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Laser, radiofrequency or tympanostomy knife? Comparison of surgical methods in tympanostomy treatment of young children and predictive value of tympanometry

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ABSTRACT

Objectives: To investigate tympanostomy tube (TT) treatment in young children, with special interest in bloodless surgical methods (laser and radiofrequency), myringosclerosis formation and tympanometric testing.
Methods: This prospective study includes 76 children whose 121 ears with middle ear effusion were treated with tympanostomy tubes. Myringotomy was performed with CO_2 laser in 37, radiofrequency in 40 and myringotomy knife in 44 ears. The ears were evaluated with otomicroscopy and tympanometry preoperatively and postoperatively every 3–4 months until spontaneous tube extrusion.
Results: All tubes extruded spontaneously (mean 12.8 months, range 3–36 months), with no persistent perforations or cholesteatomas. CO_2 laser and radiofrequency inserted tympanostomy tubes extruded faster (mean 11 months) compared to incisional myringotomy (mean 15 months, $p = 0.002$). Myringosclerosis was noted in 25 (21%) ears after treatment. There was a tendency to less myringosclerosis with bloodless techniques, but the difference was not significant. *Flat* tympanograms on the day of procedure predicted continuation of ventilation problems also after TT treatment ($p = 0.003$). Ears with preoperative type B tympanogram had significantly more myringosclerosis 21/75 (28%) compared with type A and C tympanograms 4/41 (10%) ($p = 0.032$).
Conclusions: While all myringotomy methods were effective and safe, the traditional incisional myringotomy with a tympanostomy knife is still a good, feasible and cost-effective myringotomy method. No surgical removal of tympanostomy tubes is needed before 3 years of uncomplicated tympanostomy treatment. Tympanometry turned out to be a useful tool in prediction of post TT treatment ventilation problems of the middle ear.

1. Introduction

Tympanostomy tube (TT) treatment is the gold standard for prolonged middle ear effusions (MEE). The main purpose of TT treatment is to resolve hearing loss, by reducing the MEE. This effusion usually develops as a result of a poorly functioning eustachian tube and middle ear infections [1,2]. Although the procedure is relatively minor, complications are possible. These include otorrhea, granulation tissue, medial displacement of the TT, myringosclerosis, focal atrophy, cholesteatoma, and persistent perforations [3]. The risk of complications increases with longer durations of the TT treatment. TT type and material may also have an effect on sequelae. A much-debated question is whether and when the TTs need to be surgically removed to prevent sequelae of treatment [4–6].

Myringosclerosis, the most common sequelae of TT treatment [3], appears as white plaques on the tympanic membrane (TM). These plaques are mostly clinically insignificant, with little impact on hearing, although extensive myringosclerosis in pars tensa makes it difficult to evaluate middle ear status [7,8]. Myringosclerosis is characterized by an increase of collagen tissue in the lamina propria of the TM, along with hyaline degeneration and calcification. The etiology and pathogenesis of this degenerative healing process remains as not completely understood.

Previous research has shown that trauma of the TM, such as myringotomy or perforation, increases the risk of myringosclerosis

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formation. Long-term tubes and multiple TT insertions, seem to further increase myringosclerosis formation [3,9,10]. Several theories on the etiology of myringosclerosis have been proposed, including infectious origin, genetic predisposition, oxygen free radicals and hemorrhage of the TM [10–14]. Studies show that bloodless myringotomy techniques, such as laser and radiofrequency, decrease the incidence of myringosclerosis over traditional incisional myringotomy (IM) [15,16].

Several questions regarding TT treatment await answers, for example which patients will benefit from TT insertion and when post-TT-treatment control visits are required. MEE affects audiological results [17]. However, preoperative audiometric testing has accessibility issues, also cooperation may be problematic in pediatric patients. MEEs presenting a flat type B tympanogram are unlikely to resolve spontaneously regardless of duration of effusion [18]. In lack of objective and sufficient audiometric testing, tympanometry could aid the clinician in TT insertion decision-making. The objectives of this study were: 1. To compare the usefulness and eventual problems of the available surgical methods in TT insertion, 2. Ascertain if bloodless methods, such as laser and radiofrequency, cause less myringosclerosis compared to the traditional IM, and 3. To investigate the prognostic potential of tympanometry in TT treatment.

