ORIGINAL ARTICLE
BASIC SCIENCES/OTHERS
http://dx.doi.org/10.1590/S1808-185120222104261485

PRESENTATION OF THE MULTICENTRIC COLLECTION SPINE SURGERY DATABASE

APRESENTAÇÃO DO BANCO DE DADOS DE COLETA MULTICÊNTRICA DE CIRURGIA DA COLUNA

PRESENTACIÓN DE LA BASE DE DATOS DE RECOPILACIÓN MULTICÉNTRICA DE CIRUGÍA DE LA COLUMNA VERTEBRAL

GABRIEL POKORNY[1], RODRIGO AMARAL[1], RAPHAEL PRATALI[2], RICARDO ACÁCIO[3], CARLOS ROMEIRO[4], MARCUS VINICIUS MAGNO[5], MURILO DAHER[6], CARLOS FERNANDO PS HERRERO[7]

1. Instituto de Patologia da Coluna, São Paulo, SP, Brazil.
2. Hospital do Servidor Público Estadual, São Paulo, SP, Brazil.
3. Instituto de Ortopedia e Traumatologia de Joinville, Joinville, SC, Brazil.
4. Instituto de Coluna e Ortopedia de Recife (InCore), Recife, PE, Brazil.
5. Universidade da Região de Joinville (UNIVILLE), Joinville, SC, Brazil.
6. Centro de Reabilitação e Readaptação Dr. Henrique Santillo (CRER), Goiás, GO, Brazil.
7. Universidade de São Paulo (USP), Faculdade de Medicina de Ribeirão Preto, Ribeirão Preto, SP, Brazil.

ABSTRACT

Objectives: To present the Spine Surgery Database developed by the Brazilian Spine Study Group and the methodology involved in its creation, in addition to presenting initial informationabout the use of the database. Methods: Description of the steps for selecting the questionnaires and variables to be included in the database, initial expansion of the use of the database tophysicians close to the BSSG, a brief exploration of quality control and methods for the inclusion ofnew centers, and training on the database, in addition to a brief descriptionof some of the data included in the database. Results: Currently, the database includes 428 patients who already underwent spine surgery and 9 collection centers with at least one patient collected. Conclusion: The Brazilian Spine Study Group's Multicentric Collection Database is a viable tool that allows patients from different sourcesto be included within a common flow. ***Level of Evidence V; Expert opinion.***

Keywords: Spine diseases; Database; Registries; Diffusion of innovation.

RESUMO

Objetivos: Apresentar o Banco de Dados de Cirurgia da Coluna, desenvolvido pelo Brazilian Spine StudyGroupe a metodologia envolvida em suacriação, além de apresentar dados iniciais da utilização do banco de dados. Métodos: Descrição das etapas deseleção dos questionários e variáveis a serem incluídos no banco de dados, expansão inicial do uso do banco para médicos próximos do BSSG, breve exploração do controle de qualidade e métodos de inclusão de novos centros e treinamento no banco de dados, além de breve exposição de alguns dados incluídos no banco. Resultados: Atualmente, o banco de dados conta com 428 pacientes incluídos que já realizaram a cirurgia na coluna e novecentros coletores com ao menos um paciente coletado. Conclusão: O Banco de Dados de coleta multicêntrica do Brazilian Spine StudyGroup é uma ferramenta viável que permite a inclusão de pacientes de diversas origens dentro de um fluxo comum. ***Nível de Evidência V; Opinião de Especialista.***

Descritores: *Doenças da coluna vertebral; Base de dados; Sistema de registros; Difusão de inovações.*

RESUMEN

Objetivos: Presentar la Base de Datos de Cirugía de la Columna Vertebral desarrollada por el Brazilian Spine Study Groupy lametodología utilizada ensucreación, además de presentardatosiniciales sobre el uso de la base de datos. Métodos: Descripción de las etapasde selección de cuestionarios y variables a incluir enla base de datos, ampliación inicial del uso de la base de datos a los médicos cercanos al BSSG, breve exploracióndelcontrol de calidad y de los métodos deinclusión de nuevos centros y formaciónenla base de datos, y breve exposición de algunosdatosincluidosenla base de datos. Resultados: Actualmente,la base de datoscuentacon 428 pacientes incluidos algunos que se han sometido a cirugía de columna vertebral y 9 centros de recopilacióncon al menos un paciente recogido. Conclusión: La base de datos de recopilaciónmulticéntricadel Brazilian Spine Study Group es una herramientaviable que permitelainclusión de pacientes de diferentes orígenes dentro de unflujocomún. ***Nivel de Evidencia V; Opinión experta.***

