance studies of dengue and other arboviruses in the Region of the Americas
External Evaluation of Performance in the Diagnosis of Emerging and Reemerging Infectious Diseases	PAHO/WHO/National Center of Tropical Diseases (Bolivia)	To assess the capacity of national reference laboratories of the Region of the Americas
Program for Quality Control in Bacteriology and Antimicrobial Resistance	PAHO/National Institute of Infectious Diseases (Argentina)	Quality Control Program to support ReLAVRA
Program for External Evaluation of Performance in Malaria Microscopy Diagnosis for the Countries of Mesoamerica and the Caribbean	PAHO	To establish the technical procedure for the organization, design and evaluation of national reference laboratories in the countries of the sub-region.
TB Supranational Reference Laboratory Network	WHO	Surveillance of <i>Mycobacterium tuberculosis</i> drug resistance
<i>Mycobacterium tuberculosis</i> Drug Susceptibility Quality Control Program	PAHO/WHO	To strengthen the capacity of laboratories in the countries to identify the global magnitude of <i>Mycobacterium tuberculosis</i> resistance
Network for Evaluation of Vaccine Effectiveness in Latin America and the Caribbean. Influenza	PAHO/CDC (United States)	To provide information on the effectiveness of the seasonal influenza vaccine
The External Quality Assurance System of the WHO Global Foodborne Infections Network	WHO/Technical University of Denmark (Denmark)	To assess the ability of Member States to detect and respond to outbreaks of foodborne diseases and to the emergence of antimicrobial resistance
Multinational networks		
Global Health Security Action Group-Laboratory Network	Global Health Security Initiative (Group of Seven + México)	Partnership between laboratories in the countries of the Group of Seven and Mexico in order to strengthen global public health preparedness and response to chemical, biological, radiological and nuclear terrorism threats

(Continued)

Table 3. InDRE participation in global and multinational diagnostic networks (*Continued*)

Program	Coordinating body	Objective
Multinational networks		
International Proficiency Testing Scheme for the Leptospirosis MAT	International Leptospirosis Society (National Serology Reference Laboratory, Australia)	To improve the diagnosis of leptospirosis in the world
Performance Evaluation Program	Division of Laboratory Systems, CDC	To improve surveillance and public health, clinical laboratory quality and safety, data science, biorepositories, and working competence
PulseNet and PulseNet-NGS	CDC	To compare patterns of bacterial DNA obtained from individuals involved in outbreaks related to food safety
Laboratory Response Network	CDC	Network of laboratories that can respond to biological and chemical threats, as well as to other public health emergencies
Global Microbe Identifier-Proficiency Test	Technical University of Denmark (Denmark)	To harmonize and standardize whole-genome sequencing of emerging pathogens, data analysis, and bioinformatics
United Nations Secretary-General's Mechanism-Proficiency Test	United Nations Office for Disarmament Affairs/Technical University of Denmark	To strengthen the ability to detect a biological threat, based on genomic and bioinformatics analysis

PAHO = Pan American Health Organization; WHO = World Health Organization; GISRS = Global Influenza Surveillance and Response System; ReLAVRA (*Red Latinoamericana de Vigilancia de la Resistencia a los Antimicrobianos*) = Latin American Network for Antimicrobial Resistance Surveillance; NGS = next-generation sequencing, CDC = Centers for Disease Control and Prevention.

Discussion

The opening of new and modern strategic facilities, the reengineering of processes, technological renewal, the creation of new positions and the associated hierarchical movements generated a favorable environment for the projection of InDRE in the 2012-2019 period. Together, these events constitute the deepest renovation of the Institute since its foundation in 1938.

In the review herein presented, three elements were considered: the lessons of ISET-InDRE historical recovery, Mexico's epidemiological challenges and the institution's forward planning.

The historical analysis showed the character traits present in the Institute since its birth:

- Multidimensional approach to health problems, considering the basic, entomological, clinical, epidemiological and humanistic aspects, to support priority health campaigns and programs of each period.
- The seriousness and robustness of scientific research carried out at the Institute, which offers answers to the most important health problems, although the complicated internal situation of the country, as well as in the borders, has posed challenges to national public health, which is inseparable of global public health.

From this significant institutional biography, we can conclude that InDRE must maintain its strong sense of identity and promote continuous and intense scientific, technological and humanistic development. With this, it will be able to help facing both infectious and chronic and non-communicable diseases.

In December 2019, in the province of Wuhan, China, an epidemic outbreak of the SARS-CoV2 coronavirus, the cause of Covid-19, was initiated, with disease quickly turning into a pandemic. In the face of this new global challenge, InDRE was the first institution in Latin America to carry out the confirmation of cases by molecular methods. The methodology would be transferred in a matter of few days to the RNLSP.²⁹

The diagnostic task in charge of InDRE must go beyond the laboratory and include economic, social and ecological aspects in order to explain the complexity behind the morbidity and mortality figures. In the near future, InDRE should maintain the momentum in high-level research and link with clinical areas of national health institutes as well as with reference and high specialty hospitals.

Building upon its great past, InDRE should continue in the 21st century as a national security institution, leader in global public health.

Table 4. World Health Organization designations for InDRE, 2012 to 2019

Year of designation	WHOC name	National program it supports	International program it supports
2016*	National Influenza Center	Prevention and Control of Respiratory Diseases and INFLUENZA	Global Influenza Surveillance and Response System
2016**	TB Supranational Laboratory	Prevention and Control of Tuberculosis	End TB Strategy
2017	WHO Collaborating Center for Training on Malaria Microscopy Diagnosis	Prevention and Control of Malaria	Global Technical Strategy for Malaria 2016-2030
2017	WHO Collaborating Center on Laboratory Biosafety	National Network of Public Health Laboratories	One World, One Health Agenda
2017	WHO Collaborating Centre for Arboviruses	Epidemiological Surveillance of Vector-Transmitted Viral Diseases	Arbovirus Diagnostic Laboratory Network in the Americas
2018	WHO Collaborating Centre on Laboratory Quality Management	National Network of Public Health Laboratories	Conference on Laboratory Quality Systems
2018***	Poliovirus-Essential Facilities	Polio and acute flaccid paralysis surveillance	Global Polio Eradication Initiative

*First appointment in 1951; re-designation in 2016.

**First appointment in 2005; re-designation in 2016.

***At the request of the health authority in 2018.

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Conflict of interests

None.

Ethical disclosures

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Confidentiality of data. The authors declare that no patient data appear in this article.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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