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Original Article

Real-time quality control of nuchal translucency measurements using the exponentially weighted moving average chart

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ABSTRACT

Objective: The establishment of ongoing audits for first-trimester nuchal translucency (NT) measurements is of paramount importance. The exponentially weighted moving average (EWMA) chart has been published as an efficient tool for NT quality control with the advantages of being suitable for real-time long-term monitoring. This study aimed to assess the efficacy of real-time NT quality control using EWMA charts.

Materials and methods: This was an ongoing prospective study conducted from January 2011 to December 2017 at the Centre for Fetal Medicine Gennet in Prague. The quality of NT measurements was assessed using the NT retrospective distribution parameters and EWMA charts, and the results were presented to the sonographers during collective meetings.

Results: Overall, 28,928 NT measurements obtained from six sonographers were eligible for the study. Looking at individual EWMA charts, we observed four main outcomes. First, there was a clear improvement in the performance of sonographers with initially poor performances. Second, the performance of sonographers with an initially satisfactory quality was maintained. Third, there was an observed deterioration of the performance without the audits. Last, the sonographers appreciated an unequivocal and straightforward graphical presentation of EWMA curves.

Conclusion: EWMA proved to be an efficient and suitable tool for real-time monitoring of NT quality and led to an overall improvement of the sonographers' performance.

Introduction

Nuchal translucency (NT) represents the accumulation of subcutaneous fluid behind the fetal neck and can be visualized and measured in the last third of the first trimester of pregnancy [1]. NT has become a well-established part of first-trimester multi-marker screening strategies and is by far the single best individual marker of fetal Down syndrome and other major aneuploidies [2–4]. However, the accuracy of NT measurements is highly operator-dependent and technique-dependent. Because even a small systematic shift in NT measurement can cause a considerable change in screening efficacy [4,5], international guidelines specifying a standardized measurement technique have been established [6], and regular quality assurance assessments are exceedingly recommended [6,7]. Furthermore, ongoing quality assessment leads to improvement in NT quality measurements [8–11].

There are two main approaches to NT quality review. The first one includes a retrospective assessment of the distribution of the measurements over a given period (usually a year). This assessment can evaluate the proportion of NT above and below certain centiles [6] or calculate the median NT, expressed in multiples of the median (NT-MoM) and its standard deviation, on a logarithmic scale (SD $\log_{10}$ (NT-MoM)) [4,12].

The second approach is based on the continuous evaluation of the deviation of consecutive NT measurements from a target value. Being prospective, this method has the main advantage of allowing for the early detection of deviation from target performance, with a possible prompt reaction. An example of such a method is the cumulative sum (CUSUM) chart. In 2011, Biau et al. [13] proposed its

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use for NT quality review, using NT deviation in millimetres. Subsequently, others have designed and successfully applied MoM-based CUSUM charts [14–17].

Another prospective method, the exponentially weighted moving average (EWMA) chart, has recently been determined to be an efficient tool for NT quality review, with the advantages of being suitable even for long-term, real-time monitoring, with intuitive graphical output, excellent interpretability and the ability to promptly show the rectification of an out-of-control performance to an in-control state [18].

The aim of this study was to assess the efficacy of real-time NT quality control using EWMA at a tertiary care centre over a seven-year period. On the whole, the study verifies EWMA to represent an efficient and suitable tool for real-time long-term monitoring of NT quality measurements.

Materials and methods

An ongoing prospective study, taking place in the Centre for Fetal Medicine and Reproductive Genetics GENNET in Prague, is presented in this paper together with results obtained January 2011 to December 2017. The GENNET Clinic specializes in comprehensive care in medical genetics, prenatal care, infertility treatments and reproductive disorders.

