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Patient´s age and availability of medical services affect the rate of endoscopic sinus surgery: a nationwide study on regional differences

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Competing interest statement

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Transparency declaration

The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Running title (50) max 50 characters

Endoscopic sinus surgery rate: a nationwide study

Contributorship statement:

All authors participated in the planning and conception of the study and the analytical strategy. HR, MA, KM, and IK performed the data management, analyses, tables and figures. HR, ST-S, and MH wrote the manuscript. All authors critically reviewed the manuscript.

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Abstract

290 words

Objectives: Endoscopic sinus surgery (ESS) is a common operation typically performed due to chronic rhinosinusitis (CRS). There are limited data on the nationwide ESS rate and factors contributing to its regional variation. The aim was to evaluate factors causing variation of ESS rate.

Design: Cross-sectional nationwide observational study.

Setting: Hospital discharge data collected by the National Institute for Health and Welfare in Finland.

Population: Nationwide Finnish population aged 15 years or over.

Main outcome measures: ESS rate per 1000 inhabitants between 2013 and 2015 in all 21 hospital districts and independent factors for multilevel model analyses.

Methods: We used the Finnish register data of all CRS patients who underwent ESS in 2013-2015. Patients aged under 15 years and those with ESS due to neoplasia were excluded. The age and gender standardised ESS rates were calculated, and multilevel Poisson regression models were used to evaluate variation in ESS in the 21 hospital districts. The likelihood ratio test was applied to assess the statistical significance of random components in the models.

Results: The nationwide annual rate of ESS is 0.71 per 1000 people in Finland. There is a fourfold difference between the districts with the highest and lowest rates. Compared with males, females undergo ESS significantly more frequently (57% of the procedures), more often due to CRS without nasal polyps, and at a younger age. Multilevel analyses showed that lower age and availability of medical services were independently associated with higher ESS rates.

Conclusions: This study confirms marked regional variation in the ESS rate, explained only in part by patients' age and differing availability of medical services. To analyse the cost-effectiveness of ESS across different CRS phenotypes or to compare quality registers on ESS properly, more research on regional variation is needed.

Strengths and limitations of this study

- Endoscopic sinus surgery (ESS) rate due to chronic rhinosinusitis was 0.71 per 1000 inhabitants aged over 15 years.
- A high regional variation was present in the likelihood of undergoing ESS.
- The probability of ESS was independently associated with patient´s age and differences in availability of medical services.
- Strengths of this study comprise a population-based nationwide design.
- A limitation is that no data on the actual need for sinus surgery are provided and that our data did not include information on patient's background factors.

Key Words: endoscopy, chronic rhinosinusitis, sinusitis, surgery, regional variation

Abbreviations:

CRS	Chronic rhinosinusitis
CRSwNP	Chronic rhinosinusitis with nasal polyps
CRSsNP	Chronic rhinosinusitis without nasal polyps
ENT	Ear nose throat
ESS	Endoscopic sinus surgery

What this paper adds

Endoscopic sinus surgery (ESS) is considered for patients with chronic rhinosinusitis (CRS) when disease control is not fully achieved by medical therapy. In this nationwide survey in Finland, we showed that the ESS rate due to CRS was 0.71 per 1000 inhabitants aged over 15 years. After adjusting for age and gender, a high regional variation was present in the likelihood of undergoing ESS. This is in line with studies conducted in the United States. We evaluated the factors behind the differences in ESS rates across the hospital districts. Multilevel analyses revealed that the probability of ESS was independently associated with patient´s age and differences in availability of medical services. These factors were, however, unable to fully explain the regional variation. We anticipate that patients operated on for ESS in different regions do not represent an equal severity of CRS. Further research is needed to show the cost-effectiveness of ESS in different CRS phenotypes and to implement quality control across operating institutions.

Introduction

Chronic rhinosinusitis (CRS) is a heterogeneous group of inflammatory diseases of the nose and paranasal sinuses, lasting for at least 12 weeks (1). It is one of the most common chronic adult health problems in the Western world. A European study estimated the prevalence of CRS to be 11%, although in studies with physician-led diagnosis a prevalence of 6–7% has been observed (2-5). CRS has an independent and severe impact on the quality of life. The impairment is comparable with other chronic diseases such as asthma, chronic obstructive pulmonary disease (COPD), and diabetes (1). The economic burden caused by CRS is significant and is related largely to loss of productivity, increased doctor's appointments, and medical expenses. In the United States, the CRS-related health care costs are estimated to be $6.9 to $9.9 billion dollars per year (6).

The predisposing factors of CRS include genetic, anatomical, and airborne factors in addition to host immunity (1,7). CRS is associated with airway allergy, asthma, and COPD (1,8). CRS with (CRSwNP) and without (CRSsNP) nasal polyps are considered to be phenotypes of CRS, with presumably different aetiologies and pathomechanisms (1). CRSwNP affects between 1% and 4% of the general population (1).

Endoscopic sinus surgery (ESS) has been the most common operative approach for CRS patients with failed maximal medical treatments (1). ESS is a common procedure, with an estimated 250 000 cases annually in the United States (9-11). ESS creates a considerable financial burden. One study estimated

the total cost of ESS to the UK National Health Service (NHS) to be in excess of £30 million per year (3).

Three non-population-based studies within the United States have shown ESS rates to vary according to geographic area or ethnicity. An observational cohort study performed on the MarketScan Commercial Claim and Encounters database yielded a mean ESS rate of 0.94 per 1000 employed, working-aged people in the United States (9). Moreover, the study showed four- to fivefold differences between the states with the highest and lowest rates. Venkatraman et al. investigated a twenty-percent sample of Medicare beneficiaries aged 65 to 99 years. Their study showed an increase in ESS rates for the period 1998-2006 (12). The third study based on the MarketScan Medicaid database in the United States reported overall sinus surgery rates per 1000 people in the Medicaid population to range from 0.36 to 0.40 in 2009-2013 (13). The ESS rate was significantly lower for African Americans than for persons of Hispanic origin. These three studies are limited by the fact that they were not nationwide; the study groups were composed of only a partial cohort of the population (9,12,13).

The reasons behind the detected geographic variation in ESS rates are not fully understood. This might reflect a number of factors, including both underutilization and overutilization of surgery in the treatment of CRS, a lack of clinically unambiguous applicable guidelines, and a lack of evidence in well-constructed randomised controlled trials (RCTs) (3). To our knowledge, no previous exhaustive nationwide studies have been conducted on ESS rates and the factors affecting the likelihood of the surgical procedure. This nationwide survey aimed to examine the variation in ESS rates across Finland and putative factors explaining the difference.

Materials and methods

Patients

Before beginning the study, ethical consent was sought from the Research Ethics Committee of the Finnish National Institute for Health and Welfare (approval number 9/2016/§746), and thereafter, permission to use hospital discharge register data for the patient population was also sought from the Institute. The data of all patients who had undergone ESS by opening the ostiomeatal complex (DMB20) and/or opening the ethmoid sinuses (DNB20) in Finland in 2013-2015 were extracted from the hospital discharge register maintained by the Institute for Health and Welfare. Patients aged under 15 years and those operated on due to neoplastic lesions were excluded. Age was classified into 5-year age brackets. Diagnosis was determined as CRS with nasal polyps (CRSwNP) if any of the main or secondary diagnosis codes were J33. Further, if any of the main or secondary diagnosis codes was J32 or the main diagnosis code was J01 the diagnosis was determined as CRS without nasal polyps (CRSsNP). The rest of the procedures were classified into the group "Other diagnoses". The collected data included information on the ESS procedure, code of diagnosis (IDC10), gender, age, service provider, and hospital district in which the patient was living at the time of ESS.

Hospital districts

Finland is divided into 21 hospital districts. The public hospitals within the district are owned by the federations of municipalities. In Finland, public medical care covers the vast majority (92% in 2014) of all surgical interventions in different medical fields. Most patients use the closest public hospital in their home hospital district, although they are free to choose any public or private hospital in the country. Both public and private health care providers report all hospitalisations and surgical procedures to the same nationwide hospital discharge database.

National registers

National population data in hospital districts were tabulated by gender and age in 5-year age brackets from Statistics Finland's website (http://www.stat.fi/til/vaerak/index_en.html) for the years 2013-2015. The number of working-aged physicians and ENT doctors was retrieved from the website of the Finnish Medical Association (https://www.laakariliitto.fi/tutkimus/laakarityovoima).

Statistics

The data were tabulated by hospital district according to patients' residence. To reduce random variability, all analyses were performed for the whole study period from 2013 to 2015, but results presented as annual averages. Due to the small number of cases, the smallest district of Åland islands (24 000 inhabitants aged over 15 years) was included only in the total number of ESS, but excluded from the multilevel models.

We calculated age- and gender-adjusted rates of ESS in hospital districts using a direct standardisation method with the population structure of Finland in 2013-2015 as the standard population. Two-level Poisson regression models adjusted for age group with hospital district as random level and logarithm of population at risk as an offset variable were conducted to model the regional variation in ESS. Next, factors indicating proportion of operations performed by private ENT service providers, proportions of CRSwNP and CRSsNP, and proportion of operations performed outside the hospital district of patients' residence in each stratum, as well as the density of physicians in hospital districts were added to the models. Models were estimated separately for men and women, as descriptive analyses revealed differing ESS profiles between them. Multilevel models were applied to capture the hierarchical nature of the data and effects of explaining factors were reported as risk ratios. Wald test was applied to assess the statistical significance of the variance term denoting variation at the hospital district level. Pearson's Chi-Square test was used to test the distribution of diagnoses in hospital districts. A 95% confidence level was used to indicate the statistical significance. Statistical analyses were performed by using SPSS version 22 (Chicago, IL, USA) and SAS 9.3 (SAS Institute Inc., Cary, NC, USA) software.