2. Materials and methods

The study setting was approved by the Ethics Committee of Pirkanmaa Hospital District and caretakers signed an informed consent.

Seventy-six patients (caucasian) and 143 ears with MEE were recruited, received TT-treatment, and had follow-up at the department of Otorhinolaryngology, Päijät-Häme central hospital. The patients had been referred from primary health care units due to secretory otitis media (SOM) or recurrent acute otitis media (RAOM). The criteria used for SOM were MEE over 3 months and for RAOM four or more episodes of acute otitis media in the last year. MEE diagnosis was confirmed with otomicroscopy, pneumatic otoscopy and tympanometry. Inclusion criteria for the study were: indication for TT insertion, age 8 months up to 6 years, no prior TT insertions, and MEE on the procedure day. The pneumococcal conjugate vaccine (administered at 3, 5 and 12 months of age) has been in Finnish national vaccine program since 2010 with high coverage. Exclusion criteria for the study were: previous episodes of otorrhea, perforations, cleft palate or pre-treatment detected myringosclerotic plaques. Adjuvant adenoidectomy and/or tonsillotomy/tonsillectomy were performed in the same general anesthesia if there were clear adenoid or tonsil related symptoms and findings (chronic infection, open-mouth posture with nasal obstruction, signs of sleep apnea or troublesome snoring). Adenoid and tonsil related symptoms were assessed in all participants of the study.

Changing of the surgical technique during the operating day would delay the operating room schedules and increase the risk of failures in surgery and research procedure. A biostatistician instructed that standard blinded randomization regarding surgical technique was not required. Effect size calculations were performed with a biostatistician. The aim was set at collecting 40 ears, from procedure until TT extrusion, per subgroup. The subgroups were collected consecutively in the following order: 1. Laser myringotomy (LM), 2. Incisional myringotomy (IM) and 3. Radiofrequency myringotomy (RM). Both ears of the same patient were considered independent samples.

CO_2 laser (Sharplan SurgiTouch) myringotomy was performed in 48 TT insertions; the myringotomy diameter was adjusted to 1,4–1,8 mm. Power was set to 7–10 W. One to five pulses were needed to generate a myringotomy depending on the thickness of the TM and MEE. Traditional reusable paracentesis knives were used to perform 50 myringotomies. Radiofrequency myringotomy (Ellman Surgitron 4.0 Dual RF with a reusable 1,5 mm OTO-RAM Probe (EE601)) was used in 45 ears. A few RM were performed with handswitch, but footswitch proved to be a more comfortable and safe method. Few ears allocated to RM were excluded from the study because of too narrow ear canals for RM technique.

Donaldson type silicone ventilation tubes (TympoVent, Atos Medical) were used (Fig. 1). Tympanometry (Interacoustics ®, Titan) was performed just before the procedure. The following information was routinely collected preoperatively and during the procedure: Status of the TM, middle ear effusion, bleeding of the TM, hematoma between the layers of the TM due to mechanic manipulation, use of epinephrine, count of suction used and possible deviations of routines in the procedure.

Follow-ups consisted of visits to the otorhinolaryngology department every 3–4 months until the spontaneous TT extrusion and closure of the TM perforation was noted. The study endpoint was the TT extrusion. At control visits caretakers were interviewed concerning possible ear problems, such as earache and otorrhea. Otomicroscopy and tympanometry were performed, and photographs of the TM were taken. Audiometric testing was not performed due to the young age of the patients.

2.1. Data analysis

Descriptive statistics were reported as means and medians, standard deviations (SD) or percentages. The statistical significance of categorical variables were tested by Chi-square test, Fisher's exact test and for continuous data Mann-Whitney-U or Kruskall-Wallis was used where appropriate. Kaplan-Meyer survival curves were used to compare extrusion times of the subgroups. Statistical significance for two-tailed p-values <0.05 was determined. Results were reported as p-values and 95% confidence intervals. Statistical analysis was performed using SPSS statistical software version 28 (SPSS, Inc., Chicago, IL, USA). The statistical analysis was conducted in cooperation with the Biostatistics unit of the University of Helsinki.

