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THE USE OF THE O-ARM® OR RADIOSCOPE IN SPINE SURGERY: SYSTEMATIC REVIEW WITH META-ANALYSIS

O USO DO O-ARM® OU DA RADIOSCOPIA EM CIRURGIAS DA COLUNA: REVISÃO SISTEMÁTICA COM META-ANÁLISE

EL USO DE O-ARM® O RADIOSCOPIA EN CIRUGÍAS ESPINALES: UNA REVISIÓN SISTEMÁTICA CON METAANÁLISIS

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ABSTRACT

The great advances in using new devices and imaging systems in surgeries aim to reproduce an ideal and safe scenario for the surgeon, the team, and the patient. New systems and devices are constantly available to demonstrate and facilitate intraoperative navigation, thereby reducing errors and avoiding complications for the patient and staff. This study evaluates and compares using the O-arm® system and radioscopy in the freehand technique in spine surgeries. For this, searches were conducted in PubMed and Embase for randomized and non-randomized studies using the O-arm® system and radioscopy in spine surgery. Twenty-four studies were included and compared regarding procedure time, accuracy of implant positioning, effective radiation dose, safety, and efficacy. In one study, the O-arm® group showed a shorter surgical time when compared to the freehand technique (222.5 min. [SD=38.0] vs. 255.2 min. [SD=40.3], p=0.011, respectively). In two studies, the freehand technique resulted in a lower effective radiation dose for patients. In 12 studies, a higher incidence of complications was observed among patients undergoing surgery with the freehand technique. It was concluded that using the O-arm® is associated with a reduction in malposition of implants and more safety for instrumented procedures. Still, no evidence exists that its use can result in less surgical time. ***Level of Evidence I; Diagnostic Analysis and Studies, Investigation of a Diagnostic Test.***

Keywords: Dosage; Efficacy; Radiation; Safety.

RESUMO

O grande avanço do uso de novos dispositivos e sistemas de imagem nas cirurgias tem por objetivo reproduzir um cenário ideal e seguro para o cirurgião, a equipe e o paciente. Constantemente, novos sistemas e aparelhos estão disponíveis para demonstrar e facilitar a navegação intraoperatória, com isso procurando reduzir erros e evitar complicações para o paciente e para equipe. Este estudo tem como objetivo avaliar e comparar o uso do sistema O-arm® e a utilização de radioescopia na técnica de freehand em cirurgias de coluna. Para isso, foram realizadas buscas nas bases PubMed e Embase de estudos randomizados e não randomizados sobre o uso em cirurgias de coluna do sistema O-arm® e radioscopia. Foram incluídos 24 estudos que foram comparados quanto ao tempo de procedimento, acurácia do posicionamento dos implantes, dose efetiva de radiação, segurança e eficácia. Um estudo o grupo O-arm® apresentou menor tempo cirúrgico quando comparado à técnica freehand (222,5 min. [DP=38,0] vs. 255,2 min. [DP=40,3], p=0,011, respectivamente). Em dois estudos, a técnica freehand resultou em menor dose efetiva de radiação para pacientes. Em 12 estudos observou-se maior incidência de complicações entre pacientes submetidos à cirurgia com técnica freehand. Concluiu-se que o uso do O-arm® está associado a uma redução da ocorrência do mal posicionamento dos implantes e mais segurança para os procedimentos instrumentados, porém sem evidências que seu uso possa resultar em menor tempo cirúrgico. ***Nível de Evidência I; Análises e Estudos Diagnósticos, Investigação de um Exame para Diagnóstico.***

Descritores: *Dosagem; Eficácia; Radiação; Segurança.*

RESUMEN

El gran avance en el uso de nuevos dispositivos y sistemas de imagen en las cirugías pretende reproducir un escenario ideal y seguro para el cirujano, equipo y paciente. Constantemente se encuentran disponibles nuevos sistemas y dispositivos para demostrar y facilitar la navegación intraoperatoria, buscando así reducir errores y evitar complicaciones al paciente y al personal. Este estudio tiene como objetivo evaluar y comparar el uso del sistema O-arm® y el uso de radioscopia en la técnica de manos libres en cirugías de columna. Para ello se realizaron búsquedas en PubMed y Embase de estudios aleatorizados y no aleatorizados sobre el uso del sistema O-arm® y radioscopia. en cirugía de coluna. Se incluyeron y compararon 24 estudios con respecto al tiempo del procedimiento, precisión del posicionamiento del implante, dosis de radiación efectiva, seguridad y eficacia. En un estudio, el grupo O-arm® mostró tiempo quirúrgico más corto en

Study conducted by the Hospital Alemão Oswaldo Cruz, 1815, Treze de Maio street, Bela Vista, São Paulo, SP, Brazil.
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comparación con técnica de mano alzada(222,5min [DE=38,0]vs. 255,2min[DE=40,3], p=0,011, respectivamente). En dos estudios, la técnica de mano alzada dio como resultado dosis de radiación efectiva más baja para los pacientes. En 12 estudios se observó mayor incidencia de complicaciones entre pacientes sometidos a cirugía con la técnica de mano alzada. Se concluyó que el uso del O-arm® está asociado con reducción en la ocurrencia de mala posición de los implantes y más seguridad para procedimientos instrumentados, pero sin evidencia de que su uso pueda resultar en menor tiempo quirúrgico. ***Nivel de Evidencia I; Análisis y Estudios Diagnósticos, Investigación de una Prueba Diagnóstica.***

Descriptores: *Dosificación; Eficacia; Radiación; Seguridad.*

INTRODUCTION

The advent of new technological tools in surgery seeks to offer greater safety, comfort, and efficiency in surgical procedures. As a result, various medical specialties are introducing resources and systems to assist surgeons in their procedures, aiming for greater precision, reproducibility, and better patient safety.[1]

