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# Image-Guided Surgery Influences Perioperative Morbidity from Endoscopic Sinus Surgery: A Systematic Review and Meta-Analysis



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## Abstract

**Objective.** Although image-guided surgery (IGS) is considered a valuable tool, its impact on perioperative morbidity for endoscopic sinus surgery (ESS) remains unclear. The evidence from reported literature is systematically reviewed with meta-analysis.

**Data Sources.** MEDLINE (1946 to September 14, 2012, week 2) and EMBASE (1974 to September 14, 2012, week 37).

**Review Methods.** MEDLINE and EMBASE were searched using a search strategy for publications on IGS during ESS that reported original data on perioperative morbidity. PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines were followed. Both comparative cohort studies with non-IGS cases and case series were included. Primary outcome was major and total complications. Secondary outcomes were specific orbital and intracranial injury, major hemorrhage, ability to complete the operation, and revision surgery. The incidence of these events was defined as dichotomous variables and expressed as a risk ratio (RR) in a fixed-effects model.

**Results.** In total, 2586 articles fulfilled the search, producing 55 included studies. Fourteen were comparative cohorts of IGS and non-IGS sinus surgical patient populations used for meta-analysis. Among the cohorts, major complications were more common in the non-IGS group (RR = 0.48; 95% confidence interval [CI], 0.28-0.82;  $P = .007$ ). Total complications were greater in the non-IGS group (RR = 0.66; 95% CI, 0.47-0.94;  $P = .02$ ). All other outcomes did not reach significance on meta-analysis.

**Conclusion.** Contrary to current review articles on the topic of IGS use during ESS, there is evidence from published studies that the use of IGS for sinus surgery, within

selected populations, is associated with a lower risk of major and total complications compared with non-IGS sinus surgery.

## Keywords

image-guided surgery, endoscopic sinus surgery, perioperative morbidity, major complications, patient reported outcome measures, systematic review, meta-analysis

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The use of image-guided surgery (IGS) has played an important and expanding role in endoscopic sinus surgery (ESS) over the past 2 decades. A recent

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survey<sup>1</sup> of American Rhinological Society members performed in 2010 suggests that more surgeons have access to IGS and are using this technology in a greater percentage of cases compared with a similar survey<sup>2</sup> conducted in 2005. It is generally perceived that IGS is critical to certain cases for verifying the location of vital structures surrounding the paranasal sinuses and minimizing the risk of injury. Although IGS is not a substitute for anatomical knowledge and clinical decision making, it may provide additional information to assist in complete clearance of pathology while maintaining safety. Intuitively, this would result in improved patient-based outcomes and lower complications or revision rates.

Although IGS is considered a valuable tool, its impact on perioperative morbidity and patient-reported outcome measures (PROMs) for ESS remains unclear. Current evidence based on a small number of individual cohort studies and case series has not consistently demonstrated a significant advantage of IGS over non-IGS ESS. Given the low incidence of complications, a large sample size in both the IGS and non-IGS study group arms is required. Several evidence-based reviews have recently evaluated the impact of IGS during ESS on complications and clinical outcomes.<sup>3,4</sup> However, while these studies attempt to be systematic, they provide a qualitative and opinion-based recommendation for the indications of IGS for ESS. This meta-analysis is performed using pooled data from published studies to address the impact of IGS on perioperative morbidity and PROMs.

## Methods

A systematic review of the published literature was undertaken to collate studies providing original data on the patient outcomes following IGS-based sinus surgery. A meta-analysis was performed on the studies that were randomized controlled trials, retrospective cohorts, or prospective cohorts that had a control population. PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines were followed where applicable.<sup>5</sup>

### Criteria for Considering Studies for This Review

**Types of Studies.** Studies reporting on original data for the use of IGS during ESS that fulfilled the criteria below were included. A subgroup of these studies with comparative data between IGS and non-IGS ESS was used for meta-analysis. All review articles, database coding studies, or any other types of studies not reporting original data were excluded.

**Types of Participants.** Both adults and pediatric patients having ESS or a disease requiring ESS were considered. Populations assessed included patients with inflammatory or fungal sinus disease, extradural sinonasal neoplasm, mucocele, frontal or revision sinus surgery, periorbital pathology, and any endoscopic procedure for extradural paranasal sinus pathology. Studies in which the entire or majority of the patient population had skull base lesions with intradural extension were excluded.

**Types of Interventions.** Studies involving any type of IGS tracking technology, such as optical, electromagnetic, and intraoperative methods, were considered but only in the setting of sinus surgery (not intradural skull-base surgery).

**Types of Outcome Measures.** The primary outcomes were perioperative morbidity and PROMs. The perioperative morbidity variables that were assessed included major, minor, and total complications. Major complications were defined as the following: (1) inadvertent entry into an area beyond the nasal cavity and/or paranasal sinus, (2) postoperative bleeding requiring surgical or angiographic intervention, and (3) the necessity to abort the procedure for any surgical reason. All other complications not fulfilling the above criteria were classified as minor complications such as bleeding not requiring surgical or angiographic intervention and synechiae. Total complications were defined as the sum of major and minor complications. Patient-reported outcome measures were defined by any validated disease-specific quality-of-life questionnaire, such as the Rhinosinusitis Outcome Measure 31 (RSOM-31), Sinonasal Outcome Test 20 (SNOT-20), Rhinosinusitis Disability Index, or Chronic Sinusitis Survey.

The secondary outcomes assessed were specific perioperative complications, including periorbital injuries, intracranial injuries, and major hemorrhage. Other secondary outcomes that were considered included the ability to complete the operation and the need for revision surgery.

### Data Collection and Analysis

An electronic systematic search strategy was used with a combination of MESH terms and keywords. Both MEDLINE (1946 to September 14, 2012, week 2) and EMBASE (1974 to September 14, 2012, week 37) were searched for published studies. Studies were limited to the English language. The complete MEDLINE search strategy is provided in Appendix 1 (available at [otojournal.org](http://otojournal.org)). A similar search strategy was applied using EMBASE. The reference list of included publications was assessed for additional studies not identified with the original search strategy.

