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Cataract complications study: an analysis of adverse effects among 14,520 eyes in relation to surgical experience

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Background: To evaluate the learning-curve in performing cataract surgery with respect to developments in technology and different teaching strategies by comparing the incidence of capsular bag-related complications to operator experience.

Methods: A review of the registry of 14,520 cataract surgeries carried out at the Ophthalmology Unit of Kymenlaakso Central Hospital, Kotka, Finland, from August 8, 2009 to July 31, 2017.

Results: We identified 144 cases with posterior capsule rupture and/or loss of capsular bag support (incidence 0.99% of all surgeries). The mean age of patients was 76.9±9.1 years and gender distribution ratio 29:71 male:female. Pseudoexfoliation syndrome (PXF; incidence 21%) and small pupil (incidence 14%) were over-represented in complication eyes, especially at the beginning of the study. Capsular bag-related complication rates were reported in 0.36% of surgeries for senior and 7.03% for resident surgeons at the beginning of the study, compared to 0.32% and 1.32%, respectively, at the end of the study. Best-corrected visual acuity at the final post-operative visit was 0.61±0.16 decimals at the beginning of the study, and 0.81±0.19 decimals at the end of the study. The mean number of post-operative visits was 4.3±2.7 and did not show trend over the study period.

Conclusions: Real-world evidence suggests PXF and small pupil as significant risk factors in cataract surgery. A gradual decline in the rate complications was noted with increasing surgical experience, also among residents over the follow-up period.

Keywords: Cataract surgery; complication; learning-curve; posterior capsule rupture; zonular dialysis

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Introduction

Technological advancement has made cataract surgeries faster and safer. Regardless the general decline observed in rates of adverse events several patient and ophthalmic characteristics have been associated with increased risk of perioperative complications. These characteristics comprise e.g., pseudoexfoliation (PXF) and zonular weakness, use of α 1-blockers, dense cataracts and poor mydriasis (1). Moreover, the level of surgeons' experience and annual operation volume were recognized as factors correlating with the frequency of cataract surgery adverse events. Among patients over 90 years of age, ocular comorbidity and worse preoperative visual acuity also significantly

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increased the risk of complications (2).

A variety of methods have been applied to assess the resident-performed cataract operations learning curve including. Evaluation of the frequency of complications [particularly posterior capsule rupture (PCR)], the frequency of attending surgeon takeovers, or the gradual decline in the operation time (1,3). Complication rates were found to decline significantly after the first 200 operations (4-6). A steadier decrease in the complication rate was noted at 3,000 phacoemulsifications (7). Remarkably, a peak in the complication rates was observed as a consequence of residents gaining experience followed by diminished supervisor intervention (8).

Poorly dilated pupils were associated with increased complication rates both for residents and senior surgeons (9), whereas iris complications were likely to take more time from resident surgeons (10). Longer cataract surgery operation time predicted lower visual outcomes (11) or poorer patient satisfaction (12). Furthermore, PXF and the use of α 1-blockers were associated with reduced post-operative visual acuity (13). To reduce the rate of complications, such as PCR and vitreous loss, the installation of surgical curriculum in the residency program was suggested (14,15). Posterior capsule rupture, in turn, was associated with 42-fold risk for retinal detachement and 8-fold risk for endophthalmitis within 3 months after cataract surgery (16). Implementation of wet-labs and surgical simulators in cataract surgery training were found comparably effective in terms of improving residents' surgical abilities, although residents with wet-lab training required less operation time (17). In a large study the use of surgery simulator was found to reduce the PCR rate by 38% (18). The use of simulators has been shown to improve surgical skills among novice and even intermediate level surgeons (19,20). In addition, simulators can be used to assess competency in ocular surgery (21). A method for a systematic step-by-step assessment of resident performed cataract operations was developed to better recognize the sites of improvement (22). An attempt has been made to pre-evaluate a surgeon's risk for PCR with respect to surgeon experience level (23).

Here, we examined the frequency of posterior capsule rupture and/or loss of capsular bag support between years 2009–2017 with respect to surgical experience. Further, we analyzed the outcomes of eyes with complications and discuss advances in surgical operation training during the study period.

