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Septoplasty for nasal obstruction due to a deviated nasal septum in adults: a systematic review*

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Background: The status of current evidence for the effectiveness of septoplasty is unclear. This systematic review evaluates the effectiveness of a) septoplasty (with or without concurrent turbinate surgery) versus non-surgical management, and b) septoplasty with concurrent turbinate surgery versus septoplasty alone, for nasal obstruction due to a deviated nasal septum in adults.

Methodology: Eligible for inclusion were randomised controlled trials and non-randomised designs comparing treatment strategies. Risk of bias was assessed using Cochrane's tool. Standardised mean differences and risk differences with 95% confidence intervals were calculated. Substantial heterogeneity between included studies did not allow meta-analyses.

Results: No studies were found comparing septoplasty (with or without concurrent turbinate surgery) to non-surgical management, but 11 articles were included to compare septoplasty with concurrent turbinate surgery to septoplasty alone. Five studies described both subjective and objective outcomes; six studies reported one or the other. Risk of bias was overall high. Although outcomes generally improved after treatment, eight out of nine studies on subjective measures and five out of seven studies on objective measures found no additional benefit of turbinate surgery.

Conclusions: Despite the routine application of septoplasty in clinical practice, the current body of evidence does not support firm conclusions on its effectiveness.

Key words: nasal obstruction, nasal septum, nasal surgical procedures, quality of life, turbinates

Introduction

Septoplasty, i.e., surgical correction of the deviated nasal septum, is the most common ENT-operation in adults ⁽¹⁾. However, indications seem practice-based rather than evidence-based and internationally accepted guidelines are lacking ⁽²⁾. Annual septoplasty rates differ accordingly between countries. The number of septoplasties per 10,000 inhabitants was 3.9 in England, 6.6 in the Netherlands, and 12.2 in Germany in 2014 ⁽³⁻⁵⁾. In the United States, the annual septoplasty rate was 8.7 per 10,000 inhabitants in 2006 ⁽⁶⁾.

The main indication for septoplasty is nasal obstruction, commonly defined as an unpleasant sensation of insufficient airflow through the nose ⁽⁷⁾. Nasal obstruction is associated with mucosal as well as anatomical conditions. Underlying patho-

genesis may be multifactorial. The most frequent anatomical cause is a deviated nasal septum, which can be accompanied by hypertrophy of the turbinate contralateral to the deviation ⁽⁸⁾. Septoplasty (with or without concurrent turbinate surgery) is performed to widen nasal passages and thereby improve nasal airflow ⁽⁹⁾.

Nonetheless, the effectiveness of septoplasty and additional benefits of turbinate surgery are questioned. According to the literature, nasal septal deviation may have a prevalence of up to 80%, whereas only a minority suffers from nasal obstruction. Whether straightening the deviated septum provides any benefit to those patients, remains a topic of debate in ENT-practice ⁽¹⁰⁾. The American Academy of Otolaryngology – Head and Neck Surgery initiated a consensus panel on septal surgery, which

failed to reach agreement in over one third of the 33 controversial clinical dilemmas discussed⁽¹¹⁾. Both in the United Kingdom and in the Netherlands, professional associations of ENT-surgeons recognised a need for evidence to advance the debate on indications for and benefits of septoplasty^(12,13).

The lack of clinical consensus is, however, accompanied by scarcity of scientific literature. Randomised controlled trials seem underrepresented and the status of (other) existing evidence is unclear. Remarkably, this does not appear to hamper the routine application of septoplasty in daily practice⁽²⁾. Therefore we decided to perform a systematic review of available evidence, including non-randomised designs. The aims of this systematic review are: to evaluate the effectiveness of a) septoplasty (with or without concurrent turbinate surgery) versus non-surgical management, and b) septoplasty with concurrent turbinate surgery versus septoplasty alone, for nasal obstruction due to a deviated nasal septum in adults. By discussing the findings, strengths, and weaknesses of available studies, we intend to assess the status of current evidence for the effectiveness of septoplasty.

Materials and methods

Protocol registration

The review protocol can be accessed at the website of PROSPERO, the International Prospective Register of Systematic Reviews (<https://www.crd.york.ac.uk/PROSPERO/>). The protocol was registered under the number CRD42017060632 on March 31, 2017.

Eligibility criteria

Participants

Studies in adults with nasal obstruction due to a deviated nasal septum were considered eligible for inclusion in this review. In clinical practice, nasal obstruction due to a deviated nasal septum is primarily diagnosed by an internal exam of the nose, consisting of anterior rhinoscopy and nasal endoscopy. The internal exam is performed by the ENT-surgeon to assess whether the deviation causes a mechanical nasal airway obstruction, leading to impaired nasal breathing⁽¹⁴⁾. For this review, the study authors' definition of nasal obstruction due to a deviated nasal septum was adopted. In included studies, nasal obstruction had to be the primary indication for performing septoplasty. Studies in which patients were selected for septoplasty because of other complaints (e.g., impairment of normal sinus drainage, sleep disorders, headaches) were excluded. Studies in the following patient categories were also excluded: patients with a history of nasal septal surgery; patients with nasal septal perforation; patients with untreated allergic rhinitis or allergic rhinitis unresponsive to medical treatment; and cleft lip and/or palate patients.

Intervention and comparison

Included studies had to compare septoplasty (with or without concurrent turbinate surgery) to non-surgical management, or septoplasty with turbinate surgery to septoplasty alone. Non-surgical management could consist of watchful waiting and medical treatment, such as local or systemic steroids and antihistamines. Studies in which septoplasty was combined with other procedures than turbinate surgery (e.g., rhinoplasty, spreader grafts, butterfly grafts, FESS, adenoidectomy) were excluded.