Descriptores: *Enfermedades de la columna vertebral; Base de datos; Sistema de registros; Difusión de innovaciones.*

Study conducted by the Instituto de Patologia da Coluna, São Paulo, SP; the Hospital do Servidor Público Estadual, São Paulo, SP; the Instituto de Coluna e Ortopedia de Recife (InCore), Recife, PE; the Instituto de Ortopedia e Traumatologia de Joinville; the Universidade da Região de Joinville (UNIVILLE); the Centro de Reabilitação e Readaptação Dr. Henrique Santillo (CRER), Goiânia, GO; and the Universidade de São Paulo (USP), Faculdade de Medicina de Ribeirão Preto, Ribeirão Preto, SP, Brazil.
Correspondence: Gabriel Pokorny. Rua Vergueiro, 1421, São Paulo, São Paulo, Brasil. CEP: 04101001.ghpokorny@gmail.com

Received on 02/25/2022 accepted on 06/30/2022
Reviewed by: Alexandre Fogaça Cristante

INTRODUCTION

With the advancement of technology, storage and data analysis capabilities have made the possibility of collecting multicentric data for the purpose of performing robust and increasingly powerful analyses of various pathologies more and more real. In this context, surgeons and institutions coming together to create and assemble data collection groups has become increasingly popular.[1-4]

There are severallarge database groups specifically focused on spine surgery, which not only allow surgeons to have access to more robust data, but also change the paradigms of spine surgery. Here, we mention the database of the ISSG (International Spine Study Group), which allowed the development of research that completely changed the worldview of the spine about sagittal alignment and how to treat adult deformity.[5–7] Along the same lines of reasoning, we cite the ESSG (European Spine Study Group), which more recently has launched several studies and tools that have helpedspine surgeons to understand the best strategies for identifying and preventing possible complications following deformity correction surgeries.[8, 9] Finally, the SRS (Scoliosis Research Society) is a century-old institution that, with the help of an international database and several lines of research, has revolutionized scoliosis treatment, especially idiopathic, around the world.[10–12]

Nowadays however,considering the national scenario, there are few spine surgeons who collect data about their surgeries and/or patients with scientific objectives. Furthermore, there are almost no tools, such as a database that allows the collection of multicentric data from patients who have undergone spine surgery, mostof them being exclusive to a single company or focused on a specific project.

Thus, the Brazilian Spine Study Group (BSSG) proposed the creation of a tool that, through the collection of multicentric data from spine surgery cases,would allow spine surgeons from all over Brazil, and in the future from all over Latin America, to participate in and conduct research at the highest level, making possible the entry of Brazil and its surgeons into the leading edge of spine surgery science.

METHODS

Description of the steps for selecting the questionnaires and variables to be included in the data base, initial expansion of use of the database to doctors close to BSSG, brief exploration of quality control and methods for including new centers and training in the database, in addition to a brief explanation of some of the data included in the database. Approval by the Institutional Review Board was not necessary.

Inclusion of patients in the database

Any patient who has undergone spine surgery and has consented or, in the case of underage patients, whose legal guardian has consentedto the collection of their data by completing an informed consent form.

Selection of questionnaires and variables

To select the data to be included in the database, the researchers conducted an extensive search in the literature and with internationally renowned researchers (Ex: ISSG or GSO) to define which variables would be included in the database, thus ensuring the contemporaneity of the data collected and enabling the future use of the data included in the database in international research.

Inclusion of research centers in the database

All research centers interested in collecting spine surgery data in the database may participate in the project by filling out a term of agreement with the database rules. As soon as the term of agreement is signed, the teamat the center will receive a database user manual and a one-hour training session will be scheduled with the team responsible for the database.

Conducting studies with the database

To conduct research with multicentric database data, a research project must be conducted, which will be evaluated by a scientific boardand be either approved or not. If approved, the researcher will receive the de-identified data. In addition, the researcher must obtain approval to conduct the work from an ethics and research committee.