All pregnancies between 11 and 14 gestational weeks, presented for the routine first-trimester combined screening, were included in the study. Six sonographers (labelled A-F) performed routine first-trimester ultrasound scans during the study period; overall, 28,928 NT measurements were eligible for the study. All sonographers are accredited by the Fetal Medicine Foundation (FMF), undergo annual FMF audits and perform NT measurements according to the current FMF guidelines [6]. In 2011, when the study started, sonographers A-C were younger and less experienced, whereas sonographers D-F were older and more experienced. The examinations were conducted transabdominally or transvaginally using Voluson E10, Voluson E8 and Vivid 7 ultrasound machines (General Electric Medical Systems, Kretztechnik GmbH & Co, Vienna, Austria). Only NT measurements of fetuses from singleton pregnancies with a crown-rump length (CRL) between 45 and 84 mm were included. In agreement with previous studies [12,14,18], the analysis was restricted to NT measurements between 0.1 and 4.0 mm. Each NT measurement was converted into NT-MoM (and $\log_{10}$ (NT-MoM)) using a reference curve described by Nicolaides et al. [19] according to the formula $\log_{10} NT = -0.3599 + 0.0127\,CRL - 0.000058\,CRL^2$. Subsequent analyses were conducted using $\log_{10}$ (NT-MoM).

The quality of the NT measurements for each particular sonographer was assessed by the means of two measures. First, the retrospective NT measurement distribution parameters, median (NT-MoM) and SD $\log_{10}$ (NT-MoM), were calculated from the measurements from the past year. For the SD, a nonparametric estimator based on the interdecile range divided by 2.5631 was used [4]. The acceptable ranges were set to 0.90 to 1.10 for NT-MoM and 0.07 to 0.11 for SD $\log_{10}$ (NT-MoM) [4].

Second, the real-time monitoring of NT measurements was assessed using EWMA charts. EWMA was originally described by Roberts [20] in 1959 as a statistical process control method that is very sensitive to relatively small changes in the process. It is a type of moving mean that adopts a varying weight scheme. The highest weight is assigned to the most recent observation, and the weights of the past observations fall off exponentially in a geometric series. EWMA is based on the statistic of [20,21] in the form

$$Z_i = \lambda x_i + (1-\lambda)Z_{i-1}, \quad 0 < \lambda \le 1, \tag{1}$$

where x_i is the current observation, and λ is a weighting constant that determines the rate of decay for the weights. The starting value, Z_0, is the process target μ_0. The exact time-varying upper control limit (UCL) and lower control limit (LCL) are placed symmetrically about the process target μ_0 according to the formula of [22] in the form

$$UCL_i \,/\, LCL_i = \mu_0 \pm k\sigma_{Z_i} = \mu_0 \pm k\sqrt{\left\{1-(1-\lambda)^{2i}\right\}\frac{\lambda}{2-\lambda}}\sigma_x, \tag{2}$$

where k determines the width of the control limits in standard deviation units. The control chart is continuously constructed such that with every new measurement, the statistic Z_i is calculated and plotted on the chart with the UCL_i and LCL_i. If the obtained curve does not lie within the control limits, the process is said to be out of control. The actual measurements can be plotted on the same chart to display their overall dispersion.

A detailed description of the EWMA, its adaptation and implications for MoM-based NT quality control and a comparison with CUSUM can be found in our previous study [18]. In agreement with this study [18], the optimal EWMA settings used for NT quality control were $\lambda = 0.02$ as the weighting constant and $k = 2.8$ as the width of the control limits. These parameters were first based on the thorough simulation and subsequently confirmed on real dataset which partly (from January 2011 to June 2013) overlaps with the current study. Considering the expected performance values, the desired process target, μ_0, of $\log_{10}$ (NT-MoM) was 0.0 (median (NT-MoM) 1.0), and the reference SD $\log_{10}$ (NT-MoM) was 0.0814 [18]. The constructed EWMA curves were presented to each particular sonographer during collective meetings. This audit meetings proceeded as follows. The EWMA curve was always created from the beginning of the period up to the time point of the particular meeting and was presented to the sonographer together with a comprehensible explanation.

All statistical analyses were performed using the statistical computing environment R (R Development Core Team, 2014) [23] and our modification of the additional R package qcc for quality control charts [24].