Instrumentation of the spine with pedicle screws is considered the gold standard in stabilization for arthrodesis, correction of deformities, and treatment of traumatic injuries. However, the precise positioning of these implants is a fundamental step since the stability of the fixation and the integrity of adjacent neurovascular structures depend on it. Fluoroscopy or radioscopy is the most commonly used method for obtaining two-dimensional images during the intraoperative period.[2,3]

On the other hand, the surgical technique widely used for inserting pedicle screws is the freehand technique, described by Kim et al.,[3] in which the anatomical parameters and the surgeon's tactile sensitivity are decisive and fundamental factors for inserting the screws with a low number of complications. The rate of malpositioning of pedicle screws is variable in the literature, with 3-44% using intraoperative radioscopy.[4]

The O-Arm® is an intraoperative tomography that uses a navigation system for the three-dimensional reconstruction of images reproduced intraoperatively and in real time by devices that transmit and capture signals and information to reproduce the images on monitors, demonstrating the path and precise limits of the structures and allowing the screw to be inserted safely.[2]

This study aims to evaluate the effectiveness, exposure time, and safety of using the mobile imaging and navigation system with images generated by the O-arm® for the insertion of pedicle screws when carrying out imaging examinations in the intraoperative context in spinal surgeries performed on adult and pediatric patients.

METHODS

PubMed and Embase were searched using standardized descriptors from each database and keywords related to the intervention of interest. No filters were added to the search strategies. (Table 1)

To be included, the studies had to compare orthopedic surgeries with instrumentation navigated by the O-arm® or performed using the freehand technique. Thus, only studies with a comparator group, randomized or non-randomized (randomized clinical trial, non-randomized intervention study, prospective or retrospective cohort, or case-control) were considered. Systematic reviews were assessed regarding the studies included and their methodological quality to verify their suitability and relevance to the present study. Only Portuguese, English, and Spanish articles published in any period were considered. Studies were excluded if they did not report the outcomes of interest; if they included other interventions without presenting stratified analyses; if they did not present satisfactory information to determine the technique used; if the so-called freehand surgeries used devices to guide the procedure and not just to check the positioning of the screws; if they were systematic reviews that did not comply with the present selection criteria or if they presented low or critically low methodological quality. Studies with cadavers and phantom models were also excluded.

Table 1. Search strategies.

Database	Search strategy
Pubmed	O-arm OR O-arm Surgical Imaging System
	Results: 356 references
	Date of search: 14/10/2020
Embase	('mobile x ray unit'/exp OR 'mobile x ray unit' OR 'o-arm'/exp OR 'o-arm' OR 'o-arm surgical imaging system') AND [embase]/lim
	Results: 761 references
	Date of search: 14/10/2020

A single researcher carried out all stages of the review. After excluding duplicates, all the records were evaluated using their titles and abstracts to select the studies. Those who initially met the selection criteria were assessed by reading the full text to confirm eligibility.

The included studies had their data extracted in Excel® spreadsheets and included information on their characteristics (design, study site and period, population, follow-up, interventions, and outcomes assessed); participant characteristics (indications for surgery, age, gender, and Body Mass Index); surgery characteristics, efficacy, and safety results (screw distribution, surgical time, accuracy, direction of screw deviation, radiation dose, complications). When the study evaluated more than one technology, they were presented among the characteristics of the studies. Still, only the results of the technologies/procedures of interest were reported (browsed by O-arm® or freehand).

Meta-analyses were carried out to determine the insertion accuracy, taking into account the indications for surgery, levels, and segments operated on, when possible. A cut-off point of 2mm penetration was used, which has been adopted in several studies. Since a dichotomous outcome was used ("acceptable":<2 mm), the Mantel-Haenszel method of random effects was adopted. If there were substantial heterogeneity ($I^2 > 50\%$), the possible sources would be evaluated in subgroup analyses.

All the included studies were assessed for risk of bias using specific instruments for each study design. Randomized clinical trials were evaluated using the Cochrane Risk of Bias 2.0 tool;[5] observational studies (cohort and case-control) were evaluated using the ROBINS-I tool;[6] systematic reviews with or without meta-analysis were evaluated using AMSTAR-2.[7]

The quality of the body of evidence was assessed using the GRADE methodology, which considers, in addition to the study design, the risk of bias, inconsistency, indirect evidence, imprecision, publication bias, and the three criteria that increase the quality of evidence (large magnitude of effect, dose-response gradient and residual confounding factors that increase confidence in the estimate). Thus, for each prioritized outcome, the quality of the evidence is classified as very low, low, moderate, and high.[8]

RESULTS

The studies included were comparative observational studies, most of them retrospective. All the studies compared surgeries guided by the O-arm® imaging and navigation system to the freehand technique. However, in the latter case, two imaging methods were used: based on pre-and postoperative computed tomography (CT) scans; or based on fluoroscopy to confirm the insertion of the screws. The characteristics of the included studies varied in terms of design, location, period, population, follow-up, intervention, control, outcomes, evaluation scales, and cut-off points.

There was great clinical variability among the participants, whether

Table 2. Reasons for excluding studies.