Results

ESS rate and its age and gender-based variation

In 2013-2015, the total number of ESS was 9640. Three hundred and seven patients underwent ESS twice or three times during this period. The mean annual number of ESS for patients aged over 15 years was 3181, and the nationwide mean rate was 0.71 procedures per 1000 inhabitants. Women were operated on more often than men (0.79/1000 and 0.62/1000; proportions operated 57.4% and 42.6% respectively). The mean age at the time of ESS was 44.0 (SD 15.9) years in females and 46.1 (SD 15.8) years in males (Figure 1). There was no significant difference in the age distribution of ESS patients between the hospital districts. The ESS rate of working-aged CRS patients (aged 26-65 years) was 0.86/1000 working-aged individuals. The ESS rate of retirement-aged CRS patients (> 65 years) was 0.35/1000 retirement-aged individuals. Of all ESS procedures, 87% were performed by community-run public health care providers and 96% in the patient's home district.

Diagnosis of patients undergoing ESS

Seventy-two percent of patients (62% of males, 80% of females) who underwent ESS were diagnosed as having CRSsNP (Table 1). Twenty percent of patients (30% of males, 13% of females) were diagnosed as having CRSwNP (Table 1). Other diagnoses (7%) included paranasal cysts or mucoceles, hypertrophy of turbinates, and miscellaneous reasons (Table 1).

Table 1

Diagnosis at time of surgery. Annual average of patients (> 15 years) who underwent ESS during 2013-2015.

		Men	Women	Total
Number (annual)		1355	1826	3181
Diagnosis, %				
	Chronic rhinosinusitis without nasal polyps	62	80	72
	Chronic rhinosinusitis with nasal polyps	30	13	20
	Other*	7	7	7

* Cysts, mucoceles, hypertrophy or air cells of turbinates

Regional variation in ESS rate

The mean ESS rates per 1000 inhabitants aged over 15 years in the 21 districts are shown in the heatmap (Figure 2). The regional values ranged between 1.16 and 0.26 procedures/1000 inhabitants, denoting a fourfold difference. The proportion of patients operated on for CRSsNP and CRSwNP varied significantly between districts ($p<0.001$).

Multilevel models of factors affecting the variation in ESS rate

The multilevel models were created in order to study the level of variation in the probability of ESS between the hospital districts, to examine whether certain factors had an independent effect on ESS, and to assess whether the variation found between hospital districts could be explained by these factors.

In women, after adjusting for age there was significant variation at the hospital district level ($p<0.001$). Of independent factors, lower age ($p<0.001$) and high density of physicians ($p=0.026$) were significantly associated with a high ESS rate (Table 2). Women aged 40-44 years were operated on 4.76 times more frequently than women aged over 70 years. After adjusting for independent factors, the regional variation in ESS rates remained significant ($p<0.001$).

In men, we found significant variation at the hospital district level after adjusting for age ($p<0.001$). When independent factors were added to the model, low age ($p<0.001$) and the proportion of ESS performed by private service providers ($p=0.0001$) were associated with high operation rates in the district, whereas ESS performed outside the patient´s home district ($p=0.004$) was significantly associated with a low rate (Table 2). Again, after adjustment for independent factors, the regional variation in ESS remained significant ($p<0.001$).

Table 2

Factors affecting ESS rates in men and women in an adjusted Poisson regression model.

	Men		Women	
Variable	Null model	Adjusted model	Null model	Adjusted model
Age (years)	RR (95% CI)	RR (95% CI)	RR (95% CI)	RR (95% CI)
15-24	1.29 (1.11, 1.51)	1.16 (0.96, 1.39)	2.72 (2.39, 3.11)	2.71 (2.31, 3.18)
25-34	1.79 (1.55, 2.06)	1.68 (1.45, 1.95)	3.87 (3.41, 4.39)	3.87 (3.38, 4.42)
35-39	2.59 (2.23, 3.02)	2.40 (2.05, 2.81)	4.65 (4.06, 5.32)	4.63 (4.00, 5.36)
40-44	2.57 (2.20, 3.00)	2.48 (2.12, 2.90)	4.80 (4.19, 5.50)	4.76 (4.13, 5.49)
45-49	2.49 (2.14, 2.90)	2.35 (2.01, 2.75)	3.77 (3.28, 4.34)	3.73 (3.24, 4.29)
50-54	2.40 (2.06, 2.80)	2.24 (1.91, 2.63)	3.60 (3.13, 4.14)	3.56 (3.09, 4.10)
55-59	2.23 (1.90, 2.60)	2.06 (1.75, 2.42)	3.72 (3.24, 4.27)	3.69 (3.21, 4.25)
60-64	1.99 (1.69, 2.33)	1.88 (1.59, 2.23)	2.48 (2.14, 2.88)	2.46 (2.11, 2.86)
65-69	1.74 (1.48, 2.06)	1.72 (1.46, 2.04)	1.92 (1.63, 2.25)	1.90 (1.62, 2.23)
70+	1.00	1.00	1.00	1.00
% private ORL		2.24 (1.49, 3.38)		1.22 (0.74, 2.01)
% CRSsNP		0.73 (0.42, 1.30)		1.00 (0.56, 1.76)
% CRSwNP		0.96 (0.56, 1.66)		1.27 (0.67, 2.42)
% outside HD		0.49 (0.30, 0.81)		0.89 (0.49, 1.64)
Physician density		1.11 (0.99, 1.25)		1.16 (1.02, 1.33)
HD (Var(SE))	0.1299(0.0464)	0.0751(0.0287)	0.1303(0.0463)	0.1012(0.0381)

CRSsNP = chronic rhinosinusitis without nasal polyps, CRSwNP = chronic rhinosinusitis with nasal polyps, HD = home district, ORL = otorhinolaryngologist operation, RR = risk ratio,

The proportion of patients operated on due to CRSwNP varied from one district to another ($p<0.001$). The range was from 10% to 33%. In multivariate multilevel models, the diagnosis did not explain the risk on the operation rate.

Discussion

To reduce inefficient or unwarranted practice patterns and to improve the overall performance of the health system, it is essential to define the variations in health care and the underlying reasons (9,14). In evaluating practice variation, clinical care can be grouped into three categories with different implications for patients, clinicians, and policy makers: i) effective care (benefits far outweigh the risks); ii) preference-sensitive care (more than one generally accepted treatment option); iii) supply-sensitive care (activities are related to the capacity of the local health care system) (14,15). Variation in health care utilisation has been viewed as a major threat to the quality and effectiveness of treatment because it may represent potential misuse, overuse, or underuse of scarce health care resources (9,16). Common reasons for surgical variation include differences in patient and doctor preferences, availability of services, and lack of well-defined surgical indications (9,17). Furthermore, surgeons' beliefs about the procedure and revenue logic may have an impact on the frequency of interventions.

Comparison with other studies

In Finland, the nationwide mean annual rate of endoscopic sinus surgery (ESS) among adult patients was 0.71/1000. The rate of working-aged people (0.86/1000) is fairly close to that reported among the employed cohort in the United States (0.94/1000) (9). We demonstrate here that elderly people in

Finland are operated on considerably less frequently (0.35/1000) than their peers in the United States (0.92/1000) (12). In the present study, there was marked variability in ESS rates between the 21 hospital districts after standardisation of age and gender. We found a fourfold difference between the highest and the lowest regional operation rate. This is in line with the findings in the United States (9,12) where up to fivefold differences between the states were observed. The present nationwide study of Finland shows that regional differences exist also in a country with a universal nationwide health care system where the procedures are performed mostly in publicly financed institutions.

ESS rate variation between genders

We demonstrated that ESS is performed 1.3 times more frequently on women than on men. This is in accord with the expected population-based male-to-female ratio of CRS. CRS is estimated to be 1.1 to 2 times more common in women than in men (4,19). An adult suffers common colds approximately 2–4 times annually (20,21). The infection rates in females aged between 20 and 34 years are higher probably due to a greater occupational risk to be exposed to infections relative to men (20,21). This might, in part, enhance the development of CRS in females. In the present study, the mean age of operated females was lower than that of males. This might be due to differences in host-environment interactions and pathomechanisms of CRS between females and males (22). It is also possible that women use more general health care, which might be reflected in the gender-based difference in ESS rate (23).

Effect of age on ESS rate

In this study, the ESS rate of working-aged people (26-65 years) was 2.5 times higher than that of retirement-aged people. Moreover, the multilevel models showed that the patient´s age had an independent effect on ESS rate across Finland. CRS patients who are retired might have reduced irritants and less stress in their living environment, and also more time for self-care. This might improve CRS control and reduce the need for ESS in the elderly. One might expect that sinusitis prone patients have already undergone ESS earlier in their life which makes the need of ESS low at the higher age. Also, multiple diseases and medications might reduce the likelihood of them being operated on.

