Use of a navigation system in endonasal surgery: Impact on surgical strategy and surgeon satisfaction. A prospective multicenter study

E. Vicaut, B. Bertrand, J.-L. Betton, A. Bizon, D. Briche, L. Castillo, J.-B. Lecanu, P. Lindas, B. Lombard, O. Malard, et al.

Use of a navigation system in endonasal surgery: impact on surgical strategy and surgeon satisfaction. A prospective multicenter study.

Eric Vicaut[1], Bruno Bertrand[2], Jean-Luc Betton[3], Alain Bizon[4], Denis Briche[5], Laurent Castillo[6], Jean-Baptiste Lecanu[7], Pierre Lindas[8], Bertrand Lombard[9], Olivier Malard[10], Jean-Claude Merol[11], Pierre-Jean Monteyrol[12], Talal Nasser[13], Bruno Navailles[14], Virginie Prulière-Escabasse[15], Robert Stringini[16], Benjamin Verillaud[17].

1 Unité de Recherche Clinique Lariboisière-Saint Louis, Hôpital Fernand Widal, Assistance Publique Hôpitaux de Paris, Université Paris 7, 200 Rue du Faubourg Saint Denis, 75010 Paris, France

2 Clinique de l'Atlantique, 26 Rue du Moulin des Justices, 17138 Puilboreau, France

3 Clinique du Pré, 13 Avenue René Laënnec, 72000 Le Mans, France.

4 Centre Hospitalier Universitaire, 4 Rue Larrey, 49100 Angers, France

5 Clinique Saint Barbe, 29 Rue du Faubourg National, 6700 Strasbourg, France

6 Institut Universitaire de la Face et du Cou, 31 Avenue de Valombrose, 06100 Nice, France

7 Institut Arthur Vernes, 36 Rue d'Assas, 75006 Paris, France

8 Hôpital privé Robert Schuman, Rue du Champ Montoy, 57070 Vantoux, France

9 Hôpital d'Instruction des Armées Desgenettes, 108 Boulevard Pinel, 69003 Lyon, France

10 Centre Hospitalier Universitaire, 1 Place Alexis-Ricordeau, 44000 Nantes, France

11 Hôpital Robert Debré, Avenue du Général Koenig, 51092 Reims, France

12 Clinique du Tondu, 143 Rue du Tondu, 33000 Bordeaux, France

13 Polyclinique de Courlancy, 38 Rue de Courlancy, 51100 Reims, France

14 Centre Hospitalier, 179 Avenue du Maréchal Juin, 26000 Valence, France

15 Centre Hospitalier Intercommunal, CHU Henri Mondor, 40 Avenue de Verdun, 94000 Créteil, France

16 CH de Metz, Hôpital de Mercy, 1 Allée du Château, 57085 Metz, France

17 Hôpital Lariboisière, Assistance Publique - Hôpitaux de Paris, INSERM U1141, Université de Paris, 2 Rue Ambroise-Paré, 75010 Paris, France.

Corresponding author:

Dr Benjamin Verillaud,

Service d'ORL, Hôpital Lariboisière, Assistance Publique - Hôpitaux de Paris, INSERM U1141, Université de Paris, 2 Rue Ambroise-Paré, 75010 Paris, France.

e-mail: benjamin.verillaud@gmail.com

telephone: +33 6 61 72 70 94; fax: +33 1 49 95 24 96

Abstract

Objectives

Surgical navigation systems (SNS) are now widely used in endoscopic endonasal surgery. Benefit, however, has not been fully studied. The objective of this study was to evaluate the impact of an SNS in terms of performance of the surgical procedure and of surgeon satisfaction, in a prospective multicenter study.

Materials and methods

A multicenter prospective study included patients undergoing endoscopic endonasal surgery using the electromagnetic DigiPointeur® (DGP) SNS in 16 French hospitals. An observation form, completed by the surgeon immediately at end of procedure, included type of procedure, and any changes in strategy or extent of surgery related to use of the SNS. Surgeon satisfaction was rated on an analog scale, with self-assessment of stress experienced during the procedure.

Results

The study included 311 patients operated on by 36 surgeons in 16 French hospitals. Ethmoidectomy was the most frequent procedure (90%); tumor resection was performed in 5.1% of cases. The SNS enabled more extensive surgery in 81% of cases, in particular by identifying and opening additional cells (57% of cases). Mean satisfaction was 8.6/10; surgeons reported decreased surgical stress thanks to the SNS in 95% of cases.