3. Results

The endpoint of the study was reached by 121 of the 143 ears. Twenty-two cases did not reach the endpoint because of: change of residence, reinsertion of TT between controls visit, neglect of control visits and sudden decease of one child. One TT was surgically removed due to granulation tissue and persistent otorrhea. Patients lost during the follow-up were contacted and new appointments were proposed up to three times.

Indication for TT insertion was RAOM in 89 (74%) and SOM in 29 (24%). Mean age at procedure date was 2 years and 3 months (27.0 months, median 22.2, SD 14.1) (Fig. 2) with an overrepresentation of male ears 91/121 (75%). Spontaneous TT extrusion ranged from 3 to 36 months, with a mean of 12.8 months (median 12, SD 5.4). Myringosclerosis was noted in 25/121 (21%) ears, and 15 (60%) myringosclerosis findings were already visible in the first control visit. Six of 121 (5%) cases had atrophy of the TM at the endpoint. Twenty (17%) of 121 ears had otorrhea during the TT treatment once or more. No persistent perforations or cholesteatomas were noted.

No statistically significant effect on the myringosclerosis formation or extrusion time was noted by gender, age, use of epinephrine or suction in the procedure, or episodes of otorrhea during the TT treatment.

3.1. Tympanometry results

All 121 ears had whole or partial effusion in the middle ear. Tympanometry was performed successfully in 116 ears before the procedure and at endpoint visit in 105 ears (Table 1).

3.1.1. Procedure date tympanometry results

Tympanogram was normal (type A) in 21,5% of the ears, even though all ears had whole or partial MEE, confirmed with myringotomy. Ears with a *flat* tympanogram (type B) had significantly more myringosclerosis 21/75 (28%) at study endpoint compared to partially

Fig. 1. Radiofrequency myringotomy and Donaldson type TT inserted.

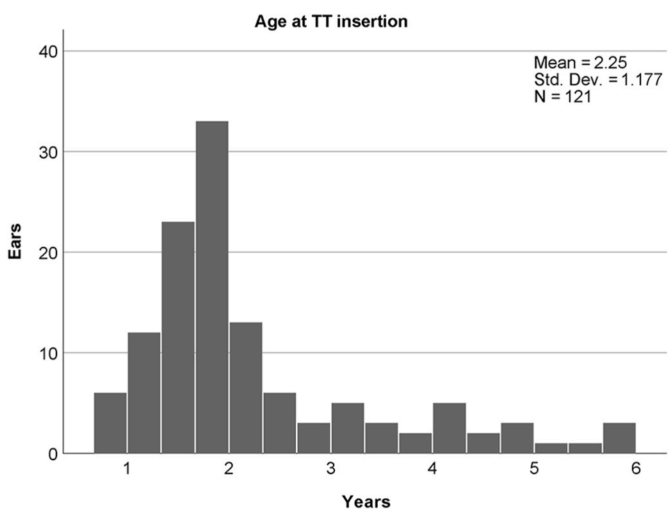

Fig. 2. Histogram showing the age distribution at TT insertion.

Table 1
Tympanometry results at procedure date and at the study endpoint. A = tympanic peak pressure (TTP) between −100 and + 100 daPa, B = *flat* curve without a distinct peak, and C = TTP < −100 daPa. The lower part of the table is a cross tabulation of the results showing that many ears with preoperative *flat* type B tympanograms still present abnormal ventilation after the tympanostomy treatment.

Tympanometry	Procedure date	Endpoint
A	26 (22%)	64 (61%)
B	75 (65%)	9 (8.6%)
C	15 (13%)	32 (30%)

		Endpoint			
		A	B	C	Total
Procedure date	A	20 (83.3%)	1 (4.2%)	3 (12.5%)	24 (100%)
	B	30 (47.6%)	6 (9.5%)	27 (42.9%)	63 (100%)
	C	10 (71.4%)	2 (14.3%)	2 (14.3%)	14 (100%)
	Total	60 (59.4%)	9 (8.9%)	32 (31.7%)	101 (100%)

aerated middle ears with type A and C tympanograms, where myringosclerosis was found in 4/41 (10%) (p = 0.032).

A correlation between procedure date tympanometry and episodes of TT otorrhea was noted. Only 7/73 (10%) of the ears with type B tympanograms had episodes of otorrhea whereas 11/41 (27%) of the ears with type A and C tympanograms had periods of otorrhea (p = 0.019). There was no difference in episodes of otorrhea between type A and C tympanometry ears.