Methods

This study was carried out as a retrospective cohort study at the Unit of Ophthalmology, Kymenlaakso Central Hospital, Kotka, Finland. The study was approved by the Research Director and Chief Medical Officer of the Kymenlaakso Central Hospital and the tenets of the Declaration of Helsinki were followed. Confidentiality of the patient records was maintained when the clinical data were entered into a computer-based standardized data base for analysis.

Patients

We reviewed the registry of operations for phacoemulsification cataract surgeries and posterior capsule ruptures and/or loss of capsular bag support between 1/8/2009 and 31/7/2017. Indications for phacoemulsification cataract surgery were based on the National Current Care Guidelines for Senile Cataract Surgery. The patient age distribution over the study period is represented in Figure S1. The Guidelines remained constant regarding patient eligibility for surgery "A patient is eligible for referral when best-corrected visual acuity (BCVA) in the better eye is ≤ 0.5 and in the weaker eye ≤ 0.3 measured in E-snellen lines" [Duodecim 2010;126(21):2541-2, updated in year 2013].

Surgery

The pre- and intraoperative methods employed to decrease the rate complications are summarized in *Table 1*. Structured referral for cataract surgery was demanded for all patients from year 2014 onwards (*Figure 1*). Simultaneously, cataract surgery risk stratification was implemented for coordination of operations with respect to the required level of surgeon competency (Table S1).

The patients were examined by the operating ophthalmologist preoperatively on the day of surgery. Cataract surgeries were performed by three seniors, three specialists, and 19 residents in ophthalmology. The level of surgical skill between specialists and seniors was defined according the surgical education responsibilities. Seniors are supervising doctors in ophthalmic surgery for residents, while specialists have finished their residency and work as independent full-time employees. All three specialists had performed their surgical training already during residency. For the residents, only the first 100 operations were counted to the registry to maintain the follow-up throughout the

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 Table 1 Methods employed to decrease the rate of operative complications in cataract surgery in Kymenlaakso Central Hospital, Kotka, Finland, during the years 2009–2017

Action	Date	Effect on cataract surgery
Preoperative phase		
Wet-labs	2011	Porcine eyes replaced rubber eyes - allows improvement in practical skills
Surgical curriculum	2014	Oculoplastic training before cataract surgery - surgical experience
Structured referral	2014	Systematic risk stratification, patient allocation according to surgeon's experience level*
Virtual reality simulator	2014	Eyesi [®] Surgical for intraocular surgery training
Intraoperative phase		
OVDs	2009	Viscous dispersive DiscoVisc $^{\ensuremath{\scriptscriptstyle \circledcirc}}$ OVD - improved space maintenance, ease of removal
One-Piece IOLs	2009	One-Piece IOLs as principal choice both for clear and blue-light filtering IOLs. Ease of manipulation in the capsular bag
Alcon Infinity Vision System with minitip phaconeedle	2010 and 2013	Phaco can be performed with less energy, better anterior chamber stability, improved efficacy, torsional ultrasound, less repulsion, procedure duration reduction, reduced surge, control over aspiration independently of vacuum and reduced occlusion breaks.
Senior in adjacent OR	2013	Consultation made easy
Silicone tip for I/A	2013	Enhanced safety in posterior capsule polishing
Pupil expansion device	2014	Malyugin ring $^{\circ}$ 6.25 mm replacing iris hooks - reduced manipulation of the iris, reduced operation time
Surgical microscopes	2015 and 2016	Zeiss OPMI Lumera 700 and Leica M844 F40 replacing Zeiss S4 and S5 microscopes - video recording for feedback and learning difficult steps
Preloaded IOLs	2015 and 2016	AU00T0, AcrySof [®] IQ, SN60WF in UltraSertTM delivery system, Alcon and PCB00, Tecnis [®] IOL in iTec [®] delivery system, Johnson & Johnson Vision - reduces need for IOL manipulation

I/A, irrigation & aspiration; IOL, intraocular lens; OR, operation room; OVD, ophthalmic viscosurgical device. *, please see Figure 1 and Table S1.

study period comparable as some of the residents performed markedly higher numbers of surgeries.