Conclusion

In this observational study, the use of an SNS increased the extent of surgery in 81% of cases, and had a positive impact on the stress perceived by the surgeon in 95% of cases.

Key-words

Endoscopic sinus surgery, surgical navigation system, image-guided navigation system, computer-assisted surgery, ethmoidectomy, sphenoidotomy, frontal sinus.

Introduction.

Endoscopic sinus surgery has greatly progressed over the last 30 years, with about 19,000 procedures (apart from middle meatal antrostomy) in France in 2014 according to the PMSI medical information system. This growth has been supported by technical innovations in optics, video systems and instrumentation and also in computer-assisted navigation.

The first computer-assisted surgical navigation system (SNS) in head and neck surgery was reported in 1993 [1]. By providing real-time correlation between endoscopic and CT visualization of anatomic structures, SNSs were first seen as a precious aid for the surgeon. Several authors reported their experience in the early 2000s [2-5]. These mainly single-center retrospective series were unable to formally demonstrate benefit; notably, benefit in terms of complications and surgical extent appeared non-significant. A more recent meta-analysis, with a larger patient pool, seemed to show a reduction in complications rates with SNS taking all surgeries together, and especially for revision surgery [6].

The possibility of achieving more complete surgery thanks to an SNS remains to be formally confirmed. "Surgeon comfort" also could not be reliably assessed in the retrospective series; the only data available, while encouraging, are from small prospective series, usually involving a single surgeon [7]. The aim of the present study was therefore to assess the contribution of an SNS in endonasal surgery in terms of extent of surgery and surgeon satisfaction, in a prospective multicenter study.

Materials and Methods.

A prospective multicenter study in 16 private or public-sector French health establishments (8 university hospitals, 2 public or non-profit general hospitals and 6 private-sector hospitals) included all adults patients undergoing endoscopic endonasal surgery using an SNS. The criteria for using an SNS were at the surgeon's discretion. All centers used the DigiPointeur® (DGP) electromagnetic location system. Data were collected from an observation form filled out by the surgeon immediately at end of procedure. Data included: the surgeon's experience in terms of number of endoscopic endonasal surgeries (<20: trainee; >100: expert; 20-100: significant experience) [8]; the surgeon's experience of using the SNS, assessed in the same way; pathology and type of procedure, including whether revision or not; type of ancillary used for the SNS; calibration precision at installation and intraoperatively; changes in surgical

extent thanks to the SNS (any change in strategy for accessing the frontal sinus, sphenoid, ethmoid roof, medial orbital wall and medial ethmoid wall/cribriform plate, and any detection and opening of additional cells); surgeon satisfaction, on a 0-10 analog scale; and difference in intraoperative stress thanks to use of the SNS.

The study was approved by the GHU Paris Nord review board (N°10076) and French data protection commission (CNIL) (N°10598). Written consent was systematically obtained.

Results.

Patients and types of procedure

Three hundred and eleven patients were included: mean age, 50.2±15.2 years; 57% male. The most frequent diagnosis was chronic sinusitis with nasal polyps (58.8%), followed by chronic sinusitis without nasal polyps (28%), benign or malignant tumor (5.1%) and mucocele (4.8%) (Table 1).

The most frequent procedure was ethmoidectomy (89.7%). Table 2 shows the various procedures performed. There were 119 revision surgeries (38.3%). Mean operating time was 1.3 hours (range, 0.25-12 hours).

Surgeons' experience

Thirty-six surgeons participated: 2 trainees (<20 procedures) (5.6%), 18 expert (>100 procedures) (50%), and 16 with significant experience (20-100 procedures) (44.4%). Two procedures (0.01%) were performed by surgeons with little SNS experience (<20 procedures), 107 (34.4%) by surgeons with moderate experience (20-100 procedures), and 202 (64.9%) by surgeons with considerable experience (>100 procedures).

Technical parameters

The DGP ancillary was a headband in 95% of cases, and an intraoral Buccostat® device in 5%. Calibration precision at end of procedure was satisfactory in 85% of cases.

Intraoperative SNS precision

Intraoperative precision was satisfactory in regard to:

- height: anterior ethmoid, 92% ; posterior ethmoid roof, 89%; maxillary sinus roof, 91%;
- depth: anterior sphenoid sinus wall, 90%;
- and laterally: medial orbital wall, 93%; posterior maxillary sinus wall, 91%.

Precision was unsatisfactory in at least 1 dimension in 35 cases (11%), and in all 3 dimensions in 9 (3%).