RESULTS

Database implementation steps

The database implementation steps were divided into 4 parts. The first step was to define the questionnaires and variables to be included in the database. The second step consisted of structuring the flow of questionnaires and pilot tests by members of the BSSG. The third step focused on the expansion of the data base to doctors close to the BSSG and included the first test of a real-world application using the database. The fourth step was establishing a constant flow of work proposals and data dissemination (Figure 1). Note that steps 3 and 4 are repetitive and will continue to occur as the database evolves.

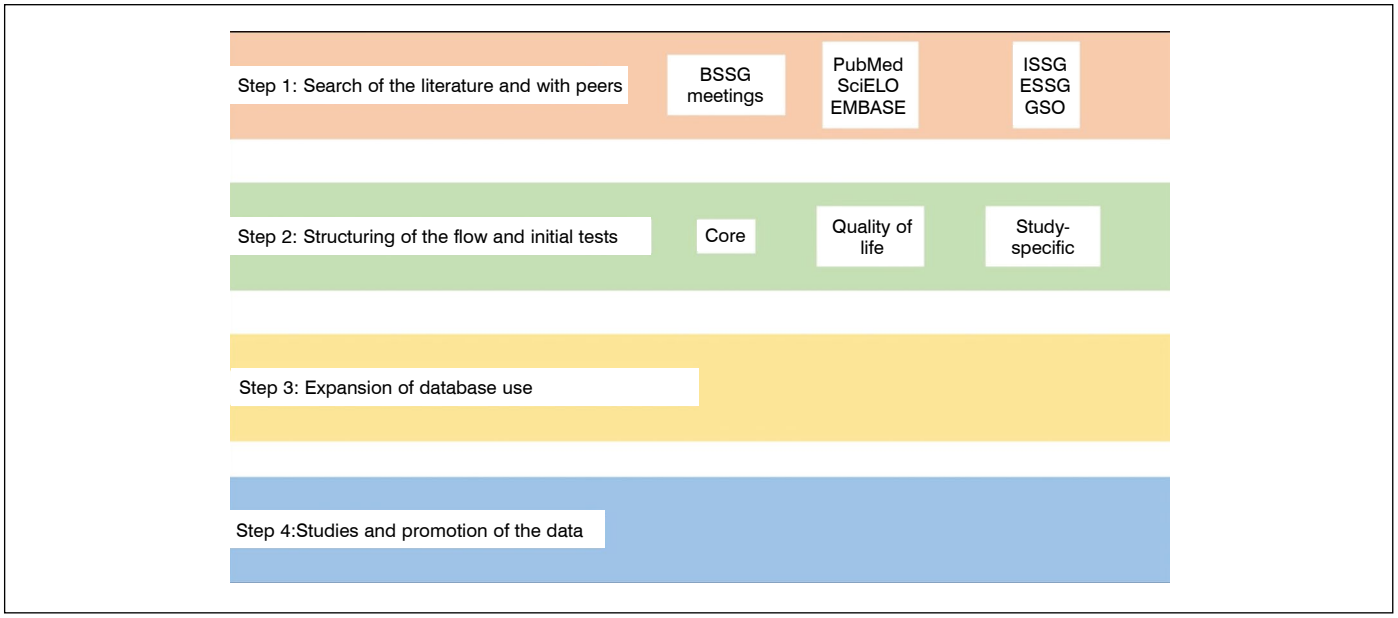

Figure 1. Steps for the elaboration and expansion of the database.

Database design and flow

After extensive research, it was determined that the database would have a longitudinal format where the patients would fill out several questionnaires in common and thenthe quality of life questionnaires would be divided based on a pathological group (Adult Deformity, Pediatric Deformity, Cervical Degenerative, Lumbar Degenerative, Trauma, Tumor) with their criteria definedaccording to international consensuses and detailed in the "Technical Instructions – General 5 – Minimum Pathological Group Specifications" document.

Thus, the database is composed of a central core of questionnaires to be completed by all patients and thenquality of life questionnaires to be completed depending on the patient's pathological group (Figure 2).

Finally, the database structure also allows the elaboration of specific (parallel) questionnaires that can be proposed for specific research, the scope of which is not addressed in the core or quality of life questionnaires. These questionnaires are temporary and only available to database members who were invited to participate in the specific research.

Quality control

To ensure that the data being input to the database meets minimum quality standards, the database has two quality control mechanisms, one passive and the other active (Figure 3).

