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Image-guided endoscopic sinus surgery for patients with chronic rhinosinusitis: a systematic review and meta-analysis

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Abstract

Objective: The aim of this study was to compare the quality of life and complications of endoscopic sinus surgery, with and without image guidance, in patients with chronic rhinosinusitis. Design and setting: Systematic review and meta-analysis of clinical trials. PubMed, Embase, Scopus, Web of Science, SciELO, Cochrane Central Register of Controlled Trials, LILACS, and ClinicalTrials.gov were searched on April 22, 2022. Main outcome measures: A search strategy was used to retrieve clinical trials that compared the quality of life and complications of endoscopic sinus surgery with and without image guidance from the databases. The risk of bias was assessed using the Cochrane Risk of Bias tool. RevMan 5.4. was used for data synthesis. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were followed. The Grading of Recommendations Assessment Development and Evaluation method was used to evaluate the strength of the evidence. Results: A total of 3281 articles were retrieved from the databases. Six studies met the inclusion criteria, and five could be combined by meta-analysis (638 patients). Image guidance showed improved efficacy in opening diseased paranasal sinuses compared with conventional endoscopic sinus surgery (risk ratio: 0.19; 95% confidence interval, 0.04-0.85; p = 0.03). There was a trend toward a reduction in complications with image-guided surgery, although it did not reach statistical significance (risk ratio: 0.53; 95% confidence interval, 0.20-1.41; p = 0.20). Conclusion: Image guidance is an important tool that helps improve surgical results and possibly increases the safety and quality of life of patients with chronic rhinosinusitis.

Image -guided endoscopic sinus surgery for patients with chronic rhinosinusitis: a systematic review and meta-analysis

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Conclusion : Image guidance is an important tool that helps improve surgical results and possibly increases the safety and quality of life of in chronic rhinosinusitis.

PROSPERO registration number : CRD4202021479

Keywords: Sinusitis, Nasal surgical procedures, Computer-assisted surgery, Systematic review

KEY POINTS

- Chronic rhinosinusitis is a prevalent disease with impairment in quality of life and economic burden.
- Endoscopic sinus surgery allows removal of diseased mucosa for paranasal sinus but has a potential for important complication.
- Image guidance can provide accurate anatomical location intraoperatively, improving surgical efficacy.
- No significant difference was found in surgical complication with or without the use of image guidance.
- Further studies assessing quality of life of patients submitted to these procedures are needed.

INTRODUCTION

Description of the condition

The European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020) defines chronic rhinosinusitis (CRS) as a clinical syndrome caused by enduring inflammation of the mucosa of the nose and paranasal sinuses, with at least two symptoms, of which one needs to be either nasal blockage/obstruction/congestion or nasal discharge ± facial pain/pressure ± reduction or loss of smell for [?]12 weeks.[1-3]

This condition affects 5 to 28% of the population and dramatically impacts patients' socioeconomic conditions and quality of life. CRS is responsible for greater costs in health care than in diseases such as peptic ulcers, asthma, and hay fever. Moreover, it leads to absenteeism and reduces productivity increasing indirect costs since affects working-age people.[2-7] A health state utility study found that patients with CRS had worse utility values than those with chronic obstructive pulmonary disease, coronary artery disease, chronic heart failure, and Parkinson's disease.[8]

The etiology of CRS is associated with bacterial superantigens, epithelial cell defects, biofilm formation, T helper 1 and 2 inflammation responses, and tissue remodeling.[9-12] CRS is classified into CRS with nasal polyps (CRSwNP) and CRS without nasal polyps (CRSsNP).[10,11]

Endoscopic sinus surgery (ESS) began in the late '80s and the early '90s and was responsible for significant advances in the managing of CRS.[12] The reduction of type 2 inflammation and minimizing irreversible remodeling of the mucosa by facilitating improved access to topical therapies are potential disease-modifying benefits of surgery.[2]