In the third year of the study all sonographers were asked to answer a short questionnaire (Table 1) to assess their opinion on EWMA audits.

Results

In total, 28,928 NT measurements were performed by six sonographers during the monitored period. The mean CRL was 66.1 mm (range 45.0–83.9 mm), the mean maternal age was 32.4 years (range 15–51 years) and the mean NT was 1.7 mm (range 0.4–4.0 mm). The number of measurements obtained throughout the whole period by sonographers A, B, C, D, E and F were 5262, 3302, 3860, 4484, 6486 and 5534, respectively. Overall, during a seven-year period, we organized sixteen audit meetings with the sonographers; there was one meeting in the first and second years, two meetings in the third year and from the fourth year onwards the meetings took place four times per year. The last year was purposely left without any EWMA audits to evaluate how the sonographers perform without EWMA feedback.

The annual results from the quality assessment using retrospective distributional parameters and the number of measurements for each sonographer are summarized in Table 2. Median (NT-MoM) was perfectly within the expected range apart from only one exception: Sonographer C showed an underestimation in the first year. Regarding the SD $\log_{10}$ (NT-MoM), the values appeared satisfactory; only sonographer B slightly dropped three times below the lower acceptable limit of 0.07.

Table 1
Questionnaire for the assessment of the sonographers' experience with EWMA audits.

Question 1
Do you prefer annual FMF audits with two figures describing your past performance or EWMA audits with the graphical output?
Question 2
Summarize the reasons for your answer to Question 1.
Question 3
How often should be the audits presented to you?

Table 2
Results of nuchal translucency quality assessment using retrospective distributional parameters and the number of measurements.

Year	2011	2012	2013	2014	2015	2016	2017
Sonographer A							
Median (NT-MoM)	0.91	0.97	1.01	1.05	1.06	1.03	1.01
SD $\log_{10}$ (NT-MoM)	0.083	0.088	0.082	0.078	0.081	0.079	0.097
N	578	479	463	749	948	949	1096
Sonographer B[a]							
Median (NT-MoM)			1.06	0.95	0.98	0.98	0.95
SD $\log_{10}$ (NT-MoM)			0.087	0.072	**0.054**[b]	**0.059**[b]	**0.058**[b]
N			924	872	674	601	231
Sonographer C							
Median (NT-MoM)	**0.86**[b]	0.94	1.01	1.03	1.03	1.00	1.04
SD $\log_{10}$ (NT-MoM)	0.081	0.072	0.070	0.072	0.076	0.077	0.079
N	381	556	529	559	510	622	703
Sonographer D							
Median (NT-MoM)	0.96	0.97	0.98	1.02	1.00	1.00	0.99
SD $\log_{10}$ (NT-MoM)	0.083	0.075	0.078	0.084	0.081	0.085	0.084
N	613	633	662	587	563	634	792
Sonographer E							
Median (NT-MoM)	0.96	0.97	0.97	0.97	0.97	0.95	0.96
SD $\log_{10}$ (NT-MoM)	0.079	0.083	0.077	0.081	0.080	0.083	0.091
N	936	1084	824	865	900	893	984
Sonographer F							
Median (NT-MoM)	0.94	1.03	1.00	1.00	1.02	1.04	1.08
SD $\log_{10}$ (NT-MoM)	0.074	0.071	0.083	0.078	0.082	0.092	0.093
N	663	789	731	720	878	849	904

NT, nuchal translucency; MoM, multiples of the median; SD, standard deviation; N, number of measurements.
[a] Sonographer B joined the study later and was not available for the first two years.
[b] The values outside the acceptable range are in bold print.

Figs. 1 and 2 show the EWMA curves for sonographers A-C and sonographers D-F, respectively, throughout the whole monitored period. The numbered black vertical lines indicate the exact time points at which audits occurred and their order.

Looking at the EWMA chart of sonographer A, we can see a considerable underestimation at the beginning of the period. However, after the first audit, the curve of the sonographer's performance clearly increased to the LCL, and after the second audit, the sonographer reached a satisfactory performance. Throughout the rest of the monitored period, several temporal crossings of the UCL followed, more profound between the seventh and 13th audits, and with an improvement of the performance after the 10th, 11th and 15th audits. The final audit-free period stayed with satisfactory performance.

