

ORIGINAL ARTICLE

Septoplasty versus non-surgical management for nasal obstruction due to a deviated nasal septum in adults: A modelling study of cost-effectiveness

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Objective: The objective of this study was to demonstrate how decision-analytic modelling can help to determine circumstances under which surgery may become cost-effective, using septoplasty as an example.

Design: We developed a decision-analytic model comparing septoplasty to non-surgical management for nasal obstruction in adults with a deviated septum. Based on the estimated cost difference between both treatments, we calculated the minimal (a) gain in quality-adjusted life-years, or (b) reduction in productivity losses needed for septoplasty to be cost-effective. Input was derived from literature and publicly available data sources. The time horizon of our model was one year, and the willingness-to-pay per quality-adjusted life-year was €20 000, in accordance with current guidelines.

Results: The cost difference between septoplasty and non-surgical management for nasal obstruction due to a deviated nasal septum was €2227 per patient from a healthcare perspective (including direct healthcare costs) and €3288 per patient from an extended perspective (additionally including travel expenses and productivity losses due to poor health). In comparison with non-surgical management, septoplasty needed to gain 0.11 to 0.16 QALYs or save 13 sick days for nasal obstruction. The longer septoplasty's effect lasts, the more time it will have to compensate its extra costs.

Conclusion: This study shows that the known cost difference between treatments can be used as the starting point to determine beneficial effects needed for cost-effectiveness of surgical interventions. The effect required by septoplasty from a healthcare perspective seems potentially achievable, meaning that it would be useful to perform an RCT assessing the actual benefits of septoplasty.

1 | INTRODUCTION

1.1 | Rationale

In the era of value-based healthcare, it is becoming increasingly important to obtain evidence that interventions provide outcomes

valued by patients and society. As both costs and demands for care are rising, the growing strain on resources is a cause for concern in healthcare policy and practice. More than ever, the benefits of interventions need to be carefully weighed against their costs, to justify their use to society.¹

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Randomised controlled trials (RCTs) are the gold standard to assess the effectiveness of surgical interventions, but conducting RCTs can be methodologically challenging, costly and time-consuming. Consequently, the number of surgical trials has been consistently low over the past decades.² As a result, surgical interventions may be routinely applied in daily practice, while high-quality evidence for their effectiveness is lacking.

Septoplasty, that is surgical correction of the deviated nasal septum, is an illustrative example within ENT-practice. Although septoplasty is a common treatment for nasal obstruction, current literature on its effectiveness is scarce and inconclusive.³ The estimated prevalence of a deviated septum ranges up to 80%, whereas only a minority suffers from nasal obstruction. It has been questioned whether straightening the septum provides any benefit to those patients, and if so, which patients benefit most.⁴ Professional associations of ENT-surgeons have called for further research, but RCTs comparing septoplasty with non-surgical management are still unavailable.^{5,6}

However, even when effectiveness data are lacking, data on the costs of an intervention are often present. These can be used to determine the circumstances under which surgery may become cost-effective, thereby indicating whether cost-effectiveness is potentially feasible and thus informing future trials. Such analyses may be performed using a decision-analytic model, in which available data are synthesised to compare alternative strategies in terms of effects, costs, or both.

1.2 | Objective

The objective of this study was to illustrate the value of decision-analytic modelling when RCTs are absent, by assessing the minimal effects or societal savings needed for septoplasty to compensate its extra costs in comparison with non-surgical management for nasal obstruction in adults with a deviated septum.

2 | MATERIALS AND METHODS

2.1 | Ethical considerations

This modelling study was based on existing evidence. No original data were collected in human participants. Approval by the institutional ethics committee was not required.

2.2 | Target population

The target population represents a fictional cohort of patients passing through the model. Our target population consisted of adults with nasal obstruction due to a deviated nasal septum and an indication to have septoplasty performed. Following regular practice in the Netherlands and most other Western European countries, the target population was not limited to those with specific characteristics, such as a pre-defined level of disease severity or a history of medical management. In Dutch medical practice, the indication for

Keypoints

- Decision-analytic modelling can help to determine circumstances under which surgical interventions may become cost-effective.
- The cost difference between septoplasty and non-surgical management for nasal obstruction due to a deviated nasal septum was €2227 per patient from a healthcare perspective and €3288 per patient from an extended perspective. As a result, septoplasty needed to gain 0.11 to 0.16 QALYs or save 13 sick days for nasal obstruction to compensate its extra costs.
- The effect required by septoplasty from a healthcare perspective seems potentially achievable, meaning that it would be useful to perform a randomised controlled trial assessing the actual benefits of septoplasty.

septoplasty is based on an internal examination of the nose, which demonstrates that the deviation obstructs the nasal airway, leading to impaired nasal breathing.