Outcomes

Follow-up needed to be at least three months to prevent direct postoperative effects like mucosal swelling from distorting outcome assessment. Desirable time points of outcome assessment were three months, six months, 12 months, and 24 months. Both subjective (e.g., health-related quality of life) as well as objective (e.g., nasal patency) outcome measures were taken into account. Health-related quality of life may be measured using patient-based questionnaires such as the Glasgow Benefit Inventory (GBI), Nasal Obstruction Symptom Evaluation (NOSE) Scale, and the Sino-Nasal Outcome Test (SNOT)⁽¹⁵⁻¹⁷⁾. Visual Analog Scales (VAS) or Likert scales can be applied to grade symptom severity^(18,19). For the objective assessment of nasal patency, several outcome measures are available, e.g., Peak Nasal Inspiratory Flow (PNIF), Acoustic Rhinometry (AR), or Active Anterior Rhinomanometry (AAR), which may be performed with a Four-Phase Rhinomanometer (4PR)^(14,20,21).

Other eligibility criteria

The preferred study design was a randomised controlled trial comparing either septoplasty to non-surgical management, or septoplasty with concurrent turbinate surgery to septoplasty alone. We were, however, apprehensive of not finding any RCTs. As it was our aim to assess the status of currently available evidence, we also considered the following study designs for inclusion in this review: quasi-randomised trials; cohort studies comparing interventions; non-randomised controlled trials; case control studies; and controlled before-and-after studies. We excluded opinion articles, animal studies, (systematic) reviews, case reports, conference abstracts, and studies on other interventions (e.g., nasal packing, various analgesia, postoperative care).

Information sources and search strategy

We systematically searched PubMed, the Cochrane Library (both from inception) and Ovid EMBASE (from 1974) up to October 10, 2017 for studies on septoplasty for nasal obstruction in adults with a deviated nasal septum. Terms relating to the patients, intervention, and outcomes were included in the search strategy, which combined synonyms for nasal obstruction, nasal septal deviation, septoplasty, turbinate surgery, and various subjective

as well as objective outcome measures. Both keywords (MeSH and Emtree) and free-text terms in title and abstract were included in the search query. Intervention terms were combined with nose-related synonyms to minimise noise from cardiovascular studies on surgery of the interventricular septum. No language or date restrictions were applied. In addition to the electronic search, articles' reference lists were scanned for any applicable studies that had not yet been identified.

Study selection

The results of the search strategy were merged and duplicates were removed using EndNote reference management software (version X7, Thomas Reuters, New York City, NY, USA). Two review authors (MvE, NvH) individually screened titles and abstracts to identify relevant reports based on the inclusion and exclusion criteria outlined above. Full texts of these potentially relevant studies were retrieved by a librarian (AT) and independently assessed for eligibility by two reviewers (MvE and NvH). Any disagreements were resolved by discussion with a third reviewer (MR).

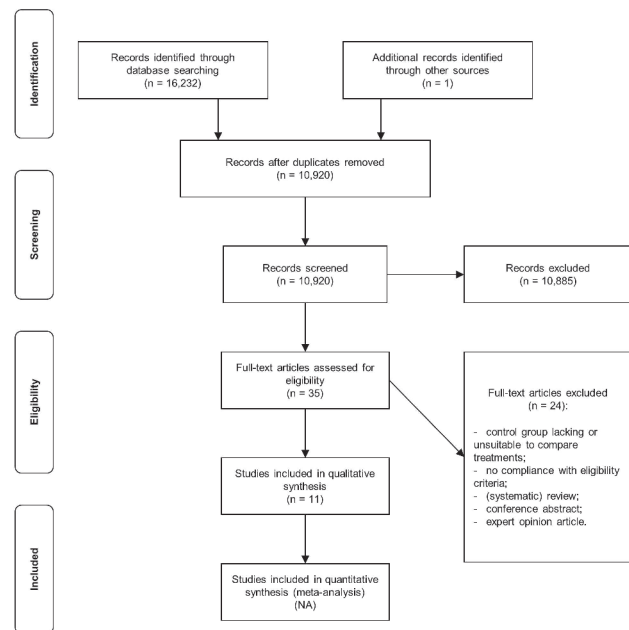
Data extraction

Data extraction was conducted by one reviewer (MvE) using a pre-defined form. Unclear issues were discussed with two other reviewers (NvH, MR) and resolved by consensus. The following data were extracted from included studies: study design; description of participants (eligibility criteria, total number, mean age, gender, country of origin, type and severity of nasal septal deviation, prior treatment); total number of intervention groups; intervention details (type of surgery or specifics of non-surgical treatment); number of participants allocated to each intervention group; total duration of follow-up; time points of outcome assessment during follow-up; primary and secondary outcomes collected and reported; missing data for each intervention group; summary data for each intervention group; and the authors' conclusions.

Risk of bias assessment

Risk of bias in included studies was independently assessed by two review authors (MvE, NvH). Any differences in opinion were resolved by discussion with a third review author (MR). Included studies were evaluated using Cochrane's risk of bias tool, which comprises a critical assessment of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias⁽²²⁾. Each domain in every individual study was assigned either a high, low, or unclear risk of bias, based on the study report and, if applicable, correspondence with study authors. Blinding of outcome assessment was scored separately for subjective and objective outcomes. Since non-randomised studies were also considered for in-

Figure 1. Flow diagram of study selection.



clusion in this review, we paid special attention to the execution of the studies and the risk of selection bias, confounding, and reporting bias including selective reporting of outcomes. For all included studies, it was evaluated whether a study protocol was available and if so, whether the study's pre-specified outcomes had been reported. Moreover, we intended to quantify publication bias with a funnel plot of the intervention effect estimate on the horizontal axis and the measure of study size on the vertical axis, but this proved to be impossible due to the great variety in outcome measures applied across a small number of included studies. Results of risk of bias assessment were graphically summarised using Review Manager 5 (RevMan5) software (version 5.3, Cochrane Collaboration, London, England).

Summary measures and synthesis of results

We planned to calculate standardised mean differences (for continuous outcomes) and risk differences (for dichotomous outcomes) with their corresponding 95% confidence intervals using RevMan 5 software. Ultimately, the studies included in our systematic review were too heterogeneous to perform meta-analyses, see also Table 1. For this reason, effect estimates reported in the individual studies were presented.