Study	Justification for exclusion
Khanna 2016 a	It does not describe the indications for surgery or the characteristics of the patients, which prevents comparisons with other studies from being assessed; it primarily assesses the procedure time without presenting clinically relevant outcome results.
Bauer 2018	All screws were placed using the freehand technique, differing only in the way the position was checked (C-arm or O-arm). None of the procedures were image-guided.
Berlin 2020	It includes only patients who have undergone freehand surgery, with a comparison of radiation results in the literature compared to different methods of image-guided surgery.
Towner 2020	It includes in the same group patients who underwent the freehand and fluoroscopy-guided technique, not necessarily using fluoroscopy only to confirm the positioning of the screw. It includes patients undergoing percutaneous fluoroscopic surgery. The authors presented an analysis that considered image-guided procedures (O-arm, C-arm, and 2D fluoroscopy) and those performed using the freehand technique. Still, there was no stratification of the data by type of image.
Mason 2014	Critically low quality; outdated review; no assessment of the risk of bias of studies; analyses not stratified by technology; inclusion of studies without a comparator group
Liu et al. 2017	Critically low quality; outdated review; no assessment of risk of bias; no stratification by technology.
Saartjes 2018	Critically low quality; outdated review; no assessment of the risk of bias of studies.
Feng 2020	Low quality; no assessment of the risk of bias; no stratification by type of technology; C-arm and O-arm comparison, without specifying whether the first is pre- or intra-operative.
Sun 2020	Critically low quality; inadequate assessment of risk of bias (Jadad Scale for RCTs)
Verhofste 2020	Case series on the use of O-arms only to confirm screw positioning without navigation
Zhao 2018	There is probably an overlap of patients in the study by Liu et al., 2016. Both studies included adolescent patients with scoliosis treated in the same hospital, with an overlap in the collection period. The study by Liu et al., 2016, was included because it included more patients and assessed the accuracy outcome according to more uniform grading and cut-off points compared to the other studies.
Houten 2012	It evaluates two percutaneous screw insertion techniques, with O-arm or fluoroscopy. The second case uses the device to check positioning and guide the introduction.
Xiao 2017	The study provides little information on surgical procedures and perioperative results.
Zhang 2017	It includes another technology among patients undergoing surgery with intraoperative navigation without presenting stratified data for the O-arm.
Hodges 2012	There is no information on patient selection criteria, outcome assessment parameters, statistical analyses, or patient characteristics.
Shimokawa 2016	Congress abstract
Lee 2020	There are no details about the surgical procedure in the control group. It is not known how fluoroscopy was used in the surgery.
Sembrano 2015	The study evaluates the balloon kyphoplasty procedure, which does not involve the placement of screws.
Peng 2020	The intervention includes combining O-arm and operative microscopy for isthmic spondylolisthesis.
.Santos 2015	The study compares groups undergoing open and percutaneous lumbar spine arthrodesis, both guided by the O-arm
Park 2011	Study based on phantom models
Garber 2012	Case series in which all patients underwent O-arm navigated surgery
Milestone 2020	One of the groups includes the use of customized fluoroscopy equipment. No additional data was provided to verify registration with Anvisa.
Chang 2020	The study includes two methods of guided surgery: one group of patients undergoing surgery navigated by o-arm and the other by fluoroscopy (C-arm). In the latter case, the technique was not freehand, and the equipment was used to guide the placement of the screws, not to confirm positioning.
Liu 2017	The study includes two methods of guided surgery: one group of patients undergoing surgery navigated by o-arm and the other by fluoroscopy (C-arm). In the latter case, the technique was not freehand, and the equipment was used to guide the placement of the screws, not to confirm positioning.
Lau 2013	There is no clarity on the techniques used for surgery. In the open surgery group, fluoroscopy is used, but the authors do not say whether the device is used to guide the placement of the screws or just to confirm the position.
Harel 2019	The author does not describe the technique used for the control group with fluoroscopy. He cites other studies that describe this procedure, not only to confirm the positioning of the screws.
Chen 2019	The intervention includes using O-arms and operative microscopy for lumbar degenerative diseases. There is no clarity on the procedure used for the control group, i.e., whether fluoroscopy was used to guide the placement of the screws or only to confirm their placement.
Knafo 2017	There is no description of the techniques used, so it is not possible to know whether the devices were used to assess the positioning of the screws or to guide their insertion.
Reynolds 2020	The comparator group includes patients who have undergone lumbar CT scans and no surgery.
Wang 2020	The author does not describe the procedure for the control group, which was carried out without navigation. It is not known whether x-rays, fluoroscopy, or any other method was used to confirm the positioning of the screws, which limits comparability.
Ricciardi 2020	Both groups include performing a surgical procedure navigated by O-arm or C-arm and using the DensAccess device, whose registration with Anvisa has not been located.
Mukhametzhanov 2019	The three groups include image-guided surgery, with no standard procedure for each indication, and surgery can be open or minimally invasive (percutaneous)
Agrawal 2016	The author does not describe the procedure for the control group, which was carried out without navigation. Apparently, fluoroscopy was used to guide the entire procedure, not just to confirm positioning.
Farah 2018	Both groups underwent navigated surgeries: one with the O-arm and the other with the AIRO System.
Zhang 2020	It includes groups of participants undergoing percutaneous surgery that does not involve the placement of screws.

Study	Justification for exclusion
Balling 2018	The comparator group included is unclear. The authors briefly mention including a control group of 100 participants who underwent non-navigated surgery but do not present data on the procedure. The results show a third group, not previously mentioned, of 100 individuals who underwent lumbar tomography.
Bratschitsch 2019	It does not describe patient selection criteria, indications for surgery, patient characteristics, discussions on comparability between the groups, or surgical procedures.
Khanna 2016 b	Both groups included underwent image-guided surgery, one for O-arm and the other for C-arm. In the last group, the equipment was used not only to confirm the position of the screws.
Mendelsohn 2016	The authors considered two groups in the study: one of patients who underwent surgery navigated by O-arm and the other not navigated (historical control). However, there is no information on the type of imaging equipment used. In addition, the author compares the data from the O-arm group with those published in the literature (a review that lacks methodological rigor) for individuals undergoing fluoroscopy-assisted surgery. Thus, the role of historical control in the study is unclear. It is unknown whether the results presented for the non-navigated group correspond to those of the control, the data in the literature, or a combination of both.
Wu 2017	Does not include an O-arm assessment.
Gelalis 2012	Does not include O-arm studies.
Rajasekaran 2007	Does not include an O-arm assessment.
Kosmopoulos 2007	It separates the groups into navigated and non-navigated surgery without differentiating the equipment used.
Li 2009	Paper in Chinese.
Miller 2017	In both arms (fluoroscopy or O-arm), the surgery was guided by the devices and not just used to check the positioning of the screws.

due to age (adolescents, adults, or both) or clinical indication (trauma, degenerative disease, scoliosis, spondylolisthesis, among others). The characteristics of the participants in the comparative studies varied; among them, the main questions were age (in years), gender (male or female), BMI (Body Mass Index), and indication for surgery.