The passive mechanism consists of training the teams, providing online access to all technical instructions for the questionnaires included in the database, providing a link to videos to assist in completing the questionnaires, in addition to making available a manual containing all the basic information about the database flow.

The active mechanism consists of defining rules within the database that identify when non-standard information is entered into the database (e.g. a patient under 18 years of age inthe adult deformity pathological group, or a patient entered into the database without the ICF attached to the demographic data questionnaire). In this case, a message is sent to the researcher asking them to resolve issue.

Summary of collected data

A total of 1778 levels, with an average of three levels per patient, were operated on. Most of the procedures were performed as open surgeries (276, 54%), followed by minimally invasive surgeries (199, 39%) (Figure 4).

Most of these fell into the degenerative lumbar pathologies group (294, 54%), the most frequently occurring pathologies in the database being disc herniation (114), followed by disc degeneration (84) and canal stenosis (76) (Figure 5).

DISCUSSION

Randomized clinical trials are the gold standard for conducting clinical studies, as they allow forthe meticulous selection of patients and treatments, thus minimizing the occurrence of bias and

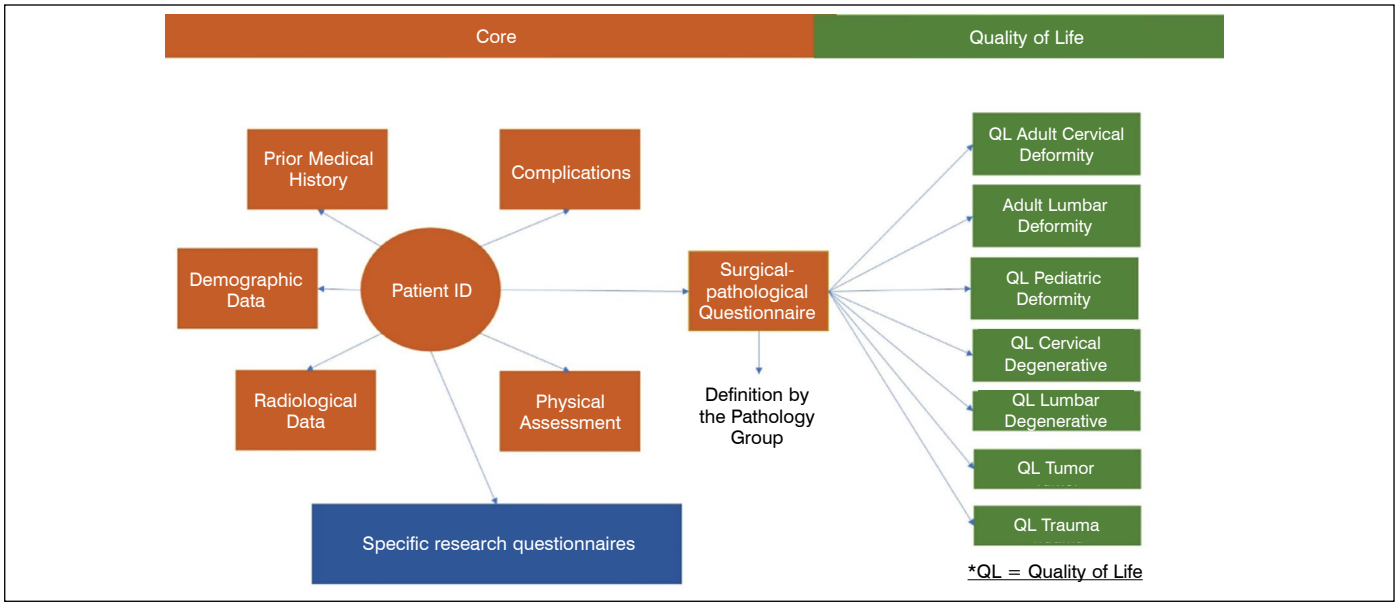

Figure 2. Internal core of the databse.