Results

Study selection

Our systematic search of PubMed, the Cochrane Library, and Ovid EMBASE yielded a total of 16,232 records, which was reduced to 10,919 results after removing duplicates. By scanning articles' reference lists we found one additional study, which was

Table 1. Schematic overview of clinical and methodological differences between included studies.

First author, year (sorted by design)	Total number of participants	Participants' eligibility criteria				Outcome measures										Maximum duration of follow-up (in months)
		Previously untreated	History of non-surgical treatment	Nasal septal deviation	Nasal septal deviation with turbinate hypertrophy	Subjective outcome measures					Objective outcome measures					
						GBI	Likert scale*	NOSE	PRQ	SNOT-20	VAS	AAR	AR	CT	ITH	
RCT																
Devseren, 2010 ⁽³⁰⁾	67	X			X						X		X			6
Grymer, 1993 ⁽³¹⁾	80	?	?	X					X				X			3
Illum, 1997 ^{† (32)}	80	?	?	X					X				X			60
Lindemann, 2008 ⁽³³⁾	12		X		X										X	6
Nasseem, 2009 ⁽³⁴⁾	86	?	?	X					X					X		9
CBA																
Akduman, 2013 ⁽²⁴⁾	134 [‡]	?	?	X	X	X	X	X								6
Balcerzak, 2014 ⁽²⁵⁾	30	?	?	X	X					X		X				6
Dinesh Kumar, 2015 ⁽²⁹⁾	60		X		X			X								6
Stewart, 2004 ⁽²⁶⁾	59		X	X			X	X								6
Uppal, 2005 ⁽²⁷⁾	75	?	?	X	X	X			X							44
Ye, 2006 ⁽²⁸⁾	83	?	?	X	X								X			6

*Likert scale ranged 5 points in Akduman et al. and 11 points in Stewart et al. † Long-term follow-up of Grymer et al. ‡ The study authors included 35 patients who underwent septoplasty and additional valve surgery; effect estimates of these patients were not included in this systematic review. AAR: Active Anterior Rhinomanometry. AR: Acoustic Rhinometry. CBA: Controlled Before-and-After study. CT: Computed Tomography measurements of turbinate thickness. GBI: Glasgow Benefit Inventory. NOSE: Nasal Obstruction Symptom Evaluation scale. PRQ: Patient-Reported Questionnaire concerning nasal symptoms or treatment satisfaction; not otherwise specified by study authors. RCT: Randomised Controlled Trial. SNOT-20: Sino-Nasal Outcome Test-20. ITH: Inspiratory air Temperature and absolute Humidity. VAS: Visual Analogue Scale.

potentially applicable even though it had not been indexed in either one of the three databases searched. Based on title and abstract, 10,885 articles needed to be excluded due to incompatibility with our eligibility criteria. Full-texts of the remaining 35 studies were screened and another 24 articles were excluded for the following reasons: in 14 studies, the control group either lacked or was unsuitable to compare treatments; five studies did not comply with our eligibility criteria concerning patients, interventions, or follow-up; two articles were (systematic) reviews; two articles were conference abstracts; and one publication

was solely based on expert opinion. A total of 11 articles could be included in this systematic review. A flow diagram of study selection is shown in Figure 1, derived from The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Group⁽²³⁾.

Study characteristics

The first aim of this review was to assess the effectiveness of septoplasty (with or without concurrent turbinate surgery) versus non-surgical management for nasal obstruction due to

Table 2. Characteristics of included studies.

First author, year (sorted by design)	Patient characteristics				Study characteristics				Outcomes (collected and reported)		
	Eligibility criteria		Number of participants	Age in years (mean and range)	Gender (number of males)	Pre-operative diagnostic assessment	Type of turbinate surgery (technique and side)	Time points of outcome assessment	Subjective	Objective	
	Inclusion criteria	Exclusion criteria									Total
RCT											
Devse- ren, 2010 ⁽⁸⁰⁾	Nasal obstruction with turbinate hypertrophy on the side contralateral to the nasal septal deviation	Previous nasal surgery; previous nasal medication; history of allergic rhinitis; nasal polyposis and/or neoplasia	67	34	30.9; 18-60*	32*	Anterior rhinoscopy and rigid endoscopy	Submucous resection of the contralateral hypertrophied inferior turbinate	Before treatment; 1 month after treatment; 3 months after treatment; 6 months after treatment	VAS	AR
Grymer, 1993 ⁽⁸¹⁾	Nasal obstruction due to a deviated nasal septum with an indication to have septoplasty performed	NR	80	42	32; 18-61	57	Anterior rhinoscopy	Anterior turbino-plasty of the inferior turbinate opposite to the main septal deviation	Before treatment; 3 months after treatment	Patient-reported concerning treatment satisfaction	AR
Illum, 1997 ⁽⁸²⁾	Nasal obstruction due to a deviated nasal septum with an indication to have septoplasty performed	NR	80	42	32; 18-61	57	Anterior rhinoscopy	Anterior turbino-plasty of the inferior turbinate opposite to the main septal deviation	60 months after treatment	Patient-reported concerning treatment satisfaction	AR
Lindemann, 2008 ⁽⁸³⁾	Nasal obstruction due to a deviated nasal septum with turbinate hypertrophy; sufficient but unsuccessful conservative treatment	Seasonal allergic rhinitis; symptoms of chronic sinusitis such as chronic rhinorrhea, nasal congestion, or postnasal drip; recurrent sinusitis; septal deviation inhibiting proper probe placement	12	6	29; 17-45	10	ENT-examination and endoscopic findings	Bilateral submucosal anterior turbino-plasty of the inferior turbinates	Before treatment; 4-6 months after treatment	NR	Inspiratory air temperature and absolute humidity
Nasseem, 2009 ⁽⁸⁴⁾	Nasal obstruction due to a deviated nasal septum	Allergic complaints	86	43	35.5; 18-56	45	Examination (not otherwise specified)	Coblation-assisted turbinate reduction of the inferior turbinate on the contralateral side of the septal deviation	Before treatment; 3 months after treatment; 6 months after treatment; 9 months after treatment	Patient-reported questionnaire concerning nasal symptoms	CT measurements of turbinate thickness
CBA											
Akdu- man, 2013 ⁽⁸⁴⁾	Age 18 years or older; indication for surgical correction of nasal septal deviation (with or without turbinate hypertrophy); complete surveys	Revision surgery; history of allergy; adenoid hypertrophy; concurrent endoscopic sinus surgery, polypectomy, or rhinoplasty; primary indication other than nasal obstruction	134 [†]	73	28.6; 18-67 [‡]	103 [†]	Anterior rhinoscopy and endoscopic examination	Turbino-plasty (outrfraction and resection of the lower part in contact with the nasal floor) of the inferior nasal turbinate	Before treatment; at least 6 months after treatment	GBI; NOSE; 5-point Likert scale	NR