Sonographer B joined the study later and was not available for the first two audits. His initial performance does not show any departures from optimality. However, after the third audit, the curve jumped considerably above the UCL, showing overestimation. Subsequently, after the fourth audit, he overcorrected his performance by falling into a clear underestimation zone. However, the correction following the fifth audit was appropriate and caused perfect performance during the rest of the period.

For sonographer C, the EWMA started with an apparent underestimation. The first audit caused an obvious improvement, but it was unfortunately only a brief one. However, during the second and third audits, this sonographer's performance gradually improved into an optimal state. After the fourth audit, the sonographer slipped into overestimation, but the fifth audit apparently rectified this overreaction. A slight overestimation was corrected also as a result of the 10th audit. Over the whole last period, when the audits ceased, we can see an apparent overestimation.

Sonographer D presented the most stable curve among all sonographers. During the monitored period there was only a small number of transient periods with malperformance.

In case of sonographer E, we observed periods of underestimation followed by periods of rectification, more profound after the fifth audit and corrected after the sixth audit and likewise more apparent after the 13th audit and corrected after the 14th audit. During the final audit-free period the sonographer's curve dropped again below the lower limit. Moreover, the underestimation was steady with no sign of more considerable rectification compared to the periods between audits.

Finally, sonographer F started with an underestimation, which the first audit corrected. Afterwards, the period of transient overestimation followed with a clear shift to normality after the second, third, fourth, 7th, 13th and 15th audits. The last period revealed the EWMA curve unambiguously above the UCL, even worsening as the time progressed from the last audit.

Should we summarize the output from the questionnaire, all sonographers stated to positively prefer the EWMA audits to annual FMF audits. The reported reasons for this preference were similar and most often included that EWMA audits are more evident, accurate, easier to understand because of a very intuitive graphical output without a need for interpreting numerical expressions. Positive evaluations were also related to the ability to reveal the performance with the exact time point of the malperformance start as well as to visualize the performance after the subsequent correction. The sonographers considered an interval of two to four months to be optimal between the audits.

Discussion

Despite strict international guidelines and unified training, even experienced sonographers in tertiary care centers may have a difficulty to perform accurate and reproducible NT measurements [3,25,26]. In addition, several studies have demonstrated that ongoing quality assessments with feedback can improve the sonographers' performances [8–11]. The importance of NT quality assessment is thus indisputable.

This study demonstrates the importance and efficacy of real-time NT quality assessment using EWMA charts. We have observed four main outcomes. First, there was a clear improvement in the performance of sonographers with an initially poor performance (sonographers A-C). The regular audits were obviously the moments that triggered the subsequent corrections and helped them faster achieve an approavable performance. Second, the performance of sonographers with an initially satisfactory quality (sonographers D-F) was maintained. In their cases, the EWMA audits may work as regular stimuli that maintain sonographer's vigilance. Third, during the last period without the audits there was an