SNS impact on surgical strategy

Surgical strategy was modified in the light of SNS feedback, resulting in more complete surgery in 81% of cases. In 57%, the SNS identified cells for opening not seen by the surgeon alone. The regions concerned comprised:

- frontal sinus (28%), by identification of the agger nasi in 42% of cases and of a fronto-ethmoidal cell in 48%;
- sphenoid (25%), by identification of an Onodi cell in 62% of cases;
- ethmoid roof (28%);
- lateral lamella and cribriform plate (22%);
- medial orbital wall (22%).

The rate of change in strategy toward more complete surgery was independent of primary versus revision surgery: revision surgery rates were virtually identical, at 38% and 39%, in the groups of procedures modified and non-modified by SNS input, respectively.

Results according to surgeon's experience

Expert surgeons changed strategies according to SNS data in 78% of cases, moderately experienced surgeons in 86%, and trainees in 100% (both of 2 cases).

Intraoperative complications

Nineteen patients (6.1%) suffered intraoperative complications: 17 minor (mainly asymptomatic lamina papyracea breach), and 2 major (0.6%), both involving meningeal breach, identified and sealed intraoperatively. Table 3 details complications. In 3 of the 19 cases (15.8%), the surgeon reported SNS imprecision in at least 1 dimension.

Surgeon satisfaction

Mean satisfaction score on a 0-10 scale was 8.6±1.5, for a median of 9. Scores lower than 7 (n=19; 6.1%) were associated with revision surgery in 62.5% of cases, and with little or only moderate SNS experience (<100 procedures) in 47.4%.

The SNS was associated with diminished stress in 95.2% of procedures.

Discussion

In the present study, the impact of an SNS in endoscopic endonasal surgery was assessed in terms of: i) extent of surgery: whether the SNS enabled more complete surgery; ii) surgeon satisfaction and more specifically reduction in surgical stress thanks to the SNS. Both parameters showed positive impact, with more complete surgery in 81% of cases and reduced stress in 95.2%.

The main strong-point of the present study was its prospective data collection via an observation form filled out immediately at end of procedure, in a multicenter design: 36 surgeons in 16 centers, with varying experience and practices, participated and included a total 311 patients. This prospective multicenter design ensured data quality.

The lack of a control group may seem to be a weakness, but the main study parameters required no control: for both endpoints (extent of surgery, and surgeon satisfaction/stress), it was the change induced by the SNS that was being assessed; comparison with a group of patients operated on without SNS would have been neither useful nor possible. It remains true, however, that patient quality of life and medium-to-long-term revision rates were not assessed, and would have required a control group. The intraoperative complications rate is also difficult to interpret, as comparison can only be made with the literature data. We therefore did not make this one of the study endpoints, and complications are reported here purely as extra information; it is, however, noteworthy that complications (notably benign), while probably reported more systematically in this kind of prospective study, seemed to be more frequent than in most previous retrospective reports [9-11], raising the question of possible overconfidence induced by the SNS, although the present data do not allow objective assessment of this.

It is important to establish whether the present study population was representative of endoscopic endonasal surgery patients in general. This was to a certain extent ensured by the

multicenter multi-surgeon design, providing a realistic snapshot of French practices; moreover, comparison was made with the PMSI medical information database. Mean patient age (50.2 years) in the PMSI is close to the present value, but there are differences in the pathologies being treated and in the types of surgery: in the present study, surgery was for tumor in 5.1% of cases, versus 1.3% in the PMSI; 11.3% of cases concerned exclusive frontal sinus or sphenoid surgery (i.e., theoretically more complex surgery), versus 5.4%; and ethmoidectomies were total in 76.3% versus 59% of cases. The rate of revision surgery (38.3%) seems rather high, but there are no PMSI data enabling comparison with the general French population. Overall, the data on SNS impact here concerned pathologies and procedures that were more complex than is normally the case. In the present study, 67% of procedures were performed in public-sector or non-profit centers, versus 33% in the PMSI. It would be interesting to know the study surgeons' indications for using an SNS: some may use it systematically, others only in complex cases such as tumor or revision surgery; this might account for the relatively high rate of "complex" surgeries, and also for the higher than normal rate of complications. In the present study, use of an SNS was at the surgeon's discretion, but indications were unfortunately not recorded.

Conclusion

The present findings suggest that using an SNS in endoscopic endonasal surgery allows surgeons to work more confidently and perform more extensive surgery. The data, however, do not allow benefit for the patient to be demonstrated: as mentioned above, a recent meta-analysis points to reduced complications rates with SNSs, but functional benefit remains to be established.