First author, year (sorted by design)	Patient characteristics				Study characteristics						
	Eligibility criteria		Number of participants		Type of turbinate surgery (technique and side)		Time points of outcome assessment		Outcomes (collected and reported)		
	Inclusion criteria	Exclusion criteria	Total	SA	Age in years (mean and range)	Gender (number of males)	Pre-operative diagnostic assessment	Objective	Subjective	Objective	
Balcerzak, 2014 ⁽²⁵⁾	Nasal obstruction due to nasal septal deviation (with or without turbinate hypertrophy)	Chronic sinusitis; allergic rhinitis; nasal obstruction caused by systemic diseases	30	15	40.3; 17-79	22	NR	Sumucosal partial resection or submucosal bipolar coagulation; side NR	Before treatment; 6 weeks after treatment; 6 months after treatment	SNOT-20	AAR
Dinesh Kumar, 2015 ⁽²⁶⁾	Age between 18 and 65 years; persistent nasal obstruction after 2 months of medical therapy; nasal septal deviation with turbinate hypertrophy	Under 18 years of age; history of septoplasty; acute and chronic rhinosinusitis; perforated nasal septum; nasal valve insufficiency; granulomatous diseases of nose and sinuses; craniofacial malformation; pregnancy; HIV- and HbsAg-positive status	60	30	NR	NR	Nasal endoscopy and CT scan	Partial inferior turbinectomy of the hypertrophied inferior turbinate	Before treatment; 1 month after treatment; 3 months after treatment; 6 months after treatment	NOSE	NR
Stewart, 2004 ⁽²⁶⁾	Age 18 years or older; nasal obstruction due to a deviated nasal septum; symptoms lasting at least 3 months and persisting after a 4-week trial of medical management	Sinonasal malignancy; radiation therapy to head and neck; septoplasty with concurrent sinus surgery, rhinoplasty, or sleep apnea surgery; septoplasty performed to get access to other sites; prior septoplasty, rhinoplasty, or turbinoplasty; history or clinical evidence of chronic sinusitis; septal perforation; craniofacial syndrome; acute nasal trauma or fracture in the past 3 months; nasal valve collapse; adenoid hypertrophy; sarcoidosis; Wegener's granulomatosis; uncontrolled asthma; pregnancy; illiteracy	59	43	44.7; NR	38	NR	Partial inferior turbinectomy; side NR	Before treatment; 3 months after treatment; 6 months after treatment	NOSE; 11-point Likert scale	NR

First author, year (sorted by design)	Patient characteristics				Study characteristics			Outcomes (collected and reported)	
	Eligibility criteria		Number of participants	Age in years (mean and range)	Pre-operative diagnostic assessment	Type of turbinate surgery (technique and side)	Time points of outcome assessment	Subjective	Objective
	Inclusion criteria	Exclusion criteria							
Uppal, 2005 ⁽²⁷⁾	Nasal obstruction due to a deviated nasal septum (with or without turbinate hypertrophy)	Septoplasty with concurrent endoscopic sinus surgery, nasal polypectomy, or rhinoplasty; primary indication for septoplasty other than nasal obstruction	75	41; 16-73	NR	Inferior turbinate reduction (submucous diathermy or trimming of inferior turbinates); side NR	Before treatment; 13-44 months after treatment	GBI; patient-reported questionnaire concerning nasal symptoms	NR
Ye, 2006 ⁽²⁸⁾	Nasal septal deviation (with or without turbinate hypertrophy; male gender)	NR	83	37.6; 19-62	NR	Unilateral or bilateral partial inferior turbinectomy	Before treatment; 6 months after treatment		NR

*The study authors have calculated mean age, age range, and number of males based on 42 patients, as 25 patients were lost to follow-up and excluded from further analyses.

† Long-term follow-up of Grymer et al. ‡ The study authors included 35 patients who underwent septoplasty and additional valve surgery; effect estimates of these patients were not included in this systematic review. Mean age, age range, and number of males were presented based on the total sample of 134 patients. AAR: Active Anterior Rhinomanometry. AR: Acoustic Rhinometry. CBA: Controlled Before-and-After study. GBI: Glasgow Benefit Inventory. NOSE: Nasal Obstruction Symptom Evaluation scale. NR: Not Reported. RCT: Randomised Controlled Trial. SA: Septoplasty Alone. SNOT-20: Sino-Nasal Outcome Test-20. ST: Septoplasty with concurrent Turbinate surgery. VAS: Visual Analogue Scale.

a deviated nasal septum in adults. We were not able to include any studies with respect to this comparison. The second aim was to compare septoplasty with concurrent turbinate surgery versus septoplasty alone for nasal obstruction due to a deviated nasal septum in adults. For this comparison, five randomised controlled trials and six controlled before-and-after studies (in which measurements were performed before and after treatment, both in patients undergoing septoplasty with concurrent turbinate surgery and in patients undergoing septoplasty alone) could be included. The number of included participants per study varied between 12 and 134 patients. The preoperative diagnostic assessment consisted of anterior rhinoscopy and nasal endoscopy in most cases. The type of turbinate surgery was often described as (anterior) turbinoplasty or partial turbinectomy. In the majority of studies, turbinate surgery was unilateral. Table 2 provides an overview of included studies and details on their methods, participants, interventions, and outcomes.