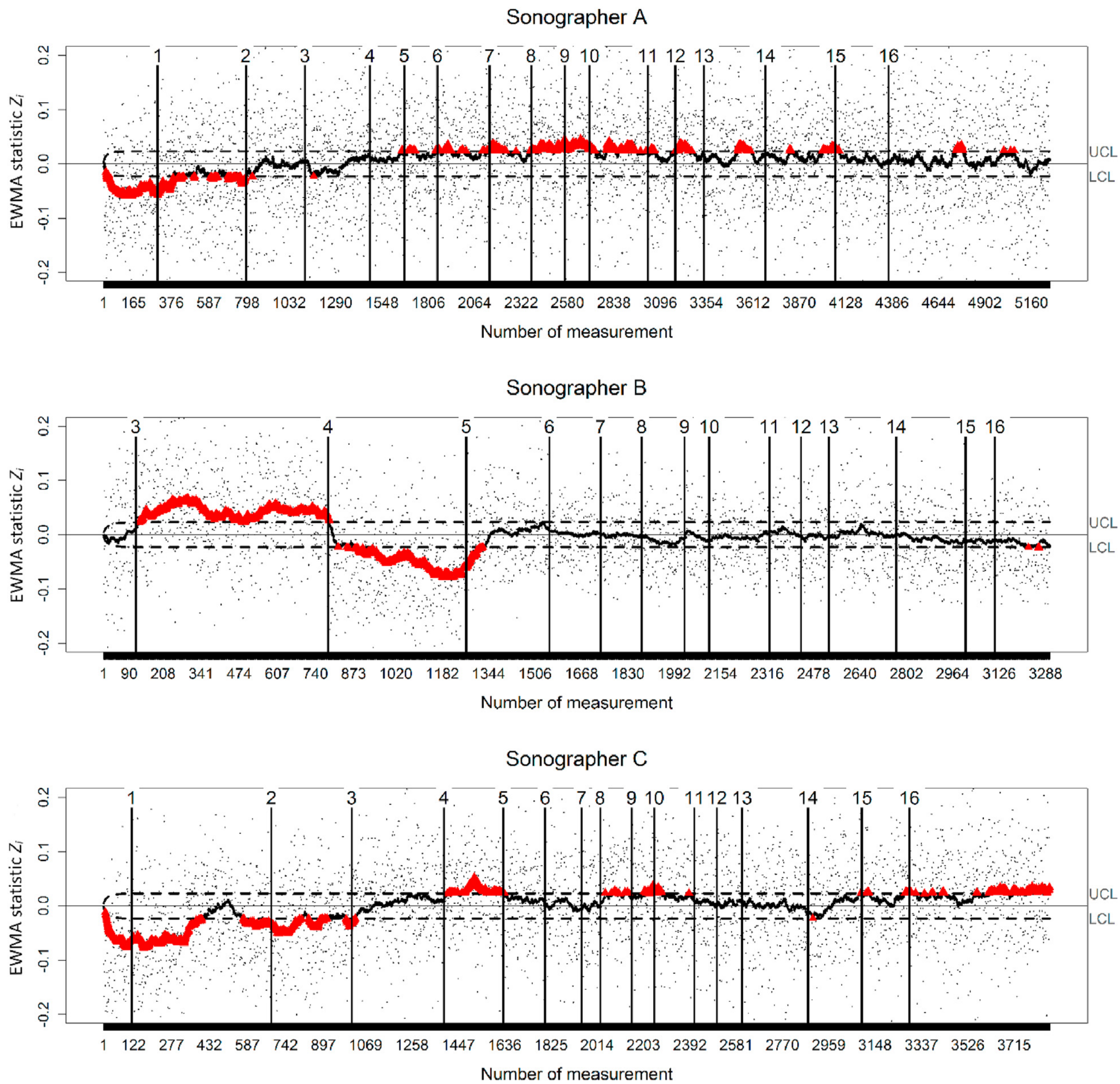

Fig. 1. EWMA charts for sonographers A-C throughout the whole study period. The black vertical lines within the charts indicate the exact time points at which the audits took place and the number represents the order of the audit. UCL, upper control limit; LCL, lower control limit.

observed deterioration of the performance in case of sonographers C, E and F, although they still underwent the annual retrospective FMF audits. Last, the sonographers greatly appreciated the unequivocal and straightforward graphical presentation of EWMA curves, which gave them a comprehensive feedback about their performance over the past period. They positively preferred the graphical way through which EWMA showed thoroughly the whole period of their work compared with the single numerical values provided by retrospective methods.

Quality review programs based on the assessment of the distribution parameters are easily implemented because of their rather simple methodology. They also have the longest history and are still the 'gold standard', which is why they are widely implemented in NT quality assessment, including annual FMF audit policy [6]. However, because they are retrospective, information about malperformance is given with a remarkable delay. Furthermore, these retrospective methods assess all measurements from the past period together and thus are unable to pick up temporal changes in performance [14,18].

