

Surgical multicenter collaborative studies: what happens in Latin America?

Estudios colaborativos multicéntricos en cirugía: ¿qué sucede en Latinoamérica?

Luis A. Boccalatte^{1,2*}, Ma. Marta Modolo^{3,4}, José A. Calvache^{5,6}, Eddy P. Lincango-Naranjo⁷, Gustavo M. Ataíde-Gomes⁸, Igor Lima-Buarque⁸, Carlos J. Pérez-Rivera^{9,10}, Sebastián B. Shu-Yip¹¹, Ximena P. Vásquez-Ojeda¹¹, Maricarmen Olivós⁵, Sylvia Batista¹², Ma. Lorena Aguilera-Arévalo¹³, Hugo Gómez-Fernández¹⁴, Danilo Arévalo¹⁵, Dimitri Nepogodiev¹⁶, Maria Picciochi¹⁷, and Joana Simoes¹⁸

¹General Surgery Service, Italian Hospital of Buenos Aires, Buenos Aires, Argentina; ²Department of Surgery, Hospital Italiano University Institute, Buenos Aires, Argentina; ³General Surgery Service, Barros Luco Trudeau Hospital, Santiago Metropolitan Region, Chile; ⁴General Surgery Service, Luis Lagomaggiore Hospital, Mendoza, Argentina; ⁵Surgery Service, Roberto del Río Children's Hospital, University of Chile, Santiago, Chile; ⁶Department of Anesthesiology, Erasmus University Medical Center, Rotterdam, The Netherlands; ⁷Knowledge and Assessment Research Unit, Mayo Clinic, Rochester, Minnesota, USA; ⁸School of Medicine, CESMAC University Center, Maceió, Brazil; ⁹Department of General Surgery, Fundación Cardioinfantil-Instituto de Cardiología, Bogotá, Colombia; ¹⁰Department of General Surgery, Universidad El Bosque, Bogotá, Colombia; ¹¹Peruvian University Cayetano Heredia, Lima, Peru; ¹²Department of Surgery and Specialty, INTEC (Technological Institute of Santo Domingo), Santo Domingo, Dominican Republic; ¹³Department of Surgery, San Juan de Dios General Hospital, University of San Carlos de Guatemala, Guatemala; ¹⁴Dissemination and Coordination Global Surg, Asunción, Paraguay; ¹⁵ARCO Women's Medical Center, San Salvador, El Salvador; ¹⁶NIHR Unit on Global Surgery, University of Birmingham, Birmingham, UK; ¹⁷America's Coordinator GlobalSurg-CovidSurg Week, North America, Central America, South America, Caribbean, Hospital Professor Doutor Fernando Fonseca, Amadora, Portugal

Abstract

Background: GlobalSurg is an international group of researchers whose purpose is to conduct and disseminate robust collaborative, international and multicenter studies. **Target:** To expose the necessary strategies and the barriers crossed in conducting massive multicenter studies in surgery. **Method:** During the second semester of 2020, the study Surg-Week Prospective International Cohort Study was carried out. Surg-Week has been the largest international study in the field of surgery to date, with 141,582 patients included. A total of 4975 mini-teams, of between 1 and 5 members, collected data from 116 countries on all continents. **Results:** The creation of an official website for the study, reports with relevant information via email or groups via WhatsApp, formation of a Dissemination Committee of the protocol, delivery of webinars on recent team publications, appointment of leaders at the national and international level, and outreach through partnerships, were the strategies used for the development of the research. However, the barriers turned out to involve different aspects. **Conclusions:** Collaborative work allows establishing networks between different professionals with the goal of improving the quality of management, health policies and care of our patients in a timely manner of constant change.

Keywords: Research. Surgery. Scientifics. Researchers. Barriers. Coordination.

Resumen

Antecedentes: GlobalSurg es un grupo internacional de investigadores que tiene como propósito la conducción y la disseminación de robustos estudios colaborativos, internacionales y multicéntricos. **Objetivo:** Exponer las estrategias necesarias y las barreras

Correspondence:

*Luis A. Boccalatte

Juan D. Perón 4190

C.P. C1181ACH, Buenos Aires, Argentina

E-mail: luis.boccalatte@hospitalitaliano.org.ar

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encontradas en la conducción de estudios multicéntricos masivos en cirugía. **Método:** Durante el segundo semestre del año 2020 se llevó a cabo el estudio *Surg-Week Prospective International Cohort Study*, hasta la fecha el estudio internacional más grande en el campo de la cirugía, con 141,582 pacientes incluidos. Un total de 4975 miniequipos, de uno a cinco integrantes, recopilaron datos de 116 países de todos los continentes. **Resultados:** La creación de un sitio web oficial del estudio, reportes con información relevante vía e-mail o grupos vía WhatsApp, conformación de un comité de diseminación del protocolo, dictado de webinars sobre publicaciones recientes del equipo, designación de líderes nacionales e internacionales, y la divulgación por medio de sociedades, fueron las estrategias utilizadas para el desarrollo de la investigación. Sin embargo, las barreras detectadas para llevar a cabo el estudio multicéntrico fueron variadas. **Conclusiones:** Los trabajos colaborativos permiten establecer redes entre diferentes profesionales con el fin de mejorar la calidad de la gestión, las políticas sanitarias y la atención a los pacientes en tiempos de constante cambio.

