


# Prophylactic antibiotics has no benefit for outcome in clean myringoplasty—A register-based cohort study from SwedEar

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## Abstract

**Objectives:** To investigate if prophylactic antibiotics (PA) in conjunction with myringoplasty of clean and uninfected ears entails a reduction of postoperative infections within 6 weeks after surgery, and whether it affects the healing rate of the tympanic membrane (TM) at follow-up, 6–24 months after surgery.

**Design:** A retrospective cohort study of prospectively collected data.

**Setting:** Data extracted from The Swedish Quality Register for Ear Surgery (SwedEar), the years 2013–2019.

**Participants:** All patients in SwedEar with a registered clean conventional myringoplasty (tympanoplasty type I) including a follow-up visit.

**Main Outcome Measures:** The effect of PA use on TM healing rate at follow-up and postoperative infection within 6 weeks of surgery.

**Results:** In the study group ( $n = 1665$ ) 86.2% had a healed TM at follow-up. There was no significant difference between the groups that had PA administered (87.2%) or not (86.1%). A total of 8.0% had a postoperative infection within 6 weeks. Postoperative infection occurred in 10.2% of the group that received PA ( $n = 187$ ) compared with 7.7% of the group that did not receive PA. However, this difference was not statistically significant. Postoperative infection within 6 weeks significantly lowered the frequency of healed TMs.

**Conclusion:** PA administered during clean conventional myringoplasty does not improve the chance of having a healed TM at follow up, nor decrease the risk of having a postoperative infection within 6 weeks after surgery.

## KEYWORDS

myringoplasty, postoperative infection, prophylactic antibiotics, tympanic membrane, tympanoplasty

## 1 | INTRODUCTION

In surgical procedures postoperative infections are a reality and prophylactic antibiotics (PA) are often administered to prevent this, with varying degrees of evidence. Important factors to

consider as bases for the decision of PA are the degree of infection of the surgical wound, and the risk for infection during surgery.

According to the Centres for Disease Control and Prevention (CDC), surgical wounds can be categorised into four sub-groups: (i) clean surgery, (ii) clean-contaminated surgery, (iii) contaminated surgery,

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(iv) dirty surgery.<sup>1,2</sup> This classification does not fully match the condition of the middle ear cavity, where respiratory mucosa is in continuum with the nasal cavity, or when the tympanic membrane (TM) skin barrier is disrupted in chronic otitis media. Regardless, it is stated that dry perforation tympanoplasty should be considered as clean surgery.<sup>3</sup>

A general principle for PA for surgery is that it should be administered within 60 min before skin incision<sup>4</sup> and not continued more than 24 h.<sup>5</sup> In a Cochrane review published 2004 and updated 2010, the authors conclude that there is no strong evidence supporting use of PA in clean or clean-contaminated ear surgery.<sup>6</sup> Two recent systematic reviews studying the use of PA declare, with a high level of evidence, that PA are not indicated for clean ears. However, for clean/contaminated ears the level of evidence is lower.<sup>7,8</sup> In a randomised prospective study, the infection rate in clean middle ear procedures was estimated to less than 5%, while in contaminated and dirty procedures it increased to over 10% without antibiotics.<sup>3</sup>

The recommendation based on evidence may be clear, but the clinical practice do not always follow the guidelines. In an American survey, a majority of surgeons confirmed routine prescription of antibiotics pre- or postoperatively for 17 common procedures, despite confessing knowledge of a poor evidence base.<sup>9</sup>

An important goal of our time is to restrict the use of antibiotics. Antibiotic resistance and the development of multi-resistant strains of bacteria are an increasing problem worldwide. It represents a threat towards global health in terms of significant morbidity and mortality, as well as a scientific and financial challenge, and is partly a result of overuse/misuse of antibiotics.<sup>10-12</sup>

Myringoplasty is a surgical procedure aiming to repair a perforated TM, in order to prevent infections in the majority of cases but also to restore hearing.<sup>13,14</sup> The surgical technique can vary internationally, in Sweden myringoplasty is usually performed with a temporal fascia graft in underlay.<sup>15</sup>