A 2.75 mm clear cornea incision was used throughout the study period. The predominant phacoemulsification technique over the study period was divide and conquer (hrrg.fi/en/videos/cataract/).

Data analysis

Data are given as mean \pm SD, except for the absolute numbers and proportions for the nominal scale. IBM SPSS Statistics 25 (SPSS Inc., Somers, NY, USA) was used for data analysis. Categorical data were analyzed with the two-factor chi-square test. BCVA was analyzed with nonparametric Mann-Whitney U test and normallydistributed continuous variables with the t-test. A mixedeffects logistic regression model, incorporating repeated measurements, was fitted during the statistical analysis. $P \le 0.05$ was considered statistically significant.

Results

Baseline variables

The number of operated eyes were 10,724 for seniors (73.9% of all operations), 2,473 for specialists (17.0%), and 1,323 for residents (9.1%) (*Table 2*). Of the total 144 PCR and/or loss of capsular bag support (total incidence from 14,520 surgeries; 0.99%), 75 were recorded at the phacoemulsification phase (52.1%), 34 at the irrigation/ aspiration (I/A) phase (23.6%), 10 at the IOL implantation phase (6.9%), and 25 in non-specified/other phase of the surgery (17.4%) (*Table 3*, Table S2).

Baseline variables of eyes with complications regarding the age and gender distribution, BCVA, incidence of small pupils and PXF are presented in *Table 4*. Baseline characteristics indicate poorer BCVA, and



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Referral for Cataract Operation

Patient name:

Social Security Number:

 \Box Right eye \Box Left eye \Box Both eyes

OPERATION TIMEFRAME	NO	YES
Medical indication for urgent cataract operation (lens induced angle-closure)		
Social indication for urgent cataract operation (e.g. occupation)		
BACKGROUND INFORMATION	NO	YES
Tremor or other condition that may complicate the operation		
Alpha-1 blockers due to benign prostatic hyperplasia		
Diabetes		
Iodine or rubber allergy		
Unable to lay on the operation table for a half an hour		
PREVIOUS OCULAR DISEASE	NO	YES
Prior ocular surgeries (PRK/LASIK, vitrectomy, filtration surgery)		
Inflammatory ocular diseases (iritis, chronic blepharitis)		
Other vision impairing ocular condition (amblyopia, AMD)		

CURRENT CLINICAL STATUS

BCVA and correction			BCVA and correction		
IOP			IOP		
	NO	YES		NO	YES
Corneal opacities			Corneal opacities		
Shallow anterior chamber			Shallow anterior chamber		
Small pupil in mydriasis			Small pupil in mydriasis		
Mature cataract			Mature cataract		
Pseudoexfoliation			Pseudoexfoliation		
Phacodonesis			Phacodonesis		
Pseudophakia			Pseudophakia		

Other relevant information (e.g. difficulty to maintain fixation)

Referring organization and date

Referring doctor and signature

RECEIVING UNIT EVALUATION

Urgency I

Urgency I

Surgeon seniority A

Figure 1 Referral for cataract operation. AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; IOP, intraocular pressure.

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 Table 2 Incidence (%) of posterior capsule rupture and/or loss of capsular bag support according to surgical experience

Time period	Senior (n=3)	Specialist (n=3)	Resident (n=19)
8/2009-7/2010	0.36		7.03
8/2010-7/2011	0.46		5.45
8/2011-7/2012	0.42		6.20
8/2012-7/2013	0.32	4.22	4.27
8/2013-7/2014	0.46	2.27	3.81
8/2014-7/2015	0.31	1.99	3.82
8/2015-7/2016	0.34	1.28	2.17
8/2016-7/2017	0.32	0.67	1.32
Overall	0.39 (n=10,724)	1.86 (n=2,473)	4.23 (n=1,323)

Data are given as incidence (%). Surgeon seniority defined by responsibility of surgical training of the Residents.