Nonetheless, ESS can be the cause of significant iatrogenic damage due to the anatomical proximity of the paranasal sinus to critical structures such as the skull base, orbit, internal carotid artery, and optic nerve.[13] Patients submitted to more than one surgical procedure are at increased risk of injuries because of the removal of anatomical landmarks.[14-16] The complication rate of ESS is approximately 0.5%, with 0.11% for intracranial complications and 0.04% for orbital complications, which can be considered low risk.[17,18] However, in the event of injury these can result in high morbidity.[17,19]

Description of the intervention

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The use of image guidance is widely set as an important tool for managing diseases of the nose and paranasal sinuses by increasing surgeons' confidence and confirming anatomic locations in challenging fields.[12]

The Image Guided Surgery (IGS) systems have the following items: a computer, video monitor, tracking system, surgical instrumentation, and data transfer hardware. The tracking system allows for the real-time determination of the instrument location relative to anatomical landmarks. Electromagnetic or optical tracking technology can be used to perform this position determination in the operating field against preoperative imaging data sets.[3,20]

How the intervention might work

In the light of the anatomy's complexity and proximity to vital structures, the possibility of confirming the anatomical position of the instruments during surgery may allow surgeons to approach more of the patient's disease. It can be speculated that if a thorough surgery is performed, all diseased sinus compartments are addressed then the quality of life of patients may be improved, and revision rates reduced.[3,20]

Why it is important to conduct this review

There is no robust scientific evidence to determine the indications and recommend using IGS in CRS. Improvements in surgical efficacy and safety are therefore believed to be relevant.[21] This review seeks to analyze trials that compare ESS with and without IGS.

METHODS

This systematic review and meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[22, 23] The protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO CRD42020214791) and published in BMJ Open.[24]

Inclusion criteria

This study included clinical trials that compared the outcomes of patients with CRS who underwent ESS with and without IGS. No language restrictions were applied when the studies were selected.

PICOT strategy

- Population/participants: Adults diagnosed with CRS.
- Intervention: ESS with image guidance.
- Comparator/control: ESS without image guidance.
- Outcomes: Complications, quality of life, operative time, blood loss, and missed paranasal sinuses.
- Type of study: Clinical trials.

Types of patients

Participants were adult patients diagnosed with CRS with indication for ESS.[2]

Types of intervention

Any type of image guidance system with optical or electromagnetic tracking used in the ESS was included.

Types of outcome measures

- Quality of life (RSOM-31).
- Blood loss.
- Operative room time.
- Missed paranasal sinuses.

Patient and public involvement

This was a systematic review. Therefore, individual patient data is not presented. An extensive literature search was conducted using the defined databases. Furthermore, there was no patient or public involvement in the study planning or application process, nor during the analysis or dissemination of the results.

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Search strategy

PubMed, Embase, Scopus, Web of Science, SciELO, Cochrane Central Register of Controlled Trials (CENTRAL), LILACS, and ClinicalTrials.gov were searched with no limitations to date or language. The Medical Subject Headings terms used to search PubMed are presented in Table 1 and were adapted to each database. All electronic databases were searched on April 22, 2022.

Data collection and analysis

Selection of the studies

The articles retrieved by the search were imported to EndNote Web, and any duplicates were removed. Two authors, MLN and HPB, independently screened the results first by title, abstract, and full text to determine whether they met the inclusion criteria. A third reviewer (AKG) resolved the discrepancies.

Data extraction and management

Two independent authors (MLN and ACAS) extracted data from the eligible and included studies. The latter were inserted into a database following the designed form: publication year, first author, number of patients per group, intervention description, control group description, number of complications, number of missed paranasal sinuses, mean estimated blood loss, and mean operative time. A meta-analysis was conducted on the outcomes that could be combined.

Risk of bias assessment

The Cochrane Risk of Bias tool was used to evaluate the random sequence generation, allocation concealment, blinding of participants, blinding of the outcome assessment, incomplete outcome data, selective reporting, and other biases.[25] We also assessed whether there were other sources of bias, such as missing data, incomplete reports, financial aid, and potential conflicts of interest in each study.

Assessment of heterogeneity

Heterogeneity was assessed using I^2 statistics, in which a percentage $< 25\%$ was considered to indicate no heterogeneity, between 25% and 50% moderate heterogeneity, and $> 50\%$ high heterogeneity.