The Swedish National Quality Register for Myringoplasty (QRM) was established in 1997. A quality register is a dynamic process that develops over time. Initially only myringoplasties were registered, but after a revision into The Swedish National Quality Register for Myringo- and Ossiculoplasty (QRMO) in 2013, also ossiculoplasties were included. The register is now renamed SwedEar (<https://myr.registercentrum.se>) from October 2020 and includes retraction pockets and cholesteatoma surgery. SwedEar contains data from all ENT clinics where otosurgery is performed. In an earlier report from QRM, the overall graft success rate for a clean myringoplasty was 88.5%,<sup>13</sup> which is in accordance with a British study that showed 89.5% graft success.<sup>16</sup>

The aim of the present study was to investigate if PA has any benefit for the surgical outcome of healed TM or postoperative infection within 6 weeks in the perioperatively clean ear.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design

A retrospective cohort study of prospectively collected data from the SwedEar was performed. In the register, data are collected at three

### Key points

- Prophylactic antibiotic treatment is used worldwide in myringoplasty.
- Although widely used, there is no evidence of an improved healing rate or decreased infection rate.
- The literature concludes that there is no strong evidence supporting the use of prophylactic antibiotics in clean or clean-contaminated ear surgery.
- This nationwide register-based cohort study from SwedEar compared healing rate and postoperative infection rate after myringoplasty in clean ears with or without systemic prophylactic antibiotics.
- In clean conventional myringoplasty, the use of prophylactic antibiotics does not improve the chance of having a healed tympanic membrane at follow up, nor decrease the risk of having a postoperative infection within 6 weeks.

different time points; an operation form at surgery and a follow-up form (after 6–24 months) filled in by the surgeon, and a patient related outcome questionnaire (data not reported here). The data were extracted in January 2020 and transferred to an Excel database and surgeries registered between 2013 and 2019 were further analysed. The study is presented according to the STROBE guidelines.

### 2.2 | Study settings and participants

All ENT clinics in Sweden participated and approximately 80% of all myringoplasties between 2014 and 2019 were captured in this database. The primary database included 3967 conventional myringoplasties.

**Inclusion criteria:** All conventional myringoplasties (commonly performed with a graft in an underlay technique) with ears assessed as infection-free at the time of surgery and with information available on perioperative antibiotics and with a follow-up visit 6–24 months after surgery with information on TM status and postoperative infection or not.

**Exclusion criteria:** All ears assessed as not being infection-free at the time of surgery ( $n = 498$ ). Lack of follow-up visit, including missing data on TM status, if a postoperative infection occurred and/or perioperative antibiotics ( $n = 1414$ ). The subjects that had been treated with preoperative antibiotics or missing data of preoperative antibiotics ( $n = 91$ ), and postoperative systemic antibiotics ( $n = 136$ ). Those with a follow-up visit earlier than 6 months or later than 24 months after surgery ( $n = 163$ ). For surgeries performed years 2018 and 2019, the number of registered follow-up visits were 48% and 4% respectively, since there is an intentional delay in registration from the clinics. For comparison during years 2013–2017, 64%–80% of the surgeries had a registered follow-up.

After all the exclusion criteria were applied, in the study group remained 1665 surgeries to be evaluated (Figure 1).

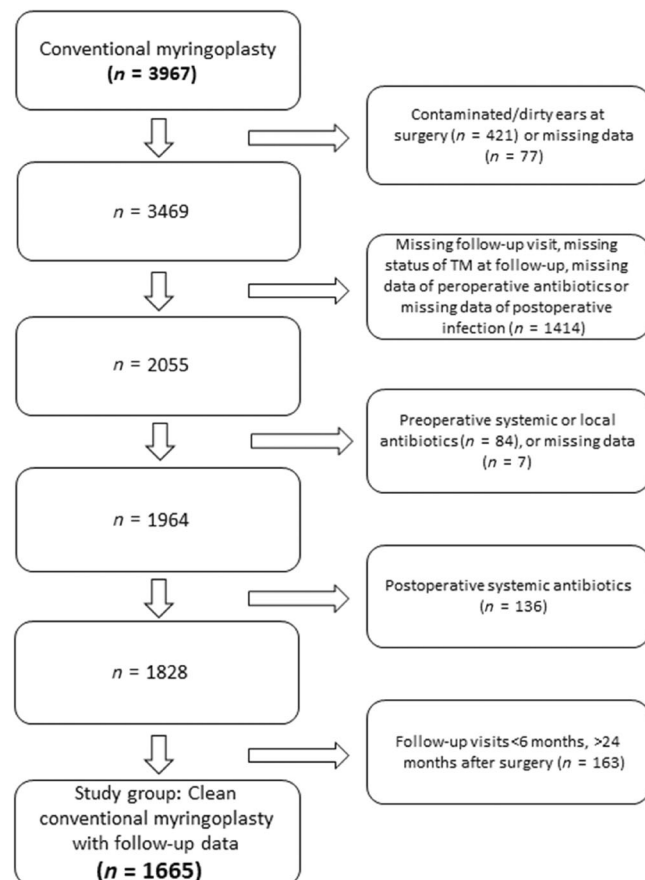
Since 2013, the use of pre-, peri-, and post-operative antibiotics are registered in the SwedEar. No information on which antibiotic that was administered is registered.