2.3 | Setting and comparators

This decision-analytic model applies to secondary or tertiary healthcare settings. In the primary healthcare setting, medical treatment is the only option both for patients later indicated to undergo surgery as well as for patients following a non-surgical strategy. As a result, there was no reason to assume a cost difference at this point and the primary healthcare setting was thus excluded from the model. After referral by a primary care physician, patients with nasal obstruction are diagnosed with nasal septal deviation by the ENT-surgeon. Treatment may consist of septoplasty or non-surgical management. As the rationale behind septoplasty is to reduce symptoms of nasal obstruction rather than merely straightening the deviated septum, non-surgical management is an equally suited alternative under current conditions of equipoise, which was confirmed by a recent systematic review.³ Surgical and non-surgical management share the same target population (adults with nasal obstruction and a deviated septum) and intended effect (relieve of nasal complaints), and are considered suitable comparators.⁷

Non-surgical management may consist of watchful waiting or medical treatment. The decision tree comparing septoplasty to non-surgical management for nasal obstruction due to septal deviation is shown in Figure 1.

2.4 | Study perspective

The cost analysis was primarily conducted from a healthcare perspective, which includes direct healthcare costs (eg, treatment and follow-up).⁸ Additionally, the perspective was extended by adding travel expenses and productivity losses due to poor health to the

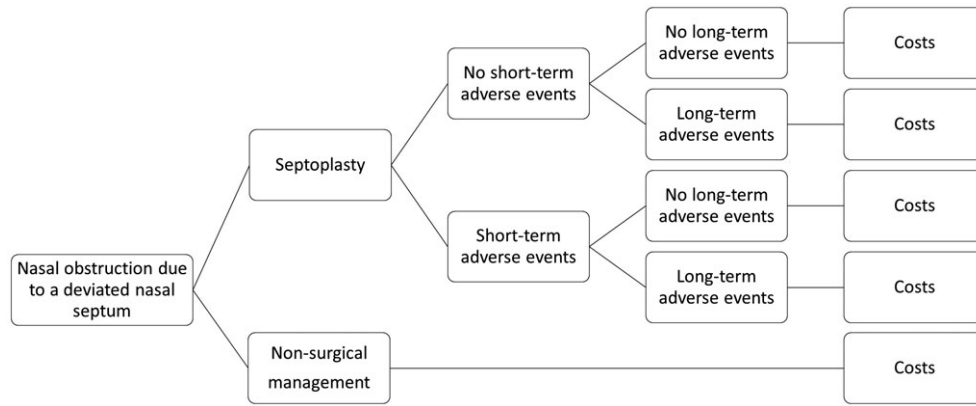


FIGURE 1 Decision tree of septoplasty versus non-surgical management

model. The extended perspective was used to assess societal savings needed for cost-effectiveness of septoplasty.

2.5 | Time horizon

The time horizon refers to the length of time covered by the model. A relevant time horizon should reflect all costs and consequences associated with each treatment strategy. The time horizon over which costs were evaluated in our model was one year. Within this year, relevant events that could contribute to the costs of each treatment strategy were expected to have occurred (including the treatment of any long-term complications after septoplasty). As non-surgical management did not involve surgery for persistent complaints, delayed septoplasty was not taken into account in the model's time horizon.

2.6 | Model input

The healthcare resources consumed and travel expenses or productivity losses incurred by each of the two treatment strategies are described below.