Measures of the treatment effect

Blood loss and operative time, as continuous variables, were collected as means and standard deviations. The risk ratio was calculated for dichotomous data on complications and missed paranasal sinuses. This was performed using Review Manager (RevMan, version 5.4) software.

Analysis

RevMan 5.4 was used to perform the statistical analysis. In the heterogeneity assessment, when I^2 was $>$ 50%, a random-effects model was used, whereas when $I^2$was $<$50%, a fixed-effect model was applied.

Some studies that met the inclusion criteria did not provide any data that could be used for quantitative synthesis. All included studies were qualitatively summarized in a table for comparison.

Grading quality of evidence

The Grading of Recommendations Assessment Development and Evaluation (GRADE) approach was used to evaluate the strength of the evidence of the systematic review results. The GRADE tool classifies evidence as low, moderate, and high quality.[26]

RESULTS

The search strategy retrieved 3281 articles from databases that were imported to EndNote Web. A total of 576 studies were duplicates. After these were excluded, two independent authors screened the remaining 2705 titles, 193 of which were assessed for eligibility using the abstract. A total of 187 studies were excluded due to inappropriate study design, population, inappropriate intervention, or lack of outcome data. After

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full-text analysis, six studies met the inclusion criteria, five of which could be combined in the meta-analysis. The PRISMA flow diagram summarizes the study selection process (Figure 1). The characteristics of the included studies are shown in Table 2.

Quality of life assessment

Only two of the studies included in this review assessed the quality of life of patients since similar instruments or measures were not used; thus, the data could not be combined into a meta-analysis. Table 3 summarizes the qualitative synthesis of the included studies.

Javer et al. compared the quality of life of patients with CRS who underwent ESS with and without the aid of IGS using a validated quality of life tool, RSOM-31. The patients completed the form preoperatively and six months postoperatively. The IGS demonstrated a statistically significant improvement in all 31 questions, while the ESS group demonstrated a statistically significant improvement in 13 of the 31 questions.[27]

Strauss et al. evaluated the subjective findings of patients who underwent ESS with and without IGS six months postoperatively. In the IGS group, 73% (65/89) of the patients referred to a general sense of well-being, compared to 69% (49/71) in the ESS group. Persistent complaints were reported by 16% (14/89) from the IGS and 30% (21/71) of the ESS group. Moreover, 96% of patients who underwent the procedure with IGS stated that they would undergo surgery again, compared to 85% of the patients operated without IGS.[28]

Blood loss

The estimated blood loss between the two groups was measured by Singh et al., and the mean and standard deviation were noted (IGS: 566.67 +- 62.23 mL; ESS: 636.33 +- 72.59 mL). This difference was not statistically significant (P = 0.64).[29]

Complications

The number of complications that occurred in each group from the studies was combined in a meta-analysis, as shown in Figure 2. Hence, the calculated I^2 showed no heterogeneity, and the fixed-effect model was used to calculate the risk ratio (RR). There was a trend of a lower risk of complications with the use of IGS, although it did not reach statistical significance (risk ratio: 0.53; 95% confidence interval, 0.20-1.41; p = 0.20).[29-31]

Operative room time

Two of the included studies evaluated the operative RT. Stelter et al. found that the operations lasted for an average of 16 min longer with the aid of IGS than with conventional ESS. Singh et al. documented a smaller difference: (IGS group 165.68 +- 6.55 (mean +- SE); ESS group 163.33 +- 5.43).[29,31]

Missed paranasal sinuses

Three of the included studies evaluated the number of diseased paranasal sinuses that should have been opened during surgery but were missed. The data were combined into a meta-analysis and are presented in Figure 3. Due to high heterogeneity, a random-effects model was used to estimate the RR. A statistically significant lower incidence of missed paranasal sinuses in the IGS group was demonstrated by the RR 0.19 [0.04, 0.085] 95% CI p=0.03.[28,31,32]

Risk of bias assessment

Only two studies included in the review (Singh et al. and Stelter et al.) had a clear statement regarding the randomization and allocation process. This raises concerns about the possibility of bias in the interpretation of the review results. The complete risk of bias assessment is summarized in Table 4.