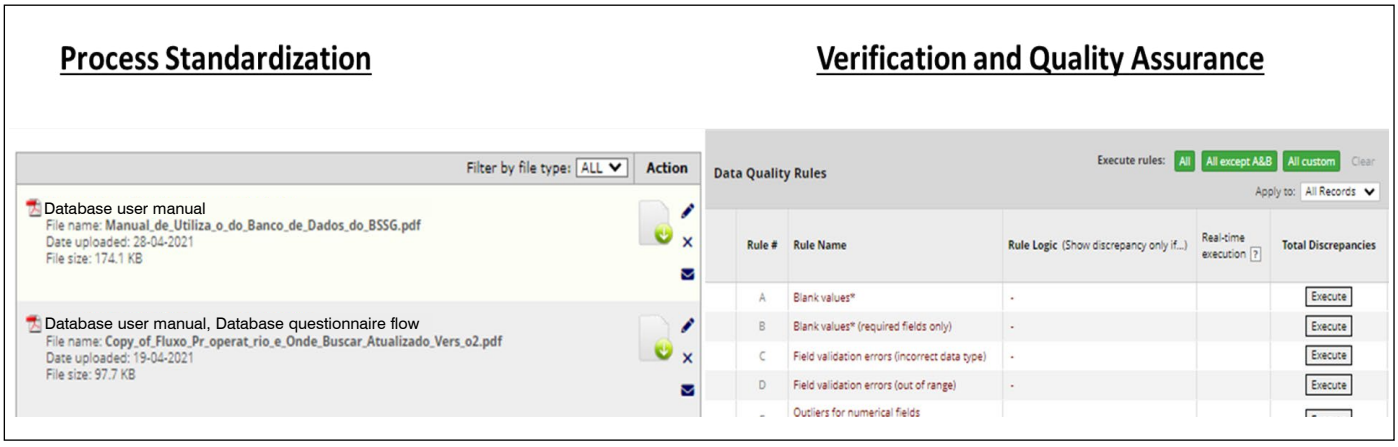

Figure 3. Systems of quality management in the database.

controlling confusion factors.However, randomized clinical trials are extremely expensive, even more so when we are talking about studies of surgical procedures. Therefore, these studies are generally used to obtain initial evidence about the effectiveness and safety of a productby conducting real-world studies to understand how it will function when reaching the general population.

In this scenario, databases or registriesare of great importance when conducting real-world studies and developing solutions that use techniques such as machine learning and artificial intelligence, given that these algorithms require large quantities of data that, if possible, include the most varied target populations of interest to enable the elaboration of reliable solutions that can be generalized effectively.[13, 14]

Databases and spine surgery

Databases play a central role in the development or support of several recent theories about sagittal alignment parameters, the risk of intraoperative complications, and even the occurrence of postoperative complications. An example of using data originating from databases that change spine surgery is the 2016 study by Lafage et al., which used 773 patients from 11 different centers in the USA to demonstrate that age could significantly impact the normative sagittal alignment values of the patients.[15] Other studies used large multicentric databases to demonstrate that surgical treatment of patients with adult deformity is capable of promoting significant clinical improvements.[16,17]

Other studies using databases have tried to predict the occurrence of complications after spine surgery procedures. In 2017, Miller et al.performed a validation of the frailty score using 417 patients from a multicenter registry.[18] More recently, in 2021, Shahrestani et al. used the national readmission database to demonstrate that using the frailty index can help predict postoperative outcomes in patients receiving treatment for lumbar spine tumors.[19] Additionally, other researchers have used large registries to identify how linking demographic data, surgical data, and radiological measurements can impact the risk of mechanical complications and surgical revisions after spine surgery. In 2019, Yagi et al. used 195 patients to develop a model to identify complications, which was rated 84% accurate in an external validation.[20] Similarly, in 2021, Lafageet al. developed a score, based on the radiographic measurements of 407 patients, capable of indicating the risks of PJK occurring after corrective adult deformity surgery.[21]

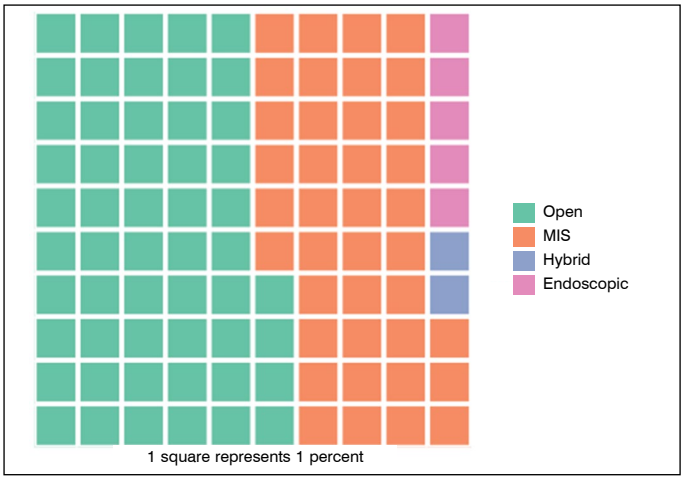

Figure 4. Figure showing the percentage of invasiveness of the procedures used from the database