Acknowledgments

The authors thank Olivier Charansonney for critical re-editing.

Disclosure of Interest: The authors declare that they have no conflicts of interest concerning this article

References

1. Mosges R, Klimek L. Computer-assisted surgery of the paranasal sinuses. J Otolaryngol 1993, 22(2):69-71.
2. Fried MP, Moharir VM, Shin J, Taylor-Becker M, Morrison P. Comparison of endoscopic sinus surgery with and without image guidance. Am J Rhinol 2002, 16(4):193-197.
3. Reardon EJ. Navigational risks associated with sinus surgery and the clinical effects of implementing a navigational system for sinus surgery. Laryngoscope 2002, 112(7 Pt 2 Suppl 99):1-19.
4. Tschopp KP, Thomaser EG. Outcome of functional endonasal sinus surgery with and without CT-navigation. Rhinology 2008, 46(2):116-120.
5. Tabaee A, Hsu AK, Shrime MG, Rickert S, Close LG. Quality of life and complications following image-guided endoscopic sinus surgery. Otolaryngol Head Neck Surg 2006, 135(1):76-80.
6. Dalgorf DM, Sacks R, Wormald PJ, Naidoo Y, Panizza B, Uren B, et al. Image-guided surgery influences perioperative morbidity from endoscopic sinus surgery: a systematic review and meta-analysis. Otolaryngol Head Neck Surg, 149(1):17-29.
7. Strauss G, Limpert E, Strauss M, Hofer M, Dittrich E, Nowatschin S, et al. [Evaluation of a daily used navigation system for FESS]. Laryngorhinootologie 2009, 88(12):776-781.
8. Keerl R, Weber R, Drees G, Draf W. [Individual learning curves with reference to endonasal micro-endoscopic pan-sinus operation]. Laryngorhinootologie 1996, 75(6):338-343.
9. Ramakrishnan VR, Kingdom TT, Nayak JV, Hwang PH, Orlandi RR. Nationwide incidence of major complications in endoscopic sinus surgery. Int Forum Allergy Rhinol, 2(1):34-39.
10. McMains KC. Safety in endoscopic sinus surgery. Curr Opin Otolaryngol Head Neck Surg 2008, 16(3):247-251.
11. Siedek V, Pilzweger E, Betz C, Berghaus A, Leunig A. Complications in endonasal sinus surgery: a 5-year retrospective study of 2,596 patients. Eur Arch Otorhinolaryngol, 270(1):141-148.

Table 1

Surgical indications

Pathology	n	%
Chronic rhinosinusitis with polyps	183	58.8
Chronic rhinosinusitis without polyps	87	28
Benign or malignant tumor	16	5.1
Inverted papilloma	*10*	*3.2*
Ethmoid cancer	*1*	*0.3*
Ethmoid osteoma	*1*	*0.3*
Hemangiopericytoma	*1*	*0.3*
Inflammatory myofibroblastic tumor	*1*	*0.3*
Non-keratinizing nasopharyngeal carcinoma	*1*	*0.3*
No data	*1*	0.3
Mucocele	15	4.8
Orbital decompression	4	1.3
Endoscopic closure of meningeal breach	1	0.3
Silent sinus syndrome	1	0.3
No data	4	1.3
Total	**311**	**100**

Table 2

Surgical procedures. (Ethmoidectomy most frequent).

Procedure	**n**	*%*
Ethmoidectomy	279	89.7
Unilateral	*75*	*24.1*
Bilateral	*204*	*65.6*
Sphenoidotomy	174	55.9
unilateral	*48*	*15.4*
bilateral	*126*	*40.5*
Draf type 1	109	35
Unilateral	*38*	*12.2*
Bilateral	*71*	*22.8*
Draf de type 2	17	5.5
unilateral	*10*	*3.2*
bilateral	*7*	*2.3*
Draf type 3	5	1.6
Other	8	2.6
No data	1	0.3

Table 3

Intraoperative complications. (lamina papyracea breach without orbital signs most frequent).

Complications	**n**	**%**
Lamina papyracea breach without orbital signs	13	52.4
Meningeal breach	2	19.0
Lamina papyracea breach with palpebral ecchymosis	1	4.8
Intraoperative sphenopalatine artery wound	2	9.6
Nasolacrimal duct lesion	1	4.8
Total	**19**	**6.1**