NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis

Sinusitis occurs when the air-filled cavities of the face (the sinuses) become inflamed. Balloon catheter dilation of paranasal sinus ostia aims to help open up blocked sinus passages by gently inflating a small balloon, introduced through the nose via a flexible tube. The aim is to restore normal sinus drainage and improve symptoms of sinusitis.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2008.

Procedure name

- Balloon catheter dilation of paranasal sinus ostia

Specialty societies

The following societies were approached to nominate Specialist Advisers.

- British Association of Otorhinolaryngologists - Head and Neck Surgeons
- British Association of Oral and Maxillofacial Surgeons

Description

Indications

Sinusitis is an inflammation of the small air-filled cavities (sinuses) located within the bony structures of the face. Sinuses communicate with the nasal space via small openings (ostia). There are 4 pairs of sinuses in total: two located on the forehead (frontal sinuses), two either side of the bridge of the nose (ethmoid and sphenoid sinuses) and two behind the cheekbones (maxillary sinuses). Sinusitis commonly affects the maxillary sinuses. It is usually a result of an infection, which causes the sinuses to become inflamed and swollen. Typical symptoms include fever, pain and tenderness over the infected area together with a blocked or runny nose. Acute sinusitis often develops following a cold or influenza, and frequently resolves spontaneously with little or no treatment required. Chronic sinusitis is a less common condition, in which symptoms persist for weeks or even months.

Instruments used to measure disease/symptom severity

Instruments used to measure the extent of morbidity in patients with sinusitis include the Sino-Nasal Outcome Test (SNOT) 20 scale. This tool determines patients' disease-specific health status by evaluating the severity of 20 distinct parameters specifically related to physical problems, functional limitations and emotional consequences of sinusitis. Scores for each parameter are rated from 0 to 5, with higher scores indicating greater severity of symptoms. A mean total score can also be calculated.

The Lund-MacKay staging system is an instrument measuring sinus ostium obstruction as evidenced radiographically through opacification, scoring each sinus ostium from 0 (no opacification) to 2 (complete opacification). The total score ranges from 0 (best) to 24 (worst) for each patient.

Current treatment and alternatives

For the majority of patients with sinusitis, no specific treatment is required. Analgesics and antibiotics are often prescribed to alleviate symptoms and accelerate symptom resolution. However, in some patients sinusitis proves refractory to medical therapy and, therefore, interventional procedures could be considered. Such procedures include certain endoscopic interventions (Functional endoscopic sinus surgery – FESS) and the use of through-cutting forceps and tissue microdebriders, all of which aim to establish a patent sinus ostium. However, circumferential scarring and adhesions can occur as a result of these procedures, which may limit the patency of the sinus ostial opening. In addition, bleeding may obscure intraoperative visualisation, making these procedures difficult to perform.

What the procedure involves

Balloon catheter dilation of paranasal sinus ostia aims to restore normal sinus drainage and function. The procedure is usually performed under general

anaesthesia. A catheter and flexible guidewire are inserted through the nostrils using endoscopic and fluoroscopic visualisation to identify the target sinus (or sinuses). A balloon catheter is then advanced over the guidewire catheter and positioned across the blocked ostium. Gentle inflation of the balloon catheter to a pressure of approximately between 2 and 8 atmospheres aims to restructure and widen the walls of the ostium through microfracturing of the bony structures underlying the ostium. If indicated, the infected sinus can also be irrigated with a sinus lavage. The catheter and guidewire are then removed.

Efficacy

Sinusotomy using the balloon catheter device was attempted in 358 sinuses (including maxillary, sphenoid, and frontal sinuses) and cannulation of the sinus ostium was achieved in 97% (347/358), in a case series of 115 patients[1]. A second case series reported an operative success rate of 100% (18/18 sinuses)[2]. However, in the latter series, sinuses deemed appropriate for balloon dilation were prioritised for intervention with this technique rather than with any other endoscopic method. In the first case series, the ostium was patent on repeat endoscopy (planned) in 68% (232/341) of sinuses after 1-week follow-up and in 81% (247/304) sinuses at 24-week follow-up; however, it was not clear whether additional endoscopic techniques had been used in these sinuses. At 24 weeks <1% (2/304) of sinuses were not patent, and in 18% (55/304) patency could not be determined. The study reported slow balloon deflation in one sinus. Revision treatment was required in 3% (3/109) of patients. However, the nature of this treatment was not defined in the publication[1].