3.1.2. Endpoint tympanometry results

After the TT extrusion, 41/105 (39%) ears still presented an abnormal tympanogram (type B and C) (Table 1). The ears with abnormal tympanograms had significantly more myringosclerosis compared to the ears with a normal tympanogram at study endpoint (p = 0.013). Myringosclerosis was found in 8/64 (13%) of ears with type A, 10/32 (31%) with type C and 4/9 (44%) with type B tympanograms.

3.2. Comparison of the subgroups

Study endpoint was reached by 121 ears (LM 37, IM 44, RM 40). No significant difference was noted in the sex distribution of the subgroups. Mean age was higher in the RM group compared to knife and laser. LM and RM presented more atrophy at the endpoint, but the difference was not statistically significant (Table 2). Bleeding was significantly higher with IM compared to LM and RM (Table 3).

3.2.1. Extrusion time

The mean time from TT insertion to extrusion was significantly shorter with laser and radiofrequency compared to tympanostomy knife (Table 2). The incidence of extrusion started to increase after 4–5 months of TT treatment (Fig. 3).

3.2.2. Myringosclerosis in the subgroups and possible confounding factors

Myringosclerosis at the endpoint was noted in 11% (4/37) with LM, 23% (9/40) with RM and 27% (12/44) with IM procedures. The rates of myringosclerosis were even higher in children with *flat* tympanometries on the day of procedure; 14% (3/22) with LM, 30% (8/27) with RM and 39% (10/26) with IM. This suggests that the ventilation problem is a significant factor in formation of myringosclerosis. However, the differences were not statistically significant (Fig. 4).

In the SOM etiology IM causes significantly more myringosclerosis than laser and radiofrequency (p = 0.01). (Laser 1/11 (9%), radiofrequency 0/12 (0%), knife 3/6 (50%))

To exclude ventilation problems as a confounding factor, we compared the surgical methods and myringosclerosis formation excluding the flat type B tympanograms at the endpoint. With this exclusion, there were no myringosclerosis found with laser, but radiofrequency presented myringosclerosis in 8/31 (26%) ears and knife in 10/37 (27%) (p = 0.008).

To rule out otorrhea as a confounding factor for myringosclerosis formation, analyses were executed also with otorrhea cases excluded. When comparing all three subgroups together, the difference in

Table 2
Comparison of the subgroups and other variables. Significant p-values are marked with *.

	LM	RM	IM	p-value
Mean age (months)	24	32	25	0.046*
Mean TT extrusion (months)	11	12	15	0.002*
Male gender	25/37 (68%)	34/40 (85%)	32/44 (73%)	0.186
Otorrhea	4/37 (11%)	7/40 (18%)	9/42 (21%)	0.458
Atrophy	2/22 (9%)	3/40 (8%)	1/43 (2%)	0.366
Epinephrine	2/37 (5%)	3/40 (8%)	9/44 (21%)	0.089

Table 3
Bleeding in procedure. Tympanostomy knife was associated with more bleeding in the procedure compared to LM and RM ($p < 0.001$). No abundant bleeding was associated with CO_2 laser. Radiofrequency, although considered a bloodless technique, caused abundant bleeding in three ears.

Bleeding in procedure	no	Little	Abundant	total
LM	44 (92%)	4 (8%)	0 (0%)	48
IM	0 (0%)	45 (90%)	5 (10%)	50
RM	35 (83%)	4 (10%)	3 (7%)	42

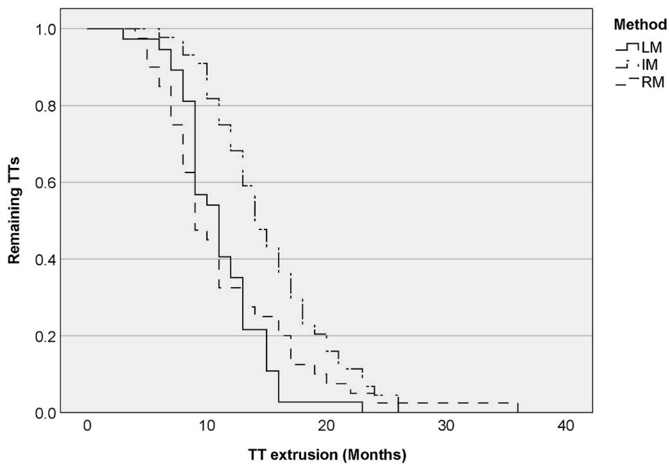

Fig. 3. Kaplan-Meier curve, showing that CO_2 laser and radiofrequency inserted TTs extrude on average 4 months earlier than IM inserted TTs.