Most of the studies grouped the results of patients undergoing spinal surgery with instrumentation for different clinical conditions without presenting stratified results. The results of the studies were presented and compared based on their outcomes.

The database search returned 1,117 studies. Six additional studies were located in a manual search, totaling 1,123 references. After excluding duplicates, 849 unique studies were evaluated by title and abstract, of which 70 had their full text read. Twenty-four studies had their eligibility confirmed and were included in this review.[9-30] The flowchart for selecting the studies can be seen in Figure 1.

Surgery Time

O-arm® vs. freehand with fluoroscopy

Eight studies reported the total surgical times for each technique. In this case, all the studies compared the O-arm® to freehand surgery with fluoroscopy.[14,16,18,22,27,29-31] Only one study that evaluated surgery with instrumentation in patients undergoing lumbar spine surgery showed a difference between the techniques. The O-arm® group had a shorter surgical time when compared to the freehand technique (222.5 min. [SD=38.0] vs. 255.2 min [SD=40.3], p=0.011, respectively).[25] For the other studies, there was no difference between the groups.[14,16,18,22,27,29-31]

Accuracy

O-arm® *vs*. freehand with preoperative CT

Two studies compared these techniques in terms of the accuracy of screw insertion in spinal arthrodesis surgeries for scoliosis. Both studies showed no difference in the accuracy of screw insertion in any pedicle size.[6,23] One of the studies, however, provided a stratified analysis for small and large pedicles. When considered separately, O-arm® (Small Pedicles) was found to be superior: O-arm®: 91.7%, freehand: 78.4, p=0.02; Large pedicles: O-arm®: 93.8%, freehand: 84.9, p=0.03).[23]

O-arm® *vs*. freehand with fluoroscopy

Nineteen studies evaluated this comparison in terms of screw insertion accuracy. The studies included a wide variety of clinical indications for the surgeries. Four studies found no statistically significant differences between the groups,[11,12,20,24] while 15 showed the superiority of the O-arm®.[13-19,25-30]

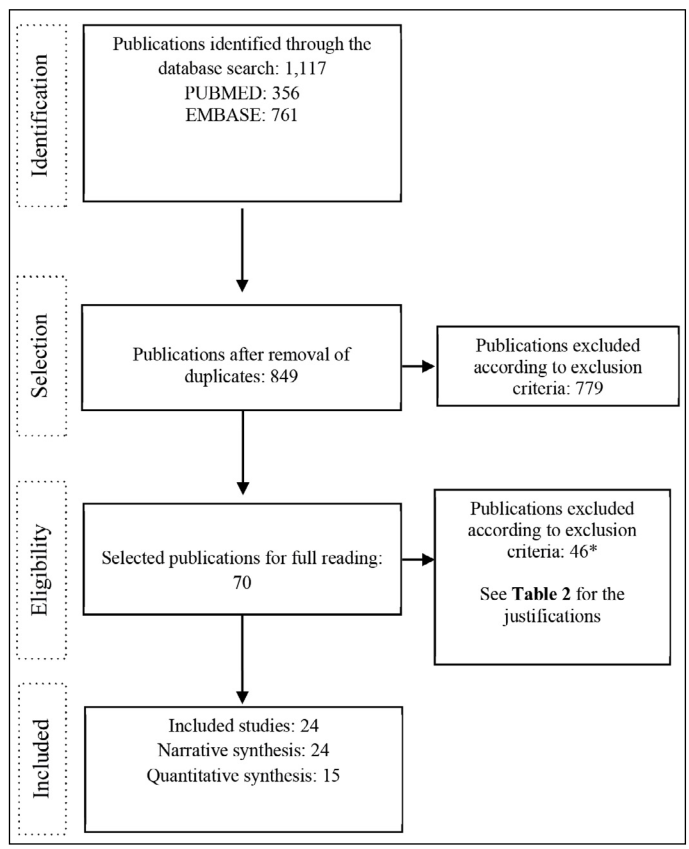

Figure 1. Flowchart of the study selection process.

Sixteen studies reported the direction of the deviations, the most frequent medial and lateral. In most studies, no statistically significant differences were observed between the groups.[1,11,13,15-18,20,22,23-25,28-30]

For this outcome, it must be considered that the characteristics of the surgery (indications, complexity, and extent) were different and possibly involved surgeons with varying lengths of experience. In addition, different scales and cut-off points were considered, resulting in differences in the frequencies obtained.

Effective Radiation Dose

O-arm® *vs*. freehand with fluoroscopy

The effective radiation dose measures the weighted risk of radiation to the organs, which can be compared to environmental radiation levels, thus making it possible to designate the radiological risk associated with the procedure. Only four studies have compared the results of O-arm® and freehand surgery with fluoroscopy.[16,19,21,25]

In two studies, the freehand technique resulted in a lower effective radiation dose for patients. In the O-arm® group, the effective radiation dose ranged from 1.11 to 1.44 milliSievert (mSv), while in the freehand group, the range was 0.27 to 0.34mSv.[19,21] In contrast, in the study by Jing et al.,[25] no differences were observed between the groups (O-arm®: 1.69[SD=1.63], freehand: 1.25[SD=1.15], p=0.249). However, these studies only considered intraoperative images. Another study reported the effective radiation dose intraoperatively, including post-surgery CT radiation. In the first case, the O-arm® group had an average effective radiation dose of 3.2mSv; in the freehand group, this measurement was 1.5mSv. Including tomography radiation, the effective doses were 8.1 and 10.5, respectively.[16] No studies were found that evaluated radiation in the surgical team that met the selection criteria.