Since the study population only included non-infected ears at surgery, the administration of antibiotics perioperatively was assumed to be of prophylactic purposes and therefore assessed as such.

## 2.3 | Main outcome measures and data parameters

Main outcome measures were postoperative infection within 6 weeks after surgery and frequency of healed TM at the follow-up visit. From the registration at surgery the following parameters were included for analyses: Age, gender, clinic, operated side, previous ear surgery other than tube insertion, aim for surgery (hearing improvement and/or infection prophylaxis), type of surgery, ear assessed as infection-free or not at the time of surgery and administration of perioperative systemic antibiotics.

From the follow-up registration the following parameters were included: a healed TM or not, and occurrence of any postoperative infection in the operated ear that required antibiotic treatment within 6 weeks after surgery.



**FIGURE 1** Flow chart on the study group, subjects ( $n = 1665$ ) with clean conventional myringoplasties and excluded subjects.

## 2.4 | Statistical analyses

The database was analysed in Excel<sup>®</sup> 2019 (Microsoft Corp.<sup>®</sup>) for descriptive data. Analyses of outcome for closure of TM and postoperative infection were performed in IBM<sup>®</sup> SPSS<sup>®</sup> Statistics version 27 (Armonk, NY: IBM Corp). A  $\chi^2$  test was used for analysing categorical variables. Binominal logistic regression was performed to estimate odds ratios (OR) for the factors associated with healed/not healed TM at follow-up visit and postoperative infection. Adjusted for confounders (age and gender) and risk factors such as revision surgery, PA, indication for operation. Statistical significance in this study is defined as a  $p$ -value  $< .05$  and for logistic regressions a confidence interval (CI) of 95% is presented.

## 2.5 | Ethical considerations

The study was performed according to the Declaration of Helsinki, ethical approval (Regionala etikprövningsnämnden i Stockholm, D-nr 2014/2203-31/4).

## 3 | RESULTS

### 3.1 | Descriptive data

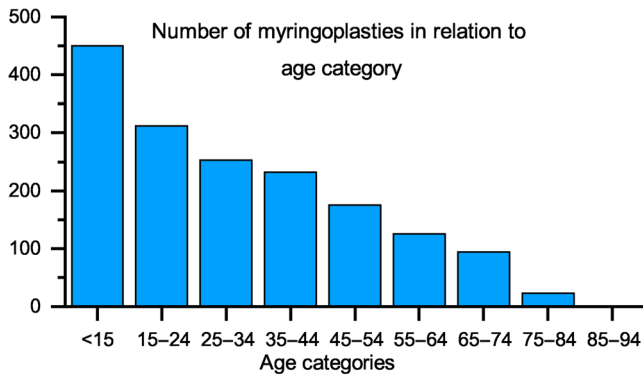
A study group of totally 1665 myringoplasties fulfilling inclusion criteria were evaluated. Gender distribution was close to equal (male 47.3%, female 52.7%). The mean age was 31.3 years, range 5–86 years. The number of surgeries in age categories are presented in Figure 2. In the study group the time interval between surgery and the registered follow-up visit was mean 1.04 years, between 6 and 24 months. Perioperative antibiotics were administered to 187 subjects (11.2%). The use of PA varied between the clinics. Most clinics gave PA in 0–5% (21 out of 32) of their surgeries (Figure 3).