Table 3 Surgical phase when posterior capsule rupture and/or loss of capsular bag support was noticed

Surgical phase	n		
Total	144 of 14,520 surgeries (0.99%)		
Phaco	75		
I/A	34		
IOL implantation	10		
not specified/other	25		

Data are given as absolute number (N) and proportion (%). I/A, irrigation aspiration; IOL, intraocular lens.

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overrepresentation of small pupils and PXF eyes subjected to complication towards the start of the study period (*Table 4*).

Incidence and outcomes of PRC and/or loss of capsular bag support over the study period

Over the study period the incidence of PCR and/or loss of capsular bag support remained constant among senior surgeons (from 0.36% to 0.32%; range, 0.31–0.46%, *Table 2*). Decline in the complication rates over the study period was observed among specialists (from 4.22% to 0.67%; *Table 2*), and likewise among residents (from 7.03% to 1.32%, *Table 2*). Overall, the frequency of cataract surgery complications has been decreasing since the year 2009 (P<0.001). Regarding surgeon's professional experience, a specialist was 46.6% (95% CI: 15.3–66.4%, P=0.008) and a senior clinician was 92.4% (95% CI: 88.1–95.1%, P<0.001) less likely to encounter complications as compared to a resident. Interestingly, over the study period a senior clinician was 85.7% (95% CI: 75.6–91.7%, P<0.001) less likely to encounter complications when compared to a specialist.

The number of post-operative visits was 3.5 ± 1.7 at the beginning of the study period and 3.0 ± 1.7 at the end of the study period (*Table 5*). BCVA at the final visit was 0.61 ± 0.16 decimals at the beginning of the study period and 0.81 ± 0.19 decimals at the end of the study period (*Table 5*).

The number of post-operative visits and BCVA at the final post-operative visit was comparable between surgeries performed by the residents and non-residents (Table S3), and between complications according to the surgical phase (Table S4). Small pupils and PXF were overrepresented

Time period	Age (y)	M:F (%)	BCVA (decimals)	Small pupil (%)	PXF (%)
8/2009-7/2010	68.5±15.7 [47–82]	25:75	0.27±0.17 (HM–0.5)	16	24
8/2010-7/2011	76.7±6.8 [64–86]	33:67	0.25±0.08 (0.1–0.3)	20	30
8/2011-7/2012	80.3±7.3 [63–95]	13:87	0.26±0.20 (CF-0.5)	36	7
8/2012-7/2013	78.1±7.7 [64–90]	29:71	0.27±0.13 (0.05–0.5)	20	30
8/2013-7/2014	78.8±5.0 [69–86]	24:76	0.22±0.15 (HM–0.5)	19	29
8/2014-7/2015	75.7±8.7 [57–89]	45:55	0.29±0.15 (0.05–0.5)	4	25
8/2015-7/2016	75.6±10.2 [45–90]	21:79	0.31±0.18 (CF-0.5)	0	0
8/2016-7/2017	78.2±11.9 [48–97]	50:50	0.47±0.29 (0.3-0.8)	0	0

Table 4 Baseline characteristics of eyes with posterior capsule rupture and/or loss of capsular bag support

Data are given as mean ± SD and range or proportion (%). BCVA, best-corrected visual acuity in decimals; CF, counting fingers; F, female; HM, hand motion; M, male; PXF, pseudoexfoliation syndrome.

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Time period	AC-IOL : Sulcus or OC (%)	No of post-op visits	BCVA at last post-op visit
8/2009-7/2010	23 : 77	3.5±1.7 [3-7]	0.61±0.16 (0.4–1.0)
8/2010-7/2011	50 : 50	4.2±2.4 [2-5]	0.52±0.17 (0.3-0.7)
8/2011-7/2012	57 : 43	3.9±2.3 [2-7]	0.60±0.37 (0.05-1.0)
8/2012-7/2013	60 : 40	4.7±1.7 [1-8]	0.61±0.30 (0.1-1.0)
8/2013-7/2014	25 : 75	3.1±1.1 [1–6]	0.66±0.30 (0.2-1.0)
8/2014-7/2015	39 : 61	5.7±4.4 [2–26]	0.59±0.27 (0.25-1.0)
8/2015-7/2016	15 : 85	4.9±2.6 [2–13]	0.71±0.29 (0.2-1.0)
8/2016-7/2017	0 : 100	3.0±1.7 [2-5]	0.81±0.19 (0.63-1.0)