Two review authors (D.M.D. and R.J.H.) agreed upon the included studies and evaluated them against the inclusion criteria for eligibility. A structured data collection form was used. Raw data were extracted from graphs and tables. The review authors (D.M.D. and R.J.H.) conducted the data extraction and assessed the quality of the methods used for each included study. Any discrepancies were resolved by discussion among the reviewing authors. Variables considered included study design, population setting (primary or tertiary), population number, age, follow-up duration, indications for ESS, IGS tracking method, and outcomes (perioperative morbidity and PROMs).

**Assessment of Risk of Bias.** Assessment of risk of bias was conducted in accordance with the Cochrane Collaboration tool for assessing risk of bias.<sup>6</sup> The included studies were assessed for risk of bias based on method of data collection, sampling method, treatment allocation, adequacy of

**Table 1.** Quality assessment for risk of bias.

Lead Author	Year	Method of Data Collection	Method of Sampling	Treatment Allocation	Adequacy of Outcome Reporting	Industry Involvement Reported	Judgment of Risk of Bias
Al-Swiahb <sup>7</sup>	2010	Retrospective	Not defined	Not defined	Complete	No	Unclear
Dubin <sup>8</sup>	2008	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	No	Low
Eliashar <sup>9</sup>	2003	Prospective	Consecutive	Disease severity	Complete	No	Low
Fried <sup>10</sup>	2002	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	Yes	Low
Gibbons <sup>11</sup>	2001	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	No	Low
Javer <sup>20</sup>	2006	Prospective	Not defined	Availability, controls from centers without IGS technology	Complete	No	Low
Metson <sup>12</sup>	1999	Prospective	Consecutive	Not defined	Complete	No	Low
Mueller <sup>13</sup>	2010	Retrospective	Consecutive	IGS use based on surgeon skill level	Complete	No	Low
Nishiike <sup>14</sup>	2011	Prospective	Consecutive	Not defined	Not defined	Not defined	Unclear
Reardon <sup>15</sup>	2002	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	No	Low
Samaha <sup>16</sup>	2003	Retrospective	Consecutive	IGS availability, controls from centers without IGS	Complete	No	Low
Stelter <sup>17</sup>	2011	Prospective	RCT	Block randomization	Blinding of outcome assessment	No	Low
Tabaee <sup>18</sup>	2006	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	No	Low
Tschopp <sup>19</sup>	2008	Retrospective	Consecutive	Availability, controls from pre-IGS era	Complete	No	Low

Abbreviations: IGS, image-guided surgery; RCT, randomized controlled trial.

outcome reporting, and industry involvement, as shown in **Table 1**. Allocation of patients into IGS and non-IGS sinus surgery groups was performed by various methods, including randomization, availability of IGS technology, disease severity, and individual surgeon training in the use of IGS. Availability of IGS technology is based on the era in which the sinus surgery was performed (before and after IGS technology was available at the same institution).

Judgment of the risk of bias for each article was evaluated and categorized as “low risk,” “high risk,” or “unclear risk” of bias,<sup>6</sup> as shown in **Table 1**. A risk of bias was defined as high risk if the sampling method was nonconsecutive. An unclear risk of bias was defined as any study with 2 or more sections that were “not defined” in **Table 1**.

#### Assessment of Heterogeneity

**Clinical heterogeneity.** All included studies were considered, and where issues appeared that might have added to clinical heterogeneity, these were noted and considered in the analysis. Subgroup analysis by publication year, study design, and IGS type was considered for heterogeneity assessment.

**Statistical analysis.** Forest plots were visually inspected to investigate statistical heterogeneity. Heterogeneity between studies was investigated using the  $I^2$  statistic, which provides an estimate of the percentage of variation observed in results that is unlikely to be due to chance. A value of 50% or

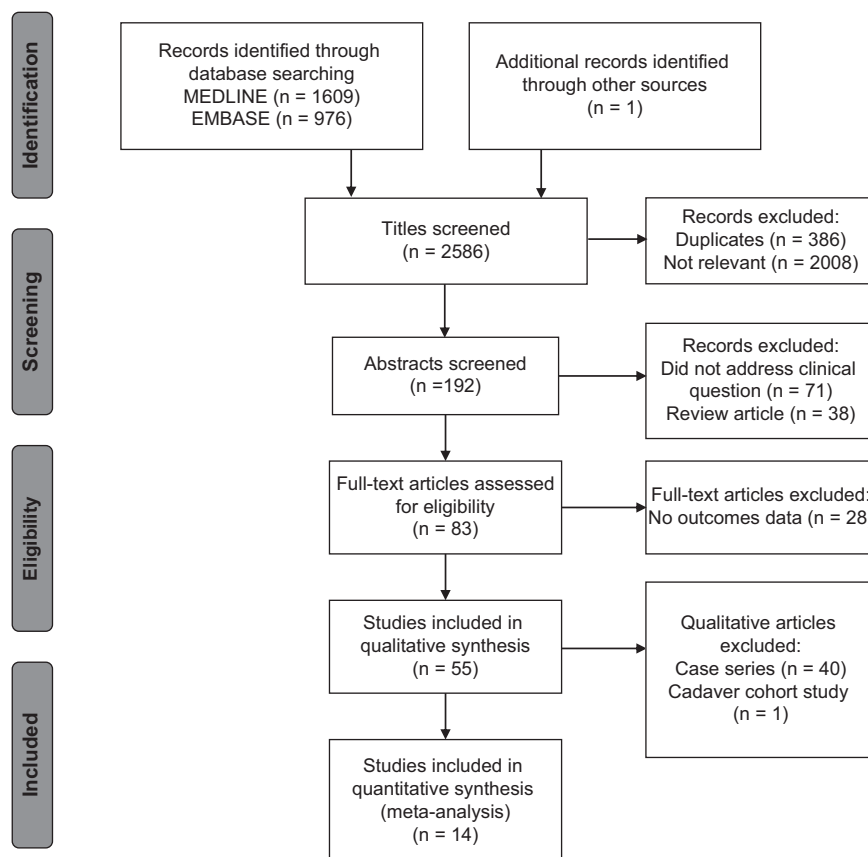
greater was taken to indicate heterogeneity. Standardized mean differences (SMDs) were obtained from the reported results to compare trials using different scales as outcome tools for disease-specific quality-of-life questionnaires. All other outcomes were defined as dichotomous variables and expressed as a risk ratio (RR) in a fixed-effects model.