Palabras clave: Investigación. Cirugía. Científicos. Investigadores. Barreras. Coordinación.

Introduction

GlobalSurg is an international group of researchers in numerous areas with an interest in perioperative medicine whose purpose is to conduct and disseminate robust prospective, observational, and randomized, collaborative, international, and multicenter studies, with an impact on daily surgical practice, coordinated by the National Institute for Health Research (NIHR), Global Health Research Unit on Global Surgery, in the United Kingdom. This collaboration is directly in line with the great need to integrate knowledge for current scientific improvement.¹ This network of researchers expanded shortly after determining the pandemic status, in response to the need to answer questions related to SARS-CoV-2 in the surgical field. For this reason the CovidSurg Collaborative arose.

In the second semester of 2020, the study was carried out *Surg-Week Prospective International Cohort Study*, the largest international study in the field of surgery to date, with 141,582 patients included. A total of 4,975 mini-teams, ranging from one to five members, collected data in 116 countries on all continents. It is the first pan-specialty study that also includes children (9.7% of the total number of patients included, $n = 13,800$). There was great stringency regarding inclusion and exclusion criteria, and data loading in RedCap, with the missing data rate for key data fields being only 0.2%. RedCap is a secure access system *on-line* for the collection of anonymous patient data. It is accessible from anywhere in the world, which enables the connectivity of research teams and achieves the collection of high-quality data.²

Method

The primary objective of the study was to determine the optimal timing of elective surgery during

the COVID-19 pandemic and, secondly, to determine relevant global surgical indicators, such as the 30-day postoperative mortality rate and associated complications (pulmonary complications, pulmonary thromboembolism and complications according to the Dindo-Clavien classification). Three patient cohorts were used: 1) those who had the infection before surgery, 2) those who became infected during the postoperative period, and 3) those without preoperative or postoperative infection. The study was addressed to all hospital levels (with various degrees of complexity), surgical specialties, age groups, and types of surgery (ambulatory, inpatient, scheduled, and emergency). Data was collected for a period of 7 days (4 weeks in October) and had a 30-day postoperative follow-up. A preliminary publication from the same group described that pulmonary complications and 30-day mortality drop to 0% when surgery is deferred 4 weeks from the positivity of the SARS-CoV-2 test³. More details about the study can be found on their website (<https://global-surg.org/surgweek/>).

Results

Latin America participation

In Latin America, 377 mini-teams from 16 countries participated, recruiting a total of 11,168 patients. In fact, in Latin America we have never seen such a successful collaboration in the surgical field. Participating countries (Fig. 1), the number of teams per country and the number of enrolled patients are detailed in Table 1. The number of centers and countries that participated in the SurgWeek study was greater than in studies conducted in previous years by the GlobalSurg Collaborative. This international team seeks to guide clinical practice based on high-quality evidence generated, focusing on patient



Figure 1. Participating countries in Latin America: Colombia, Argentina, Brazil, Mexico, Paraguay, Peru, Guatemala, Chile, Dominican Republic, Uruguay, Ecuador, Trinidad and Tobago, Puerto Rico, El Salvador, Panama, and Cuba.

outcomes and aiming to change and guide health policies according to the institutional level and resources, always contextualizing the results obtained in countries of similar human development.

Finally, Latin American participation in this collaboration has been substantial, with Colombia and Argentina being the countries that contributed the most patients. In the region, these countries contributed 42% of the total, with their capitals contributing the most patients recruited and followed-up at 30 days. Additionally, the Argentine Republic was the country that presented the highest ratio of number of patients per mini-team, with 41.54 (nine centers registered in the country). It should be noted that 181 mini-teams presented fewer than 20 patients, and there may be several reasons: 1) the smaller centers in the interior of the country substantially decreased surgical activity; 2) the scarcity or lack of data to complete the entire form or few recruited patients; 3) physical and mental exhaustion of the team or impossibility of monitoring the patients over time; and 4) decrease in the number of surgeries due to not having an exclusive operating room for patients infected with coronavirus.