Databases, spine surgery, and machine learning

With the advances in statistical and computational techniques, and in addition to advances in the data storage capacity of existing registries, several algorithms and models have been developed to identify predictive factors and even to identify and classify pathologies from imaging tests.[13,14,22]

Various examples of the combination of machine learning and databases appear daily in the literature on spine surgery. In 2021, Ounajim et al. used the data from two studies ofspinal cord stimulator implantationafter cases of failed back syndrome to demonstrate that algorithms, even simple ones, have a greater ability to predict a positive response to spinal cord stimulation than gold standard selection methods.[23] Researchers have also used this combinationof technologies to predict postoperative outcomes after spine surgery. In 2021, Zhang et al. developed 5 models using a database of 1281 patients with levels of accuracy between 63 and 83% in predicting hospitalization time after posterior fusion.[24] Shah et al., in 2021, used a database containing 38,788 patients to identify complication and readmission risks after lumbar fusion.[25] And finally, in 2021, Li et al. used a database of 1019 patients to demonstrate that using a computational vision algorithm couldmore accurately identify the occurrence of vertebral fractures, especially osteoporotic fractures, than human specialists.[26]

CONCLUSION

The use of database platforms to store data for subsequent use in scientific research is a tool that is increasingly in vogue for the development of new algorithms and guidelines to make spine surgery safer and more effective.

The multicentric collective database of the Brazilian Spine Study Group is a viable tool that allows the inclusion of patients from different sources within a common data collection flow, thusproviding better data quality assurance and supporting the future use of the data for scientific research.

All authors declare no potential conflict of interest related to this article.

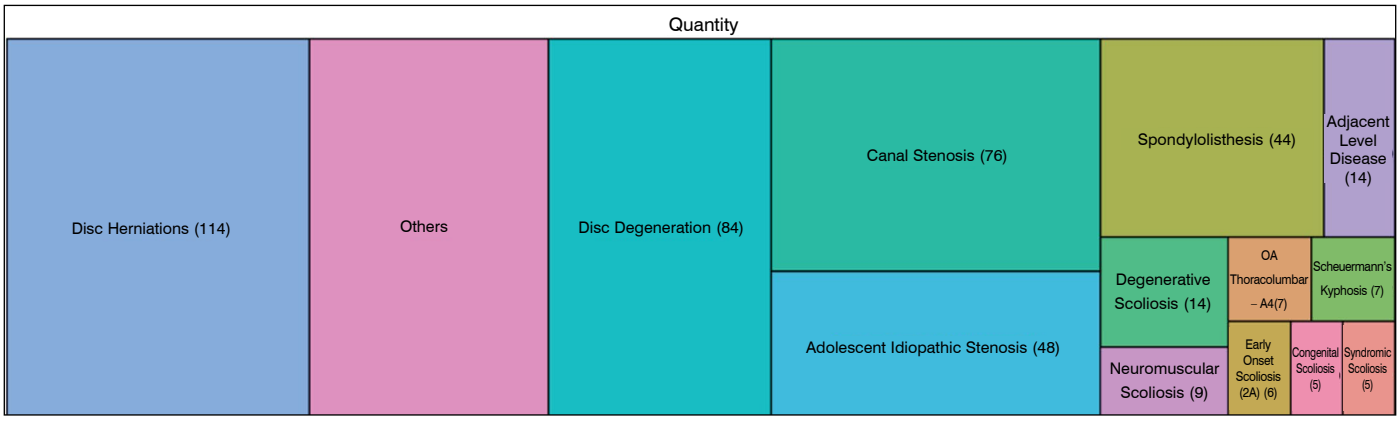

Figure 5. Figure showing the number of cases included in the database by pathology. Othersrepresented to sum of all the pathologies that did not reach a minimum of 5 occurrences.