## Results

### Description of Studies

**Results of the Search.** A total of 2586 references were received from the search: 2394 were removed in first-level screening (ie, removal of duplicates and clearly irrelevant references), leaving 192 references for further consideration. A flowchart of study selection is provided in **Figure 1**. Fifty-five studies met the inclusion criteria: 15 controlled cohort studies considered for quantitative synthesis (meta-analysis) and 40 case series for qualitative synthesis. There was 1 randomized, single-blinded controlled trial.

**Included Studies.** The included studies were divided into 4 categories based on the indicated use of IGS during ESS. The 4 categories were controlled cohort studies of IGS and non-IGS sinus surgery, as well as case series comprising critical use of IGS, specific use of IGS, and general use of IGS. Of the 15 controlled cohort studies identified, 14 were used for meta-analysis.<sup>7-20</sup> One cohort study was excluded



**Figure 1.** PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) flow diagram of study selection process.

from the meta-analysis as it was a cadaveric study that compared the use of IGS, transillumination, sinus probing, and 6-foot Caldwell radiography for mapping frontal sinus margins during osteoplastic flap.<sup>21</sup> One cohort study was a randomized single-blinded clinical trial. The use of IGS and non-IGS sinus surgery was randomized based on side of operation within the same patient procedure using block randomization. The outcomes, including completion of surgery, were assessed by blinded evaluation.<sup>17</sup> Overall, 3 cohort studies reported PROMs. There were 7 “critical use of IGS” case series studies identified in which the use of IGS was critical to the procedure,<sup>22-28</sup> such as frontal sinusotomy after failed frontal sinus obliteration. There were 17 “specific use of IGS” case series studies in which IGS was used for a specific procedure,<sup>29-45</sup> such as drainage of mucocoeles or resection of inverted papillomas. There were 16 “general use of IGS” case series studies in which IGS was used for a variety of indications.<sup>46-61</sup> The characteristics of the included studies for the controlled cohorts (**Table 2**) and case series (**Tables 3-5**) are shown.

**Excluded Studies.** Most references retrieved from the search (2008 articles) were not within the scope of our review. Of the 192 studies identified, 71 (36.9%) did not focus on the use of IGS during ESS, and 38 (19.7%) were review articles. Eighty-three full-text articles were considered for eligibility, of which 28 did not report any outcome data, leaving

55 studies. Forty IGS case series and 1 controlled cohort cadaver study<sup>21</sup> were excluded from the meta-analysis.

### Effects of Interventions

The use of any type of tracking technology (ie, optical, electromagnetic, intraoperative) for IGS during ESS was considered together for meta-analysis.

#### Perioperative Morbidity for IGS vs Non-IGS ESS

**Major complications.** Data on major complications were collected from 13 studies for meta-analysis.<sup>7-19</sup> There were a total of 1119 patients allocated to the IGS group and 1282 allocated to the non-IGS group. With respect to the defined criteria for major complications, there were 14 and 42 events in the IGS and non-IGS groups, respectively. Pooled results favored the use of IGS over non-IGS in the risk of major complications (RR = 0.48; 95% confidence interval [CI], 0.28-0.82;  $P = .007$ ). The  $I^2$  statistic was 1%, with good homogeneity ( $\chi^2 = 11.10$ ,  $df = 11$ ,  $P = .43$ ). A forest plot illustrating this outcome is provided in **Figure 2**. A second analysis was conducted in which the original description of major complications used by the authors of the controlled cohort studies was applied. These pooled results also showed a significant benefit of IGS over non-IGS in the risk of major complications (RR = 0.51; 95% CI, 0.29-0.91;  $P = .02$ ).

**Total complications.** For total complications, data on 13 studies were collected for meta-analysis.<sup>7-19</sup> A total of 1119



**Table 2.** Characteristics of included studies for meta-analysis.

Lead Author	Year	Method	n	Population	Outcomes
Al-Swiahb <sup>7</sup>	2010	Retrospective	60	Inflammatory sinus disease	Complications unspecified, orbital
Dubin <sup>8</sup>	2008	Retrospective	24	Orbital pathology	Major and minor complications, orbital
Eliashar <sup>9</sup>	2003	Retrospective	165	Inflammatory, frontal and revision sinus surgery, orbital	Major and minor complications, orbital
Fried <sup>10</sup>	2002	Retrospective	160	Inflammatory sinus disease	Major and minor complications, orbital, intracranial
Gibbons <sup>11</sup>	2001	Retrospective	203	Inflammatory sinus disease, revision sinus surgery	Major and minor complications
Javer <sup>20</sup>	2006	Prospective	95	Inflammatory sinus disease	RSOM-31
Metson <sup>12</sup>	1999	Prospective	121	Inflammatory, orbital, neoplasia, revision sinus surgery	Major and minor complications
Mueller <sup>13</sup>	2010	Retrospective	276	Inflammatory sinus disease	Major and minor complications, orbital, intracranial
Nishiike <sup>14</sup>	2011	Retrospective	66	Inflammatory sinus disease, neoplasia	Complications unspecified, orbital, intracranial
Reardon <sup>15</sup>	2002	Retrospective	800	Frontal sinus surgery, revision sinus surgery	Major and minor complications, intracranial, orbital
Samaha <sup>16</sup>	2003	Retrospective	100	Inflammatory, revision sinus surgery	Major and minor complications
Stelzer <sup>17</sup>	2011	RCT	32	Inflammatory sinus disease	Major and minor complications, orbital
Tabaee <sup>18</sup>	2006	Retrospective	239	Inflammatory sinus disease	Major and minor complications, intracranial, SNOT-20
Tschopp <sup>19</sup>	2008	Prospective	123	Inflammatory sinus disease, neoplasia	Major complications, orbital, QOL VAS

Abbreviations: QOL VAS, quality-of-life visual analog scale; RCT, randomized controlled trial; RSOM-31, Rhinosinusitis Outcome Measure 31; SNOT-20, Sinonasal Outcome Test 20.

**Table 3.** Characteristics of included studies for qualitative assessment (controlled cohort and critical use of IGS studies).