Both statistical process control methods, CUSUM and EWMA, offer the possibility to prospectively evaluate consecutive NT measurements [13,18]. They both use the information from the entire data collected over the time, but they deal with the data differently. CUSUM plots the cumulative sum of the deviations of each sample value from a target value, giving equal importance (weight) to all of the historical observations. On the other hand, EWMA assigns the weight to every observation, reducing the contribution of older data by progressively forgetting the past, i.e. its weights are progressively decreasing with time [18].

The prospective nature of CUSUM has the important advantage of allowing for the early detection of deviation from the target with prompt feedback and possible correction. CUSUM has the benefit of a relatively simple formulation, intuitive graphical presentation and the ability to show a close agreement with the retrospective

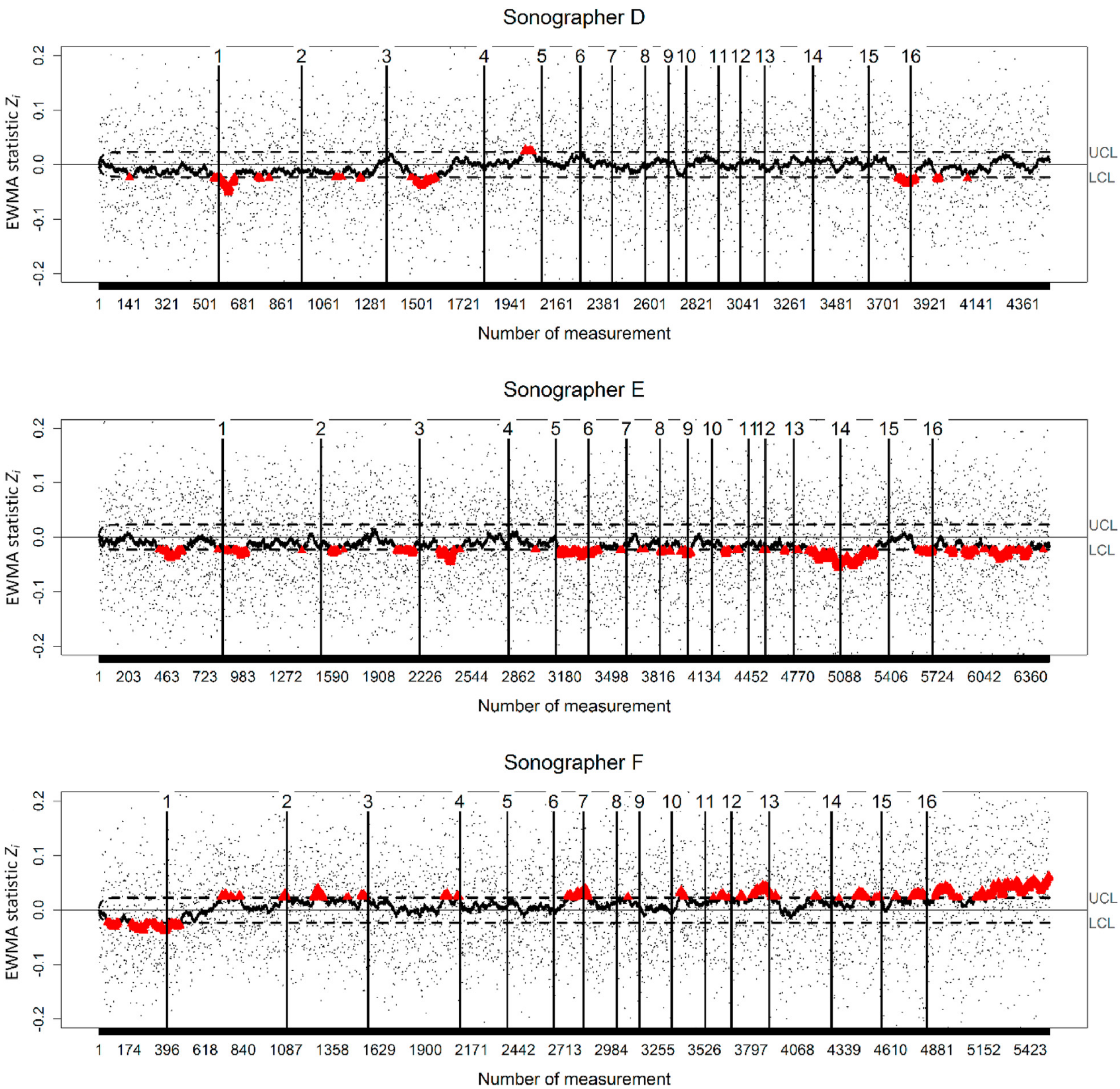

Fig. 2. EWMA charts for sonographers D-F throughout the whole study period. The black vertical lines within the charts indicate the exact time points at which the audits took place and the number represents the order of the audit. UCL, upper control limit; LCL, lower control limit.

quality review methods [14,17,18,27]. As shown in published studies, the CUSUM method provides a valuable contribution to prospective NT quality control [14–17,27]. However, the main disadvantage of CUSUM is the lack of ability to return rapidly to within the control limits after the out-of-control process is rectified to an in-control state [18]. In such cases, it is rather difficult to interpret the CUSUM chart [18], and long-term or retrospective use is limited because CUSUM must be restarted to determine whether a corrective action has been sufficient. This may not be necessarily regarded as a drawback. However, we feel the possibility to observe the continuity of the sonographer's measurements is advantageous as well as the chance to experience the rectification of the malperformance.

EWMA represents the latest modality of prospective continuous NT quality assessment. The EWMA model can be easily applied and shows a close agreement with the CUSUM model [18]. Similar to the CUSUM, the EWMA can detect out-of-control performance quickly and effectively with a low false positivity rate [18]. However, because of the different methodology and the distinctive weighting scheme, this type of chart has several attractive properties. Due to its ability to indicate promptly the rectification of the out-of-control process, the chart is straightforward and easy to interpret even in more complicated cases for which CUSUM fails, and its