Table 1. Distribution of teams and enrolled patients in Latin America

Countries (n = 16)	Hospitals (n = 152)	Mini teams (n = 377)	Enrolled patients (n = 11,168)	Patients enrolled by mini-team	Patients enrolled by hospital
Argentina	9	46	1911	41.54	212.33
Barbados	1	3	13	4.33	13
Brazil	39	70	1906	27.23	48.87
Chile	9	15	459	30.60	51
Colombia	22	78	2605	33.40	118.41
Cuba	1	1	2	2	2
Dominican Republic	2	33	399	12.09	199.50
Ecuador	2	2	54	27	27
El Salvador	1	1	11	11	11
Guatemala	10	16	567	35.44	56.70
Mexico	26	44	1406	31.95	54.08
Panama	1	1	10	10	10
Paraguay	11	39	988	25.33	89.82
Peru	15	22	698	31.73	46.53
Trinidad and Tobago	1	2	32	16	32
Uruguay	2	4	107	26.75	53.50

Table 2. Strategies used for the coordination of the study, advantages and barriers imposed by the chosen method

Coordination strategy	Aim	Advantages	Barriers and areas for improvement
Website	Grouping of information in an accessible <i>online</i> site translated into different languages Examples: Research protocol Explanatory audiovisual material Ethics committee approval and informed consent models	Availability of useful and accessible resources Quick form of introduction to the model and the objective of the study for interested hospitals	Need for stable internet connection The literal translation of the protocol into different languages can cause confusion for interested researchers
E-mail	Recruitment of researchers: global distribution according to previous databases of professionals who had already participated in collaborative consortium work General (massive) coordination of research development Examples: Beginning of the study Deadlines Clarifications Authorship Publications	Increase in the incorporation of new centers Granted study fluency through ongoing guidance from investigators	Some notices corresponded to previous publications that led to confusion for researchers not related to them. Excessive number and content of emails (at certain times)
Whatsapp groups	Dissemination of the points previously expressed in "Website" Regionalization of researchers (America, Europe, Asia, Dissemination Committee, Help Desk support, Hospital leads, etc.) National groups with dissemination of translated information	More fluid communication Faster resolution of the problems of each researcher Increased participation and views Discussion of aspects common to a region	Excess messages Messages received in different time zones Need for a good command of the written English language, with some exceptions
Dissemination committee	Convey the main guidelines of the study and updates to each national leader	Identification of a person in charge per country to enforce the regulations	Due to the large number of integrations, one-on-one interaction is difficult Need for a good command of the English language
<i>Webinar</i>	Inform about updates and updating of the development of the study in the different countries	Meet the needs and concerns of each country	Due to time differences, many attendees were unable to connect in a timely manner
National leader and hospital	Ensure that the study is carried out in that country and hospital, and refer to it if problems are identified	Organization and completion of the study Leadership position and group management (stage of personal growth)	The role implies a lot of commitment and dedication, which is why some countries did not have a national leader Fluent command of the English language
Local scientific societies	Dissemination of the study in various formats (4) Promote the enrollment of surgeons and surgical residents in research	Scientific societies enjoy national recognition and capture the attention of their members Strengthen a network of contacts between surgeons or participants	Non-members did not access the information Some scientific societies did not support the disclosure of the study Low response rate