The strength of the evidence assessed by GRADE was low to moderate due to the small number of events, to the risk of bias of the included studies and to the high heterogeneity among the studies (Figure 4).

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DISCUSSION

The paranasal sinuses are in close anatomical proximity to vital and delicate structures, such as the skull base, orbit, internal carotid artery, and optic nerve. Broad and detailed anatomical knowledge is essential for surgeons to perform safe and effective procedures.[12]

With the advent of intraoperative imaging, surgeons have acquired a greater operative domain. Undoubtedly, a thorough knowledge of anatomy is essential to nasal surgeons. Nevertheless, malformations, previous surgeries, and nasal polyposis can make orientation in the surgical field difficult, even for an experienced surgeon.[15]

Vreudenburg et al. and Dalgorf et al. found a reduction in the likelihood of total, major, and orbital complications in complex ESS procedures with the use of IGS. They included case-control and cohort studies in their systematic reviews, while the current review did not. The small number of clinical trials on the subject was a limitation of our findings; hence, the low incidence of complications in ESS.[19,33]

Tschopp et al. conducted a case-control study comparing ESS with and without image guidance, and although they did not reach statistical significance for the reduction of complications, they calculated the necessary sample size to achieve significant conclusions regarding the prevention of complications based on their own complication rate. In their analysis, a sample size of at least 880 was necessary to draw reliable conclusions on the subject.[34]

There is a lack of data in the literature regarding the estimated blood loss. Metson et al. in their prospective cohort found similar data to Singh, with 178.4 +- 18 mL in the IGS group and 149.4 +- 20.1 and no statistical significance (p=0.31).[35] Conversely, Tschopp et al. reported 180 +- 124 mL (IGS group) and 201 +- 198 mL (ESS group).[34]

Despite the limited number of studies that conducted quality of life assessments in patients with CRS who underwent ESS with and without IGS, the evidence suggests a greater improvement in the quality of life of patients operated on with navigation. Due to the heterogeneity of the outcome measures used in the literature, it is difficult to combine or compare data from different studies.[27,28]

One of the concerns since the inception of image guidance technology is that it would lead to a significant increase in the operative time and therefore increase the procedure cost. Evidence from the literature suggests that IGS does increase the preparation time, but it may lead to a reduction in the incision to suture time, thereby compensating for the overall operating room time.[29,31,34,35]

In addition to the possible decrease in the complication rate for ESS, the possibility of opening more of the diseased paranasal sinuses is an important question. This review provides important evidence that IGS is more effective than conventional ESS. To the best of our knowledge this is the first paper to present this evidence. Whether this may lead to better patient-reported outcome measures should be the subject of future research.[28,31,32]

The small number of high-quality studies with a low risk of bias is a limitation of this review. New clinical trials are important to better elucidate the role of image guidance in endoscopic surgery of the paranasal sinus.

CONCLUSION

Image guidance surgery is a valuable tool in ESS for patients with CRS, especially those with extensive paranasal disease or submitted to revision surgery. It provides the surgeon with important orientation information, increasing the efficacy of ESS in opening diseased paranasal sinuses. Moreover, IGS possibly reduces complication rates and improving the quality of life of patients with CRS. Therefore, more clinical trials are needed to confirm this evidence.

REFERENCES

1. Fokkens WJ. EPOS2020: a major step forward. *Rhinology*2020;58(1):1. doi: 10.4193/Rhin20.401

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2. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. *Rhinology* 2020;58(Suppl S29):1-464.

3. Orlandi RR, Kingdom TT, Smith TL, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. *Int Forum Allergy Rhinol.* 2021;11(3):213-739.

4. Chen Y, Dales R, Lin M. The epidemiology of chronic rhinosinusitis in Canadians. *Laryngoscope.* 2003 Jul;113(7):1199-205.

5. Wahid NW, Smith R, Clark A, et al. The socio-economic cost of chronic rhinosinusitis study. *Rhinology* . 2020;58(2):112-125.