In this case, it should be borne in mind that the number of images obtained for both methods depends on the complexity and extent of the surgery, the surgeon's experience, the fluoroscopy time, and the density of the implant, among others.[19] The freehand technique with fluoroscopy requires post-operative radiography since 2D images do not provide entirely reliable images of screw positioning. In the case of the O-arm®, this additional image is unnecessary since the quality of the images obtained by this equipment is comparable to that of tomography.[25]

Security

Seventeen studies evaluated the occurrence of complications resulting from surgery.[2,5,13-14,21-24,26-30] In five studies, there were no complications in either group.[6,18,21,24] In the other studies, a higher incidence was observed among patients who underwent freehand surgery. In both groups, the most frequent complications were dural injury, surgical site infection, and transient lower limb paresthesia.[1,2,13,14,17,22,26-29] Similarly, a higher proportion of patients in the freehand group required intraoperative revisions (freehand: 24.6[SD=6.9], O-arm: 8 [SD=3.4], p=NR)[14] or return to the operating room for re-approach (freehand: 3.6, O-arm: 0%, p=0.048).[22]

Risk of study bias

The studies presented a serious risk of bias when assessed by the ROBINS-I tool. Most studies did not report how the interventions were assigned to the participants. Of those who reported, in most cases, it was done according to the surgeon's judgment, which could reflect their preferences and familiarity with the methods. Most of the studies had a small sample, with no formal sample size calculation. In some cases, there were differences in the baseline characteristics of the participants, which could favor one group over another. Furthermore, in most studies, the outcome assessors were not blinded to the interventions received. (Figure 2)

Meta-analysis of results

A meta-analysis of the results for the screw insertion accuracy outcome was carried out, considering the O-arm vs. freehand comparison using fluoroscopy to confirm screw positioning or based on pre-and post-operative CT scans. In these analyses, the sample size corresponded to the number of screws inserted and not the number of patients.

O-arm® *vs.* freehand with preoperative CT

Only two studies have evaluated this comparison, and both included only patients with scoliosis. In the O-arm® group, 95.1% of the screws had an acceptable degree of insertion. In the freehand group, 85.2% had this classification. The first group had 2.40 times higher odds (95% CI: 1.40 to 4.10) to present acceptable screw insertion. The analysis showed moderate heterogeneity (I^2=33%), which may be due to the difference in sample size between the studies or reflect the clinical variability of the participants. (Figure 3)

O-arm® *vs.* freehand with fluoroscopy

All spinal surgeries

For this comparison, 13 studies were included. 95.8% and 91.0% of the screws had acceptable insertion in the O-arm® and freehand fluoroscopy groups, respectively. The first group had 2.30 times higher odds (95% CI: 1.45 to 3.61) to present acceptable screw insertion. This analysis showed high heterogeneity (I^2=64%), possibly due to the participants' clinical heterogeneity in the individual studies (Figure 4). The patients had a variety of surgical indications (trauma, tumor, scoliosis, degenerative disease, among others). Although uniting these participants in a single analysis may not be appropriate from a clinical and methodological point of view, most studies included a collection of indications without presenting a stratified analysis.

In a sensitivity analysis, the study by Yang et al.[16], which included patients with burst fractures, was excluded, as it was the only one that considered a specific indication for these surgeries. This sub--analysis reduced heterogeneity to 47%, with an OR of 1.90 (95% CI: 1.28 a 2.80). (Figure 5)

The funnel plot analysis for this meta-analysis is asymmetrical, which suggests publication bias, including studies mostly with large sample sizes and results higher than the summary mean estimate. (Figure 6)

Spinal surgeries by region

In the analysis of studies evaluating the accuracy of screw insertion in the thoracolumbar region, there was a superiority of surgeries navigated by the O-arm®. This group had 2.35 times higher odds (95% CI: 1.34 to 4.11) of presenting an acceptable introduction than the freehand technique. As in the previous analysis, there was substantial heterogeneity (I^2=64%), possibly due to the clinical variability of the patients included. In the analysis that included only screws inserted in the thoracic region, there was no statistically significant difference between the groups (OR = 6.51, 95% CI: [0.84 to 50.53], I^2=0%). On the other hand, in the analysis that considered the insertion of screws in the lumbosacral region, screws inserted using the O-arm® had an odds ratio 2.84 times higher (95% CI: 1.78 to 4.53) of having an acceptable rating when compared to the freehand technique. No statistical heterogeneity was observed for this sub-analysis (I^2=0%). (Figure 7)

Quality of evidence

O-arm® *vs.* freehand with preoperative CT

For this comparison, the quality of the evidence was low for the outcome acceptable degree of screw insertion. There was a downgrade because the included studies presented a very serious risk of bias, and the measure of effect was imprecise. The only two studies in question, both observational, with serious risk of bias by the ROBINS-I tool and with strong associations, showed low certainty of evidence for comparing the freehand technique with preoperative tomography versus the O-arm.

O-arm® *vs.* freehand with fluoroscopy

Considering the accuracy of all spinal surgeries (without specifying the indication or segment operated on), the quality of the evidence was very low due to the risk of very serious bias in the studies, with more than two domains with a serious classification; inconsistency, with statistical heterogeneity of 64%; and suspicious publication bias, with asymmetry in the funnel plot.