Comparison of patients with and without nasal polyps

It is difficult to evaluate the population-based prevalence of CRSwNP and CRSsNP due to limitations of diagnostic methods in primary care. In the European population, the prevalence of CRSwNP has been estimated at 1-4% and CRSsNP about 10% (1,26). In the present study, 20% of ESS was performed on patients with CRSwNP. This is slightly higher than the ratio of CRSwNP and CRSsNP phenotypes in the literature cited above. It is consistent with the greater need for surgery with nasal polyposis.

ESS due to CRSwNP was performed nearly three times more frequently on males than on females. In a retrospective, cross-sectional American study, data on CRS patients and their non-CRS controls were analysed (22). The authors found that the proportion of females with CRSwNP was 38% and that these women had more severe disease than men (22). In our study, 27% of the operated CRSwNP patients were female. This figure is in line with the previous study.

Potential factors behind variation in ESS

The multilevel models showed that in females, young age and high density of physicians were significantly associated with a high ESS probability. In males, independent factors associated with a high probability of ESS were young age and a high proportion of ESS performed by private ENT specialists. ESS performed out of the patient´s home district was associated with a low operation probability. Excluding the age factor, these findings reflect the impact of availability on operation rates. Higher ESS rates were detected also in hospital districts with a high density of ENT specialists as well as those with medical faculties. Yet, due to multicollinearity, these factors could not be included in the multilevel Poisson model. Taken together, our findings suggest that, in addition to the population's age structure, the availability of medical services has an independent effect on ESS probability.

Putative other reasons for regional variation in ESS rate

In both females and males, after adjusting for age and factors related to the availability of medical services, a clear regional variation remained in ESS rates. The indications for ESS are usually relative and are based on ENT specialists' and patients' opinions after discussion of potential risks and benefits. Thus, it is evident that a district´s poor availability of ENT services and long distances decrease the likelihood of CRS patients undergoing ESS. In industrialized countries, ESS is usually a preference-sensitive care. This indicates that more than one generally accepted treatment option, such as elective surgery, is available. Thus, the operation rate depends on informed patient choice and the treatment strategies available; the rate can vary extensively because of differences in professional opinions (14,15). Thus, despite equal education of medical doctors and similar nationwide health care systems, regional and/or personal variation may be present in patients' views and in physicians' or ENT surgeons' opinions and interpretations of ESS indications (14). Future research should focus more on evidence-based treatments for CRS and indications of ESS in different disease course and phenotypes.

Strengths and limitations of the study

Strengths of this study comprise a population-based nationwide design and reliable register-based data, including information on all surgical procedures performed in Finland (27). Meticulously collected data on diagnosis, operating institution, and patient´s municipality of residence as well as data on the density of physicians and ENT specialists are readily available. We focused only on the population

aged 15 years or over who had undergone ESS due to inflammation and/or recurrent infection in order to decrease the bias caused by different disease types.

The study includes some limitations that must also be addressed. No data on the actual need for sinus surgery are provided, as we examined the numbers of operated patients instead of the CRS patient population. Further, our data did not include information on patient's socioeconomic status, general health, subjective nasal symptoms, or x-ray findings. Despite relatively small differences in socioeconomic or ethnic status of the Finnish population, some regional dissimilarities might exist, which could affect the probability of being operated on. Due to the limited register-based data these factors could not be added to the multilevel models.

Conclusions

This nationwide study shows that high regional variation in ESS rate exists also in a country where the vast majority of procedures are performed in a public health care system. Patient´s age and the availability of medical services are associated with ESS probability. Nevertheless, some unexplained factors appear to affect the regional variation in ESS. According to our results, we anticipate that in different geographic areas patients receiving ESS do not represent an equal severity or clinical course

of CRS. Therefore, further research is needed to show the cost-effectiveness of ESS across different CRS phenotypes and to ensure unbiased quality control among the operating institutions.

Data sharing statement

No additional data available.

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Figure legends

Figure 1

Age distribution of endoscopic sinus surgery (ESS) in Finland. Included are patients operated on during 2013-2015, presented as annual averages.

Figure 2

Age- and gender-standardised rate of endoscopic sinus surgery (ESS) by hospital districts in Finland (mean of the years 2013-2015). Darker colours represent higher operation rates. The circle indicates the site of the central hospital and the size represents the number of inhabitants within the district. Districts with white circles have a medical faculty.

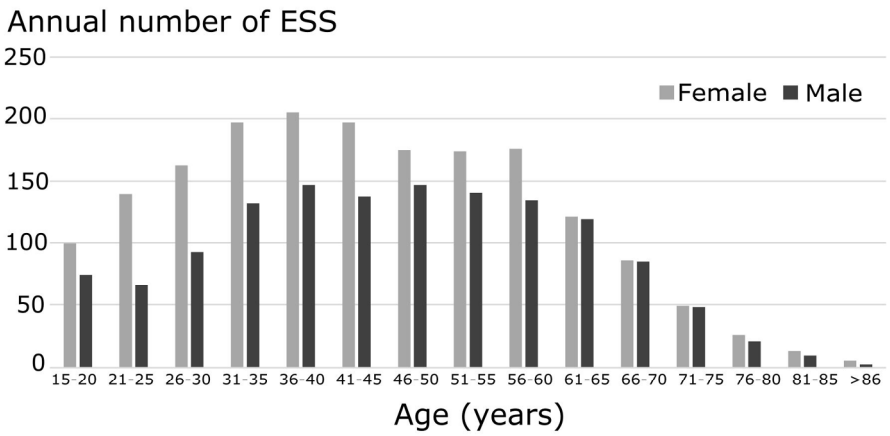

Figure 1
Age distribution of endoscopic sinus surgery (ESS) in Finland. Included are patients operated on during 2013-2015, presented as annual averages.

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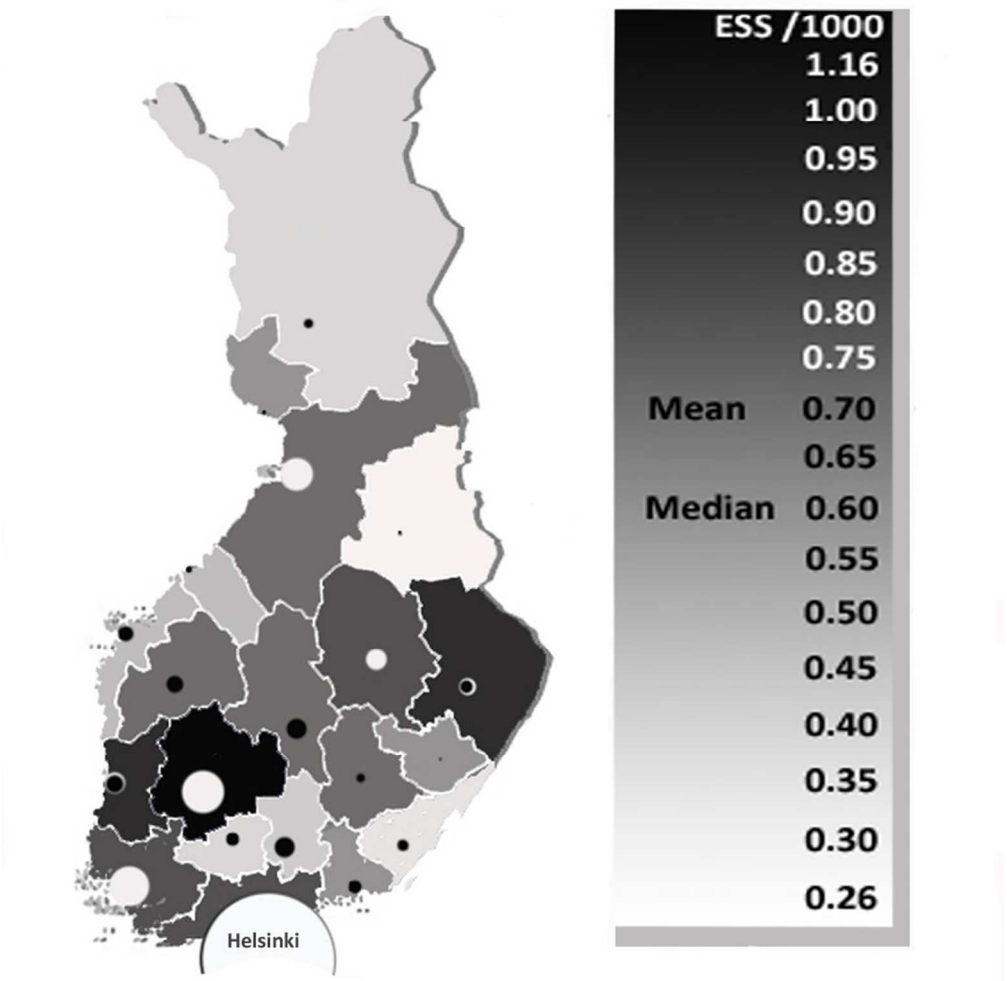

Figure 2
Age- and gender-standardised rate of endoscopic sinus surgery (ESS) by hospital districts in Finland (mean of the years 2013-2015). Darker colours represent higher operation rates. The circle indicates the site of the central hospital and the size represents the number of inhabitants within the district. Districts with white circles have a medical faculty.