Risk of bias assessment

Results of risk of bias assessment are graphically summarised in Figures 2 and 3. In Figure 2, judgments about each risk of bias item are presented as percentages across all included studies, whereas Figure 3 shows scores on each risk of bias item for every included study separately.

Sequence generation and allocation concealment

In five out of 11 included studies, the indication to have septoplasty performed with or without turbinate surgery was based on clinical judgment or patient preferences⁽²⁴⁻²⁸⁾. In one study, correspondence with study authors learned that patients were alternately divided between two groups⁽²⁹⁾. The remaining five studies all mentioned a random component in the sequence generation process. None of these studies, however, reported an adequate method of allocation concealment⁽³⁰⁻³⁴⁾.

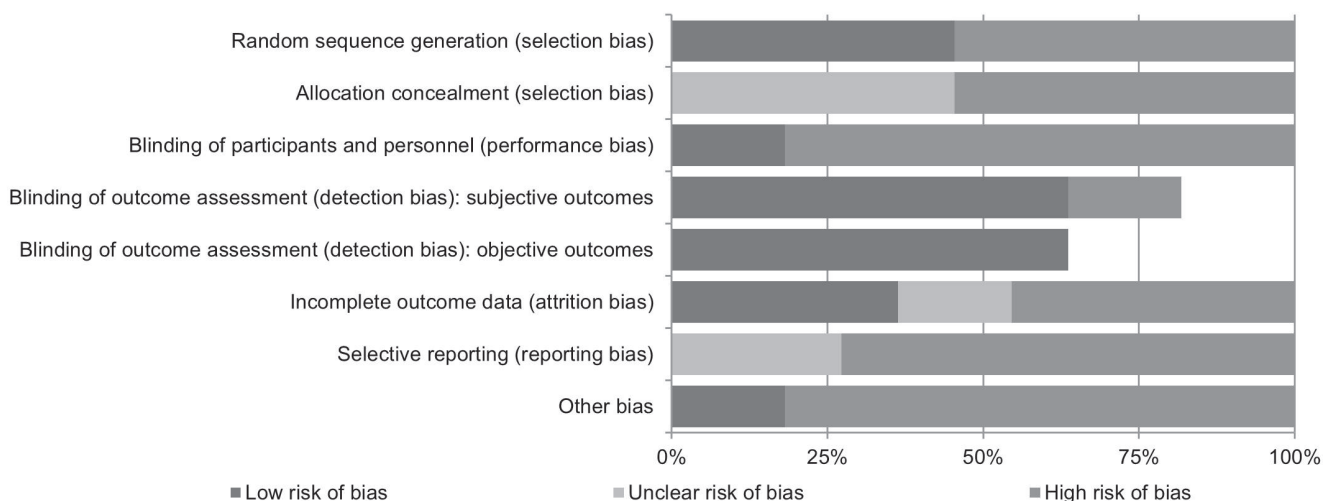


Figure 2. Risk of bias graph: review authors' judgment about each risk of bias item presented as percentages across all included studies.

Blinding

Only two publications described efforts to prevent performance bias due to knowledge of the allocated interventions. Both in Balcerzak et al. and Stewart et al., ENT-surgeons were not involved in collecting follow-up data^(25, 26). Moreover, Stewart et al. blinded physicians to patients' pre- and postoperative scores on study outcomes⁽²⁶⁾.

The risk of detection bias was assessed separately for subjective and objective outcomes. In all included studies, patients were aware of the type of surgery performed. Taking the patients' perspective into account, we estimated that the difference in perceived desirability between two types of surgical treatment would be less pronounced than between septoplasty and non-surgical management. For this reason, most subjective outcome measurements were considered unlikely to be influenced by lack of blinding. The risk of detection bias was found to be high only in Grymer et al. and Illum et al., since subjective outcomes of these studies mainly addressed satisfaction with the treatment received^(31, 32). For objective outcomes, the risk of detection bias was judged to be low irrespective of the lack of blinding.

Incomplete outcome data and selective reporting

Four studies reported that all outcome data were complete^(27, 28, 33, 34). In two studies, no information on missing outcome data was provided^(25, 29). Four other studies presented proportions of missing outcomes, but reasons for loss to follow-up were rarely stated and adequate methods for handling incomplete outcome data were never described^(26, 30-32). Some studies appeared to have adopted a per protocol approach by simply excluding dropouts^(24, 30, 31).

A study protocol could not be obtained for any of the included studies. Moreover, none of the randomised controlled trials were listed on ClinicalTrials.gov or in the ISRCTN (International

Standard Randomised Controlled Trial Number) Registry. Consequently, it was impossible to verify whether all of the studies' pre-specified outcomes had been published. Obvious evidence of selective outcome reporting was identified only in Stewart et al., where one of the outcome measures listed in the Methods section (i.e., an 11-point Likert scale) was entirely omitted from the Results⁽²⁶⁾. Additionally, risk of reporting bias was high in seven other studies, whose summary measures could not be calculated due to incomplete reporting of outcomes^(24, 27, 29-33).

Other potential sources of bias

Systematic differences in baseline characteristics between the two groups were likely to have occurred especially in studies allocating treatments based on clinical judgment or patient preferences⁽²⁴⁻²⁸⁾.