Lead Author	Year	n	Population	Outcome	Use of IGS
Controlled cohort studies					
Ansari <sup>21</sup>	2003	5	Frontal sinus surgery	Operative	Mapping frontal sinus for osteoplastic flap
Critical use of IGS					
Chandra <sup>22</sup>	2004	11	Inflammatory sinus disease, frontal sinus surgery	Complications unspecified	Frontal sinusotomy after failed FSO
Chiu <sup>23</sup>	2004	10	Inflammatory sinus disease, frontal sinus surgery	Operative	Lateral frontal sinus mucoceles
Fakhri <sup>24</sup>	2005	5	Neoplasia	Operative	Sphenoid sinus inverted papilloma
Murchison <sup>25</sup>	2011	18	Neoplasia, orbital pathology	Major complications, orbital, intracranial	Orbital apex lesions
Reh <sup>26</sup>	2008	13	Inflammatory sinus disease, revision sinus surgery	Major and minor complications, intracranial	Revision ESS after previous skull base repair
Stankiewicz <sup>27</sup>	2003	10	Frontal sinus surgery, revision sinus surgery	Complications unspecified, PROM	Lothrop after failed FSO
Zacharek <sup>28</sup>	2006	13	Inflammatory, neoplasia, frontal and revision sinus surgery	Complications unspecified	IGS-directed trephination for difficult frontal sinus lesions

Abbreviations: ESS, endoscopic sinus surgery; FSO, frontal sinus obliteration; IGS, image-guided surgery; PROM, patient-reported outcome measure.

patients were allocated to the IGS group and 1282 allocated to the non-IGS group. Overall, there were 44 and 81 total complications in the IGS and non-IGS groups, respectively.

Pooled results favored the use of IGS over non-IGS in the risk of total complications (RR = 0.66; 95% CI, 0.47-0.94;  $P = .02$ ). The  $I^2$  statistic was 0%, with good homogeneity

**Table 4.** Characteristics of included studies for qualitative analysis (specific use of IGS).

Lead Author	Year	n	Population	Outcome	Use of IGS
Benoit <sup>29</sup>	2009	33	Inflammatory, neoplasia, pediatric, frontal, orbital	Major and minor complications, operative	Pediatric pathology
Bonne <sup>30</sup>	2012	15	Neoplasia, pediatric pathology, skull base pathology	Major complications, intracranial, operative	Intranasal gliomas
Chandra <sup>31</sup>	2006	3	Neoplasia, skull base pathology	Operative	Epidermoids of PPF, SOE, petrous apex
Chen <sup>32</sup>	2004	3	Neoplasia, frontal sinus surgery, orbital pathology	Complications unspecified, operative, PROM	Frontal sinus osteoma
Chiu <sup>33</sup>	2004	67	Inflammatory, frontal and revision sinus surgery	Major complications, intracranial, orbital, operative, PROM	Revision frontal sinus surgery
Crawley <sup>34</sup>	2009	102	Inflammatory sinus disease	Major and minor complications, operative	Surgical trainees
Dou <sup>35</sup>	2010	7	Orbital pathology	Complications unspecified, orbital, operative	Orbital pathology
Fuchsmann <sup>36</sup>	2008	20	Inflammatory, pediatric pathology, revision sinus surgery	Major complications, operative, PROM	Cystic fibrosis
Hofmann <sup>37</sup>	2005	21	Neoplasia	Major complications, operative	Juvenile nasopharyngeal angiofibroma
Klimek <sup>38</sup>	1995	14	Inflammatory, neoplasia, orbital, skull base pathology	Complications unspecified, operative	Pediatric skull base pathology
Kuhn <sup>39</sup>	2001	71	Neoplasia	Complications unspecified, operative	Benign and malignant sinonasal tumors
Lam <sup>40</sup>	2002	6	Skull base pathology, neoplasia	Operative, PROM	Sphenoid sinus pathology
Parikh <sup>41</sup>	2009	33	Inflammatory sinus disease, pediatric pathology, neoplasia	Complications unspecified, operative	Pediatric pathology
Philpott <sup>42</sup>	2010	76	Neoplasia, revision sinus surgery	Major and minor complications, intracranial, operative, PROM	Inverted papilloma
Sautter <sup>44</sup>	2007	5	Neoplasia, frontal sinus surgery	Intraoperative and postoperative complications, operative	Frontal sinus inverted papilloma
Sautter <sup>45</sup>	2008	57	Inflammatory, frontal sinus surgery, orbital, skull base	Complications unspecified, orbital, intracranial, operative, PROM	Mucoceles with skull base and/or orbital erosion
Samaha <sup>43</sup>	2003	10	Neoplasia, revision sinus surgery, orbital pathology	Complications unspecified, orbital, operative, PROM	Fibro-osseous lesions

Abbreviations: IGS, image-guided surgery; PROM, patient-reported outcome measure; PPF, pterygopalatine fossa; SOE, supraorbital ethmoid.

( $\chi^2 = 9.75$ ,  $df = 11$ ,  $P = .55$ ). A forest plot illustrating this outcome is provided in **Figure 3**.

#### Specific Complications for IGS vs Non-IGS ESS

**Orbital complications.** Seven studies were pooled for meta-analysis regarding the incidence of orbital complications with the use of IGS and non-IGS sinus surgery.<sup>9,10,14,15,17-19</sup> A total of 718 and 899 patients were allocated to the IGS and non-IGS groups, respectively. There were 11 orbital complications in the IGS group and 25 in the non-IGS group. Pooled results showed no statistically significant benefit of IGS over non-IGS sinus surgery in the risk of orbital complications (RR = 0.60; 95% CI, 0.31-1.15;  $P = .12$ ). The  $I^2$  statistic was 11%, with good homogeneity ( $\chi^2 = 5.63$ ,  $df = 5$ ,  $P = .34$ ). A forest plot illustrating this outcome is provided in **Figure 4**.