95x110mm (300 x 300 DPI)

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Reporting checklist

Title and abstract

1. Title Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety,effectiveness, patient-centredness, timeliness, cost, efficiency and equity of healthcare). p.1

2. Abstract

a. Provide adequate information to aid in searching and indexing. p.5

b. Summarise all key information from various sections of the text using the abstract format of the intended
publication or a structured summary such as: background, local problem, methods, interventions, results,
conclusions. p.5-6

Introduction

3. Problem description Nature and significance of the local problem. p. 10-11

4. Available knowledge Summary of what is currently known about the problem, including relevant previous studies. p.10-11

5. Rationale Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work p. 11

6. Specific aims Purpose of the project and of this report. p. 11

Methods

7. Context

Contextual elements considered important at the outset of introducing the intervention(s). p. 12-13

8. Intervention(s)

a. Description of the intervention(s) in sufficient detail that others could reproduce it. p. 12-14

b. Specifics of the team involved in the work. p. 12-14

9. Study of the intervention(s)

a. Approach chosen for assessing the impact of the intervention(s). p. 12-14

b. Approach used to establish whether the observed outcomes were due to the intervention(s). p. 12-14

10. Measures

a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing
them, their operational definitions and their validity and reliability. p. 13-14

b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. p. 13-14

c. Methods employed for assessing completeness and accuracy of data. p. 12-14
11. Analysis
a. Qualitative and quantitative methods used to draw inferences from the data. p. 13-14.
b. Methods for understanding variation within the data, including the effects of time as a variable. p. 13-14
12. Ethical considerations Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest. p. 12

Results

13. Results
a. Initial steps of the intervention(s) and their evolution over time (eg, time-line diagram, flow chart or table),
including modifications made to the intervention during the project.p. 15
b. Details of the process measures and outcomes. p. 16-18
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e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the
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f. Details about missing data. p.13 and p. 15

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a. Key findings, including relevance to the rationale and specific aims. p. 19-23

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b. Comparison of results with findings from other publications. p. 19-20

c. Impact of the project on people and systems. p. 19-24

d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. p. 19-24

e. Costs and strategic trade-offs, including opportunity costs. p. 19-24

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c. Efforts made to minimise and adjust for limitations. p. 24

17. Conclusions

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b. Sustainability. p. 24

c. Potential for spread to other contexts. p. 24

d. Implications for practice and for further study in the field. p. 24

e. Suggested next steps. p. 24

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OPEN ACCESS

SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): revised publication guidelines from a detailed consensus process

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ABSTRACT

Since the publication of Standards for QUality Improvement Reporting Excellence (SQUIRE 1.0) guidelines in 2008, the science of the field has advanced considerably. In this manuscript, we describe the development of SQUIRE 2.0 and its key components. We undertook the revision between 2012 and 2015 using (1) semistructured interviews and focus groups to evaluate SQUIRE 1.0 plus feedback from an international steering group, (2) two face-to-face consensus meetings to develop interim drafts and (3) pilot testing with authors and a public comment period. SQUIRE 2.0 emphasises the reporting of three key components of systematic efforts to improve the quality, value and safety of healthcare: the use of formal and informal theory in planning, implementing and evaluating improvement work; the context in which the work is done and the study of the intervention(s). SQUIRE 2.0 is intended for reporting the range of methods used to improve healthcare, recognising that they can be complex and multidimensional. It provides common ground to share these discoveries in the scholarly literature (http://www.squire-statement.org).

In 2005, draft publication guidelines for quality improvement reporting debuted in *Quality and Safety in Health Care*.[1] At that time, publications of scholarly work about healthcare improvement were often confusing and of limited value. Leaders in the field were working to consolidate the evidence for a science of improvement[2 3] and without guidance on how to write their findings, authors struggled to report their improvement work in a reliable and consistent way.[4 5] These factors influenced the initial publication in 2008 of the Standards for QUality Improvement Reporting Excellence (SQUIRE),[6] which we will refer to as SQUIRE 1.0. The guidelines were developed in an effort to reduce uncertainty about the information deemed to be important in scholarly reports of healthcare improvement and to increase the completeness, precision and transparency of those reports.

In the intervening years, the reach of systematic efforts to improve the quality, safety and value of healthcare has grown. Health professionals' education worldwide now includes improvement as a standard competency.[7–11] The science of the field also continues to advance through guidance on applying formal and informal theory in the development and interpretation of improvement programmes;[12] stronger ways to identify, assess and describe context;[13–16] recommendations for clearer, more complete descriptions of interventions[17] and development of initial guidance on how to study an intervention.[18]

In this setting, we have undertaken a revision of SQUIRE 1.0. When we began, it rapidly became apparent that a wide variety of approaches had developed for improving healthcare, ranging from formative to experimental to evaluative. Rather than limiting the revised guidelines to only a few of these, we fashioned them to be applicable across the many methods that are used. We aimed to reflect the dynamic nature of the field and support its further development. This article describes the development and content of SQUIRE 2.0 (table 1).

SQUIRE 2.0 DEVELOPMENTAL PATH

We developed SQUIRE 2.0 between 2012 and 2015 in three overlapping phases: (1) evaluation of the initial

Table 1 Revised Standards for QUality Improvement Reporting Excellence (SQUIRE 2.0) publication guidelines

Text section and item name	Section or item description
Notes to authors	▶ The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare. ▶ The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). ▶ A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. ▶ Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. ▶ The SQUIRE glossary contains definitions of many of the key words in SQUIRE. ▶ The explanation and elaboration document provides specific examples of well-written SQUIRE items and an in-depth explanation of each item. ▶ Please cite SQUIRE when it is used to write a manuscript.
Title and abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centredness, timeliness, cost, efficiency and equity of healthcare).
2. Abstract	a. Provide adequate information to aid in searching and indexing. b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions.
Introduction	*Why did you start?*
3. Problem description	Nature and significance of the local problem.
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies.
5. Rationale	Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work
6. Specific aims	Purpose of the project and of this report.
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s).
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it. b. Specifics of the team involved in the work.
9. Study of the intervention(s)	a. Approach chosen for assessing the impact of the intervention(s). b. Approach used to establish whether the observed outcomes were due to the intervention(s).
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions and their validity and reliability. b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost. c. Methods employed for assessing completeness and accuracy of data.
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data. b. Methods for understanding variation within the data, including the effects of time as a variable.
12. Ethical considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest.
Results	*What did you find?*
13. Results	a. Initial steps of the intervention(s) and their evolution over time (eg, time-line diagram, flow chart or table), including modifications made to the intervention during the project. b. Details of the process measures and outcomes. c. Contextual elements that interacted with the intervention(s). d. Observed associations between outcomes, interventions and relevant contextual elements. e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s). f. Details about missing data.

Continued

Table 1 Continued

Text section and item name	Section or item description
Discussion	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims. b. Particular strengths of the project.
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes. b. Comparison of results with findings from other publications. c. Impact of the project on people and systems. d. Reasons for any differences between observed and anticipated outcomes, including the influence of context. e. Costs and strategic trade-offs, including opportunity costs.
16. Limitations	a. Limits to the generalisability of the work. b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis. c. Efforts made to minimise and adjust for limitations.
17. Conclusions	a. Usefulness of the work. b. Sustainability. c. Potential for spread to other contexts. d. Implications for practice and for further study in the field. e. Suggested next steps.
Other information	
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting.

SQUIRE guidelines, (2) early revisions and (3) pilot testing with late revisions.

We began the evaluation of SQUIRE 1.0 by collecting data to assess its clarity and usability.[19] Semistructured interviews and focus groups with 29 end users of SQUIRE 1.0 revealed that many found SQUIRE 1.0 helpful in planning and doing improvement work, but less so in the writing process. This issue was especially apparent in the efforts to write about the cyclic, iterative process that often occurs with improvement interventions. SQUIRE 1.0 was seen by many as unnecessarily complex with too much redundancy and lacking a clear distinction between 'doing improvement' and 'studying the improvement'. A recent independent study and editorial also documented and addressed some of these challenges.[20 21]

In the second phase, we convened an international advisory group of 18 experts that included editors, authors, researchers and improvement professionals. This group met through three conference calls, reviewed SQUIRE 1.0 and the results of the end-user evaluation, and provided detailed feedback on successive revisions. This advisory group and additional participants attended two consensus conferences in 2013 and 2014 where they engaged in intensive analysis and made recommendations that further guided the revision process.

In the third phase, 44 authors used an interim draft version of the updated SQUIRE guidelines to write sections of a manuscript. Each author then provided comments on the utility and understandability of the draft guidelines, and in their submitted section, identified the portions of their writing samples that fulfilled the items of that section.[22] We also obtained detailed feedback about this draft version through semistructured interviews with 11 biomedical journal editors. The data from this phase revealed areas needing further clarification, and which specific items were prone to misinterpretation. Finally, a penultimate draft was emailed to over 450 individuals around the world, including the advisory group, consensus meeting participants, authors, reviewers, editors, faculty in fellowship programmes and trainees. This version was also posted on the SQUIRE website with an invitation for public feedback. We used the information from this process to write SQUIRE 2.0 (table 1).