In the analysis that considered the regions of the spine operated on, the quality of the evidence for the thoracolumbar region was very low. Although it received an upgrade for the large magnitude of the effect, the body of evidence presented a very serious risk of bias; serious inconsistency, with moderate statistical heterogeneity (I^2=33%); and significant imprecision, with a wide confidence interval for the measure of effect. For the thoracic region, the quality of the evidence was also very low, with very serious bias and imprecision. Although the effect measure was of great magnitude, there

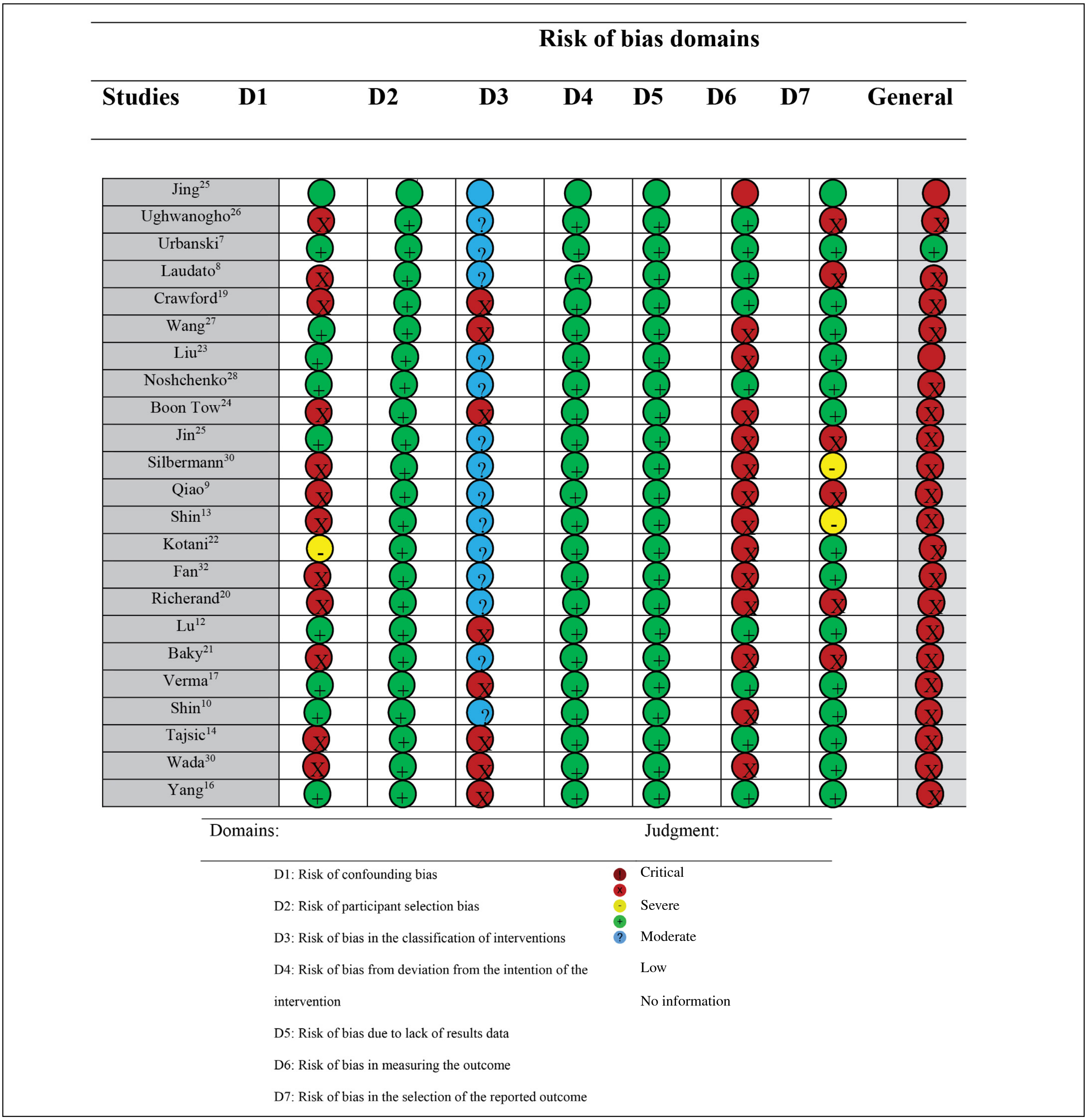

Figure 2. Assessment of the risk of bias of the included studies.

was no upgrade due to the great imprecision of the results. In the evaluation of the lumbar region, the quality of the evidence was low. As with the other evaluations, the risk of bias was very serious, and the results were inaccurate. In this case, there was an upgrade due to the large magnitude of the effect observed.

DISCUSSION

Improper positioning of the screws in the vertebral pedicles can result in vascular and neurological damage, dural injury, and pedicle fractures. In turn, these injuries can compromise the stability of the fixation, resulting in the need for a surgical reapproach and an increase in the cost of healthcare services.[18,33] Therefore, obtaining maximum accuracy when inserting the screws is a priority. With this goal in mind, different imaging methods have been used. More recently, using the O-arm® has become increasingly common, and different studies have shown a possible benefit of this technique over freehand.[34,35]

Regarding surgical time, there is no conclusive evidence that the O-arm® results in shorter surgical time. Only one study showed a reduction in total surgery time,[27] although there appear to be no differences between the techniques. Furthermore, it should be noted that time can vary according to the surgeon's experience with a particular technique, the complexity of the deformity, the number of segments addressed, and the patient's clinical condition. Among the studies analyzed, the characteristics of the surgery (indications,

Study or Subgroup	O-arm Events	O-arm Total	Freehand Events	Freehand Total	Weight	Odds Ratio M-H, Random,95% CI
	403	416	211	222	32.4%	1.62 [0.71, 3.67]
	320	344	585	712	67.6%	2.89 [1.83, 4.57]
Total (95% CI)		760		934	100%	2.40 [1.40, 4.10]
Total events	723		796			

Heterogeneity: Tau^2 = 0.06; Chi^2 = 1.49, df = 1 (p=0.22); I^2 = 33%
Test for overall effect: Z =3.19 (p=0.001)

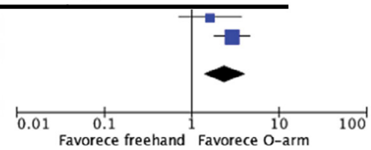

Figure 3. Meta-analysis comparing O-arm® vs. freehand with preoperative CT in patients with scoliosis (Outcome: Acceptable degree of screw insertion).