### 3.2 | Surgical outcome TM

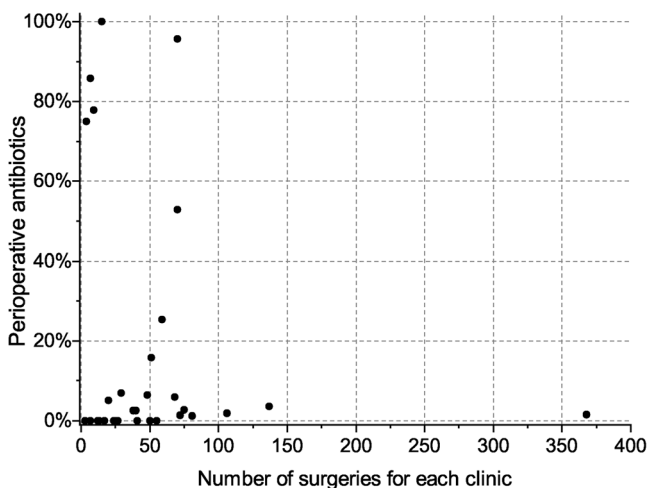
At follow-up visit a healed TM was observed in 86.2% ( $n = 1436$  out of 1665) of the cases in the study group. Of those administered PA, 87.2% achieved a healed TM ( $n = 163$  out of 187), while those not administered PA had a healed TM in 86.1% ( $n = 1273$  out of 1478). The difference was not significant. There was no statistically significant difference between genders (Table 1).

If a postoperative infection occurred within 6 weeks after surgery ( $n = 133$ ) there was a significant difference in healing rate of TM ( $p = .005$ ). In the group who had a postoperative infection a healed TM was achieved in 78.2% ( $n = 104$  out of 133) of the cases, compared to the group who did not get a postoperative infection who had a success rate of 86.9% ( $n = 1332$  out of 1532).

In subjects with prior ear surgery ( $n = 318$ ), there was no significant difference for having a healed TM if PA was used or not. The proportion of healed TM with PA was 71.8% (28 out of 39), and without PA 81.4% (227 out of 279).



**FIGURE 2** The number of myringoplasties in each age category is presented ( $n = 1665$ ).



**FIGURE 3** For each of the included 32 clinics, the percentage of prophylactic antibiotics (perioperative antibiotics) is presented in relation to the number of myringoplasties performed registered in the database.

**TABLE 1** For the groups with unsuccessful surgical outcome, postoperative infection within 6 weeks ( $n = 133$ ) and not healed tympanic membrane (TM) at follow-up ( $n = 229$ ), data concerning age, gender, prophylactic antibiotics, operated side, revision surgery and indication for surgery are presented.

Parameters	Postop infection (yes) $n = 133$ out of 1665	$p$ -value (Chi-square)	Not healed TM (perforation) $n = 229$ out of 1665	$p$ -value (Chi-square)
Age, <15 years / $\geq 15$ years, (450/1215)	26/107 19.5%/80.5%	.04*	51/178 22.3%/77.8%	.08
Gender, male/female, (788/877)	73/60 54.9%/45.1%	.59	106/123 46.3%/53.7%	.74
Prophylactic antibiotics, yes/no (187/1478)	19/114 14.3%/85.7%	.25	24/205 10.5%/89.5%	.70
Operated side, right/left, (765/900)	59/74 44.4%/55.6%	.70	97/132 42.4%/ 57.6%	.24
Revision surgery, yes/no, (318/1346) (1 missing)	23/110 17.3%/82.7%	.58	63/165 27.6%/72.4%	.00*
Indication water resistant, yes/no, (1541/123) (1 missing)	126/7 94.7%/5.3%	.33	212/17 92.6%/7.4%	.98
Indication hearing improvement, yes/no, (880/776) (9 missing)	72/61 54.1%/45.9%	.81	113/115 49.6%/50.4%	.24

Note: Chi-square tests were performed for each group and  $p$ -values are presented.

\* $p$ -value < .05 is considered significant.

Logistic regression adjusted for age, gender, and risk factors did not show any increased risk for those that did not receive PA to have a reoperated TM at follow up. Other factors are included in Table 2. There were no significant differences for operated side or indication for surgery regarding the chance of having a healed TM at the follow up. Previous ear surgery (not tube) showed an increased risk for having a reoperated TM ( $p = .001$ , OR 1.72) (see Table 2).