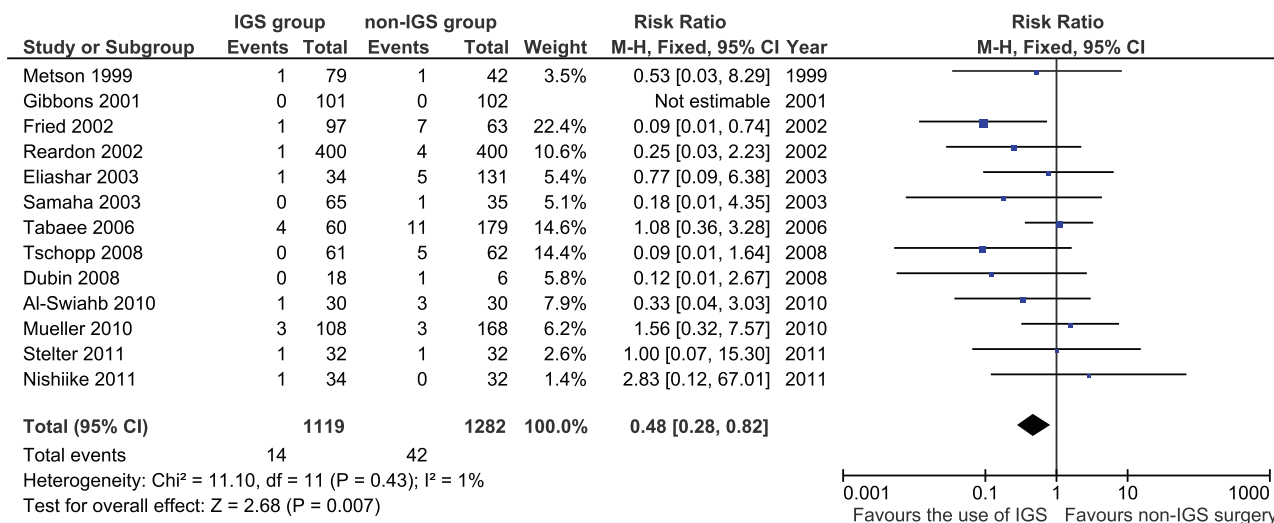
**Intracranial complications.** Intracranial complication data were collected on 5 studies for meta-analysis<sup>14,15,17-19</sup> with a total of 587 and 705 patients in the IGS and non-IGS groups, respectively. There was 1 intracranial complication in the IGS group and 9 intracranial complications in the non-IGS group. Pooled results showed no benefit of IGS over non-IGS ESS in the risk of intracranial complications (RR = 0.29; 95% CI, 0.06-1.34;  $P = .11$ ). The  $I^2$  statistic was 0%, with good homogeneity ( $\chi^2 = 0.07$ ,  $df = 2$ ,  $P = .96$ ). A forest plot illustrating this outcome is provided in **Figure 5**.

**Major hemorrhage.** For major hemorrhage, data from 7 studies were collected for meta-analysis.<sup>7,12-15,17,18</sup> There were 743 patients allocated to the IGS group and 883 patients allocated to the non-IGS group. A total of 8 major hemorrhage events occurred in the IGS group, with 7

**Table 5.** Characteristics of included studies for qualitative analysis (general use of IGS).

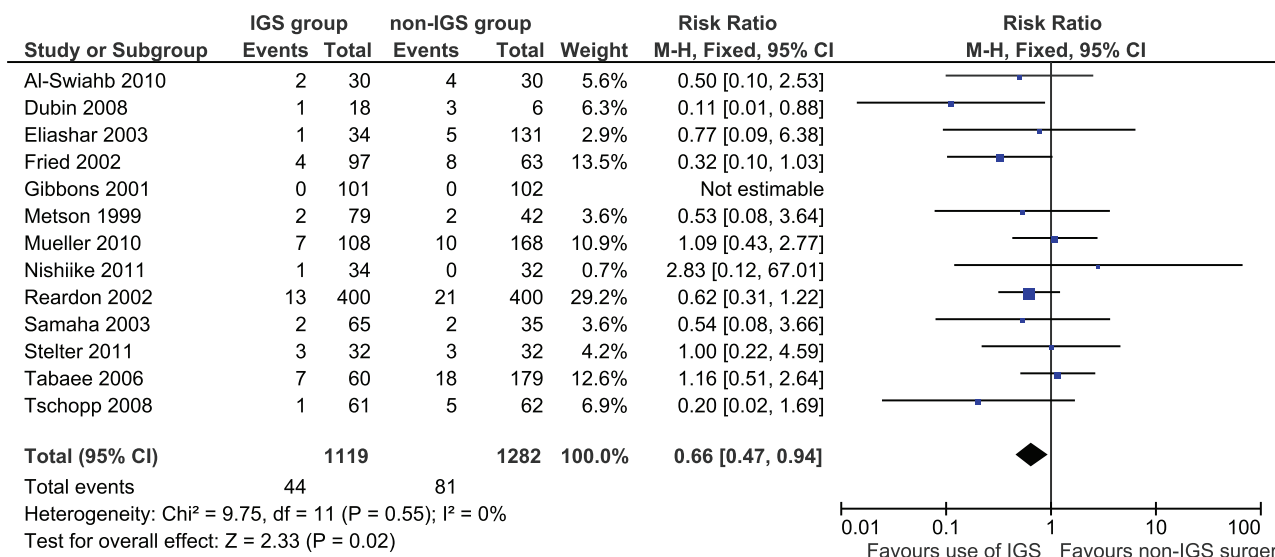
Lead Author	Year	n	Population	Outcome	Use of IGS
Chu <sup>46</sup>	2006	79	Not reported	Major and minor complications, orbital, intracranial, operative	
Farhadi <sup>47</sup>	2011	62	Inflammatory, orbital, neoplasia, frontal, revision, skull base	Major complications, operative	
Han <sup>48</sup>	2003	28	Inflammatory sinus disease, neoplasia	Complications unspecified, operative	
Jackman <sup>49</sup>	2008	20	Inflammatory sinus disease, revision sinus surgery	Complications unspecified, operative	IGS with intraoperative CT to assess surgical completion
Kherani <sup>50</sup>	2003	39	Inflammatory sinus disease, revision sinus surgery	Major and minor complications, operative	
Metson <sup>52</sup>	2000	754	Not reported	Intraoperative and postoperative complications, operative	
Metson <sup>51</sup>	2003	1000	Not reported	Major complications, operative	
Neumann <sup>53</sup>	1999	109	Inflammatory, orbital, skull base, revision surgery	Complications unspecified, operative	
Philpott <sup>54</sup>	2010	300	Inflammatory sinus disease	Operative	Surgery at 200 tertiary vs 100 nonacademic centers
Rassekh <sup>55</sup>	2003	21	Inflammatory, neoplasia, skull base pathology	Major and minor complications, orbital, intracranial, operative	
Rombaax <sup>56</sup>	2003	32	Inflammatory, frontal and revision surgery, neoplasia	Major and minor complications	
Roth <sup>57</sup>	1995	12	Inflammatory, orbital, neoplasia, frontal sinus surgery	Complications unspecified	
Stankiewicz <sup>58</sup>	2011	3402	Inflammatory sinus disease, revision sinus surgery	Major and minor complications, orbital, intracranial, operative	
Stelter <sup>59</sup>	2006	368	Inflammatory, neoplasia, revision surgery, skull base	Major and minor complications, orbital, intracranial, operative	
Suzuki <sup>60</sup>	2005	14	Inflammatory, revision sinus surgery, neoplasia, orbital	Complications unspecified, operative	IGS with intraoperative MR
Tabaee <sup>61</sup>	2003	110	Inflammatory, frontal and revision surgery, skull base	Major complications, operative, orbital, intracranial	