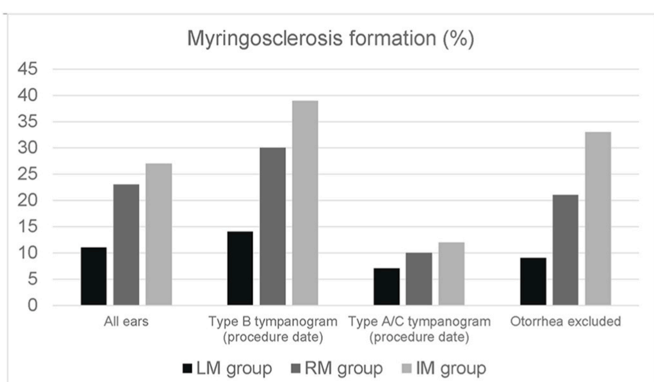

Fig. 4. Percentages of myringosclerosis formation associated with the different surgical methods.

myringosclerosis formation was close to significant LM 3/33, RM 7/33, IM 11/33) ($p = 0.063$). Furthermore, the difference was significant when comparing only LM and IM ($p = 0.033$).

4. Discussion

The objective of this study was to compare CO_2 laser, radiofrequency, and incisional myringotomy in TT treatment of young children. Special emphasis was on myringosclerosis formation and tympanometric testing. Duration of the TT treatment with spontaneous extrusion ranged from 3 to 36 months and no persistent perforations or cholesteatoma were noted. After TT extrusion 39% of the ears still presented an abnormal tympanogram (type B or C) indicating the eustachian tube still had poor function. This ventilation problem, as well as *flat* type B tympanograms at procedure date were significantly associated with myringosclerosis formation. Myringosclerosis formation was also, to lesser extent, associated with bloodless surgical methods, especially CO_2 laser. Myringosclerosis was found in 21% of all ears. Majority of these findings were visible in the first control visit, suggesting myringosclerosis develops shortly after the myringotomy as Mattson et al. proposed in 1999 [14].

There is a lack of consensus regarding TT removal. Recently, one study suggested TT removal after 18 months of treatment. Another study suggests follow-up until 3 years of uncomplicated treatment [4,5]. Surgical removal of TT tubes often requires general anesthesia, as many patients are young children. In this study, no correlation between episodes of otorrhea and TT duration was noted. This is in line with the study of Knutsson J et al. [19]. Interestingly, in this study LM and RM inserted TTs extruded on average 4 months earlier than IM inserted TTs. We suggest that LM and RM vaporize tissue, leaving reduced support to the tube. Despite this earlier extrusion of LM and RM inserted TTs, even 13% (16/121) of all TTs in this study extruded spontaneously after 18 months of treatment. To avoid unnecessary procedures and risks of general anesthesia, our findings support the 3-year follow-up before surgical removal of TTs in uncomplicated cases.

The high amount of middle ear ventilation problems after TT extrusion was an unanticipated finding and previous literature on this subject is scarce. TT treatment protocols highlight the follow-up until tube extrusion and closure of the TM perforation [2]. This study suggests there is a need for extended follow-up, at least if a post TT treatment tympanogram is abnormal. This could prevent long-term complications of poorly ventilated middle ears, such as TM atrophy, chronic otitis media and cholesteatoma.

The finding of effusion in many ears with type A tympanograms was an important finding, suggesting that ventilation problems and effusion cannot be excluded with only tympanometry. This was a surprising finding, indicating that MEE does not exclusively lead to *flat* tympanometry. The A type finding can be the result of highly mobile TM or the effusion is not highly viscous or both. This means that the clinician cannot rely only on tympanometric testing when considering TT treatment.