### 3.3 | Postoperative infection

In the study group, postoperative infections requiring antibiotic treatment within 6 weeks after surgery were reported in 8.0% ( $n = 133$  out of 1665). Of those administered PA, 10.2% ( $n = 19$  out of 187) had a postoperative infection, while those not administered PA had a postoperative infection in 7.7% ( $n = 114$  out of 1478). There was no statistically significant difference between the genders. Adults had a statistically significant increased risk to have a postoperative infection compared to children (<15 years) (adults 8.8%, children 5.8%;  $p = .043$ ) (Table 1).

Logistic regression adjusted for age, gender and risk factors did not show any increased risk for those that did not receive PA to have a postoperative infection. There were no significant differences for operated side, previous ear surgery or indication for surgery regarding the risk of having a postoperative infection (Table 2).

## 4 | DISCUSSION

In the present study, no significant impact of PA on the overall healing rate of the TM after clean myringoplasty procedures, nor for the incidence of postoperative infection within 6 weeks after surgery could be confirmed.

In many other types of surgery, research has proved an advantage of PA use in reducing the incidence of postoperative infection. Orthopaedic implant surgery is an example where the benefit is well established.<sup>17</sup>

**TABLE 2** Odds ratios (OR) adjusted for age, gender, and risk factors (included in table) with 95% confidence intervals (CI) for the risk of postoperative infection within 6 weeks and the chance of healed tympanic membrane (TM), as reported by physician at follow-up after myringoplasty in SwedEar ( $n = 1654$ , 11 missing).

Parameters	Postoperative infection		Healed TM	
	OR (CI)	<i>p</i> -value	OR (CI)	<i>p</i> -value
Prophylactic antibiotics administered	1.34 (.80–2.23)	.27	1.10 (.70–1.73)	.69
Right side	.93 (.65–1.33)	.69	1.20 (.90–1.59)	.22
If indication infection prophylaxis	1.55 (.69–3.48)	.29	.99 (.57–1.74)	.98
If indication hearing improvement	1.08 (.75–1.56)	.67	1.18 (.88–1.58)	.27
Previous ear surgery (not tube)	.87 (.54–1.40)	.56	.59 (.42–0.82)	.00*

\**p*-value < .05 is considered significant.

Even though a perforated TM is a risk factor for contaminating microbioms from both the external auditory canal and the epipharynx, a surprising number of ears stay dry. This is probably due to the combination of several factors. The external ear canal has a self-cleaning activity propulsing squamous cell-rests and debris from the TM and laterally, combined with bactericidal properties of the cerumen.<sup>18</sup> In addition, the middle ear mucosa hold capacities of innate and adaptive immune system to prevent infections.<sup>19,20</sup>

The evidence in the literature so far for the benefit of PA in ear surgery varies for different procedures and infectious status of the middle ear. In contaminated or dirty ENT surgery, it has been suggested that PA could play an important role.<sup>2</sup> A systematic Cochrane review from 2004, and updated in 2010, that included 10 different studies on clean-and clean-contaminated ear surgery found no significant contribution of PA.<sup>6</sup> The present study has a longer follow-up time for graft failure (mean 1.04 years) and a well-defined study cohort purely investigating PA in a non-infected ear, and surgeries within the last decade. In the Cochrane review any subgroup analyses were difficult, while in the current study cohort it was possible to select for clean surgery. The myringoplasties included in this study were deemed as clean surgeries which in light of the current evidence could be expected to have a low usage of PA in the study group. Despite that, SwedEar data shows that there is a substantial difference in the utilisation of PA nation-wide (Figure 3). This discrepancy in clinical PA use from results shown in studies is a reality globally. In an American study investigating the use of PA by otolaryngologists, there was a common belief that there was not enough evidence to support the recommendation to abstain from PA in tympanoplasty. There was also a reported routine use of PA in tympanoplasty surgeries by approximately half of the surgeons.<sup>9</sup> There might be several explanations to why this discrepancy exists, for example length of surgical procedure, longstanding tradition, belief that the results in studies do not apply to actual clinical settings, cultural and financial aspects, and risk of postoperative infections.

The study shows that patients who had a postoperative infection within 6 weeks had a significantly greater risk of having a perforated TM. That is in line with earlier research: the risk of not getting an intact TM after myringoplasty is greater if the patient has a postoperative infection.<sup>21</sup> This could explain the motivation for the current use of PA. However, there is no connection between the rate of postoperative infection and PA or between the rate of healed TMs and PA in our study. In addition, the article by Jackson et al<sup>21</sup> also demonstrates inability of PA to affect postoperative

infection rates across stratified observation of operation duration, patient age and preoperative findings.