Table 5 Outcomes of posterior capsule rupture and/or loss of capsular bag support

Data are given as proportions (%) or mean ± SD and range. AC, anterior chamber; BCVA, best-corrected visual acuity; IOL, intraocular lens; OC, optic capture.

in eyes with a need for AC-IOL (incidence of small pupils 24% vs. 9%, P=0.013, and of PXF 42% vs. 9%, P<0.001, among those with and without AC-IOL, Table S5). With respect to IOL positioning, having anterior chamber (AC)-IOL the number of post-operative visits was higher (5.2 ± 3.5 vs. 3.8 ± 2.1 , P=0.006, Table S5) and BCVA at the final post-operative visit lower (0.46 ± 0.27 vs. 0.71 ± 0.23 , P<0.001, Table S5) when compared to complications without the need for AC-IOL.

Discussion

The safety of patients must be guaranteed in public teaching hospitals particularly when surgeries are performed by non-skilled residents. Phacoemulsification cataract surgery has a relatively steep and long learning curve (24). For example, the study by Randleman et al. showed that the risk of PCR is 6.3% in the first 80 cases and 3.5% in the next 80 surgeries, which is much higher than the complication rates reported in large studies (5,25). In another investigation, the overall PCR rate in residentperformed surgeries reached 17.3% in 183 cases (26). Various methods have been utilized to decrease the risk of complications in resident-performed surgeries including early introduction of cataract surgery training during the residency (15), one-step rather than stepwise introduction of various surgical maneuvers (26), employing an extensive surgical curriculum (14) along with surgical simulator (27) and wet-lab training. Moreover, the use of risk stratification system prior to cataract surgery is widely accepted and practiced with small variations around the world (1). For example, it has been suggested that the Buckinhamshire

risk assessment better correlates with post-operative complications, while the Muhtaseb variation is more accurate in predicting intraoperative complications (28). A structured risk stratification not only allows routine assessment by referring ophthalmologists, but also helps in gathering information for systematic evaluation.

Within our study it is difficult to relate the risk reductions to any single improvement, either in the preoperative or perioperative phase. During the followup and assessment of the study, the national guidelines have remained the same for cataract surgery eligibility. The patients' average age at surgery has also remained constant. Thus, the indications for surgery are comparable throughout the study period. In this single site retrospective cohort study, we found a gradually declining rate of complications among residents and improved BCVA at the final visit towards the end of the study period, whereas no significant variation was observed in the number of postoperative visits. The use of AC-IOL was associated with a higher number of post-operative visits and the lower BCVA at final postoperative visit.

Small pupils and PXF were more frequent among non-resident surgeons when compared to the residents, which reflects the allocation of risk patients with the risk stratification system. The greater rate of female patients in resident-performed surgeries compared to non-residents could be associated with patient stratification; e.g., the medical treatment for benign prostatic hyperplasia involves predominantly men and such patients were directed to more experienced non-resident surgeons. This partially could have accounted for our low complication rates; within the final period of our study the incidence of PCR among

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Table 6 Studies analyzing the posterior capsule rupture rate (PCR) in resident-performed phacoemulsification cataract surgeries (published within the last 10 years and involving a minimum number of 100 surgeries per study)