2.6.1 | Septoplasty

Undergoing septoplasty requires: an intake at the ENT outpatient clinic; pre-anaesthetic assessment; surgery (as day-case or overnight procedure); and one or two follow-up appointments. Medication is not usually needed, apart from postoperative analgesics. As maximum pain is commonly experienced within the first 24 to 48 hours after septoplasty, we assumed that patients would need mild analgesics (that is acetaminophen) during the first two postoperative days.⁹

Additional follow-up is needed in case of short-term adverse events, that is, complications occurring within 6 weeks after septoplasty: nasal infection, epistaxis, septal haematoma, or adhesions.¹⁰ Furthermore, nasal infection or septal haematoma requires medication. Based on a meta-analysis of studies on short-term adverse events after septoplasty, the risk of developing nasal infection or

septal haematoma was estimated to be 2%.¹¹ It was assumed that patients with nasal infection or septal haematoma would be treated with oral antibiotics (that is amoxicillin-clavulanate) during 1 week.

Additional healthcare resources are also consumed in case of long-term adverse events: severe adhesions, nasal septal perforation, or saddle nose deformity.¹² These complications occur typically within the first year after surgery and may develop after a previously uncomplicated recovery. Based on literature, the risk of developing long-term adverse events was estimated to be 1%.^{13,14} As the treatment of long-term complications consists of septal surgery, they required the same healthcare resources as primary septoplasty: outpatient consultation (intake and one or two follow-up visits); pre-anaesthetic assessment; surgery (as day-case or overnight procedure); and mild analgesics (that is acetaminophen) during the first two postoperative days.

Based on clinical experience, uncomplicated septoplasty was estimated to incur travel expenses for five hospital visits: three appointments with the ENT-surgeon, one appointment with the anaesthesiologist, and one day of surgery. One additional visit was added for the proportion of patients with short-term complications, and five additional visits for the proportion of patients with long-term adverse events.

According to literature and clinical experience, patients may take one to two weeks of sick leave for postoperative recovery.¹⁵ Seven days of absence from work were taken into account in calculating productivity losses after uncomplicated septoplasty. Another seven days were added in case of long-term complications, which were assumed to be treated surgically.

2.6.2 | Non-surgical management

To be conservative towards the potential cost-effectiveness of septoplasty, we assumed that all patients following a non-surgical strategy would receive nasal medication. Thus, undergoing non-surgical management involves outpatient consultation and intranasal corticosteroids, as meta-analyses have shown that these are more effective than antihistamines in the treatment of nasal obstruction.¹⁶ Intranasal corticosteroids have a limited risk of complications. Short-

term adverse events are usually mild, such as mucosal irritation or self-limiting epistaxis.¹⁷ The main long-term adverse event is nasal septal perforation, which occurs very rarely and is associated with improper spray application.¹⁸ Therefore, complications after non-surgical management were not included in the decision-analytic model.

It was estimated that non-surgical management would incur travel expenses for three hospital visits (intake and follow-up at the ENT outpatient clinic).

Following a non-surgical strategy may entail productivity losses due to persistent complaints of nasal obstruction despite medical treatment. As no data are available on sick days of patients undergoing non-surgical management, we calculated the reduction in productivity losses needed for septoplasty to compensate its extra costs.

2.7 | Data sources

In the Netherlands, fixed revenues for healthcare resources are derived from a case-mix system, based on "diagnosis treatment combinations" (DBC's). The fixed revenue for septal surgery (including outpatient consultation) and the fixed revenue for outpatient consultation only (when following non-surgical management) were published by the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa) on www.opendisdata.nl.

Nasal medication costs were calculated by averaging costs of eight frequently prescribed local steroids (both generic and brand-name). Medication costs were provided by the Dutch Healthcare Authority on www.farmacotherapeutischkompas.nl. All healthcare costs were based on the 2017 price level.

Travel expenses for each hospital visit were composed of motor vehicle expenses and parking costs. Standard rates were derived from the Dutch guideline for costing research and based on the 2017 price level.⁸

To calculate productivity losses, the proportion of employed persons and the average working hours per week in 2016 were obtained from Statistics Netherlands (Centraal Bureau voor de Statistiek, CBS). Costs for one hour of lost work were derived from the Dutch guideline for costing research and based on the 2017 price level.⁸

2.8 | Analyses

We determined the total costs for each of the two treatment strategies and assessed the minimal effects or societal savings needed for septoplasty to compensate its extra costs in comparison with non-surgical management.