6. Lourijsen ES, Fokkens WJ, Reitsma S. Direct and indirect costs of adult patients with chronic rhinosinusitis with nasal polyps.*Rhinology.* 2020;58(3):213-217.

7. Gliklich RE, Metson R. The health impact of chronic sinusitis in patients seeking otolaryngologic care. *Otolaryngol Head Neck Surg*1995;113(1):104-9.

8. Soler ZM, Wittenberg E, Schlosser RJ, et al. Health state utility values in patients undergoing endoscopic sinus surgery.*Laryngoscope* . 2011;121(12):2672-2678.

9. Rudmik L, Soler ZM. Medical Therapies for Adult Chronic Sinusitis: A Systematic Review. *Jama* 2015;314(9):926-39.

10. McCormick JP, Thompson HM, Cho DY, et al. Phenotypes in Chronic Rhinosinusitis. *Curr Allergy Asthma Rep* 2020;20(7):20.

11. Grayson JW, Hopkins C, Mori E, et al. Contemporary Classification of Chronic Rhinosinusitis Beyond Polyps vs No Polyps: A Review. *JAMA Otolaryngol Head Neck Surg* 2020;146(9):831-38.

12. Wormald PJ. *Endoscopic Sinus Surgery* . 4th edition ed: Thieme Medical Publishers, Inc. 2018.

13. Sharma B, Ranwa A, Garg K. Complication Avoidance in Endonasal Endoscopic Pituitary Surgery. *Neurology India* 2020;68(7):S85-S91.

14. Sedaghat AR. Chronic Rhinosinusitis. *Am Fam Physician*2017;96(8):500-06.

15. Alanin MC, Hopkins C. Effect of Functional Endoscopic Sinus Surgery on Outcomes in Chronic Rhinosinusitis. *Curr Allergy Asthma Rep*2020;20(7):27.

16. Ayoub N, Walgama E, Thamboo A, et al. Correlation between extent of sinus surgery, radiographic disease, and postoperative outcomes.*Rhinology* 2020;58(1):36-44.

17. Krings JG, Kallogjeri D, Wineland A, et al. Complications of primary and revision functional endoscopic sinus surgery for chronic rhinosinusitis. *Laryngoscope* 2014;124(4):838-45.

18. Koizumi M, Suzuki S, Matsui H, et al. Trends in complications after functional endoscopic sinus surgery in Japan: A comparison with a previous study (2007-2013vs. 2013-2017). *Auris Nasus Larynx*2020;47(5):814-19.

19. Vreugdenburg TD, Lambert RS, Atukorale YN, et al. Stereotactic Anatomical Localization in Complex Sinus Surgery: A Systematic Review and Meta-Analysis. *Laryngoscope* 2016;126(1):51-59.

20. Schmale IL, Vandelaar LJ, Luong AU, et al. Image-Guided Surgery and Intraoperative Imaging in Rhinology: Clinical Update and Current State of the Art. *Ear Nose Throat J.* 2021;100(10):NP475-NP486.

21. Beswick DM, Ramakrishnan VR. The Utility of Image Guidance in Endoscopic Sinus Surgery A Narrative Review. *Jama Otolaryngology-Head & Neck Surgery* 2020;146(3):286-90.

22. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement.*Syst Rev* 2015;4:1.

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23. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*2021;372:n71.

24. Nobre ML, Sarmento ACA, Nobre MG, et al. Image guidance for endoscopic sinus surgery in patients with chronic rhinosinusitis: a systematic review and meta-analysis protocol. *BMJ Open* . 2022;12(4):e053436.

25. Higgins JPT, Thomas J, Chandler J, et al. *Cochrane Handbook for Systematic Reviews of Interventions* version 6.1 (updated September 2020): Cochrane, 2020.

26. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*2008;336(7650):924-26.

27. Javer AR, Genoway KA. Patient quality of life improvements with and without computer assistance in sinus surgery: outcomes study. *J Otolaryngol* . 2006;35(6):373-379.

28. Strauss G, Limpert E, Strauss M, et al. Untersuchungen zur Effizienz eines Navigationssystems fur die HNO-Chirurgie: Auswertungen von 300 Patienten [Evaluation of a daily used navigation system for FESS].*Laryngorhinootologie* . 2009;88(12):776-781.