SQUIRE 2.0

Many publication guidelines, including CONSORT (randomised trials), STROBE (observational studies) and PRISMA (systematic reviews) focus on a particular study methodology (http://www.equator-network.org). In contrast, SQUIRE 2.0 is designed to apply across the many approaches used for systematically improving the quality, safety and value of healthcare. Methods range from iterative changes using plan–do–study–act cycles in single settings to retrospective analyses of large-scale programmes to multisite randomised trials. We encourage authors to apply other

publication guidelines—particularly those that focus on specific study methods—along with SQUIRE, as appropriate. Authors should carefully consider the relevance of each SQUIRE item, but recognise that it is sometimes not necessary, nor even possible, to include each item in a particular manuscript.

SQUIRE 2.0 retains the IMRaD (introduction, methods, results and discussion) structure.[23] Although used primarily for reporting research within a spectrum of study designs, this structure expresses the underlying logic of most systematic investigations, and is familiar to authors, editors, reviewers and readers. We continue to use A. Bradford Hill's four fundamental questions for writing: Why did you start? What did you do? What did you find? What does it mean?[24] In our evaluation of SQUIRE 1.0, novice authors found these questions to be straightforward, clear and useful.

SQUIRE 2.0 contains 18 items, but omits the multiple subitems that were a source of confusion for SQUIRE 1.0 users.[19] A range of approaches exists for improving healthcare, and SQUIRE may be adapted for reporting any of these. As stated above, authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE item in a particular manuscript. In addition, authors need not use items in the order in which they appear. Major changes between SQUIRE 1.0 and 2.0 are concentrated in four areas: (1) terminology, (2) theory, (3) context and (4) studying the intervention(s).

Terminology

The elaborate detail in SQUIRE 1.0 was seen by users as both a blessing and a curse[19]: helpful in designing and executing quality improvement work, but less useful in the writing process. The level of detail sometimes led to confusion about what to include or not include in a manuscript. Consequently, we made the items in SQUIRE 2.0 shorter and more direct.

A major challenge in the reporting of systematic efforts to improve healthcare is the multiplicity of terms used to describe the work, which is challenging for novices and experts alike. Improvement work draws on the epistemology of a variety of fields, and depending on one's field of study, the same words can carry different connotations, a particularly undesirable state of affairs. Terms such as 'quality improvement', 'implementation science' and 'improvement science' refer to approaches that have many similarities, but can also connote important (and often-debated) differences. Other terms such as 'healthcare delivery science', 'patient safety' and even simply 'improvement' are also subject to surprising variation in interpretation. To address this problem in semantics, we created a glossary of terms used in SQUIRE 2.0 (box 1). The glossary provides the intended meaning of certain key terms as we have used them in SQUIRE 2.0 (table 1). These definitions may be helpful in other endeavours, but are not necessarily intended to be adopted for use in other contexts. Overall, we sought terms and definitions that would be useful to the largest possible audience. For example, we chose 'intervention(s)' to refer to the changes that are made. We decided not to use the word 'improvement' in the individual items (although it remains in the SQUIRE acronym) to encourage authors to report efforts that did not lead to changes for the better. Reporting well done, negative studies is vital for the learning in this discipline.

Theory

SQUIRE 2.0 includes a new item titled 'rationale'. Biomedical and clinical research is driven by iterative cycles of theory building and hypothesis testing. Healthcare improvement work has not consistently based the planning, design and execution of its programmes solidly in theory, to the detriment of the work. For this reason, SQUIRE 2.0 explicitly includes an item devoted to theory, although we chose to use the broader and less technical label 'rationale' to encourage authors to be explicit in reporting formal and informal theories, models, concepts or even hunches as to why they expected a particular intervention to work in a particular context. A plain language interpretation of 'rationale' might be, 'why did you think this would work?' A recent narrative review of the nature of theory and its use in improvement describes the many types and applications of theory, and considers pitfalls in using and not using theory.[12]

The addition of the 'rationale' item is intended to encourage clarity around assumptions about the nature of the intervention, the context and the expected outcomes. The presence of a well thought out rationale will align with appropriate measures and with the study of the intervention; it may also be the starting point for the next round of work. The 'summary' item in the discussion section encourages authors to revisit the original rationale in the light of its findings and in the larger context of similar projects.

Context

SQUIRE 2.0 accepts 'context' as the key features of the environment in which the work is immersed and which are interpreted as meaningful to the success, failure and unexpected consequences of the intervention(s), as well as the relationship of these to the stakeholders (eg, improvement team, clinicians, patients, families, etc).[13–16] Systematic efforts to improve healthcare should contain clear descriptions and acknowledgement of context, rather than efforts to control it or explain it away. SQUIRE 1.0 included context with items in all sections of the manuscript, but context did not rise to the level of a distinct item itself. SQUIRE 2.0 recognises context as a fundamental item in the methods section, but its relevance is not limited to this section. In addition to affecting the

Box 1 Glossary of key terms used in Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0. This glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 guidelines. They may, and often do, have different meanings in other disciplines, situations and settings

Assumptions
Reasons for choosing the activities and tools used to bring about changes in healthcare services at the system level.
Context
Physical and sociocultural make-up of the local environment (eg, external environmental factors, organisational dynamics, collaboration, resources, leadership and the like), and the interpretation of these factors ('sense-making') by the healthcare delivery professionals, patients and caregivers that can affect the effectiveness and generalisability of intervention(s).
Ethical aspects
The value of system-level initiatives relative to their potential for harm, burden and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety and value of healthcare services include opportunity costs, invasion of privacy and staff distress resulting from disclosure of poor performance.[25]
Generalisability
The likelihood that the intervention(s) in a particular report would produce similar results in other settings, situations or environments (also referred to as external validity).
Healthcare improvement
Any systematic effort intended to raise the quality, safety and value of healthcare services, usually done at the system level. We encourage the use of this phrase rather than 'quality improvement', which often refers to more narrowly defined approaches.
Inferences
The meaning of findings or data, as interpreted by the stakeholders in healthcare services—improvers, healthcare delivery professionals and/or patients and families.
Initiative
A broad term that can refer to organisation-wide programmes, narrowly focused projects or the details of specific interventions (eg, planning, execution and assessment).
Internal validity
Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare system.
Intervention(s)
The specific activities and tools introduced into a healthcare system with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities and outputs (eg, in the form of a logic model) and the mechanism(s) by which these components are expected to produce changes in a system's performance.[17]
Opportunity costs
Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test or sustain a particular improvement initiative.
Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff or the system as a whole, or that prevents care from reaching its full potential.
Process
The routines and other activities through which healthcare services are delivered.
Rationale
Explanation of why particular intervention(s) were chosen, and why it was expected to work, be sustainable and be replicable elsewhere.
Systems
The interrelated structures, people, processes and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient to the individual provider–patient dyad system, to the microsystem, to the macrosystem and all the way to the market/social/insurance system. These levels are nested within each other.
Theory or theories
Any 'reason-giving' account that asserts causal relationships between variables (causal theory) or that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to be explicit and well founded about any informal and formal theory (or theories) that are used.

development of the rationale and subsequent design of the intervention(s), context plays a key role in the iterations of intervention(s) and the outcomes. While it is often not simple to capture or describe context, understanding its impact on the design, implementation, measurement and results make it a vital contributor in identifying and reporting the factors and mechanisms responsible for the success or failure of the intervention(s).

Studying the intervention(s)

The study of the intervention is, perhaps, the most challenging item in SQUIRE. In the evaluation of SQUIRE 1.0[19] and in the pilot testing,[22] many were perplexed by this item and its subelements. This item was intended to encourage a more formal assessment of the intervention and its associated outcomes. In SQUIRE 2.0, this section is called 'study of the intervention(s)' (table 1).

'Doing' an improvement project is fundamentally different from 'studying' it. The primary purpose of 'doing' improvement is to produce better local processes and outcomes rather than contribute to new generalisable knowledge. In contrast, the reason for 'studying' the intervention is mainly to contribute to the body of knowledge about the efficacy and generalisability of efforts for improving healthcare. Both 'doing' and 'studying' are required for a deep understanding of the nature and impact of the intervention(s) as well as the possible underlying mechanisms. 'Study of the intervention(s)' focuses mainly on whether and why an intervention 'works'. It should align with the rationale and may include, but is not limited to, preplanned formal testing of the proposed theory that the intervention(s) actually produced the observed changes, as well as the impact of the intervention(s) on the context in which the work was done.

SQUIRE 2.0 asks authors to be as transparent, complete and as accurate as possible about reporting 'doing' and 'studying' improvement work as both aspects of the work are key to scholarly reporting. The 'summary' and 'interpretation' items in the discussion encourage authors to explain potential mechanisms by which the intervention(s) resulted (or failed to result) in change, thereby developing explanatory theories that can be subsequently tested.

CONCLUSIONS

The development of SQUIRE 2.0 consisted of a detailed analysis of SQUIRE 1.0, input from experts in the field and thorough pilot testing. Many methods and philosophical approaches to improve the quality, safety and value of healthcare are available. The systematic efforts to improve healthcare are often complex and multidimensional, and their effectiveness is inherently context dependent. SQUIRE 2.0 provides common ground on which the discoveries contributed by the various approaches can advance the field by sharing them in the published literature.