CONTRIBUTIONS OF THE AUTHORS: Each author made significant individual contributions to this manuscript.GP: Writing of themanuscript, elaboration of the concept, preparation of the graphs and tables; RA: Elaboration of the concept and review of the manuscript; RP: Elaboration of the concept and review of the manuscript; RA: Assistance with data collection and elaboration of the concept; CR: Assistance with data collection and elaboration of the concept; MVM:Assistance with data collection and elaboration of the concept; MD: Assistance with data collection and elaboration of the concept; CFPSH: Elaboration of the concept and review of the manuscript.

REFERENCES

1. Ahmad FA, Payne PRO, Lackey I, Komeshak R, Kenney K, Magnusen B. et al. Using REDCap and Apple ResearchKit to integrate patient questionnaires and clinical decision support into the electronic health record to improve sexually transmitted infection testing in the emergency department. J Am Med Inform Assoc.2020;27(2):265-73. https://doi.org/10.1093/JAMIA/OCZ182.
2. Vaz J, Abelin AP, Schmidt MM, De Oliveira PP, Gottschall CAM, Rodrigues CG, et al. Creation and Implementation of a Prospective and Multicentric Database of Patients with Acute Myocardial Infarction: RIAM. Arq Bras Cardiol.2020;114(3):446-55. https://doi.org/10.36660/ABC.20190036.
3. Beam AL, Kohane IS. Big Data and Machine Learning in Health Care. JAMA.2018;319(13):1317-8. https://doi.org/10.1001/JAMA.2017.18391.
4. Agarwal Y, Jain M, Sinha S, Dhir S.Delivering high-tech, AI-based health care at Apollo Hospitals. GBOE.2020;39(2):20-30. https://doi.org/10.1002/JOE.21981.
5. Hart RA, Rastegar F, Contag A, Kane A, Kane M, Daniels A, et al. Inter-and intra-rater reliability of the hart-ISSG proximal junctional failure severity scale. Spine.2018;43(8):E461-7. https://doi.org/10.1097/BRS.0000000000002498.
6. Lafage R, Schwab ÄF, Glassman ÄS, Bess S, Harris B, Sheer J, et al. Age-Adjusted Alignment Goals Have the Potential to Reduce PJK. Spine. 2017;42(17):1275-82.
7. ScheerJK, Tang JA, Smith JS, Acosta Jr FL, Protopsaltis TS, Blondel B, et al. Cervical spine alignment, sagittal deformity, and clinical implications: A review. JNeurosurg Spine.2013;19(2):141-59.doi: 10.3171/2013.4.SPINE12838.
8. Yilgor C, Sogunmez N, Boissiere L, Yavuz Y, Obeid I, Kleinstück F, et al. Global Alignment and Proportion (GAP) Score: Development and Validation of a New Method of Analyzing Spinopelvic Alignment to Predict Mechanical Complications after Adult Spinal Deformity Surgery. J Bone Joint Surg Am.2017;99(19):1661-72. https://doi.org/10.2106/JBJS.16.01594.
9. Obeid I, Boissière L, Yilgor C, Larrieu D, Pellisé F, Alanay A, et al.Global tilt: a single parameter incorporating spinal and pelvic sagittal parameters and least affected by patient positioning. Eur Spine J.2016;25(11):3644-9. https://doi.org/10.1007/s00586-016-4649-3.
10. Terran J, Schwab F, Shaffrey CI, Smith JS, Devos P, Ames CP, et al. The SRS-Schwab Adult Spinal Deformity Classification:assessment and clinical correlations based on a prospective operative and nonoperative cohort. Neurosurgery.2013;73(4):559-68. https://doi.org/10.1227/NEU.0000000000000012.
11. Fletcher AN, Schwend RM. The Ecuador Pediatric Spine Deformity Surgery Program: An SRS-GOP Site, 2008–2016. Spine Deform.2019;7(2):220-7. https://doi.org/10.1016/J.JSPD.2018.07.006.
12. ShillingfordJN, LarattaJL, Reddy H, Ha A, Lehman Jr RA, Lenke LG, et al. Postoperative Surgical Site Infection After Spine Surgery: An Update From the Scoliosis Research Society (SRS) Morbidity and Mortality Database. Spine Deform.2018;6(6):634-43. https://doi.org/10.1016/J.JSPD.2018.04.004.