29. Singh A, Kumar R, Thakar A, Sharma SC, Bhalla AS. Role of Image Guided Navigation in Endoscopic Surgery of Paranasal Sinuses: A Comparative Study. *Indian J Otolaryngol Head Neck Surg* . 2020;72(2):221-227.

30. Lorenz KJ, Fruhwald S, Maier H. Einsatz des Brainlab-Kolibri-Navigationssystems bei der endoskopischen Nasennebenhohlenchirurgie in Lokalanasthesie. Erfahrung an 35 Patienten [The use of the BrainLAB Kolibri navigation system in endoscopic paranasal sinus surgery under local anaesthesia. An analysis of 35 cases]. *HNO* . 2006;54(11):851-860.

31. Stelter K, Ertl-Wagner B, Luz M, et al. Evaluation of an image-guided navigation system in the training of functional endoscopic sinus surgeons. A prospective, randomised clinical study. *Rhinology* . 2011;49(4):429-437.

32. Jiang RS, Liang KL. Image-guided sphenoidotomy in revision functional endoscopic sinus surgery. *Allergy Rhinol* (Providence). 2014;5(3):116-119.

33. Dalgorf DM, Sacks R, Wormald PJ, et al. Image-guided surgery influences perioperative morbidity from endoscopic sinus surgery: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg* . 2013;149(1):17-29.

34. Tschopp KP, Thomaser EG. Outcome of functional endonasal sinus surgery with and without CT-navigation. *Rhinology* . 2008;46(2):116-120.

35. Metson R, Cosenza M, Gliklich RE, Montgomery WW. The role of image-guidance systems for head and neck surgery. *Arch Otolaryngol Head Neck Surg* . 1999;125(10):1100-1104.

Figure Legends

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the selection process.

Figure 2. Forest plot illustrating the risk ratio for complications in intraoperative image-guided surgery vs. endoscopic sinus surgery. Note: M-H (Mantel-Haenszel).

Figure 3. Forest plot illustrating the risk ratio for missed paranasal sinuses in intraoperative image-guided surgery vs. endoscopic sinus surgery. Note: M-H (Mantel-Haenszel).

Figure 4. The Grading of Recommendation Assessment, Development, and Evaluation.

Tables

Table 1. Search strategy for PubMed.

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1	Sinusitis
2	Skull Base
3	Chronic Rhinosinusitis
4	Nasal Polyps
5	Nasal Surgical Procedures
6	Endoscopic Sinus Surgery
7	Nasal Surgery
8	OR/1-8
9	Image-Guided Surgery
10	Neuronavigation
11	Computer-Assisted Surgery
12	OR/ 9-12
13	Quality of Life
14	Life Quality
15	Health Related Quality of Life
16	Morbidity
17	Complication
18	Intraoperative Complication
19	Postoperative Complication
20	Patient-Reported Outcome Measures
21	Bleeding
22	Death
23	Cerebrospinal Fluid Leak
24	Operative Time
25	Length of Stay
26	Orbital Diseases
27	Brain Diseases
28	Revision Surgery
29	Recurrence
30	OR/13-29
31	8 AND 12 AND 30

Table 2. Included study characteristics.

First author	First author	Year	Year	Location	Location	Sample (n)	Sample (n)	Intervention
Javer	Javer	2006	2006	Canada	Canada	95	95	Computer-assisted
Jiang	Jiang	2016	2016	Taiwan	Taiwan	81	81	Stealth-Station Tr
Lorenz	Lorenz	2006	2006	Germany	Germany	70	70	BrainLAB Kolibri
Singh	Singh	2020	2020	India	India	60	60	Stealth-Station go
Stelter	Stelter	2011	2011	Germany	Germany	32	32	Vector Vision com
Strauss	Strauss	2009	2009	Germany	Germany	300	300	Karl Storz Naviga

Table 3. Qualitative synthesis of the included studies.