usage can be extended to long-term and retrospective evaluations without needing to restart [18]. It can be very convenient to simultaneously plot the actual observations on the same chart that provides information about the overall spread of the data. In our study, in the case of sonographer B, it is apparent from the EWMA chart (Fig. 1) that the departure of the curve beyond the control limits was accompanied by a corresponding shift in the distribution of the actual measurements. Finally, the beginnings of the EWMA charts of sonographers A and C might be interpreted and viewed as learning curves, indicating the points from which the sonographer reached a sufficient level of performance. For CUSUM, a different method called the “Learning Curve CUSUM” with inverted hypotheses would be needed to determine the same points [28].

During the monitored period, we conducted quality audits initially once to twice per year. Subseqently, based on the sonographers' request, the frequency of audits were increased to four time a year. This rate is according to our experience optimal. Of course, it depends on the number of measurements which sonographer performs annually and can be increased or decreased as necessary. However, the frequency should be kept rather high to allow an early detection of the deviation.

Finally, there is one important issue of the EWMA which must be mentioned. The retrospective distributional methods focus on shifts in the process mean and in the variability. EWMA method is efficient to detect shifts in the mean but not able to detect measurements with insufficient variability. Therefore, the additional use of other charts may be warranted to monitor the dispersion of measurements. Two modifications of EWMA charts dealing with the variability can be found in the field of engineering statistics. EWMA-S^2 control chart monitors the sample variance [29,30] and its extension, EWMA-S control charts, controls the sample standard deviation [30]. However, these approaches have not been reported to be adapted for NT monitoring and will be the part of our next study.

In conclusion, EWMA proved to be an efficient and suitable tool for real-time long-term monitoring of NT quality measurements. Regular EWMA audits led to an overall improvement of the sonographers' performance and helped to maintain this level of performance. The contribution to performance improvement of EWMA audits was apparent in cases of younger, less-experienced sonographers as well as in cases of senior sonographers.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article. The authors alone are responsible for the content and writing of this article.

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