Study or Subgroup	O-arm events	O-arm total	Freehand events	Freehand total	Weight	Odds Ratio M-H, Random,95% CI
Fan[32]	212	234	270	346	11.9%	2.71 [1.63, 4.51]
Jin[29]	73	92	81	121	11.0%	1.90 [1.01, 3.57]
Jing[25]	183	191	135	150	9.1%	2.54 [1.05, 6.17]
Laudato[8]	183	191	294	314	9.5%	1.56 [0.67, 3.61]
Lu[12]	249	266	294	307	10.2%	0.65 [0.31, 1.36]
Noshchenko[28]	396	401	191	196	6.8%	2.07 [0.59, 7.25]
Shin[13]	103	106	192	204	6.6%	2.15 [0.59, 7.78]
Shin[10]	122	124	127	138	5.4%	5.28 [1.15, 24.33]
Tajsic[14]	161	162	487	504	3.7%	5.62 [0.74, 42.56]
Urbanski[7]	432	451	370	384	10.5%	0.86 [0.43, 1.74]
Wada[31]	39	39	33	39	2.1%	15.33 [0.83, 282.24]
Wang[27]	158	160	161	168	5.2%	3.43 [0.70, 16.79]
Yang[16]	176	180	135	172	8.0%	12.06 [4.20, 34.66]
Total (95% CI)		2597		3043	100%	2.30 [1.45, 3.62]
Total events	2487		2770			

Heterogeneity: Tau^2 = 0.39; Chi^2 = 33.04, df = 12 (p=0.001); I^2 = 64%
Test for overall effect: Z =3.57 (p=0.0004)

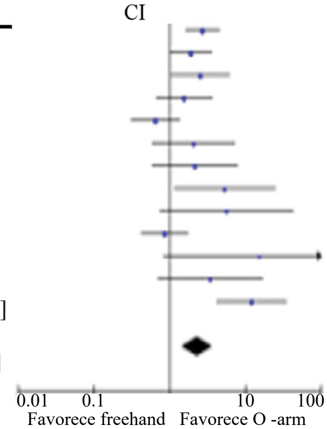

Figure 4. Meta-analysis of the comparison of O-arm® vs. freehand with fluoroscopy in patients undergoing spinal surgery with instrumentation (Outcome: Acceptable degree of screw insertion).

Study or Subgroup	O-arm events	O-arm total	Freehand events	Freehand total	Weight	Odds Ratio M-H, Random,95% CI
Fan[32]	212	234	270	346	15.1%	2.71 [1.63, 4.51]
Jin[29]	73	92	81	121	13.3%	1.90 [1.01, 3.57]
Jing[25]	183	191	135	150	9.9%	2.54 [1.05, 6.17]
Laudato[8]	183	191	294	314	10.5%	1.56 [0.67, 3.61]
Lu[12]	249	266	294	307	11.7%	0.65 [0.31, 1.36]
Noshchenko[28]	396	401	191	196	6.6%	2.07 [0.59, 7.25]
Shin[13]	103	106	192	204	6.3%	2.15 [0.59, 7.78]
Shin[10]	122	124	127	138	4.9%	5.28 [1.15, 24.33]
Tajsic[14]	161	162	487	504	3.1%	5.62 [0.74, 42.56]
Urbanski[7]	432	451	370	384	12.2%	0.86 [0.43, 1.74]
Wada[31]	39	39	33	39	1.6%	15.33 [0.83, 282.24]
Wang[27]	158	160	161	168	4.7%	3.43 [0.70, 16.79]
Yang[16]	176	180	135	172	0.0%	12.06 [4.20, 34.66]
Total (95% CI)		2417		2871	100%	1.90 [1.28, 2.80]
Total events	2311		2635			

Heterogeneity: Tau^2 = 0.20; Chi^2 = 20.87, df = 11 (p=0.03); I^2 = 47%
Test for overall effect: Z =3.22 (p=0.001)

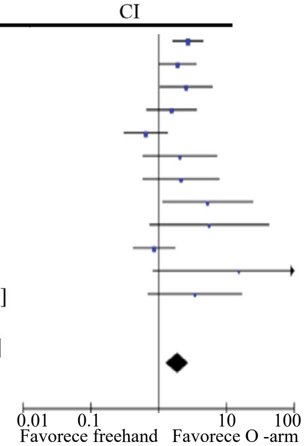

Figure 5. Sensitivity analysis of the meta-analysis comparing O-arm® vs. freehand with fluoroscopy in patients undergoing spinal surgery with instrumentation (Outcome: Acceptable degree of screw insertion).

complexity, and extent) were different and possibly involved surgeons with varying lengths of experience. Therefore, no conclusive statements can be made as to the superiority of one technique over another.

Concerning accuracy, the use of the O-arm® seems to be associated with a reduction in the occurrence of screw malpositioning when all spinal segments are considered in a single group. In stratified analyses, however, the difference remained significant only for the lumbosacral region. Different studies have reported greater difficulty and failure in positioning screws in thoracic pedicles due to their smaller diameter, which may justify the results obtained.[6]

For this outcome, one must consider the great statistical and clinical heterogeneity of participants with different health conditions and complexities. In addition, among the studies that reported how the interventions were assigned, the majority were done according to the surgeon's preferences, and the results may reflect familiarity and skill with the chosen technique.