Abbreviations: CT, computed tomography; IGS, image-guided surgery; MR, magnetic resonance.

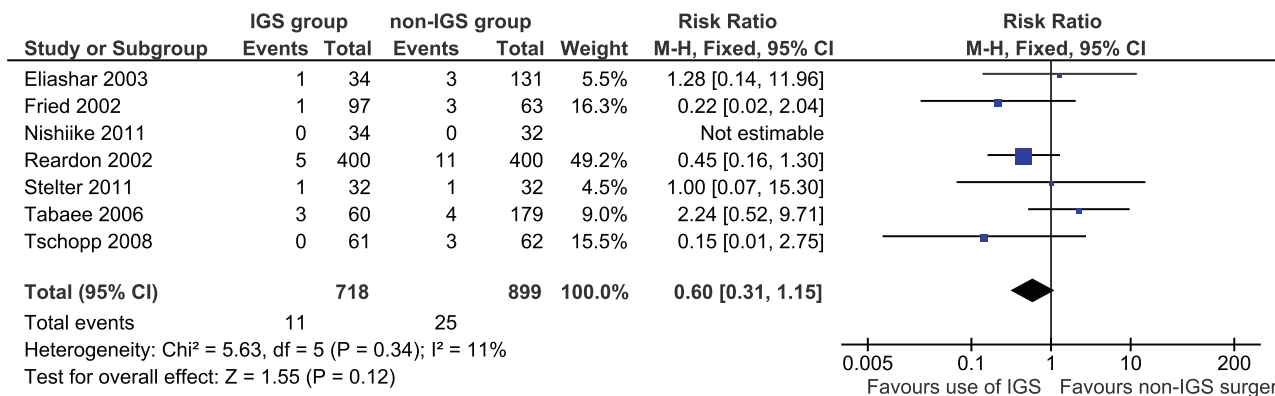


**Figure 2.** Forest plot illustrating risk ratio (RR) for major complications. CI, confidence interval; IGS, image-guided surgery; M-H, Mantel-Haenszel.

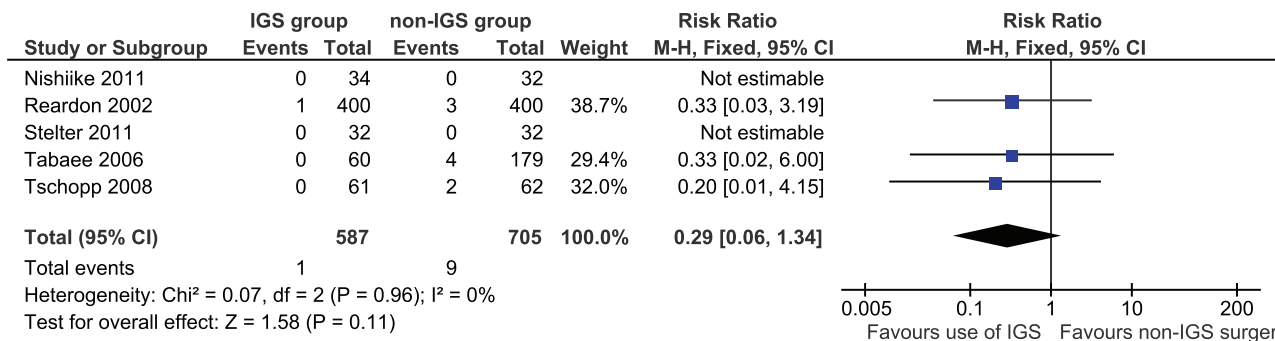




**Figure 3.** Forest plot illustrating risk ratio (RR) for total complications. CI, confidence interval; IGS, image-guided surgery; M-H, Mantel-Haenszel.



**Figure 4.** Forest plot illustrating risk ratio (RR) for orbital complications. CI, confidence interval; IGS, image-guided surgery; M-H, Mantel-Haenszel.

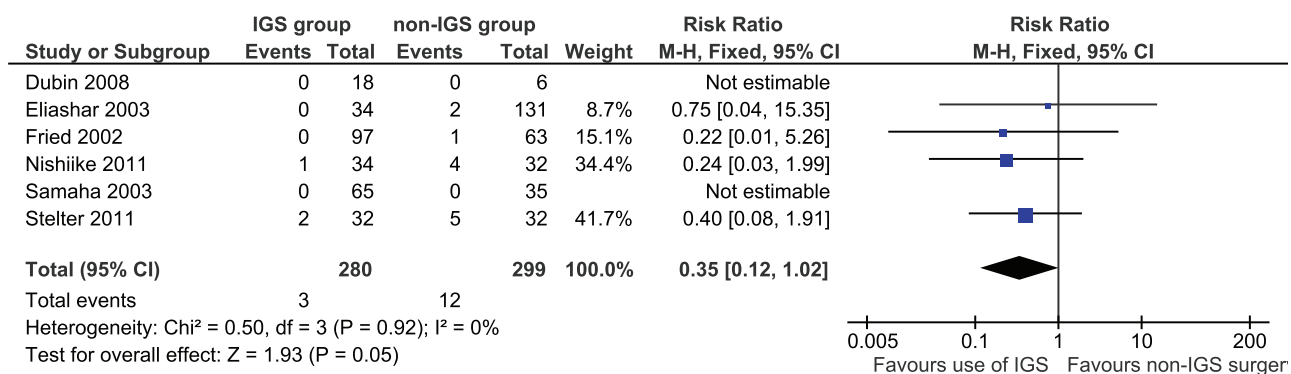


**Figure 5.** Forest plot illustrating risk ratio (RR) for intracranial complications. CI, confidence interval; IGS, image-guided surgery; M-H, Mantel-Haenszel.