Table 3. Barriers observed during the development of the study

Barriers in Latin American countries	Possible causes	Improvement strategies
Idiomatic	Spanish as a native language in most countries The medical population does not, for the most part, have high levels of English	Promote and train doctors during early training stays (hospital practices, residences, etc.) in English Active training in a second language at universities In the short term: generate translations of the main protocol and necessary documentation
Health system conditions	Impact of the pandemic on chronically weak health systems, whose human resources were insufficient due to the demand for specialists in the surgical field, such as anesthesiologists High number of sick health personnel Poor availability and slow results of polymerase chain reaction tests and access to computed tomography images Scarce availability of medical and surgical supplies in countries where importation was not available Some centers (mainly private) were able to respond strategically and effectively to the adverse conditions derived from the pandemic Structural weakness Example: Fewer intensive care beds for post-operative care, complete cancellation of elective surgeries, etc.	Strengthening health systems through coherent policies Schedule protected for scientific activity Equitable distribution of health resources and research resources Promote research in residents/grantees Establish institutional protocols according to the availability of human, structural and economic resources
Inadequate recording of data in the medical history	Countries that do not have a computerized medical record Impossibility or less follow-up of patients due to the pandemic Incomplete surgical records in the area of COVID-19 symptoms for not belonging to the specialty	Universal medical record preformed and digitized through a server with encrypted access Train in the importance of correct and complete documentation, monitoring and recording of data in research studies ICD-10 universal coding system for recording diagnoses and procedures
Problems obtaining study approval by the ethics committee or ministerial authorization	Ethics committees closed or very slow in their resolution Ethics committees with little training in this type of study (request for unnecessary papers) Lack of staff Ministry of health without knowledge of conducting international studies Lack of approval by novice or inexperienced investigators	Stimulate the creation of ethics committees Train committees on this type of study Agility of resolutions through virtual sessions Knowledge of not requesting informed consent in observational studies Extended methodological training in hospital and research committees
Competition and egoism in different strata	Need for leadership and individual and collective recognition Understand the concept of collaborative work and its advantages Increase the number of indexed publications Lack of leadership Disbelief that the study could be internationally recognized Lack of economic incentive and professional income Lack of communication and collective help between peers from the same institution, region or province Lack of institutional, regional and national identity or commitment Little time available for surgeons to dedicate to research	Exalt in undergraduate and medical residency systems the importance of scientific research and collaborative work among colleagues in order to improve the quality of care for our patients Understanding of medical and health activity as a science Encourage teamwork and improve communication between colleagues Encourage research in the surgical field with protected and paid time through international and national collaborations with scientific societies
Difficulties in handling RedCap	Little used system in Latin America English language Lack of training to enter data in a web platform	Access to RedCap through subsidies to institutions with high scientific production Access to the RedCap platform provided by the study to enter the data collected from the patients of each institution In collaborative projects like this, access to the system is free for collaborators

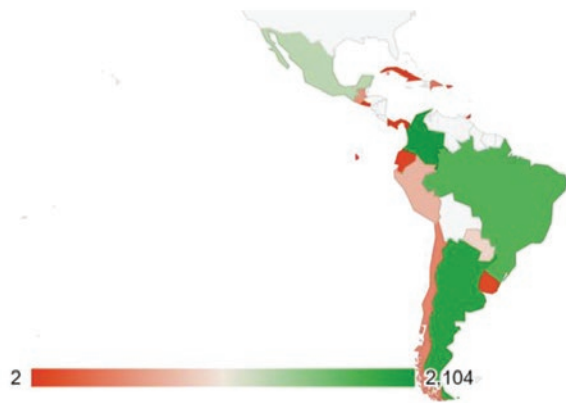


Figure 2. Number of patients recruited in each country.

Figure 2 shows the degree of recruitment of the participating countries.

Strategies for coordinating multicenter studies

This group presents different relevant principles of collaborative research. Within its conformation is a core team responsible for coordinating the entire project, based at the University of Birmingham, United Kingdom. For the dissemination and promotion of the enrollment of as many centers as possible, a dissemination committee was created, which includes national leaders responsible for coordinating the study in the different participating countries. In Table 2 the strategies used for the coordination of the study, the resolution of doubts and the issuance of recommendations are exposed, pointing out the successes and the barriers that were found.

Barriers in the development of multicenter studies in Latin America

Our main interest is to improve the quality of patient care. However, the possibility of being cited in high-impact and indexed international journals is attractive to all associated collaborators. Through our role as national leaders, obstacles or difficulties could be identified both in the coordination and in the development and management of the project⁴. One of the first appreciations was the temporal difference in the spread and course of the pandemic

and the development of the study between Europe and Latin America, which implied many human resources dedicated to care activity, to the detriment of academic and research activity, in different periods of time. In addition, the lack of socioeconomic resources of Latin American nations compared to European ones increased this gap, implying a large number of researchers dedicated exclusively to the care task. For this reason, it was necessary to double the effort to achieve greater recruitment and enrollment of centers while maintaining the interest and quality of the study. Another critical point when talking about barriers was the approval of local, ministerial or national institutional ethics committees. Most of the requests were difficult for the above reasons, and in other centers they required unnecessary documentation. The excessive bureaucracy and the inability to incorporate digital processes led the researchers to give up on the attempt to participate. Other inconveniences that arose during the start-up and the recruitment of patients are detailed in Table 3.

Conclusions

The development and execution of collaborative multicenter studies is a fundamental and necessary strategy to obtain studies of high scientific quality and a good level of evidence. During the current pandemic, it is imperative to have fast and reliable results for consensual decision-making. Detecting the barriers and the different aspects of improvement determines an internal audit with the aim of continuous improvement. Collaborative work allows the establishment of networks between different professionals with the ultimate goal of improving the quality of management, health policies and patient care in times of constant change.

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Conflicts of interest

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Ethical disclosures

Protection of people and animals. The authors declare that no experiments were carried out on humans or animals for this research.

Data confidentiality. The authors declare that they have followed the protocols of their work center regarding the publication of patient data.

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

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