A case series of 1036 patients (3276 sinuses) treated with balloon sinuplasty reported that revision surgery was required in 2% (25/1036) of patients, either due to mucosal alteration or opacified sinuses at a mean follow-up of 40 weeks[3]. In the same study 95% of patients reported improvements in sinus symptoms, and 73% were completely free of symptoms at a mean follow-up of 40 weeks (absolute numbers not reported).

Mean SNOT 20 scores in 35 patients treated with balloon sinuplasty were significantly better than those among 35 patients treated by FESS (0.78 and 1.29 points respectively) in a non-randomised controlled trial at 3 months follow up ($p = 0.006$)[4]. In the same study, mean Global patient assessment (GPA) scores (a questionnaire that rates the experience of the procedure from –5 points ‘worst’ to +5 points ‘best’) were significantly better in the balloon sinuplasty group (3.71) than in the FESS group (2.94) ($p = 0.0016$). Also in the same study, recurrent sinus infection occurred in 17% (6/35) of patients treated with balloon sinuplasty and 25% (9/35) of patients treated with FESS; this difference was not statistically significant ($p = 0.646$).

Following balloon catheter dilation as a stand-alone procedure, sinus symptoms (measured by the SNOT 20 scale) had improved significantly from a mean score of 2.14 at baseline to 1.27 after both 1- and 24-week follow-up ($p < 0.0001$) in a case series of 115 patients[1]. In the same study, patient satisfaction surveys reported that 80% (35/44) of patients experienced an

improvement in sinusitis symptoms at 24-week follow-up (patients that only received balloon dilation procedures).

Safety

No serious adverse events relating to the balloon sinuplasty procedure were reported in any case series (n = 1036[3], n = 115[1] and n = 10[2] patients, respectively).

In a non-randomised controlled trial turbinate lateralisation/scarring occurred in 23% (8/35) of the balloon sinuplasty group and 9% (3/35) of the FESS group; this difference was not statistically significant (p = 0.188)[4]. In one case series, bacterial sinusitis following the procedure occurred in 8% (9/109) of patients. However, these cases resolved with appropriate antibiotic treatment[1].

Device malfunction was reported in 3% (12/358) of sinuses; the balloon ruptured in seven sinuses, and a problem occurred with the catheter tip in four[1].

In the larger case series, the mean fluoroscopy time per sinus was 0.81 minutes, with an average radiation dose of 730 millirem per patient[1]. For comparative purposes this is greater than the average exposure with a standard CT scan of the head (roughly 200 millirem). In the second series, the mean fluoroscopy time was 9.3 minutes per patient[2].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to balloon catheter dilation of paranasal sinus ostia. Searches were conducted of the following databases, covering the period from their commencement to 11/09/2007 and updated to 26/03/08: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix C for details of search strategy.)

The following selection criteria were applied to abstracts identified during the literature search (Table 1). Where selection criteria could not be determined from the abstracts, the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology.
Patient	Patients with sinusitis
Intervention/test	Balloon catheter dilation of paranasal sinus ostia
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on one non randomised controlled trial[4], and three case series.[1,2,3]

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) are listed in Appendix A.

Existing reviews on this procedure

No published systematic reviews with meta-analysis or evidence-based guidelines were identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures

None

Technology appraisals

None

Clinical guidelines

None

Public health

None

Table 2 Summary of key efficacy and safety findings on balloon catheter dilation of paranasal sinus ostia

Abbreviations used: ATM, atmospheres; SNOT 20, Sino-Nasal Outcome Test 20; GPA, global patient assessment.; FESS, functional endoscopic sinus surgery