Furthermore, specific issues that raised concern about the possibility of bias were identified in two of the controlled before-and-after studies and three of the included RCTs. In Akduman et al., patients were allocated to septoplasty alone, septoplasty with concurrent turbinate surgery, or septoplasty with additional valve surgery⁽²⁴⁾. Given this third treatment option, the selection of patients enrolled in our two groups of interest may have been different, had only two options been present. Dinesh Kumar et al. presented inconsistent tables, which showed different numbers for the same outcomes⁽²⁹⁾. In Devseren et al. and Grymer et al., respectively two and six patients with postoperative complications were excluded from the analyses^(30, 31). Nasseem et al. performed additional turbinate surgery in patients allocated to septoplasty alone in case of persistent complaints⁽³⁴⁾.

Study results

A summary of findings from included studies is provided in Table 3. In case of repeated measurements, we planned to

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias); subjective outcomes	Blinding of outcome assessment (detection bias); objective outcomes	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Adkuman 2013	-	-	-	+	-	-	-	-
Balcerzak 2014	-	-	+	+	+	?	?	-
Devseren 2010	+	?	-	+	+	-	-	-
Dinesh Kumar 2015	-	-	-	+	-	?	-	-
Grymer 1993	+	?	-	-	+	-	-	-
Illum 1997	+	?	-	-	+	-	-	+
Lindemann 2008	+	?	-	-	+	+	-	+
Nasseem 2009	+	?	-	+	+	+	?	-
Stewart 2004	-	-	+	+	-	-	-	-
Uppal 2005	-	-	-	+	-	+	-	-
Ye 2006	-	-	-	-	+	+	?	-

Figure 3. Risk of bias summary: review authors' judgment about each risk of bias item for every included study.

present outcomes at 12 months. In none of the included studies, however, data were collected at one year of follow-up. Median follow-up was six months; data at this time point were presented whenever possible^(24-26, 28-30, 33, 34). In the remaining three studies, no repeated measurements were conducted. Therefore, we presented outcomes at the time point selected by study authors, which ranged between three and 60 months^(27, 31, 32).

Subjective outcome measures

Subjective outcomes were reported in nine out of 11 included studies^(24-27, 29-32, 34). Six different subjective outcome measures could be distinguished, some of which were applied in only one study (i.e., SNOT-20, VAS) and others in two to three studies (i.e., GBI, Likert scale, NOSE); four studies assessed nasal symptoms

or treatment satisfaction using a patient-reported questionnaire (PRQ) which was not otherwise specified by study authors. Eight out of nine studies reported subjective benefit after treatment, irrespective of whether septoplasty had been performed with or without concurrent turbinate surgery. Only Dinesh Kumar et al. reported that septoplasty with concurrent turbinate surgery resulted in significantly greater improvement in symptoms than septoplasty alone, but the basis for this conclusion was unclear due to inconsistent reporting of results within this study⁽²⁹⁾.

Objective outcome measures

Objective outcomes were reported in seven studies. Four types of objective outcome measures were described, i.e., active anterior rhinomanometry, acoustic rhinometry, CT measurements of turbinate thickness, and measurements of inspiratory air temperature and absolute humidity. Each objective outcome was used in one study apart from AR, which was applied in four studies. Three reports indicated that AAR or AR had been performed after decongestion of nasal mucosa; Devseren et al. and Ye et al. did not specify whether this was the case^(28, 30). Most studies reported significant improvement in objective outcomes after treatment^(28, 30, 31, 33, 34). Five out of seven studies found no additional benefit of concurrent turbinate surgery^(25, 28, 30, 32, 33).

Complications

Only three studies reported on complications^(30, 31, 34). The most frequent complications were development of nasal septal perforation and nasal adhesions or synechiae, with a reported total of seven and six affected patients out of 233, respectively. Other complications were nasal hematoma and secondary hemorrhage, each of which occurred in one out of 233 patients⁽³⁴⁾. In all three studies, complications were more frequent after septoplasty with concurrent turbinate surgery than after septoplasty alone.

Discussion

Summary of evidence

This systematic review includes five randomised controlled trials and six controlled before-and-after studies comparing the effectiveness of septoplasty with concurrent turbinate surgery to septoplasty alone for nasal obstruction due to a deviated nasal septum in adults. Included studies demonstrated substantial heterogeneity in study population, outcomes measured, and time points of outcome assessment. Risk of bias was considered high in most reports. Therefore we decided not to perform meta-analyses, but instead present effect estimates of individual studies. Subjective and objective outcomes generally appeared to have improved after treatment. However, the additional benefit of turbinate surgery was not evident. Moreover, subjective benefit was not always accompanied by objective improvement, and vice versa. Complications appeared to be rare and were re-

Table 3. Summary of findings from included studies.