occurring in the non-IGS group. Pooled results showed no benefit of IGS over non-IGS ESS in the risk of major hemorrhage (RR = 1.44; 95% CI, 0.56-3.72; P = .45). The I<sup>2</sup> statistic was 0%, with good homogeneity ( $\chi^2 = 2.18, df = 5, P = .82$ ).

*Completion of Operation and Revision Surgery for IGS vs Non-IGS ESS*

*Completion of operation.* Six studies were pooled for meta-analysis<sup>8-10,14,16,17</sup> regarding completion of operation with 280 and 299 patients allocated to the IGS and non-IGS



**Figure 6.** Forest plot illustrating risk ratio (RR) for completion of operation. CI, confidence interval; IGS, image-guided surgery; M-H, Mantel-Haenszel.

groups, respectively. There were 3 events in the IGS and 12 events in the non-IGS group in which completion of the operation was not achieved. Reasons for this included failure to enter the paranasal sinus,<sup>14,17</sup> anatomical malformation,<sup>9</sup> and having to halt the procedure due to major bleeding.<sup>9,10</sup> Pooled results did not show any significant benefit of IGS over non-IGS in the risk of failure to complete the operation (RR = 0.35; 95% CI, 0.12-1.02;  $P = .05$ ). The  $I^2$  statistic was 0%, with good homogeneity ( $\chi^2 = 0.50$ ,  $df = 3$ ,  $P = .92$ ). A forest plot illustrating this outcome is provided in **Figure 6**.

**Revision surgery.** Data regarding the need for further revision surgery were collected in 7 studies for meta-analysis.<sup>7,8,10,13,16,18,19</sup> A total of 439 patients were included in the IGS group and 543 patients in the non-IGS group. There were 32 and 51 patients requiring additional revision surgery in the IGS and non-IGS groups, respectively. The need for revision surgery was determined during the follow-up period of each individual study. Pooled results did not show any significant benefit of IGS over non-IGS in the risk of a patient requiring additional revision surgery (RR = 0.72; 95% CI, 0.47-1.10;  $P = .13$ ). The  $I^2$  statistic was 0%, with good homogeneity ( $\chi^2 = 3.17$ ,  $df = 6$ ,  $P = .79$ ).

**Patient-Reported Outcome Measures for IGS vs Non-IGS ESS.** Three comparative cohort studies reported on PROMs for meta-analysis.<sup>18-20</sup> A total of 186 patients were allocated to the IGS group and 179 patients to the non-IGS group. Pooled results from several validated disease-specific quality-of-life questionnaires were used, including the SNOT-20,<sup>18</sup> visual analog scale,<sup>19</sup> and the RSOM-31.<sup>20</sup> There was no statistically significant benefit of IGS over non-IGS sinus surgery using posttreatment SMD (0.07; 95% CI, -0.16 to 0.29;  $P = .56$ ). The  $I^2$  statistic was 0%, with good homogeneity ( $\chi^2 = 1.44$ ,  $df = 2$ ,  $P = .49$ ).

## Discussion

This meta-analysis provides objective evidence from published literature that both major complications and total complications are less likely to occur with the use of IGS than the use of non-IGS during ESS. A retrospective study

by Fried et al<sup>10</sup> is the only other study to report a statistically significant benefit of IGS over non-IGS sinus surgery. There were fewer major complications in the IGS group as compared with the non-IGS group; however, similar to our findings, there was no difference in minor complications, which were not clearly defined.

Ramakrishnan et al<sup>62</sup> performed a large retrospective review based on a nationwide database using insurance claim codes and compared the complication rates between ESS with and without IGS. This study identified up to 62,823 patients using specific inclusion and exclusion criteria. The overall major complication rate was 1.0% with specific complication rates including cerebrospinal fluid leak (0.17%), orbital injury (0.07%), and hemorrhage requiring transfusion (0.76%). There was no statistically significant difference found in the IGS and non-IGS groups for the rate of cerebrospinal fluid leak or major hemorrhage, but orbital injuries occurred more frequently in the IGS group ( $P < .005$ ). However, this study is not based on original data, and any retrospective study using a large database is likely to be subject to reporting and selection biases. Due to study design, the authors were unable to draw conclusions regarding the impact of IGS on complication rates during ESS.

Although a sufficiently powered randomized prospective clinical trial of IGS and non-IGS sinus surgery is required to fully evaluate the unbiased impact of IGS on perioperative morbidity and PROM, such a study is unlikely to be undertaken. Without the benefit of such a trial, the available evidence is limited to cohort studies and case series. The data presented demonstrate the pooled results of published studies that major and total complications are less likely with the use of IGS compared with non-IGS during ESS in selected populations.