Study details	Key efficacy findings	Key safety findings	Comments
Friedman M (2008)[4] **Non randomised controlled trial** USA and Taiwan Study period: Dec 1005 to May 2006 **n = 70 – 208 sinuses (35 balloon catheter dilation – 100 sinuses)** Population: age = 43 years (mean) , males = 57%, previous endoscopic sinus surgery n = 25 Indications: Patients with chronic sinusitis unresponsive to medical treatment. Patients with severe sinusitis (Lund-Mackay score >12), significant nasal polyposis, sinus osteoneogenesis, or systemic disease were excluded. Technique: Under endoscopic visualisation balloon sinuplasty with general or local anaesthetic, or FESS with general anaesthetic. 1 to 4 sinuses treated per patient **Follow-up: 3 months minimum** Conflict of interest: study supported by manufacturer.	**Sinus symptoms** Symptoms measured using the SNOT 20 scale. Mean scores and standard deviation. Baseline / 3 months / p = Balloon sinuplasty: 2.8 ± 0.52 / 0.78 ± 0.55 / < 0.0001 FESS: 2.7 ± 0.85 / 1.29 ± 0.87 / < 0.0001 At 3 months follow up mean SNOT 20 scores in the balloon sinuplasty group (0.78) were significantly better than the FESS group (1.29) (p = 0.006). **Pain** Postoperative narcotic pain medication usage was significantly shorter in the balloon sinuplasty group (0.80 ± 0.72 days) than in the FESS group (1.34 ± 0.99 days) (p < 0.011). **Patient satisfaction** Patients were asked whether they would undergo the procedure again Yes / Not sure / No Balloon sinuplasty: 91.4% / 5.7% / 2.9% FESS: 48.6% / 45.7% / 5.7% P<0.0001 balloon sinuplasty vs FESS **GPA:** Mean GPA scores in the balloon sinuplasty group (+3.71 ± 1.20) were significantly better than that among patients in the FESS group +2.94 ± 1.39) (p = 0.0016).	**Complications** Balloon sinuplasty / FESS / p= Turbinate lateralisation / scarring: 23% (8/35) / 9% (3/35) / 0.188 Recurrent sinus infection: 17% (6/35) / 25% (9/35) / 0.646 Infection requiring revision surgery: 3% (1/35) / 0% / N/R	Retrospective chart review of a prospective cohort of patients. The GPA questionnaire rates the experience of the procedure from –5 points 'worst' to +5 points 'best'. The Lund-MacKay staging system scores each sinus from 0 (no opacification) to 2 (complete opacification). The total score ranges from 0 (best) to 24 (worst) for each patient. Patients who were treated with a combination of balloon sinuplasty and functional endoscopic sinus surgery in different sinuses were excluded. All procedures undertaken by the same surgeon. Sample size calculation was used to determine sample required. Clinical sinus scores were similar between the groups at baseline. No ethmoid sinuses were treated in the balloon sinuplasty group. US cost data presented, but not extracted here. Authors state that 3-month follow-up is insufficient to evaluate efficacy

Abbreviations used: ATM, atmospheres; SNOT 20, Sino-Nasal Outcome Test 20; GPA, global patient assessment.; FESS, functional endoscopic sinus surgery			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Levine HL (2008)[3] **Case series** USA Study period: Decemeber 2005 to May 2007 **n = 1036 (3276 sinuses)** Population: age = 47 years (mean) , males = 50%, previous endoscopic sinus surgery = 17%. Indications: Patients over 18 years with chronic sinusitis unresponsive to medical treatment, with endoscopic sinus surgery planned. Technique: Under general anaesthesia (except for 2 patients) and endoscopic visualisation balloon dilation of the sinus via a catheter system. All operators received standardised training **Mean follow-up: 40 weeks (range 8 to 88 weeks)** Conflict of interest: study supported by manufacturer.	**Operative success** 63% (691/1036) of patients received concomitant ethmoidectomy. The mean operative time was 73.0 minutes (range 6 to 230).The mean blood loss for balloon sinuplasty-only procedures was 27.7 ml. Revision surgery was required in 2% (25/1036) of patients, either for recurrent sinus symptoms with mucosal alteration (n = 17) or opacified sinuses (n = 13) (some patients had both). As analysed per sinus, the revision rate was 1% (41/3276). There were fewer postoperative visits for debridement procedures following balloon sinuplasty (mean 0.8 visits) than following hybrid procedures of sinuplasty and FESS (mean 1.4 visits) (measure of significance not stated). **Sinus symptoms** Of the patients treated with balloon sinuplasty, 95.5% reported improvement in symptoms, 3.8% had no change, and 1.0% worsened compared with baseline (absolute figures not reported). 73% of patients were free of sinus symptoms during the mean follow-up period of 40 weeks (absolute figures not reported).	**Complications** There were no major adverse events attributable to the use of balloon catheters. Cerebrospinal fluid leak occurred in <1% (2/691) of patients undergoing ethmoidectomy; both cases were due to the use of standard FESS grasping tools. Similarly, minor bleeding occurred in <1% (6/691) of patients undergoing ethmoidectomy, requiring standard packing or cautery.	27 participating centres. A mean of 38.4 patients (range 10 to 178) were treated per site. There was no statistically significant difference in patient characteristics between sites. Retrospective case history review Authors state that patients included in this series had not previously been reported in the literature. Authors state that registry data represent 'real-world' experience. Data were self-collected by physicians. Standardised data collection tools were not used. The authors state that 8 weeks follow-up may be too short to determine patency and durability.