13. Joshi RS, Lau D, ScheerJK, Serra-Burriel M, Vila-Casademunt A, Bess S, et al. State-of-the--art reviews predictive modeling in adult spinal deformity: applications of advanced analytics. Spine Deform.2021;9(5):1223-39. https://doi.org/10.1007/S43390-021-00360-0.
14. D'Antoni F, Russo F, Ambrosio L, Vollero L, Vadalà G, Merone M, et al. Artificial Intelligence and Computer Vision in Low Back Pain: A Systematic Review. Int J Environ Res Public Health. 2021;18(20):10909. https://doi.org/10.3390/IJERPH182010909.
15. Lafage R, Schwab F, Challier V, Henry JK, Gum J, Smith J, et al. Defining Spino--Pelvic Alignment Thresholds. Spine.2016;41(1):62-8. https://doi.org/10.1097/BRS.0000000000001171.
16. Buell TJ, Smith JS, Shaffrey CI, Kim HJ, KlinebergEO, Lafage V, et al. Operative Treatment of Severe Scoliosis in Symptomatic Adults: Multicenter Assessment of Outcomes and Complications With Minimum 2-Year Follow-up. Neurosurgery. 2021;89(6):1012-26. https://doi.org/10.1093/NEUROS/NYAB352.
17. Pellisé F, Serra-Burriel M, Vila-Casademunt A, Gum JL, Obeid I, Smith JS, et al. Quality metrics in adult spinal deformity surgery over the last decade: a combined analysis of the largest prospective multicenter data sets. J Neurosurg Spine. 2021;1:1-9. https://doi.org/10.3171/2021.3.SPINE202140.
18. Miller EK, Neuman BJ, Jain A, Daniels AH, Ailon T, Sciubba DM, et al. An assessment of frailty as a tool for risk stratification in adult spinal deformity surgery. Neurosurg Focus.2017;43(6):E3. https://doi.org/10.3171/2017.10.FOCUS17472.
19. Shahrestani S, Bakhsheshian J, Solaru S, Ton A, Ballatori AM, Chen XT, et al. Inclusion of Frailty Improves Predictive Modeling for Postoperative Outcomes in Surgical Management of Primary and Secondary Lumbar Spine Tumors. World Neurosurg.2021;153:e454-63. https://doi.org/10.1016/J.WNEU.2021.06.143.
20. Yagi M, Hosogane N, Fujita N, Okada E, Tsuji O, Nagoshi N, et al. Predictive model for major complications 2 years after corrective spine surgery for adult spinal deformity. Eur Spine J. 2018;28(1):180-7. https://doi.org/10.1007/S00586-018-5816-5.
21. Lafage R, Smith JS, Elysee J, Passias P, Bess S, Klineberg E, et al. Sagittal age-adjusted score (SAAS) for adult spinal deformity (ASD) more effectively predicts surgical outcomes and proximal junctional kyphosis than previous classifications. Spine Deform. 2021;10:(1):121-31. https://doi.org/10.1007/S43390-021-00397-1.
22. MeraliZA, Colak E, Wilson JR.Applications of Machine Learning to Imaging of Spinal Disorders: Current Status and Future Directions. Global Spine J. 2021;11(Suppl 1):23S-9S. https://doi.org/10.1177/2192568220961353.
23. Ounajim A, Billot M, Goudman L, Louis PY, Slaoui Y, Roulaud M, et al. Machine Learning Algorithms Provide Greater Prediction of Response to SCS Than Lead Screening Trial: A Predictive AI-Based Multicenter Study. J Clin Med. 2021;10(20):4764. https://doi.org/10.3390/JCM10204764.
24. Zhang AS, Veeramani A, Quinn MS, Alsoof D, Kuris EO, Daniels AH. Machine Learning Prediction of Length of Stay in Adult Spinal Deformity Patients Undergoing Posterior Spine Fusion Surgery. J Clin Med.2021;10(18):4074. https://doi.org/10.3390/JCM10184074.
25. Shah AA, Devana SK, Lee C, Bugarin A, Lord EL, Shamie AN, et al. Prediction of Major Complications and Readmission After Lumbar Spinal Fusion: A Machine Learning–Driven Approach. World Neurosurg.2021;152:e227-34. https://doi.org/10.1016/J.WNEU.2021.05.080.
26. Li YC, Chen HH, Lu HHS, Wu HTH, Chang MC, Chou PH. Can a Deep-learning Model for the Automated Detection of Vertebral Fractures Approach the Performance Level of Human Subspecialists?.ClinOrthopRelat Res. 2021;479(7):1598-612. https://doi.org/10.1097/CORR.0000000000001685.