At the same time, we recognise that simply publishing SQUIRE 2.0 will not effect this change; additional efforts and resources are required. For example, we have created an explanation and elaboration (E&E) document (Goodman D, Ogrinc G, Davies L; personal communication, 2015) to accompany this article. For each item in SQUIRE 2.0, the E&E provides one or more examples from the published literature and a commentary on how the example(s) meets or does not meet the item's standards; this information brings the content of each item to life. The SQUIRE website (http://www.squire-statement.org) contains a number of resources in addition to the guidelines themselves, including interactive E&E pages and video commentaries. The website supports an emerging online community for the continuous use, conversation about and evaluation of the guidelines.

Writing about improvement can be challenging. Sharing successes, failures and developments through scholarly literature is an essential component of the complex work required in order to improve healthcare services for patients, professionals and the public.

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SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence)* : revised publication guidelines from a detailed consensus process

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Regional differences in endoscopic sinus surgery in Finland: a nationwide register based study

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Competing interest statement

All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work.

Transparency declaration

The corresponding author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Endoscopic sinus surgery rate: a nationwide study

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All authors participated in the planning and conception of the study and the analytical strategy. HR, MA, KM, and IK performed the data management, analyses, tables and figures. HR, ST-S, and MH wrote the manuscript. All authors critically reviewed the manuscript.

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Abstract

290 words

Objectives: Endoscopic sinus surgery (ESS) is a common operation typically performed due to chronic rhinosinusitis (CRS). There are limited data on the nationwide ESS rate and factors contributing to its regional variation. The aim was to evaluate factors causing variation of ESS rate.

Design: Cross-sectional nationwide observational study.

Setting: All patients undergoing ESS in Finland 2013-2015.

Population: Nationwide Finnish population aged 15 years or over.

Main outcome measures: ESS rate per 1000 inhabitants between 2013 and 2015 in all 21 hospital districts and independent factors for multilevel model analyses.

Methods: We used the Finnish register data of all CRS patients who underwent ESS in 2013-2015. Patients aged under 15 years and those with ESS due to neoplasia were excluded. The age and gender standardised ESS rates were calculated, and multilevel Poisson regression models were used to evaluate variation in ESS in the 21 hospital districts. The likelihood ratio test was applied to assess the statistical significance of random components in the models.

Results: The nationwide annual rate of ESS is 0.71 per 1000 people in Finland. Hospital district rates varied from 0.25/1000 (95% Confidence interval 0.18-0.32) to 1.15/1000 (1.09-1.21). Compared with males, females undergo ESS significantly more frequently (57% of the procedures), more often due to CRS without nasal polyps, and at a younger age (mean age 44.2 and 46.2 years, correspondingly).

Multilevel analyses showed that lower age (between 24-45 years) and availability/ease of medical services were independently associated with higher ESS rates.

Conclusions: This study confirms marked regional variation in the ESS rate in Finland, explained only in part by patients' age and differing availability of medical services. To analyse ESS across different CRS phenotypes or to compare quality registers on ESS properly, more research on regional variation is needed.

Strengths and limitations of this study

- Strengths of this study comprise a population-based nationwide design including all patients undergoing ESS in both public and private hospitals in Finland for the study years and information concerning the diagnoses, procedures performed and individual level demographic data.
- The completeness and accuracy of the hospital discharge register have consistently been shown to be good.
- Multilevel models enabled us to capture the hierarchical nature of the data (patients nested in hospital districts) allowing us to analyse the association more efficiently.
- A limitation is that no data on the need for sinus surgery are provided as no register data exist concerning the prevalence of conditions leading to ESS.
- Our data did not include information on health behaviors, earlier treatment of the condition or clinical information

Key Words: endoscopy, chronic rhinosinusitis, sinusitis, surgery, regional variation

Abbreviations:

CRS	Chronic rhinosinusitis
CRSwNP	Chronic rhinosinusitis with nasal polyps
CRSsNP	Chronic rhinosinusitis without nasal polyps
ENT	Ear nose throat
ESS	Endoscopic sinus surgery

Introduction

Chronic rhinosinusitis (CRS) is a clinical disorder encompassing a heterogeneous group of endotypes and two main phenotypes (1). It is one of the most common chronic adult health problems in the Western world with a prevalence of 6-11 % (1-4). CRS has an independent and severe impact on the quality of life similar to chronic diseases such as asthma, chronic obstructive pulmonary disease (COPD), and diabetes (1). In the United States, the CRS-related health care costs are estimated to be $6.9 to $9.9 billion dollars per year (5).

The predisposing factors of CRS include genetic and airborne factors in addition to host immunity (1,6,7). CRS is associated with airway allergy, asthma, and COPD (1,8). CRS with (CRSwNP) and without (CRSsNP) nasal polyps are considered to be phenotypes of CRS, with presumably different aetiologies and pathomechanisms (1). CRSwNP affects between 1% and 4% of the general population (1).

Endoscopic sinus surgery (ESS) has been the most common operative approach for CRS patients among whom maximal medical treatments have failed (1). ESS is a common procedure, with an estimated 250 000 cases annually in the United States (9-11). ESS also creates a considerable financial burden. One study estimated the total cost of ESS to the UK National Health Service (NHS) to be in excess of £30 million per year (12).

Three non-population-based studies within the United States have shown ESS rates to vary according to geographic area or ethnicity. An observational cohort study performed on the MarketScan Commercial Claim and Encounters database yielded a mean ESS rate of 0.94 per 1000 employed, working-aged people in the United States (9). Moreover, the study showed four- to fivefold differences between the states with the highest and lowest rates. Venkatraman et al. investigated a twenty-percent sample of Medicare beneficiaries aged 65 to 99 years. Their study showed an increase in ESS rates for the period 1998-2006 (13). The third study based on the MarketScan Medicaid database in the United States reported overall sinus surgery rates per 1000 people in the Medicaid population to range from 0.36 to 0.40 in 2009-2013 (13). The ESS rate was significantly lower for African Americans than for persons of Hispanic origin.

The reasons behind the detected geographic variation in ESS rates are not fully understood. Geographical variation might reflect a number of factors, including both underutilization and overutilization of surgery in the treatment of CRS, a lack of clinically unambiguous applicable guidelines, and a lack of evidence in well-constructed randomised controlled trials (RCTs) (12). To our knowledge, no previous exhaustive nationwide studies have been conducted on ESS rates and factors affecting the likelihood of the surgical procedure. This nationwide study aimed to examine the number and rates of ESS performed due to inflammatory sinonasal diseases across Finland and putative factors explaining the difference.

Materials and methods

Data

The data of all patients who had undergone ESS by opening the ostiomeatal complex (DMB20) and/or opening the ethmoid sinuses (DNB20), due to sinonasal inflammations in Finland in 2013-2015 were extracted from the hospital discharge register, which registers all ESS procedures in Finland and is maintained by the Institute for Health and Welfare. Patients aged under 15 years and those operated on due to neoplastic lesions were excluded. CRS patients under 15 years of age were not included due to potential differences in their disease etiopathogenesis and treatment (1). Age was classified into 5-year age brackets. Diagnosis was determined as CRS with nasal polyps (CRSwNP) if any of the main or secondary diagnosis codes were J33 (1). Further, if any of the main or secondary diagnosis codes was J32 or the main diagnosis code was J01 the diagnosis was determined as CRS without nasal polyps (CRSsNP) (1). Recurrent acute rhinosinusitis without NPs were regarded as belonging to the CRSsNP group. The rest of the procedures were classified into the group "Other diagnoses". The collected data included information on the ESS procedure, code of diagnosis (IDC10), gender, age, service provider, and hospital district in which the patient was living at the time of ESS.

The data concerning hospitals performing ESS was classified into hospital districts, which own the public hospitals. Finland is divided into 21 hospital districts. The public hospitals within the district are owned by the federations of municipalities and mainly serving residents of their catchment area. In Finland, public medical care covers the vast majority (92% in 2014) of all surgical interventions in different medical fields. Patient´s possibility to choose any public hospital in the country increased in

the beginning 2014, yet most patients have used the closest public hospital in their home hospital district also after that (https://www.kkv.fi/2016/kkv-selvityksia-3-2016). Both public and private health care providers report all hospitalisations and surgical procedures to the same nationwide hospital discharge database.

National population data in hospital districts were tabulated by gender and age in 5-year age brackets from Statistics Finland's website (http://www.stat.fi/til/vaerak/index_en.html) for the years 2013-2015. The number of working-aged physicians and ENT doctors was retrieved from the website of the Finnish Medical Association (https://www.laakariliitto.fi/tutkimus/laakarityovoima).

Ethical consent was obtained from the Research Ethics Committee of the Finnish National Institute for Health and Welfare (approval number 9/2016/§746), and the Institute granted the permission to use hospital discharge register data for the patient population as the competent register authority in charge of the register.

Patient and Public Involvement

This study used National Register data and did not involve patients in the recruitment or conduct of the study.

Statisticsal analyses

The data were tabulated by hospital district according to patients' residence. To reduce random variability, all analyses were performed for the whole study period from 2013 to 2015, but results presented as annual averages. Due to the small number of cases, the smallest district of Åland islands (24 000 inhabitants aged over 15 years) was included only in the total number of ESS, but excluded from the multilevel models.