First author, year (sorted by design)	Summary data		Missing data	Complications	Study authors' conclusion
	Subjective outcome measures	Objective outcome measures			
RCT					
Devseren, 2010 ⁽³⁰⁾	VAS*: ST mean 2.7 (SD NR); SA mean 3.0 (SD NR).	ARI [±] : side of septal deviation: ST mean 1.3 (SD NR); SA mean 1.3 (SD NR). ARI [±] side of turbinate hypertrophy: ST mean 1.5 (SD NR); SA mean 1.4 (SD NR).	ST 13/34 patients excluded from follow-up; SA 12/33 patients excluded from follow up. Reasons: address change, noncompliance, or postoperative complications.	ST 2 patients with septal perforation; SA NR.	In both treatment arms, subjective as well as objective outcomes significantly improved 6 months after surgery.
Grymer, 1993 ⁽³¹⁾	PRQ: ST 70% satisfied; SA 66% satisfied; RD 5% (95%CI -17% – 27%).	ARI [±] : outcomes classified into two groups based on preoperative severity of nasal septal deviation; outcomes per treatment arm NR.	ST 5/42 patients excluded from follow-up; SA 1/38 patients excluded from follow-up. Reason: postoperative complications.	ST 3 patients with septal perforation and 2 patients with synechiae between septum and inferior turbinate; SA 1 patient with synechiae between septum and inferior turbinate.	No significant difference between ST and SA was found in subjective benefit 3 months after surgery. Nasal passage on the deviated side of the nose significantly increased after surgery, irrespective of preoperative severity of nasal septal deviation.
Illum, 1997 ⁽³²⁾	PRQ: ST 39% satisfied; SA 50% satisfied; RD -11% (95%CI -40% – 17%).	ARI [±] : side of septal deviation: outcomes per treatment arm NR. ARI [±] non-deviated side: ST mean 0.73 (SD 0.21); SA mean 0.76 (SD 0.16); SMD could not be calculated as number of patients per treatment arm NR.	PRQ: ST 11/42 patients lost to follow-up; SA 20/38 patients lost to follow-up. AR: 43/80 patients lost to follow-up; distribution across treatment arms NR. Reasons NR.	NR	No significant difference between ST and SA was found in subjective as well as objective outcomes 60 months after surgery.
Lindemann, 2008 ⁽³³⁾	NR	ITH [±] temperature: ST median 6.5; SA median 6.0; mean and SD NR. ITH [±] humidity: ST median 21.6; SA median 19.1; mean and SD NR.	NR	NR	In both treatment arms, objective outcomes significantly improved 6 months after surgery.
Nasseem, 2009 ⁽³⁴⁾	PRQ-1: ST 77% completely relieved of nasal obstruction on the side of septal deviation; SA 84% completely relieved of nasal obstruction on the side of septal deviation; RD -7% (95%CI -24% – 10%). PRQ-2*: ST 7% experienced nasal obstruction on the non-deviated side; SA 37% experienced nasal obstruction on the non-deviated side; RD -30% (95%CI -47% – -14%).	CT [±] : ST mean 7.44 (SD 1.55); SA mean 10.4 (SD 1.05); SMD 2.22 (95%CI 1.67 – 2.76).	NR	ST 1 patient with septal perforation, 3 patients with adhesions, and 1 patient with secondary hemorrhage; SA 1 patient with septal perforation and 1 patient with septal hematoma.	In both treatment arms, nasal obstruction on the side of septal deviation improved 6 months after surgery. CT measurements of turbinate thickness 9 months after surgery were significantly smaller after ST compared to SA.

First author, year (sorted by design)	Summary data		Missing data	Complications		Study authors' conclusion
	Subjective outcome measures	Objective outcome measures				
CBA						
Akduman, 2013 ⁽²⁴⁾	GBI [†] : ST mean 63.58 (SD 9.40); SA mean 66.55 (SD 8.21); SMD -0.32 (95%CI -0.77 – 0.13). NOSE [*] : mean scores presented per questionnaire item; total mean and SD per treatment arm NR. 5-point Likert scale [‡] : ST mean 4.11 (SD 0.66), SA mean 4.30 (SD 0.61); SMD -0.29 (95%CI -0.74 – 0.16).	NR	Completeness of pre- and postoperative surveys applied as inclusion criterion by study authors.	NR	None of the outcome measures showed a significant difference between ST and SA in postoperative improvement 6 months after surgery.	
Balcerzak, 2014 ⁽²⁵⁾	SNOT-20 [*] : ST mean 12.20 (SD 12.74); SA mean 20.53 (SD 16.27); SMD 0.55 (95%CI -0.18 – 1.29).	AAR [*] expiration left: ST mean -0.368 (SD 0.901); SA mean -0.178 (SD 0.478); SMD 0.26 (95%CI -0.46 – 0.98). AAR [*] expiration right: ST mean -0.096 (SD 0.868); SA mean -0.372 (SD 0.801); SMD -0.32 (95%CI -1.04 – 0.40). AAR [*] inspiration left: ST mean -0.449 (SD 0.840); SA mean -0.183 (SD 0.486); SMD 0.38 (95%CI -0.35 – 1.10). AAR [*] inspiration right: ST mean -0.052 (SD 0.913); SA mean -0.343 (SD 1.016); SMD -0.29 (95%CI -1.01 – 0.43).	NR	NR	In both treatment arms, subjective outcomes significantly improved 6 months after surgery. No significant difference between pre- and postoperative objective outcomes was found in both groups.	
Dinesh Kumar, 2015 ⁽²⁶⁾	NOSE [*] : outcomes unclear due to inconsistent reporting of results.	NR		NR	Septoplasty with concurrent turbinate surgery resulted in significantly greater improvement in symptoms 6 months after surgery than septoplasty alone.	
Stewart, 2004 ⁽²⁶⁾	NOSE [*] : ST mean 21.5 (SD 21.3); SA mean 38.6 (SD 25.9); SMD could not be calculated as number of patients per treatment arm NR. 11-point Likert scale [‡] : NR.	NR	In total 21/59 patients lost to follow-up. Distribution across treatment arms and reasons NR.	NR	In both treatment arms, subjective outcomes significantly improved 6 months after surgery. The difference between treatment arms was not statistically significant.	
Uppal, 2005 ⁽²⁷⁾	GBI [†] : outcomes classified into two groups based on whether nasal obstruction persisted after treatment; total mean and SD per treatment arm NR. PRQ [†] : ST 70% reported to feel better or much better after treatment; SA 64% reported to feel better or much better after treatment; RD 6% (95%CI -17 – 30%).	NR		NR	No significant difference between ST and SA was found in subjective benefit 13–44 months after surgery.	

First author, year (sorted by design)	Summary data		Missing data	Complications	Study authors/conclusion
	Subjective outcome measures	Objective outcome measures			
Ye, 2006 ⁽²⁸⁾	NR	AR [†] : side of septal deviation: ST mean 0.44 (SD 0.28); SA mean 0.38 (SD 0.62); SMD 0.13 (95%CI -0.31 – 0.56). AR ^{††} non-deviated side: ST mean 0.46 (SD 0.98); SA mean 0.45 (SD 0.82); SMD 0.01 (95%CI -0.42 – 0.44).	NR	NR	In both treatment arms, nasal passage on the deviated side of the nose significantly increased 6 months after surgery.