Study	Population	n	Outcomes	Results	Conclusion

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Javer 2006	CRS	IGS: 80 ESS: 15	RSOM-31	A significant improvement in quality of life was observed, following IGS compared with ESS, in the subgroups nasal symptoms, ear symptoms, general symptoms and practical problems.	The improvement in overall quality of life six months post-ESS appeared to be further enhanced when computer assistance was added to endoscopic sinus surgery.
Jiang 2014	CRS (revision surgery)	IGS: 51 ESS: 30	Sphenoid sinus penetration	IGS: 83 out of 91 sphenoid sinuses were successfully opened. ESS: 35 out of 51 sphenoid sinuses were successfully opened.	IGS was a beneficial procedure for opening the sphenoid sinus, especially in the revision cases.
Lorenz 2006	CRS	IGS: 35 ESS: 35	Navigation Accuracy, Set up time Gain in security for the surgeon, Complications	IGS: two patients had complications. ESS: six patients had complications. Gain in safety (1-5) with IGS: average 4.4 ($\pm$0.25) Additional effort with IGS (1-3): Average 1.8 ($\pm$0.75).	The question, whether using IGS a higher security can be reached with a lower complication rate cannot be answered so far. It is remarkable the subjective assessment of the surgeon who claim to have experienced a security gain with IGS.

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Singh 2020	CRS	IGS: 30 ESS: 30	Operating room time System accuracy Blood loss Complication	IGS: No complications. Blood loss: 566.67 (± 62.23) Operating room time: 165.68 (± 6.55) ESS: One complication (orbital swelling) Blood loss: 636.33 (± 72.59) Operating room time: 163.33 (± 5.43) Accuracy within 2 mm.	IGS improves the confidence of surgeons in reaching difficult areas safely leading to thorough disease clearance, especially in revision cases, altered anatomy, or extensive disease cases. The additional time taken for device setup and registration was effectively overcome by the reduced intraoperative time. Blood loss and complications did not differ significantly with or without IGS.
Stelter 2011	CRS	IGS: 80 ESS: 77	Postoperative drained paranasal sinuses	IGS: two missed paranasal sinuses / three complications ESS: five missed paranasal sinuses/ three complications.	IGS should have an assured place in training and teaching for paranasal sinus operations. Even if this new technology means extra costs, it was welcomed by all study participants (surgeons and patients).

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Strauss 2009	CRS	IGS: 150 ESS: 150	Operating room time Successful sphenoidal sinusotomy Patient subjective assessment	Incision-suture time: average 10.1 min less with IGS. Perioperative preparation time: 7 min on average more with IGS. Successful sinusotomy: IGS: 31/31 ESS: 9/40. Patient assessment: general feeling of well-being 73% IGS / 69% ESS; Minimal improvement, no improvement or worsening 16% IGS /30% ESS; would have the surgery again: 96% IGS/85% ESS.	The advantages of the examined navigation system compared to the gold standard of ESS are proven. Navigation assistance led to reduced intraoperative time, increased postoperative results, and lowered the workload of the surgeons.

Table 4. Risk of bias of the included studies.

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Javer 2006							
Jiang 2014							
Lorenz 2006							
Singh 2020							
Stelter 2011							