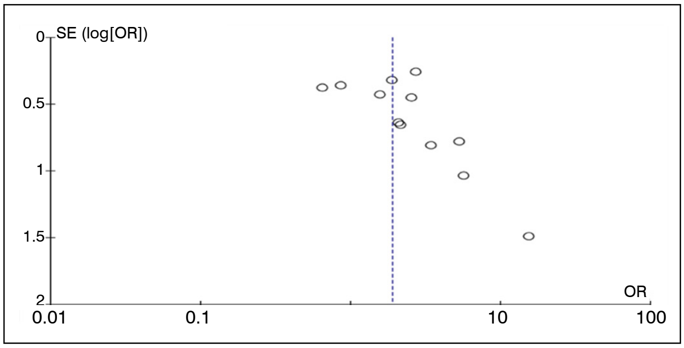

Figure 6. Funnel graph for the meta-analysis of all spinal surgeries.

Several studies have reported a learning curve for both techniques, but this curve seems steeper for the O-arm®. The process of acquiring skills for this technique can be reflected in the time taken for surgery and improved mastery of the technique.[13,18,34]

Surgeries navigated by the O-arm® have the advantage of being able to identify the malpositioning of the screws during surgery and correct it, avoiding readmissions, higher costs linked to human and material resources, and operating room utilization rates, among others. It is also associated with a lower incidence of post-operative complications. The use of the O-arm®, however, results in higher radiation for the patient,[19,21,36] but lower radiation for the healthcare team. This is because professionals can leave the room when the images are taken.[34,37] In the freehand technique with fluoroscopy, on the other hand, the team must remain in the operating room throughout the procedure. Although they are dressed in lead aprons and thyroid shields, some areas are still exposed to radiation.[36]

Limitations of the meta-analysis

The results of meta-analyses should be evaluated with caution. The vast majority of the included studies had a serious risk of bias; for some analyses, there was moderate to substantial heterogeneity. There was great clinical variability between and within studies. The

Study or Subgroup	O-arm events	O-arm total	Freehand events	Freehand total	Weight	Odds Ratio M-II, Random,95% CI
1.4.1thoracolumbar						
Jin[29]	73	92	81	121	11.0%	1.90 [1.01, 3.57]
Jing[25]	183	191	135	150	9.1%	2.54 [1.05, 6.17]
Laudato[8]	183	191	294	314	9.5%	1.56 [0.67, 3.61]
Noshchenko[28]	396	401	191	196	6.8%	2.07 [0.59, 7.25]
Shin[13]	103	106	192	204	6.6%	2.15 [0.59, 7.78]
Shin[10]	122	124	127	138	5.4%	5.28 [1.15, 24.33]
Urbanski[7]	432	451	370	384	10.5%	0.86 [0.43, 1.74]
Yang[16]	176	180	135	172	8.0%	12.06 [4.20, 34.66]
Subtotal (95%CI)		1736		1679	72.4%	2.35 [1.34, 4.11]
Total events	1668		1525			
Heterogeneity: Tau² = 0.39; Chi² = 19.30, df = 12 (p=0.007); I² = 64%						
Test for overall effect: Z =2.99 (p=0.003)						
1.4.2 thoracic						
Lu[12]	35	35	33	37	1.6%	9.54 [0.49, 183.98]
Tajsic[14]	66	66	362	374	1.7%	4.59 [0.27, 78.60]
Subtotal (95%CI)						
Total events	101		395			
Heterogeneity: Tau² = 0.00; Chi² = 0.12, df = 1 (p=0.73); I² = 0%						
Test for overall effect: Z =2.99 (p=0.003)						
1.4.3 lumbar						
Fan[32]	212	234	270	346	15.4%	2.71 [1.63, 4.51]
Lu[12]	51	51	60	62	1.5%	4.26 [0.20, 50.69]
Tajsic[14]	95	96	125	130	2.8%	3.80 [0.44, 33.77]
Wang[27]	158	160	161	168	4.6%	3.43 [0.70, 16.79]
Subtotal (95%CI)		541		704	24.3%	2.84 [1.78, 4.53]
Total events	516		616			
Heterogeneity: Tau² = 0.00; Chi² = 0.22, df =3 (p=0.97); I² = 0%						
Test for overall effect: Z =4.39 (p<0.0001)						

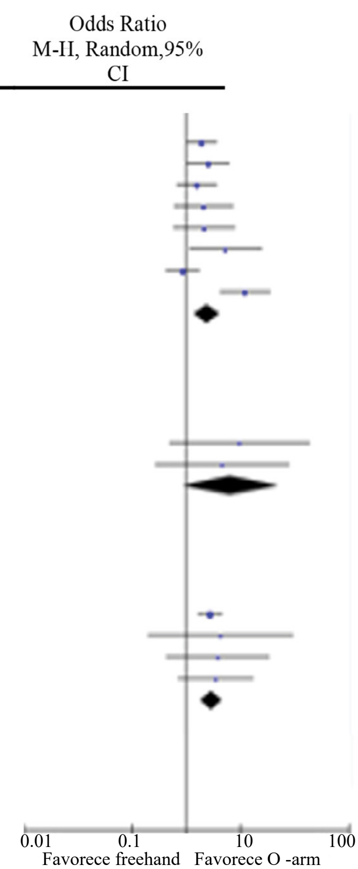

Figure 7. Sensitivity analysis of the meta-analysis comparing O-arm® vs. freehand with fluoroscopy in patients undergoing spinal surgery with instrumentation by region (Outcome: Acceptable degree of screw insertion).

fact that the results were reported in groups did not allow for stratified analysis by indication. Furthermore, the funnel graph suggests publication bias for the analysis considering all patients undergoing spinal surgery. However, the asymmetry may be due to using the odds ratio (correlated with standard error) as a measure of effect rather than a real publication bias. Another limitation was that this study was not compared with similar studies in the literature.

CONCLUSION

Although this study's results suggest that surgery navigated by the O-arm® is superior to the freehand technique in terms of accuracy and the occurrence of complications, these findings should be evaluated with caution; the included studies presented a high risk of bias, the clinical heterogeneity of the participants in each study was substantial, and the quality of the evidence for the accuracy outcome ranged from very low to low. Additional, more homogeneous studies should be carried out, taking into account the surgeon's experience and the specific disease evaluated.

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