Abbreviations used: ATM, atmospheres; SNOT 20, Sino-Nasal Outcome Test 20; GPA, global patient assessment.; FESS, functional endoscopic sinus surgery

Study details	Key efficacy findings	Key safety findings	Comments
Bolger WE (2007)[1] **Case series** USA and Australia Study period: April–December 2005 **n = 115 (358 sinuses)** Population: age = 48 years (mean), males = 36%, previous endoscopic sinus surgery = 18%. Indications: Patients over 18 years with chronic sinusitis unresponsive to medical treatment, with endoscopic sinus surgery planned. Technique: Under endoscopic visualisation a catheter was introduced and placed adjacent to the obstructed maxillary, sphenoid or frontal ostium. The sinus was catheterised under fluoroscopic guidance and dilated with a balloon catheter (5–7 mm). If indicated, the sinus was irrigated with a sinus lavage. **Follow-up: up to 24 weeks** Conflict of interest: study supported by manufacturer.	**Operative success** Sinusotomy using the balloon catheter device was attempted in 358 sinuses and cannulation of the sinus ostia was achieved in 97% (347/358), including 143 in the maxillary ostia, 75 in the sphenoid ostia and 124 frontal recesses. In 5 patients additional endoscopic surgery was required to achieve sufficient opening **Sinus patency** Endoscopic evaluation of the sinus Follow-up: Fraction patent 1 week: 68% (232/341) 12 weeks: 78% (212/268) 24 weeks: 81% (247/304) At 24 weeks <1% (2/304) of sinuses were not patent, and in 18% (55/304) patency could not be determined. **Sinus symptoms** Data for 36 patients who had balloon catheter sinusotomy as a unique procedure. Symptoms measured using the SNOT 20 scale (0 to 5 point scale low scores better). Mean scores, for patients with data available at each time point. Follow-up: Score: p Baseline: 2.14: 1 week: 1.27: < 0.0001 12 weeks: 1.08: < 0.0001 24 weeks: 1.27: < 0.0001 p values vs baseline at each follow-up point. Results from structured questionnaire regarding sinusitis symptoms. Sores are for patients reporting improvement in symptoms Follow-up: n: % improved 1 week: 48: 85% (41/48) 12 weeks: 42: 98% (41/42) 24 weeks: 44: 80% (35/44)	**Complications** There were no serious adverse events (cerebrospinal fluid leak, orbital injury, nasal bleeding requiring packing). Bacterial sinusitis following the procedure developed in 8% (9/109) of patients, which resolved with antibiotic treatment. The device malfunctioned in 3% (12/358) of sinuses, balloon ruptures (n = 7), catheter tip problem (n = 4), balloon deflated slowly (n = 1) Revision treatment was required in 3% (3/109) of patients (treatment type not defined). Mean fluoroscopy time per sinus was 0.81 minutes, and the average (method not stated) radiation dose was 730 millirem per patient.	Prospective multicentre study. Consecutive patients who met inclusion criteria were offered entry to the study. In 5% (6/115) of patients initially entering the study, the balloon catheter procedure was not possible owing to scarring, polyps or anatomic restrictions. The procedure was converted to endoscopic treatment using traditional instrumentation. These patients were excluded from analysis. Follow-up endoscopy at each visit was planned in the study protocol. Loss to follow-up at 12 and 24 weeks did not distinguish the proportions with patent sinuses at previous visits. 52% (57/109) of patients had one or more sinuses treated with the balloon catheter procedure, while additional sinuses were treated by other endoscopically guided surgery. Sinusotomy using balloon catheters alone was the only intervention in 48% (52/109) of patients. Results for SNOT 20 scores extracted here are for those patients where only the balloon catheter method was used. Authors state that the learning curve for this technique is not steep.