Earlier research has shown less myringosclerosis formation with bloodless techniques compared to IM, [15,16]. In this study, the percentage differences in the subgroups shows a tendency for less myringosclerosis formation with bloodless techniques, especially CO_2 laser. However, the differences were statistically significant only in the SOM etiology and therefore, we analyzed the possible confounding factors. Our results show that both ventilation problems and the surgical technique used affect the myringosclerosis formation.

Noteworthy, the overall myringosclerosis formation in the IM group in this study was low (27%) compared to the study of Erdurak et al. where IM caused myringosclerosis in 50% of the ears [15]. This may be due to several confounding factors, for example age. This study illustrates that the typical age for TT insertion in Finland is between one to three years of age (Fig. 2). Most studies investigating myringosclerosis have higher mean age compared to this study. In older children, the MEE etiology probably shifts from RAOM to eustachian tube dysfunction. This may explain the higher frequencies of myringosclerosis in other studies [8,9,12,15]. The Power for this study was calculated with the background of incidence from earlier studies. Our study showed less myringosclerosis than expected. This may have led to bias in Power calculations and further studies are needed to confirm if the tendency to less myringosclerosis with bloodless methods is statistically significant.

RAOM and SOM may have different tendencies to myringosclerosis formation. The possibility of two different etiologies in the study material is also supported by the findings of otorrhea. Type A and C tympanograms at procedure date presented significantly more otorrhea during TT treatment. These cases probably present more RAOM etiology, where recurrences are seen as TT otorrhea. Therefore, a change towards a more conservative approach with RAOM might be reasonable. This is also supported by a recent study of RAOM, where no significant difference was noted in two-year rate of acute otitis media in TT treated patients compared to medical management [20]. On the other hand, TT insertion with adjuvant adenoidectomy could be beneficial in children with pure SOM etiology [21]. In this study, bloodless techniques showed significantly less myringosclerosis formation in the 29 cases with SOM etiology. The etiology information, however, has some uncertainty as it is based on anamnesis. In primary health care SOM is sometimes probably misdiagnosed as RAOM. Further studies are needed with patients of pure SOM or RAOM etiology.

4.1. Comparison of the techniques

Traditional tympanostomy knives are undoubtedly cheap, fast, and available at every department of otorhinolaryngology. IM causes bleeding that is easily treated with topical epinephrine and causes minor delays. In this study, all TT insertions with IM were performed without problems.

CO_2 laser equipment is more expensive and therefore not accessible. LM technique had many advantages; excellent visibility, minimal bleeding and easy TT insertion. All LM insertions were performed successfully.

The cost of radiofrequency equipment is affordable, and since it is used for many types of otorhinolaryngological procedures, it is available in most otorhinolaryngology departments. Preparations for radiofrequency myringotomies were easy. However, the insulation material covering the reusable 1,5 mm OTO-RAM Probe (EE601) made the probe diameter large, impairing visibility. Therefore, few radiofrequency-planned procedures were excluded from the study, which led to higher mean age in the RM group. Another disadvantage with the 1,5 mm probe was its precision. The long and thick probe makes the RM procedure technically demanding. Our experiences suggest avoiding the use of the round 1,5 mm probe.

4.2. Limitations and strengths of the study

Despite the relatively large sample size of 121 ears, there may be an effect size problem, explaining the challenges in finding significant differences in myringosclerosis formation in the subgroups. Study strengths include the prospective study setting with close and long follow-up, comprehensive tympanometric data, and participants with a typical age profile for acute otitis media [22].

5. Conclusions

All TTs extruded spontaneously without major complications, such as persistent perforations or cholesteatoma, indicating no need for surgical removal before 3 years of treatment. LM and RM inserted TTs extruded faster and may cause less myringosclerosis. Poor middle ear ventilation seems to be a confounding factor. Incisional myringotomy remains a good, feasible and cost-effective method, but the bloodless surgical methods are good alternatives. Tympanometry shows more predictive value than previously thought and is a useful tool in evaluation of long-term ventilation problems. A type tympanometry does not exclude effusion in the middle ear.

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Authorship statement

Juha Silvola designed the work; Atte Sjövall and Juha silvola collected the material; Atte Sjövall analyzed the data; Atte Sjövall, Juha Silvola and Anu Laulajainen-Hongisto drafted, revised and approved the manuscript, Atte Sjövall agrees to be accountable for all aspects of the work.

Data Availability Statement

The anonymized data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declaration of competing interest

None.

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