Legend:
Low risk bias
Uncertain risk of bias
High risk bias

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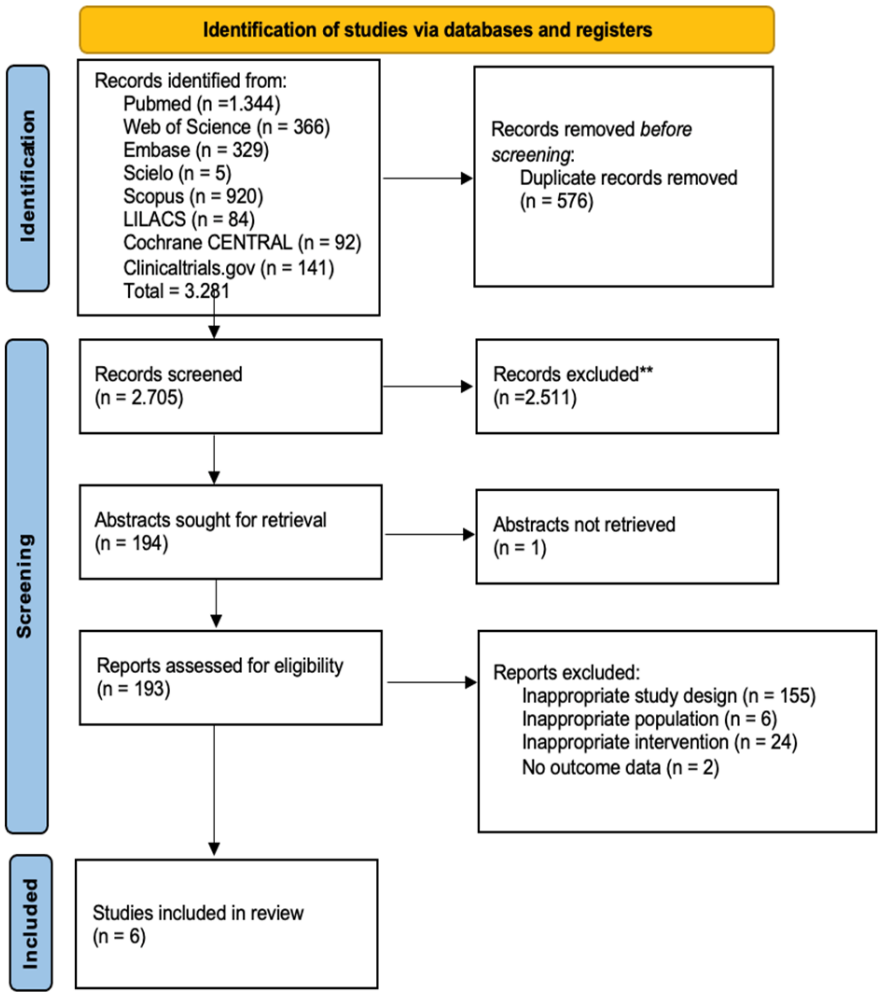
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Strauss 2009							



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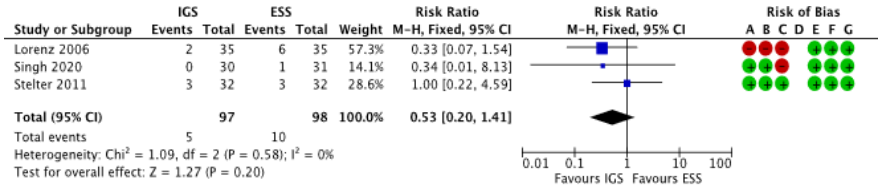
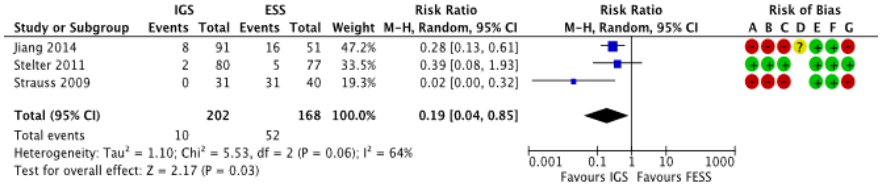


Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias



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(**G**) Other bias

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	IGS	FESS	Relative (95% CI)	Absolute (95% CI)		
Complication												
3	randomised trials	not serious	not serious	not serious	serious[a]	none	5/97 (5.2%)	10/98 (10.2%)	**RR 0.53** (0.20 to 1.41)	**48 fewer per 1.000** (from 82 fewer to 42 more)	⨁⨁⨁◯ Moderate	IMPORTANT
Missed paranasal sinuses												
3	randomised trials	serious[b]	serious[c]	not serious	not serious	none	10/202 (5.0%)	52/168 (31.0%)	**RR 0.19** (0.04 to 0.85)	**251 fewer per 1.000** (from 297 fewer to 46 fewer)	⨁⨁◯◯ Low	CRITICAL

CI: confidence interval; **RR:** risk ratio

Explanations

a. Few events.
b. Randomization failure and lack of allocation.
c. I^2: 64%