Abbreviations used: ATM, atmospheres; SNOT 20, Sino-Nasal Outcome Test 20; GPA, global patient assessment.; FESS, functional endoscopic sinus surgery			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Brown CL (2006)[2] **Case series** USA and Australia Study period: not stated **n = 10 (18 sinuses)** Population: age = not stated, male = not stated Indications: Patients over 18 years with chronic sinusitis unresponsive to medical treatment, with endoscopic sinus surgery planned. Technique: Under general anaesthetic and endoscopic visualisation a catheter was introduced and placed adjacent to the obstructed maxillary, sphenoid or frontal ostium. With fluoroscopic guidance the sinus was catheterised and dilated with a balloon catheter (5–7 mm) to a mean of 13 ATM. If indicated, the sinus was irrigated with a sinus lavage. **Follow-up: not stated** Conflict of interest: study supported by manufacturer.	**Operative success** Procedural success was defined as the ability to catheterise the targeted sinus and complete balloon dilation. 100% (18/18) of the sinuses were successfully catheterised.	**Complications** There was minimal bleeding and tissue trauma. No adverse events occurred. Mean fluoroscopy time per patient was 9.3 minutes (range 3.25–17.5 minutes).	Potentially some crossover of patients with the Bolger (2007) study report. However, the study period for this cohort was not stated. An independent otolaryngologist was used to review any complications. Sinuses deemed appropriate for balloon dilation were selected first and a maximum of two sinuses treated by balloon dilation method. No clinical efficacy outcomes reported. Authors state that the easiest sinus to dilate with the balloon catheter method was the sphenoid sinus.

Validity and generalisability of the studies

- Few data are available on clinical efficacy outcomes.
- Selection of specific sinuses and of the number of sinuses to be treated is not clear form available evidence. It is likely that operators varied in such selection.
- Significant patient selection may have occurred to choose which sinuses to treat with the balloon dilation procedure or with traditional endoscopic methods.
- Published data are currently available from one centre only (see below).
- Follow-up length ranged from a minimum of 3 months to a maximum of 88 weeks. The sinus ostia may not remain patent over time and sinusitis symptoms may return.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr M Timms (British Association of Otorhinolaryngologists - Head and Neck Surgeons), Mr J Rowe-Jones (British Association of Otorhinolaryngologists - Head and Neck Surgeons), Mr G Morrison (British Association of Otorhinolaryngologists - Head and Neck Surgeons), Mr J Elgan Davies (British Association of Otorhinolaryngologists - Head and Neck Surgeons).

- Two Specialist Advisers considered this procedure to be established and no longer new, while a third adviser classified it as a minor variation on an established procedure which may improve its safety, and a fourth that it is a novel procedure the safety and efficacy of which are uncertain.
- Anecdotal adverse events reported include a case of balloon rupture resulting in intra-orbital leak of X-ray contrast fluid which caused no adverse sequelae.
- Additional, theoretical adverse events may include misplacement of the balloon, brain injury and cerebrospinal fluid leak, or orbital damage.
- The procedure is only being used by a few clinicians at present but this number was thought likely to grow.
- The speed of diffusion may be slow as the technique can be cumbersome and difficult to learn.
- Training courses may be available from the manufacturer and practice on human cadavers with X-ray image intensification is recommended.
- There are no randomised controlled trial data available at present.
- If performed well it should be as safe (or safer) than functional endoscopic sinus surgery.
- If found to be safe and efficacious the procedure is likely to be offered at all hospitals offering sub-specialist rhinology services.
- The Specialist Advisers highlighted the key efficacy outcomes for this procedure to be persistent sinus ostia patency, SNOT scores, standard sino-nasal symptom scores, and QOL measures.

- The Specialist Advisers highlighted the key safety outcomes for this procedure to be intracranial injury and cerebrospinal fluid leak, scarring of the mucosa, orbital damage and bleeding.