We calculated age- and gender-adjusted rates of ESS in hospital districts using a direct standardisation method with the population structure of Finland in 2013-2015 as the standard population. Two-level Poisson regression models adjusted for age group with hospital district as random level and logarithm of population at risk as an offset variable were conducted to model the regional variation in ESS. Next, factors indicating proportion of operations performed by private ENT service providers, proportions of CRSwNP and CRSsNP, and proportion of operations performed outside the hospital district of patients' residence in each stratum, as well as the density of physicians in hospital districts were added to the models. Models were estimated separately for men and women, as descriptive analyses revealed differing ESS profiles between them. Multilevel models were applied to capture the hierarchical nature of the data and effects of explaining factors were reported as risk ratios. Wald test was applied to assess the statistical significance of the variance term denoting variation at the hospital district level. Pearson's Chi-Square test was used to test the distribution of diagnoses in hospital districts. A 95% confidence level was used to indicate statistical significance. Statistical analyses were performed by using SPSS version 22 (Chicago, IL, USA) and SAS 9.3 (SAS Institute Inc., Cary, NC, USA) software.

Results

Variation in ESS rates

In 2013-2015, the total number of ESS was 9640 and the nationwide mean rate was 0.71 procedures per 1000 inhabitants. Three percent of the patients underwent ESS twice or three times during this period. Operations were more common among women (age-standardised rates: 0.79/1000 and 0.62/1000, respectively). The mean age at the time of ESS was 44.0 (SD 15.9) years in females and 46.1 (SD 15.8) years in males (Figure 1). The ESS rate of working-aged CRS patients (aged 26-65 years) was higher (0.86/1000) than the one among older CRS patients aged 65 years or older (0.35/1000). No significant differences were found in the age distribution of ESS patients between the hospital districts. Of all ESS procedures, 87% were performed by community-run public health care providers and 96% in the patient's home district.

Seventy-two percent of patients (62% of males, 80% of females) who underwent ESS were diagnosed as having CRSsNP. Twenty percent of patients (30% of males, 13% of females) were diagnosed as having CRSwNP. Other diagnoses (7%) included paranasal cysts or mucoceles, hypertrophy of turbinates, and miscellaneous reasons.

The mean ESS rates per 1000 inhabitants aged over 15 years in the 21 districts are shown in the heatmap (Figure 2). Hospital district rates varied from 0.25/1000 (95% Confidence interval 0.18-0.32)

to 1.15/1000 (1.09-1.21) denoting a fourfold difference. The proportion of patients operated on for CRSsNP and CRSwNP varied significantly between districts ($p<0.001$).

Multilevel models of factors affecting the variation in ESS rate

The multilevel models were created in order to study the level of variation in the probability of ESS between the hospital districts, to examine whether certain factors had an independent effect on ESS, and to assess whether the variation found between hospital districts could be explained by these factors.

Table 1 presents the results of multilevel modeling. In women, after adjusting for age there was significant variation at the hospital district level ($p<0.001$). After adjusting for independent factors, the regional variation in ESS rates remained significant ($p<0.001$). In men, we found significant variation at the hospital district level after adjusting for age ($p<0.001$). Again, after adjustment for independent factors, the regional variation in ESS remained significant ($p<0.001$). No differences from the national average were found in half of the HDs after controlling for age only among both men and women. Controlling for other independent factors leveled out the operation risk compared to the national average in seven HDs among men and four among women. However, part of the variation between hospital districts remained unexplained.

Of the independent factors, younger age (p<0.001) and high density of physicians (p=0.026) were significantly associated with a high ESS rate (Table 1). Women aged 40-44 years were operated on 4.76 times more frequently than women aged over 70 years. Among men, age (p<0.001) and the proportion of ESS performed by private service providers (p=0.0001) were associated with high operation rates in the district, whereas ESS performed outside the patient´s home district (p=0.004) was significantly associated with a low rate.

Table 1

Factors affecting ESS rates in men and women in an adjusted Poisson regression model.

	Men		Women	
Variable	Null model	Adjusted model	Null model	Adjusted model
Age (years)	RR (95% CI)	RR (95% CI)	RR (95% CI)	RR (95% CI)
15-24	1.29 (1.11, 1.51)	1.16 (0.96, 1.39)	2.72 (2.39, 3.11)	2.71 (2.31, 3.18)
25-34	1.79 (1.55, 2.06)	1.68 (1.45, 1.95)	3.87 (3.41, 4.39)	3.87 (3.38, 4.42)
35-39	2.59 (2.23, 3.02)	2.40 (2.05, 2.81)	4.65 (4.06, 5.32)	4.63 (4.00, 5.36)
40-44	2.57 (2.20, 3.00)	2.48 (2.12, 2.90)	4.80 (4.19, 5.50)	4.76 (4.13, 5.49)
45-49	2.49 (2.14, 2.90)	2.35 (2.01, 2.75)	3.77 (3.28, 4.34)	3.73 (3.24, 4.29)
50-54	2.40 (2.06, 2.80)	2.24 (1.91, 2.63)	3.60 (3.13, 4.14)	3.56 (3.09, 4.10)
55-59	2.23 (1.90, 2.60)	2.06 (1.75, 2.42)	3.72 (3.24, 4.27)	3.69 (3.21, 4.25)
60-64	1.99 (1.69, 2.33)	1.88 (1.59, 2.23)	2.48 (2.14, 2.88)	2.46 (2.11, 2.86)
65-69	1.74 (1.48, 2.06)	1.72 (1.46, 2.04)	1.92 (1.63, 2.25)	1.90 (1.62, 2.23)
70+	1.00	1.00	1.00	1.00
% private ORL		2.24 (1.49, 3.38)		1.22 (0.74, 2.01)
% CRSsNP		0.73 (0.42, 1.30)		1.00 (0.56, 1.76)
% CRSwNP		0.96 (0.56, 1.66)		1.27 (0.67, 2.42)
% outside HD		0.49 (0.30, 0.81)		0.89 (0.49, 1.64)
Physician density		1.11 (0.99, 1.25)		1.16 (1.02, 1.33)
HD (Var(SE))	0.1299(0.0464)	0.0751(0.0287)	0.1303(0.0463)	0.1012(0.0381)

CRSsNP = chronic rhinosinusitis without nasal polyps, CRSwNP = chronic rhinosinusitis with nasal polyps, HD = home district, ORL = otorhinolaryngologist operation, RR = risk ratio, CI=confidence interval

The proportion of patients operated on due to CRSwNP varied from one district to another ($p<0.001$). The range was from 10% to 33%. In multivariate multilevel models, the diagnosis did not explain the risk on the operation rate.

Discussion

To reduce inefficient or unwarranted practice patterns and to improve the overall performance of the health system, it is essential to define the variations in health care and the underlying reasons (9,14). We found regional variation in endoscopic sinus surgery (ESS) not explained by variations in gender and age of the patient population.

Comparison with other studies

In Finland, the nationwide mean annual rate of endoscopic sinus surgery (ESS) among adult patients was 0.71/1000. The number is similar to what another study group has detected in the UK population (12). The ESS rate of working-aged people (0.86/1000) in the current study is fairly close to that reported among the employed cohort in the United States (0.94/1000) (9). We demonstrate here that elderly people in Finland are operated on considerably less frequently (0.35/1000) than their peers in the United States (0.92/1000) (13). In the present study, there was marked variability in ESS rates between the 21 hospital districts after standardisation of age and gender. We found a fourfold difference between the highest and the lowest regional operation rate. This is in line with the findings in the United States (9,13) where up to fivefold differences between the states were observed. Private hospitals, in which 13 % of all ESS procedures were performed, lack precise catchment areas in

Finland and thereby population at risk. Yet, the risk ratios of the current study suggest that the proportion of private hospitals in the hospital district did have an effect on ESS operations. Nevertheless, the present nationwide study of Finland shows that regional differences exist also in a country with a universal nationwide health care system where the procedures are performed mostly in publicly financed institutions.

The effect of independent factors to ESS variation

We demonstrated that ESS is performed 1.3 times more frequently on women than on men. This is in accord with the expected population-based male-to-female ratio of CRS. CRS is estimated to be 1.1 to 2 times more common in women than in men (2,15). The infection rates in females aged between 20 and 34 years are higher probably due to a greater occupational risk to be exposed to infections relative to men (16,17). This might, in part, enhance the development of CRS in females. In the present study, the mean age of operated females was lower than that of males. This might be due to differences in host-environment interactions and pathomechanisms (18). It is also possible that women use more general health care services (19).

In this study, the ESS rate of working-aged people (26-65 years) was 2.5 times higher than that of retirement-aged people. Moreover, the multilevel models showed that the patient´s age had an independent effect on ESS rate across Finland, which could putatively be related to differences in life style, operation eligibility or probability to have been already operated.

It is difficult to evaluate the population-based prevalence of CRSwNP and CRSsNP due to limitations of diagnostic methods in primary care. In the European population, the prevalence of CRSwNP has been estimated at 1-4% and CRSsNP about 10% (1,20). In the present study, 20% of ESS was performed on patients with CRSwNP. This is slightly higher than the ratio of CRSwNP and CRSsNP phenotypes in the literature cited above. It is consistent with the greater need for surgery with nasal polyposis.