The required effect was expressed as a gain in quality-adjusted life-years (QALYs). QALYs are the product of quantity (duration) and quality of health (expressed in a utility score ranging from 0 to 1, with 0 representing death and 1 representing perfect health). One QALY thus equals one year spent in perfect health. The QALY-gain yielded by an intervention is weighed against its cost using the willingness-to-pay (WTP) per QALY as a reference. A WTP of €20 000 per QALY means that society is willing to pay on average €20 000 per patient

for an intervention, if the patient will spend one year in perfect health due to that intervention. The Dutch WTP ranges from €20 000 to €80 000 per QALY, depending on the burden of disease.⁸ For this modelling study, we adhered to a WTP of €20 000 per QALY.

The societal savings needed for septoplasty to compensate its extra costs were expressed as reduced productivity losses, that is a decrease in sick days for nasal obstruction due to having undergone septoplasty. Sick days were calculated based on an average of 36 working hours per week.

The analyses were performed using Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA).

3 | RESULTS

3.1 | Model input

Input parameters from a healthcare perspective (including direct healthcare costs) and from an extended perspective (also including travel expenses and productivity losses due to poor health) are shown in Tables 1 and 2, respectively.

3.2 | Healthcare perspective

Mean total costs per patient undergoing septoplasty were €2407. Mean total costs per patient following a non-surgical strategy were €180. Consequently, the difference in costs between both treatment strategies was €2227. Given a WTP of €20 000 per QALY, septoplasty needed to gain at least 0.11 QALYs to be cost-effective, that is 40 days spent in perfect health. A durable effect is favourable to septoplasty: the required utility-gain per unit of time decreases as the effect duration increases.

3.3 | Extended perspective

Taking travel expenses and productivity losses due to postoperative recovery into account, mean total costs per patient were €3485 for septoplasty and €197 for non-surgical management. The cost difference between treatments thus became €3288. Based on a WTP of €20 000 per QALY, septoplasty needed to gain at least 0.16 QALYs to be cost-effective, that is 58 days spent in perfect health. Assuming no difference in QALYs, septoplasty could also be cost-effective by preventing at least 13 sick days, that is 95 hours of work that would otherwise have been lost due to nasal obstruction and accompanying complaints, such as sleep disturbances or (recurrent) infections.

3.4 | Uncertainty

To examine the impact of uncertainty in the model input, we changed the value of one specific input parameter per time and then repeated our analyses.

We started with recalculating outcomes using the upper range limit of medication costs, to be conservative towards septoplasty. The cost difference decreased to €2194 from a healthcare

TABLE 1 Input parameters of the decision-analytic model comparing septoplasty to non-surgical management from a healthcare perspective, including direct healthcare costs

Input parameter	Value	Range	Source
Septoplasty			
Fixed revenue for septoplasty ^a	€2335.00	NA	DBC Information System (DIS) 2017—Dutch Healthcare Authority
Two days of postoperative analgesics	€1.38	€0.24–€2.52	Pharmacy Purchase Price Index 2017—Dutch Healthcare Authority
Seven days of postoperative antibiotics for nasal infection ^b	€7.77	€2.10–€13.44	Pharmacy Purchase Price Index 2017—Dutch Healthcare Authority
Seven days of postoperative antibiotics for septal haematoma ^b	€7.77	€2.10–€13.44	Pharmacy Purchase Price Index 2017—Dutch Healthcare Authority
Fixed revenue for severe adhesions ^{a,c}	€2335.00	NA	DBC Information System (DIS) 2017—Dutch Healthcare Authority
Fixed revenue for nasal septal perforation ^{a,c}	€2335.00	NA	DBC Information System (DIS) 2017—Dutch Healthcare Authority
Fixed revenue for saddle nose deformity ^{a,c}	€2335.00	NA	DBC Information System (DIS) 2017—Dutch Healthcare Authority
Non-surgical management			
Fixed revenue for outpatient consultation	€125.00	NA	DBC Information System (DIS) 2017—Dutch Healthcare Authority
One year of intranasal corticosteroids	€55.32	€21.57–€89.06	Pharmacy Purchase Price Index 2017—Dutch Healthcare Authority

^aFixed revenue includes: outpatient consultation (pre- and postoperative visits); pre-anaesthesia evaluation; surgery (day-case or overnight).