*Outcome decreases with improvement after treatment. †Outcome increases with improvement after treatment. ‡Minimal cross-sectional area (MCA) in cm². §End-inspiratory increase in air temperature (in °C) and absolute humidity (in g/m³). ¶CT measurements of turbinate thickness in mm; outcomes available only at 9 months of follow-up. || Nasal resistance in Pa/mL/s; means and standard deviations provided by study authors were change scores. AAR: Active Anterior Rhinomanometry. AR: Acoustic Rhinometry. CBA: Controlled Before-and-After study. CI: Confidence Interval CT: Computed Tomography measurements of turbinate thickness. GBI: Glasgow Benefit Inventory. ITH: Inspiratory air Temperature and absolute Humidity. NOSE: Nasal Obstruction Symptom Evaluation scale. NR: Not Reported. PRQ: Patient-Reported Questionnaire concerning nasal symptoms or treatment satisfaction; not otherwise specified by study authors. RCT: Randomised Controlled Trial. SA: Septoplasty Alone. SD: Standard Deviation. SMD: Standardised Mean Difference. SNOT-20: Sino-Nasal Outcome Test-20. ST: Septoplasty with concurrent Turbinate surgery. VAS: Visual Analogue Scale.

ported in only three studies. Most complications occurred after septoplasty with concurrent turbinate surgery.

Strengths and limitations

The major strength of our systematic review is that we are the first to provide an extensive evaluation of current evidence for the effectiveness of septoplasty (with or without concurrent turbinate surgery) as well as for the effectiveness of septoplasty with concurrent turbinate surgery compared to septoplasty alone, both in terms of subjective and objective outcome measures. Considering its annual performance rate combined with the existing lack of management consensus, evidence for the effectiveness of septoplasty is of high relevance to many healthcare providers, patients, and policy makers. This systematic review has been performed with strict adherence to the registered review protocol and following PRISMA guidelines⁽²³⁾.

However, several limitations should be addressed as well. First, a non-surgical control group was lacking in all eligible studies. Since improvement in complaints could also be induced by other factors such as natural history, beneficial effects of surgery may be overestimated. Some study authors considered septoplasty the only possible treatment for a deviated nasal septum^(24, 26). Yet the primary aim of septoplasty is reducing symptoms of nasal obstruction, rather than merely straightening the septum. For this purpose, non-surgical management is an equally suited alternative under conditions of clinical equipoise⁽³⁵⁾. Second, follow-up of most included studies was relatively short. This may provide a distorted view on the effectiveness of septoplasty, as long-term results tend to be less favourable than short-term outcomes. Illum et al. found that only 39 to 50 percent of patients remained satisfied 5 years after treatment⁽³²⁾. An uncontrolled study by Jessen et al. showed that the proportion of patients relieved of nasal obstruction dropped from 51 percent at 9 months of follow-up to 26 percent after 9 years⁽³⁶⁾. To assess durability of symptom improvement, studies with longer follow-up are needed.

Third, we used Cochrane's risk of bias tool instead of the

Newcastle-Ottawa Scale (NOS), which may seem more appropriate for non-randomised studies⁽³⁷⁾. However, Cochrane's risk of bias tool is tailored to our type of systematic review, addressing the effectiveness of interventions⁽²²⁾. Moreover, the validity and reliability of the NOS have been questioned, and its evaluation is still in progress⁽³⁷⁻³⁹⁾. Cochrane's tool has been developed for RCTs, but the dimensions of bias to be assessed are accordingly applicable to non-randomised studies⁽²²⁾.

Fourth, systematic reviews of non-randomised studies entail particular difficulties, especially when meta-analyses are involved. Supplementing evidence from RCTs with non-randomised studies bears the risk of changing an imprecise but unbiased estimate into a precise but biased one⁽²²⁾. Nonetheless, including non-randomised studies may allow a systematic review to address interventions not studied in RCTs, and examine the case for undertaking future trials^(22,40). Recent years have seen an increase in literature dedicated to methodological issues surrounding systematic reviews of non-randomised studies^(41,42). When randomised and non-randomised evidence are available, including both in the same systematic review but synthesising their results separately may be considered the preferred approach⁽⁴⁰⁾.

Clinical implications

Uncertainty about the effectiveness of septoplasty has been a long-time concern in ENT-practice. Accordingly, it was the clinical experience of ENT-surgeons that prompted a call for further research. In 2010, the professional association of UK otorhinolaryngologists noted that some hospital administrations were suggesting to abolish or severely restrict septoplasty, because of doubts about its benefits⁽¹²⁾. The Dutch ENT society highly prioritised research on this topic, considering it one of the most important knowledge gaps in otorhinolaryngology⁽¹³⁾. Our extensive literature search shows that the evidence gap persists. We were unable to include studies comparing septoplasty to non-surgical management, and studies comparing septoplasty with concurrent turbinate surgery to septoplasty alone were limited in number and methodologically flawed. As a result, evidence-based conclusions regarding the effectiveness of septoplasty still cannot be drawn. To assess the effectiveness of interventions, a pragmatic randomised controlled trial remains the design of choice⁽⁴³⁾. After years of routinely performing sep-

tal surgery, it may seem challenging to initiate an RCT comparing septoplasty to non-surgical management. Two such trials, however, are currently underway^(2,44). Together their results will help to determine which patients can benefit from septoplasty to a greater or lesser extent.

Conclusion

Although septoplasty is routinely applied in clinical practice, the current body of evidence does not support firm conclusions on its effectiveness. No studies were found comparing septoplasty to non-surgical management. The limited number of studies comparing septoplasty with concurrent turbinate surgery to septoplasty alone generally showed postoperative improvement, but their results must be interpreted with caution due to methodological flaws.

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Authorship contribution

MvE, MR, and NvH conceived the systematic review and initiated the review protocol. AT and MvE performed the systematic literature search. AT retrieved applicable reports. MvE, MR, and NvH selected studies, assessed risk of bias, and extracted data. MvE and MR performed data analyses. All review authors drafted this manuscript and approved the final version.

Conflict of interest

The authors declare that they do not have any competing interests.

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