Issues for consideration by IPAC

- The balloon sinuplasty system is CE marked. At present this is the only device with published data.
- This overview focuses on patients with sinusitis refractory to optimal medical treatment. Some studies of endoscopic sinus surgery have included patients with nasal polyps though none used the balloon dilation procedure.

References

1. Bolger WE. (2007) Safety and outcomes of balloon catheter sinusotomy: A multicenter 24-week analysis in 115 patients. Otolaryngology - Head and Neck Surgery 137:10-20.

2. Brown CL. (2006) Safety and feasibility of balloon catheter dilation of paranasal sinus ostia: A preliminary investigation. Annals of Otology, Rhinology and Laryngology 115: 293-299.

3. Levine HL, Sertich AP, Hoisington D et al. (2008) Multicenter Registry of Balloon Catheter Sinusotomy Outcomes for 1,036 Patients. Annals of Otology, Rhinology & Laryngology 117: 263-270.

4. Friedman M, Schalch P, Lin HC et al. (2008) Functional endoscopic dilation of the sinuses: Patient satisfaction, postoperative pain, and cost. American Journal of Rhinology 22 (2): 204-209.

Appendix A: Additional papers on balloon catheter dilation of paranasal sinus ostia for chronic sinusitis not included in summary table 2

The following table outlines studies considered potentially relevant to the overview not included in the main data extraction table (Table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
No additional studies were identified			

Appendix B: Related published NICE guidance for balloon catheter dilation of paranasal sinus ostia for chronic sinusitis

Guidance programme	Recommendation
Interventional procedures	None applicable
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for balloon catheter dilation of paranasal sinus ostia for chronic sinusitis

IP 670 Balloon catheter dilation of paranasal sinus ostia		
Database	**Date searched**	**Version searched**
Cochrane Library	11/09/2007	2007, Issue 3
CRD databases	11/09/2007	2007, Issue 3
Embase	11/09/2007	1980 to 2007 Week 36
Medline	11/09/2007	1950 to August Week 5 2007
Premedline	11/09/2007	September 10, 2007
CINAHL	11/09/2007	1982 to September Week 1 2007
British Library Inside Conferences	11/09/2007	–
NRR	12/09/2007	2007, Issue 3
Controlled Trials Registry	11/09/2007	–

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1	Balloon Dilatation/
2	Balloon Occlusion/
3	(balloon adj3 (sinuplas$ or cathet$ or dilation$ or sinusotom$ or occlusio$)).tw.
4	or/1-3
5	Paranasal Sinus Diseases/
6	exp Sinusitis/
7	Sinusit$.tw.
8	exp Paranasal Sinuses/
9	(Paranasa$ adj3 sinus$).tw.
10	(nasal adj3 (inflamm$ or virus$ or bacteri$ or infectio$ or sinus$)).tw.
11	Rhinitis/
12	Rhinit$.tw.
13	Rhinosinusit$.tw.
14	(Sinus$ adj3 ostia$).tw

15	or/5-14
16	4 and 15
17	Animals/
18	Humans/
19	17 not (17 and 18)
20	16 not 19
21	from 20 keep 1-43
22	(parotid adj3 mass$).tw.
23	(parotid adj3 gland adj3 (neoplasm$ or cancer$ or carcinoma$ or adenocarcinom$ or tumour$ or tumor$ or malignan$)).tw.
24	(parotid adj3 (neoplasm$ or cancer$ or carcinoma$ or adenocarcinom$ or tumour$ or tumor$ or malignan$)).tw.
25	(salivary adj3 gland$ adj3 (neoplasm$ or cancer$ or carcinoma$ or adenocarcinom$ or tumour$ or tumor$ or malignan$)).tw.
26	(warthin$ adj3 (neoplasm$ or cancer$ or carcinoma$ or adenocarcinom$ or tumour$ or tumor$ or malignan$)).tw.
27	"Head and Neck Neoplasms"/
28	((head or neck) adj3 (neoplasm$ or cancer$ or carcinoma$ or adenocarcinom$ or tumour$ or tumor$ or malignan$)).tw.
29	or/20-28
30	19 and 29
31	Animals/
32	Humans/
33	31 not (31 and 32)
34	30 not 33