^bEstimated proportion of patients affected: 2%.¹¹

^cEstimated proportion of patients affected: 1%.^{13,14}

TABLE 2 Input parameters of the decision-analytic model comparing septoplasty to non-surgical management from an extended perspective, including direct healthcare costs, travel expenses and productivity losses due to poor health

Input parameter	Value	Range	Source
Average distance to the hospital (one-way)	7.0 km	NA	Dutch guideline for costing research 2017
Average motor vehicle expenses per kilometre	€0.19	NA	Dutch guideline for costing research 2017
Average parking costs per hospital visit	€3.00	NA	Dutch guideline for costing research 2017
Total travel expenses per hospital visit ^a	€5.66	NA	Dutch guideline for costing research 2017
Proportion of employed persons	65.8%	♀: 60.9% ♂: 70.8%	Statistics Netherlands 2016
Average hours worked per week ^b	32.2 h	♀: 26 h ♂: 36 h	Statistics Netherlands 2016
Average costs per hour of lost work	€35.00	NA	Dutch guideline for costing research 2017
Total societal costs per sick day ^c	€148.27	NA	Statistics Netherlands 2016 and Dutch guideline for costing research 2017

^aTotal number of hospital visits per treatment strategy: 5 for uncomplicated septoplasty; 6 for septoplasty with short-term complications; 10 for septoplasty with long-term complications; 3 for non-surgical management.

^bWeighted average based on the contribution of men (61.9%) and women (38.1%) to the total number of hours worked.

^cTotal number of sick days: 7 for uncomplicated septoplasty and septoplasty with short-term complications; 14 for septoplasty with long-term complications.

perspective and €3255 from the extended perspective. However, the required effects or societal savings remained unchanged.

Next, we varied the sick leave taken to recover from septoplasty and repeated our analyses from the extended perspective. If the duration of sick leave decreased from 7 to 5 working days, the cost difference between treatments decreased to €2988. The required QALY-gain became 0.15, that is 55 days spent in perfect health. The number of sick days for nasal obstruction to be prevented by septoplasty dropped to 12, that is 86 hours of work that would otherwise have been lost.

Nonetheless, if the duration of sick leave increased from 7 to 10 working days, the cost difference between treatments increased to

€3737. Accordingly, the required QALY-gain became 0.19, that is 96 days spent in perfect health. The number of sick days to be prevented by septoplasty became 15, that is 107 hours of work otherwise lost because of nasal obstruction.

Furthermore, we subsequently subtracted and added 10% of each fixed revenue as a measure of sensitivity. After subtracting 10%, the cost difference decreased to €1998 from a healthcare perspective and €3059 from an extended perspective, leading to a 0.01 decrease in the required QALY-gain, which became 0.10 and 0.15, respectively. The number of sick days to be prevented by septoplasty decreased to 12 instead of 13. Adding 10% had the opposite effect: the cost difference increased to €2454 from a healthcare

perspective and €3515 from an extended perspective, leading to an increase of 0.01 in the required QALY-gain (for both perspectives) and an increase of 1 day in the number of sick days to be prevented by septoplasty.

Finally, we tested whether the model was sensitive to a reduction in the number of hospital visits required by septoplasty, but this did not change the outcome. Also a reduction in the odds of developing long-term adverse events did not alter the results.

A graphical overview of the sensitivity analyses from an extended perspective is provided in Figure 2.

4 | DISCUSSION

4.1 | Key findings

Our decision-analytic model showed that the cost difference between septoplasty and non-surgical management for nasal obstruction due to a deviated nasal septum was €2227 per patient from a healthcare perspective and €3288 per patient from the extended perspective. Given a WTP of €20 000 per QALY, the minimal QALY-gain required for cost-effectiveness of septoplasty was 0.11 (that is 40 days spent in perfect health) and 0.16 (that is 58 days spent in perfect health), respectively. Septoplasty would also be cost-effective by preventing at least 13 sick days because of nasal obstruction. Regarding the extended perspective, uncertainty in the duration of sick leave for postoperative recovery had considerable impact on the required QALY-gain (ranging from 0.15 to 0.19, that is 55 to 96 days spent in perfect health) and societal savings (ranging from 12 to 15 sick days for nasal obstruction to be prevented by septoplasty).