ESS due to CRSwNP was performed nearly three times more frequently on males than on females. In a retrospective, cross-sectional American study, data on CRS patients and their non-CRS controls were analysed (18). The authors found that the proportion of females with CRSwNP was 38% and that these women had more severe disease than men (18). In our study, 27% of the operated CRSwNP patients were female. This figure is in line with the previous study. Hypertrophy or air cells of the turbinates does not normally fulfil criteria for ESS and could in part be related to wrong or incomplete insertion of diagnosis code.

Potential factors behind variation in ESS

The multilevel models showed that in females, young age and high density of physicians were significantly associated with a high ESS likelihood. In males, independent factors associated with a high probability of ESS were young age and a high proportion of ESS performed by private ENT specialists. ESS performed out of the patient´s home district was associated with a low operation

likelihood. Excluding the age factor, these findings reflect the impact of availability on operation rates. Availability of medical services would mean any kind of ease to get the medical service including distance, queuing time, easiness to get appointment, etc. Higher ESS rates were detected also in hospital districts with a high density of ENT specialists as well as in hospital districts having a University Hospital with medical faculty. Yet, due to multicollinearity, these factors could not be included in the multilevel Poisson model. Taken together, our findings suggest that, in addition to the population's age structure, the availability of medical services has an independent effect on ESS probability.

Putative other reasons for regional variation in ESS rate

In both females and males, after adjusting for age and factors related to the availability of medical services, a clear regional variation remained in ESS, probably due to in part relative indications for ESS In industrialized countries, ESS rate might depend on informed patient choice and the treatment strategies available and the rate can vary extensively because of differences in professional opinions (14,21). Future research should focus more on evidence-based treatments for CRS and indications of ESS in different disease course and phenotypes.

Strengths and limitations of the study

Strengths of this study comprise a population-based nationwide design and reliable register-based data, including information on all surgical procedures performed in Finland (22). Meticulously collected data on diagnosis, operating hospital, and patient´s municipality of residence as well as data on the density of physicians and ENT specialists are readily available.

The study includes some limitations that must also be addressed. No data on the need for sinus surgery are provided, as we examined the numbers of operated patients instead of the CRS patient population as no register data exist on the total patient population eligible for the operation. Further, our data did not include information on patient's socioeconomic status, general health, subjective nasal symptoms, or x-ray findings. Despite relatively small regional variation in socioeconomic or ethnic status of the Finnish population, some regional dissimilarities might exist, which could affect the probability of being operated on. We acknowledge that the register-based data has limited information on background factors and thus they could not be added to the multilevel models. A limitation is that pediatric CRS patients under 15 years of age were not included due to potential differences in their disease etiopathogenesis and treatment. Future studies should address potential variation in ESS in pediatric population. We acknowledge that lack of data of patient´s allergy and other associating conditions, as well as of ESS costs limit interpretation of the results.

Conclusions

This nationwide study shows that high regional variation in ESS rate exists in Finland where the vast majority of procedures are performed in a public health care system. Patient´s age and the availability of medical services are associated with ESS probability. Nevertheless, some unexplained factors appear to affect the regional variation in ESS. of ESS across different CRS phenotypes and to ensure unbiased quality control among the operating institutions.

Data sharing statement

No additional data available.

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Figure legends

Figure 1

Age distribution of endoscopic sinus surgery (ESS) in Finland. Included are patients operated on during 2013-2015, presented as annual averages.

Figure 2

Age- and gender-standardised rate of endoscopic sinus surgery (ESS) by hospital districts in Finland (mean of the years 2013-2015). Darker colours represent higher operation rates. The circle indicates the site of the central hospital and the size represents the number of inhabitants within the district. Districts with white circles have a medical faculty.

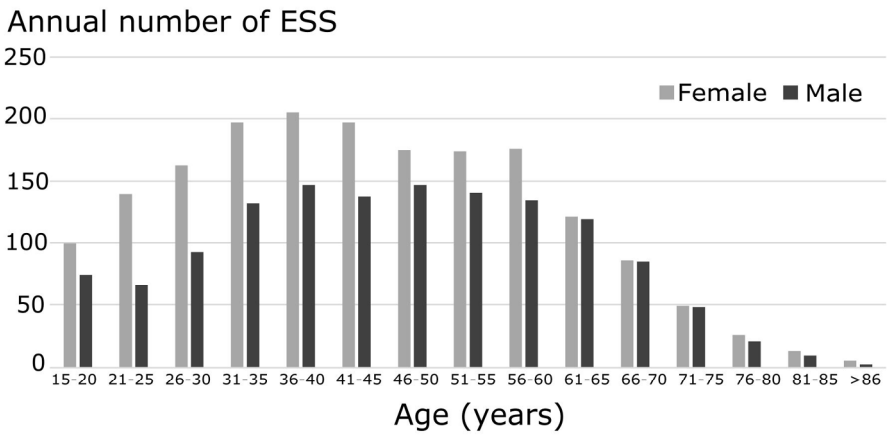

Figure 1
Age distribution of endoscopic sinus surgery (ESS) in Finland. Included are patients operated on during 2013-2015, presented as annual averages.

169x80mm (300 x 300 DPI)

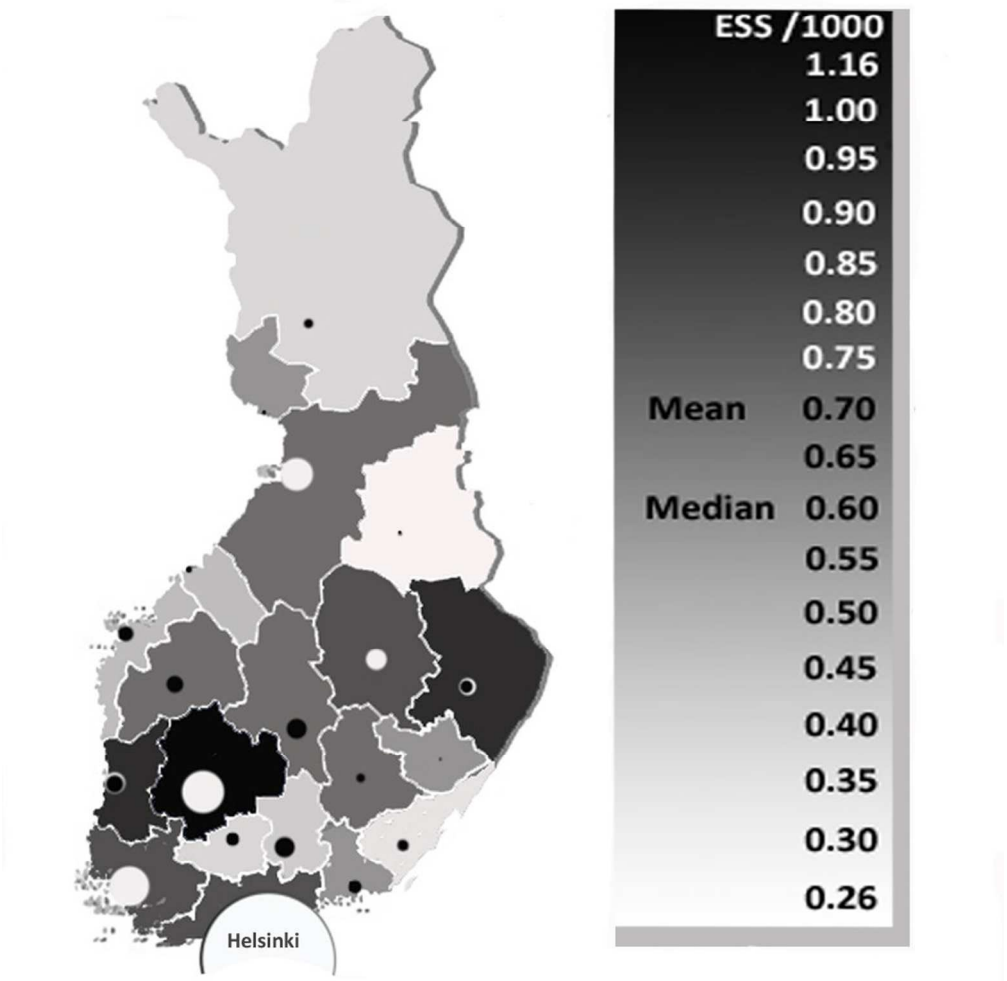

Figure 2
Age- and gender-standardised rate of endoscopic sinus surgery (ESS) by hospital districts in Finland (mean of the years 2013-2015). Darker colours represent higher operation rates. The circle indicates the site of the central hospital and the size represents the number of inhabitants within the district. Districts with white circles have a medical faculty.

95x110mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	5
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	10-11
Objectives	3	State specific objectives, including any prespecified hypotheses	12
Methods			
Study design	4	Present key elements of study design early in the paper	12-14
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	12-14
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	12-14
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	12-14
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	12-14
Bias	9	Describe any efforts to address potential sources of bias	12-14
Study size	10	Explain how the study size was arrived at	12-14
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	12-15
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	15
		(*b*) Describe any methods used to examine subgroups and interactions	15
		(*c*) Explain how missing data were addressed	N/A
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	N/A
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	N/A

		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	N/A
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16-20
		(*b*) Report category boundaries when continuous variables were categorized	13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	18-19
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	18-19
Discussion			
Key results	18	Summarise key results with reference to study objectives	21
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	26
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	21-26
Generalisability	21	Discuss the generalisability (external validity) of the study results	27
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	4

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.