A review showed that prolonged operative time can increase the risk of surgical site infection, but the studies included for otolaryngology surgery were few.<sup>22</sup> The SwedEar register the number of operations at the clinics, but not the duration of the surgery, nor the experience of the surgeon (ENT-resident to consultant). Another reason for high use of PA at certain clinics in our study, could presumably be explained by local treatment guidelines that has not been updated recently. However, the majority of included clinics use PA in less than 5% of their surgeries and about a third in zero percent. Currently in Sweden there are no national treatment guidelines, which might also influence the considerable disparity.

Previous middle ear surgery (not tube) was a parameter that increased the risk for a failed surgical outcome in this study. This is in line with earlier published reports,<sup>16,23</sup> and PA in revision surgeries is shown to not significantly increase a successful surgical result.

The rate of postoperative infection in this study was 8.0%. The described incidence of postoperative infection in myringoplasties varies from under 5% in clean procedures to over 10% in contaminated procedures.<sup>3</sup> In SwedEar the assessment of postoperative infection is retrospective and based on the medical charts. Individuals older than 15 years, had a significantly higher risk of postoperative infection, but no other included variables increased the risk. Several factors might influence the increased risk in an older population, including co morbidities<sup>24</sup> and smoking,<sup>25</sup> which cannot be analysed in this study.

A national quality register gives access to a vast group of patients spread across the country, and entered data are irrespective of factors such as hospital size, surgeon's experience, and comorbidities. The coverage nation-wide is high, participation is voluntary and entails no cost for the clinic. Despite missing surgeries, the procedures included in SwedEar are covering approximately 80% of performed myringoplasties nationwide and represent the clinical reality. In these subjects, only registered parameters are scrutinised, and not medical records, resulting in a limitation in the detail of the data.

Another limitation of the study is the absence of follow-up data in 1414 subjects. From the data extracted, myringoplasties that lacked the required variables for analysing the intended outcomes were excluded. For the majority, no follow-up visit was recorded, and from the database it is not possible to derive the cause.

A follow-up visit is recommended 1 year after surgery, and due to a delay in registrations from the participating clinics, only a minority

(4%) of the surgeries performed in 2019 had a registered follow-up visit. Other reasons for patients lost to follow-up include patients moving, and the lack of resources in the health care system which can result in patients not being offered a follow-up visit, or the absence of responsibility from the physician to register. However, in SwedEar, validation has been conducted to assess the quality of the data, demonstrating reliable data. After reviewing medical records from selected clinics in 2017, the missing follow-up visits for registered surgeries were scrutinised and no statistical difference in the healing rate was found with or without a follow-up visit (submitted manuscript). Overall, the results from this study should be deemed reliable, taking these limitations into consideration.

## 5 | CONCLUSION

Using data from 1665 patients registered in the SwedEar, we find no support for routine usage of PA in myringoplasties in ears assessed as infection free. It does neither improve results considering rates of postoperative infection nor long-term healing of the TM. These findings will provide evidence for future national guidelines in routine otologic surgery.

### AUTHOR CONTRIBUTIONS

Eva Westman, Per Olof Eriksson designed the work. Eva Westman, Maria Höglund, Frida Brännström Nilsson, Åsa Bonnard, Erling Englund, Per Olof Eriksson acquired and analysed data. Eva Westman, Maria Höglund, Frida Brännström Nilsson, Åsa Bonnard, Erling Englund, Per Olof Eriksson drafted, revised, and approved the manuscript. Eva Westman, Maria Höglund, Frida Brännström Nilsson, Åsa Bonnard, Erling Englund, Per Olof Eriksson agree to be accountable for all aspects of the work.

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### CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

### PEER REVIEW

The peer review history for this article is available at <https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/coa.14089>.

### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from Registercentrum Västra Götaland. Restrictions apply to the availability

of these data, which were used after ethical approval and under license for this study. Data are available for anyone from Registercentrum Västra Götaland ([registercentrum@vgregion.se](mailto:registercentrum@vgregion.se)) after ethical approval and the permission of Registercentrum Västra Götaland.

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