4.2 | Comparison with the literature

The required QALY-gain was evaluated in the light of benefits from other surgical interventions, see Table 3. We searched the literature for RCTs comparing elective minor surgery to non-surgical strategies in terms of quality-adjusted life-years as measured with the EQ-5D in adults. This type of RCTs was found to be especially common in the field of orthopaedics. We decided to include these in Table 3, as the interventions were elective and minor like septoplasty, and the

QALY as a generic measure of disease burden particularly facilitates a trans-disciplinary view. Large differences in effect were found, ranging from 0.01 to 0.13 QALYs, that is 4 to 48 days spent in perfect health. Overall, the QALY-gain required by septoplasty from a healthcare perspective seems potentially achievable. Our model, however, does not provide insight in the effect of septal surgery in daily practice. To determine the effectiveness of septoplasty, a pragmatic RCT is needed.

4.3 | Strengths and limitations

The major strength of this modelling study is that we have approached the current evidence gap surrounding septoplasty from a new angle. The known difference in costs between septoplasty and non-surgical management was the starting point to determine the beneficial effects required for cost-effectiveness of septoplasty, using a decision-analytic model. Our study shows that decision-analytic modelling can help to determine conditions for cost-effectiveness, even when RCTs are absent. Furthermore, this study is reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).¹⁹ The completed CHEERS checklist is provided in Appendix 1.

Nonetheless, several limitations should also be discussed. First, our input parameter values were not prospectively measured. Instead, the model input was composed of fixed revenues and standard rates, which included all relevant component costs. This was the best available alternative (given the status of current evidence) and an acknowledged substitute to prospective data.⁸

Second, since all costs were based on Dutch healthcare prices, small differences with other countries may exist. It is expected, however, that the overall trend will be similar. Furthermore, the detailed presentation of this model provides the opportunity to repeat our analyses with values specific to other situations and countries. To demonstrate the value of decision-analytic modelling in a clinical setting, we developed a model for septoplasty from a Dutch perspective; but the potential application of this methodology is certainly not limited to a specific field or region.

Third, the time horizon of our model was one year, during which all relevant expenses were expected to have occurred. For modelling

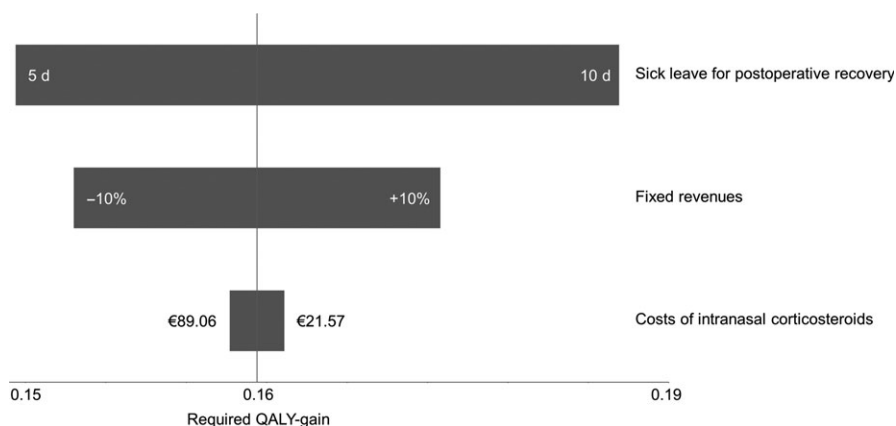


FIGURE 2 Tornado plot of sensitivity analyses from an extended perspective

TABLE 3 QALY-gains from surgical interventions other than septoplasty, in comparison with non-surgical management