A limitation of this meta-analysis involves the included studies design. In the majority of these studies, allocation to IGS or non-IGS sinus surgery groups was largely based on availability of IGS (before and after the equipment was purchased). Only 1 study allocated treatment groups based on disease severity, in which cases deemed more difficult were treated with IGS surgery.<sup>9</sup> It is also possible that more

**Table 6.** Recommendations for the use of image guidance during endoscopic sinus surgery.

Australian Expert Panel Recommendations for IGS	American Academy of Otolaryngology—Head and Neck Surgery Indications for IGS
<p><b>1. Recommended</b></p> <ul style="list-style-type: none"> <li>a. Stereotactic directed external localization of frontal pathology (not mini-trephination)</li> <li>b. Endoscopic frontal sinus surgery in the setting of prior external frontal or external ethmoid surgery</li> <li>c. Endoscopic sinus surgery in the setting of prior reconstruction of the ventral skull base</li> <li>d. Pathology beyond the anatomical limits of the paranasal sinuses (excluding lacrimal surgery and biopsy of exophytic tumor)<sup>a,b,c</sup></li> <li>e. Benign and malignant neoplasia involving the ventral skull base (not diagnostic)</li> <li>f. Draf 3 procedure</li> </ul> <p><b>2. Optional (important)</b></p> <ul style="list-style-type: none"> <li>a. Extensive nasal polyposis (involving all sinuses either unilateral or bilateral) in which all sinuses are addressed</li> <li>b. Revision frontal sinus surgery</li> <li>c. Benign and malignant neoplasia of the paranasal sinuses not involving the ventral skull base (not diagnostic)</li> </ul> <p><b>3. Optional (helpful)</b></p> <ul style="list-style-type: none"> <li>a. Revision sinus surgery</li> <li>b. Distorted sinus anatomy of developmental, postoperative, or traumatic origin</li> <li>c. Congenital abnormality</li> <li>d. Training/education</li> <li>e. Specific <ul style="list-style-type: none"> <li>i. Pediatrics</li> <li>ii. Cystic fibrosis</li> <li>iii. Sphenoid surgery</li> <li>iv. Frontal sinus surgery</li> <li>v. Mucoceles</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>1. Revision sinus surgery</li> <li>2. Distorted sinus anatomy of development, postoperative, or traumatic origin</li> <li>3. Extensive sinonasal polyposis</li> <li>4. Pathology involving the frontal, posterior ethmoid, and sphenoid sinuses</li> <li>5. Disease abutting the skull base, orbit, optic nerve, or carotid artery</li> <li>6. CSF rhinorrhea or conditions in which there is a skull base defect</li> <li>7. Benign and malignant sinonasal neoplasms</li> </ul>

Abbreviations: CSF, cerebrospinal fluid; IGS, image-guided surgery.

<sup>a</sup>Orbital decompression included.

<sup>b</sup>Optic nerve is outside the limits of the paranasal sinuses.

<sup>c</sup>No simple transnasal biopsy of nasopharynx tumor.

difficult cases were undertaken once IGS was available at centers. No descriptive data suggest that the use of IGS was associated with less severe pathology. However, despite this allocation bias potentially to more complex pathology in the IGS sinus surgery group, there were more complications in the non-IGS compared with the IGS group. The only randomized trial included in the meta-analysis was single blinded, in which the use of IGS and non-IGS sinus surgery among surgical trainees was randomized based on side of operation within the same patient procedure.<sup>17</sup> This study demonstrated no difference in complications between groups and involved only 32 patients total (one side allocated to IGS and the other side allocated to non-IGS). The potential for type II error is great considering that our understanding of the rate of major complications is less than 1% to 2% in

recent studies.<sup>58,62</sup> In this situation, the pooled meta-analysis has value in determining differences in uncommon or rare events.

Clinical relevance of the data presented here is critical. All of the included studies were conducted in a tertiary hospital setting, which likely involves more complex patients, greater disease severity, and trainees. Thus, the results of this meta-analysis cannot apply to the majority of patients undergoing sinus surgery. Future studies are required to more clearly identify which patient populations would benefit most. However, randomized comparative studies are unlikely and ethically challenging given the wide adaptation of IGS technology.

Image-guided surgery for ESS, although not necessary for routine sinus surgeries, has enormous advantages, and thus its

use needs to be defined, acknowledged, and supported where appropriate. Several working groups have attempted to identify patient populations in which the use of IGS would influence patient outcomes. Defining indications for the use of IGS is complicated by variations in procedure complexity, patient anatomy, inflammatory or neoplastic disease burden, and surgeon skill and training. The American Academy of Otolaryngology—Head and Neck Surgery endorses the use of IGS during ESS in select cases based on expert consensus opinion and literature evidence.<sup>63</sup> These recommendations set out a list of general indications that serve as a guideline to be used at the discretion of the operating surgeon. The authors of this review formed part of a working group in Australian rhinology with the goal of creating more specific recommendations for the use of IGS during ESS (see **Table 6**). These recommendations are divided into 3 categories based on the level of importance that the role of IGS is likely to have on the outcome of the procedure. Level 1 recommendations are highly recommended, level 2 are optional but deemed important, and level 3 recommendations are optional and deemed helpful for the procedure. These recommendations were created both on the basis of the data presented in this study and on local surgical practices.

## Conclusion

Contrary to current review articles on the topic of IGS use during ESS, there is evidence from published studies that the use of IGS for sinus surgery is associated with a lower risk of major and total complications compared with non-IGS sinus surgery in selected populations.

## Author Contributions

**Dustin M. Dalgorf**, conception and design, acquisition of data, analysis and interpretation of data, drafting the article, final approval; **Raymond Sacks**, conception and design, critical review of article, final approval; **Peter-John Wormald**, conception and design, critical review of article, final approval; **Yuresh Naidoo**, conception and design, critical review of article, final approval; **Ben Panizza**, conception and design, critical review of article, final approval; **Brent Uren**, conception and design, critical review of article, final approval; **Chris Brown**, conception and design, critical review of article, final approval; **John Curotta**, conception and design, critical review of article, final approval; **Kornkiat Snidvongs**, conception and design, search strategy, review of article, final approval; **Richard J. Harvey**, conception and design, acquisition of data, analysis and interpretation of data, critical review of article, final approval.

## Disclosures

**Competing interests:** Raymond Sacks is a consultant for Medtronic and has served on the speakers bureau for Merek Sharp Dolme. Peter-John Wormald receives royalties from Medtronic ENT for instrument design and is a consultant for Neilmed Pty Ltd, and has part ownership in a patent for Chitosan. Richard J. Harvey has served on an advisory board for Schering Plough, NeilMed Pharmaceuticals, and GlaxoSmithKline; has acted as a consultant for Olympus and Medtronic; has served on the speakers bureau for Merek Sharp Dolme, GlaxoSmithKline, and Arthrocare;

has received grant support from NeilMed Pharmaceuticals and Medtronic; and has served as a speaker and consultant for Stallergenes.

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## Supplemental Material

Additional supporting information may be found at <http://oto.sagepub.com/content/by/supplemental-data>

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