Study	Patient risk stratification	What did the study evaluate?	PCR rate (total number of cases)
Borboli-Gerogiannis et al. 2019	Yes (complicated cases excluded)	Before (n=804) vs. after (n=1,282) employing extended surgical curriculum (including pre-OR, intra-OR and post-OR training)	7.7% vs. 1.4%*
Ellis <i>et al.</i> 2018	Yes	Early (first year of residency; n=540) vs . late (during final year; n=780) introduction of cataract surgery during residency	1.9% <i>vs.</i> 6.5% (with anterior vitrectomy)*
Staropoli <i>et al.</i> 2018	Yes (cases selected by surgeons)	Virtual simulator training (n=501) vs. no such training (n=454)	2.2% vs. 4.8%*
Low <i>et al.</i> 2018	Not used formally	3,142 cases, 18% of resident-performed surgeries conducted with staff surgeon	0.8%
Clarke et al. 2017	No	1,290 cases	7.0%
Tzamalis <i>et al.</i> 2015	N/A	Step-by-step (n=185) vs. one-step (n=317) introduction of difference phacoemulsification steps	17.3% vs. 7.3% (with zonular dehiscence and vitreous loss)*
Puri <i>et al.</i> 2015	N/A	Novice vs. experienced attendings	0.5% vs. 2.3% (however, vitreous loss in 10.6% and 2.3%*, respectively)
Hashemi <i>et al.</i> 2013	Yes (complicated cases excluded)	500 patients	9.6%
Pokroy <i>et al.</i> 2013	N/A	Virtual simulator training (n=50) vs. no such training (n=50)	7.0% vs. 8.0%
Yulan <i>et al.</i> 2013	N/A	First 30 cases vs. last 30 cases (n=1,013)	10.8% vs. 1.7%
Woodfield et al. 2011	l Yes	2nd (n=228) vs. 3rd year (n=463) of residency	7.0% vs. 4.8%
Carricondo <i>et al.</i> 2010	Yes (complicated cases excluded)	First 40 cases vs. the cases 41–80 vs. cases 81 and more	9.7% vs. 7.4% vs. 5.8%
Rogers <i>et al.</i> 2009	No	Before (n=823) <i>vs.</i> after (n=1,009) employing extended surgical curriculum (including wet lab training, backing up by a senior resident, formative feedback and capsulorhexis practice)	7.2% vs. 3.8%*

*, statistically significant.

resident-performed surgeries was only 1.32%. This is one of the lowest values reported for phacoemulsification cataract surgery {*Table 6* [Sources: (29-32)]}. Low *et al.* presented a PCR rate of 0.8%; however, in their study 18% of resident-performed cases were performed with an attending surgeon (33). Moreover, there was no difference in overall complication rates between resident and staff surgeons in their study, although it is not clear how patient selection was conducted. Low PCR rates, under 2%, were also reported by other authors (15,34,35); however, in some studies such low rates were achieved only in the final phase of training and not presented as an overall complication rate through the whole training period (35).

In addition to higher intraoperative complication rates, which obviously are related with insufficient surgical skills, also other hazards associated with resident training have been reported. Resident-performed cataract surgery can predispose to persistent postoperative inflammation; in the study by Patel *et al.* 6.6% of eyes suffered from such inflammation which was classified as idiopathic, due to a complicated cataract surgery or nonadherence to topical therapy (36). Moreover, it is estimated that residentperformed surgeries can take up to 27 minutes longer than those performed by attending surgeon; this could translate to an average additional cost of \$105.40 per surgery with the cost of running an operating room in mind (37).

This study has several limitations. First, we could not specify the efficacy of any particular method employed to decrease the rate of complications during surgery. Thus, we cannot recommend one specific practice to improve

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surgical outcomes in resident-training. Second, we did not analyze the complication rates and the advancement in resident training in particular timeframes; this data could reveal more detailed information regarding the learning-curves. Nevertheless, we believe that our study presents real-life statistics and highlights the fact that with proper methodology it is possible to significantly decrease intraoperative complication rates among residents as well as experienced surgeons.

What was known

- Intraoperative complication rates for resident-perform cataract surgery vary greatly, however, in several studies they are higher than for experiences surgeons;
- Patients with PXF syndrome or with a small pupil are at risk of developing intraoperative complications during cataract surgery.

What this paper adds

- Several methods can be applied to decrease the complication rates in cataract surgery including patient risk stratification, employing virtual reality simulators and wet-lab training, irrigation/aspiration with a silicone tip and video recording for feedback;
- Within this study, we were able to reduce the posterior capsult rupture rate from 7.03% to 1.32% in residentperformed surgeries, and from 4.22% to 0.67% in specialist-surgeons.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was approved by the Research Director and Chief Medical Officer of the Kymenlaakso Central Hospital and the tenets of the Declaration of Helsinki were followed.

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