First author and year of the study	Condition	Intervention	Comparison	QALY-gain after 1 y
Gauffin (2014) ²⁰	Meniscal symptoms (knee pain, aching, or stiffness)	Knee arthroscopy for resection of any significant meniscal injuries	Structured exercise programme	0.01
Hout (2008) ²¹	Sciatica from lumbar disc herniation	Surgical removal of disc herniation	Information and counselling by the general practitioner	0.04
De Goede (2018) ²²	Asymptomatic to mild inguinal hernia	Surgical inguinal hernia repair	Watchful waiting	0.05
Skou (2015) ²³	Knee osteoarthritis	Total knee arthroplasty	Exercise, education, dietary advice, use of insoles, and pain medication	0.09
Michaels (2006) ²⁴	Uncomplicated varicose veins	Flush ligation of sites of reflux, stripping of the long saphenous vein and multiple phlebectomies, as appropriate	Lifestyle advice	0.13

studies with trial data, a longer horizon may be appropriate. In our case, however, both the magnitude and the duration of septoplasty's effect remain to be assessed. In general, a durable effect is favourable to septoplasty: the longer the effect lasts, the more time septoplasty will have to compensate its extra costs, that is the lower the utility-gain per unit of time needs to be.

4.4 | Clinical implications

As septoplasty is routinely performed in ENT-practice, the total societal costs incurred by this treatment are significant. Consequently, evaluating the cost-effectiveness of septal surgery is of high relevance to many patients, healthcare providers, and policy makers, especially in the current era of value-based healthcare. The methodology presented in this study can be applied to other surgical interventions which, like septoplasty, are commonly performed while high-quality evidence is lacking. Determining the health gain required to compensate the extra costs of surgery helps to inform future trials, whose effectiveness data can be entered in the model when they become available. With data from a pragmatic trial, the cost-effectiveness of septoplasty can also be assessed in a population of patients undergoing a mix of medical and surgical therapy, as often seen in clinical practice. Our results indicate that an RCT on the effectiveness of septoplasty is by no means superfluous: as septal surgery has the potential to be cost-effective, further research is needed to assess the effectiveness of septoplasty in clinical practice.

5 | CONCLUSION

This study shows that a decision-analytic model can be used to determine under which circumstances surgery may become cost-effective, even when RCTs are absent. In comparison with non-surgical management, septoplasty needed to gain 0.11 to 0.16 QALYs (that is 40 to 58 days spent in perfect health) or save 13 sick days for

nasal obstruction to compensate its extra costs. This seems potentially achievable. A future RCT is required to determine septoplasty's effectiveness.

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CONFLICT OF INTEREST

None to declare.

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<https://doi.org/10.1111/coa.13234>

APPENDIX

COMPLETED CHEERS CHECKLIST: ITEMS TO INCLUDE WHEN REPORTING ECONOMIC EVALUATIONS OF HEALTH INTERVENTION

Section/item	Item No	Recommendation	Reported on page No/line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis,” and describe the interventions compared.	P. 1/L. 1,2
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses) and conclusions.	P. 3,4/L. 40-71
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	P. 5,6/L. 78-116 P. 5,6/L. 78-116
Methods			

(Continues)

APPENDIX 1 (Continued)

Section/item	Item No	Recommendation	Reported on page No/line No
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	P. 7/L. 123-129
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	P. 7/L. 131-140
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	P. 8/L. 142-147
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	P. 7/L. 131-140
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	P. 8/L. 149-154
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	NA
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	P. 11,12/L. 232-251
Measurement of effectiveness	11a	<i>Single study-based estimates</i> : Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	NA
	11b	<i>Synthesis-based estimates</i> : Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	NA
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	NA
Estimating resources and costs	13a	<i>Single study-based economic evaluation</i> : Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	NA
	13b	<i>Model-based economic evaluation</i> : Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	P. 8-10/L. 160-211
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	P. 10,11/L. 213-230
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	P. 7/L. 131-140
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	P. 7-12/L. 117-251
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	P. 11,12/L. 232-251
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	P. 13/L. 254-257
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	P. 13/L. 259-273

(Continues)

APPENDIX 1 (Continued)

Section/item	Item No	Recommendation	Reported on page No/line No
Characterising uncertainty	20a	<i>Single study-based economic evaluation:</i> Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	NA
	20b	<i>Model-based economic evaluation:</i> Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	P. 13,14/L. 275-292
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	NA
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	P. 15-17/L. 293-364
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct and reporting of the analysis. Describe other non-monetary sources of support.	P. 2/L. 34-39
Conflict of interests	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	P. 18/L. 365-367

For consistency, the CHEERS statement checklist format is based on the format of the CONSORT statement checklist.