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Signal Loss During Fetal Heart Rate Monitoring Using Maternal Abdominal Surface Electrodes Between 28 and 42 Weeks of Pregnancy

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A – research concept and design; **B** – collection and/or assembly of data; **C** – data analysis and interpretation; **D** – writing the article; **E** – critical revision of the article; **F** – final approval of article; **G** – other

Abstract

Background. Fetal electrocardiography is one of the methods for monitoring the well-being of the fetus. Signal loss limits the proper interpretation of electrocardiogram traces.
Objectives. The aim of this study was to assess the average signal loss in non-invasive abdominal fetal electrocardiogram (fECG) monitoring using the KOMPOREL fetal monitoring system (ITAM, Zabrze, Poland) in women between 28 and 42 week of pregnancy. The results were compared to FIGO (International Federation of Gynaecology and Obstetric) and DGGG (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e.V.) recommendations concerning fetal heart monitoring. The correlation between fetal ECG signal quality, week of pregnancy and patient BMI was evaluated.
Material and Methods. 773 pregnant women, hospitalized and diagnosed in the Department of Gynecology and Obstetrics, Wroclaw Medical University, underwent 30 min of abdominal fECG recordings using the KOMPOREL fetal monitoring system.
Results. The average signal loss in abdominal fECG monitoring in the study group was 32%. FIGO recommendations describe an acceptable fetal signal loss of 20%. In our study, 46% (357/773) of the recordings were up to FIGO standards, with fetal heart rate success rates above 80%. According to DGGG guidelines, with acceptable fetal signal loss of 15%, only 39% (303/773) of the recordings could be assessed as accurate. No correlation between fECG signal quality, week of pregnancy and patient BMI was proved.
Conclusions. The average signal loss in abdominal fECG monitoring in our study group was 32%. Low fECG signal quality may constitute a potentially limiting factor of the described fetal heart monitoring system. No relationship between fECG signal quality, week of pregnancy and patient BMI was proved (**Adv Clin Exp Med 2014, 23, 5, 813–819**).

Key words: non-invasive fetal electrocardiography, fetal heart rate monitoring, abdominal fetal electrocardiography, signal loss in abdominal fetal electrocardiography.

Fetal electrocardiography (fECG) is one the methods for registering the electrical activity of the heart of the fetus, which makes it possible to assess fetal well-being during pregnancy and labor. This method was presented for the first time by Cremer at the beginning of the 20th century. He measured the electric signal from the heart of the fetus using a string galvanometer invented by Willem Einthoven, the device used for recording the heart's electrical activity in adults [1]. Cremer's studies on obtaining the fECG signal were carried out with electrodes located on the abdomen, in the vagina, the esophagus and the rectum of pregnant woman. In this way, he demonstrated the capabilities of diagnostic techniques in those times. The quality of his recordings was poor, mainly due to unwanted background interference such as the maternal electrocardiography waveform, noise from adjacent tissues and the device. In practice, the low quality did not allow accurate assessment of fetal intrauterine status.

Over the last 40 years, many researchers have struggled with the problem of isolating the fetal

signal, but only the use of modern computers, amplifiers and dedicated software have made it possible to obtain a clear signal and a complete image of the atrio-ventricular complexes of the fetal heart and typical fECG traces of the fetal cardiac cycle [2]. In 1953, Smyth et al. used an electrode attached to the amniotic membranes for the first time, while Hon et al. in 1962 designed and described an electrode which could be attached directly to the fetal scalp or other presenting part of the fetus [1]. In this way, it was possible to precisely assess the characteristics of *P* and *T* waves. Currently, a similar type of electrode is used in the STAN monitoring system (Neoventa Medical, Mölndal, Sweden), whereas in British systems such as Monica AN24 Monitor (Monica Healthcare, Nottingham, UK), American – MindChild Medical (North Andover, MA, USA) and Polish KOMPOREL (ITAM, Zabrze, Poland), transabdominal electrodes are used [3]. Depending on the application mode on the abdominal wall, the number of electrodes varies from 6 to 16.

Since the 60s of the last century, classical cardiotocography (CTG) with fetal heart rate analysis is a standard, non-invasive procedure for monitoring fetal well-being before and during labor. The fetal monitor is an ultrasound transducer which uses the Doppler effect to detect the heart beat of the fetus. The fECG is an alternative to the classical CTG. The advantage of this method is the additional information which can not be obtained by CTG [4].

Aim of the Study

Assessment of the average signal loss obtained during recording of fetal heart rate and uterine electrical activity using the KOMPOREL fetal monitoring system (ITAM, Zabrze, Poland) in women between 28 and 42 weeks' gestation. The results obtained were compared to the FIGO criteria (International Federation of Gynecology and Obstetrics) and DGGG (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e.V.) recommendations [5, 6].

Correlation between fECG signal quality, week of pregnancy and patient's BMI was evaluated.

Material and Methods

The study group consisted of 773 pregnant women whose pregnancies ranged from 28 to 42 weeks gestational age, either hospitalized or diagnosed in outpatient settings in the Second Department of Gynecology and Obstetrics, Wroclaw Medical University. The study group was divided into 3 subgroups:

1. Physiological pregnancies, in which ultrasound examination confirmed normal, singleton pregnancy with eutrophic fetus – 601 cases.

2. Pregnancies complicated by intrauterine growth retardation between 28 and 38 weeks of gestation and by pregnancy induced hypertension between 28 and 41 weeks of gestation – 91 cases.

3. Woman threatening preterm labor between 28 and 37 weeks of gestation – 81 cases.

The study protocol was approved by the Commission of Bioethics at Wroclaw Medical University. Each patient was instructed in study procedures and methodology prior to entering the study. All women gave written informed consent.

With each patient, the recording of the electrical signal of fetal heart and uterine contraction activity lasted 30 min. The KOMPOREL (ITAM, Zabrze, Poland) fetal monitoring system was used for the signal registration. The device records and analyses bioelectric signals. During the examination, the woman laid in the supine or left lateral recumbent position, depending on which of them provided the best signal quality. Prior to electrode placement, the skin was prepared with a mild skin abrasion to the electrode site using sand paper material for electrocardiography from 3M in order to remove part of the stratum corneum. Disposable electrodes of 3M type 2222 were used. In order to obtain the best electrode adhesion, an additional gel layer on the sensing element was applied. Six electrodes were placed as follows:

1) on the level of the umbilicus, 5 cm on the right side,

2) on the level of the umbilicus, 10 cm on the right side,

3) in the midline, 5 cm above the umbilicus,

4) on the left side, 1 cm from the umbilicus,

5) in the midline, 10 cm below the umbilicus, the so-called ground reference electrode,

6) 10 cm below the inguinal region on the front side of thigh, the so-called return electrode.

Electrode placement is presented in Fig. 1.

The signal received by the abdominal electrodes was transmitted to the signal recorder and then through the RS 232 interface to a standard personal computer (Hewlett-Packard) with Windows XP operating system and the KOMPOREL software. A signal recorder amplified and filtered input signals. Next, the processed signals were transmitted through a galvanic barrier to the RS 232 interface and to the computer where the recorded signals were analyzed and stored. All the parameters were presented in graphical form, as well as stored as numerical values.

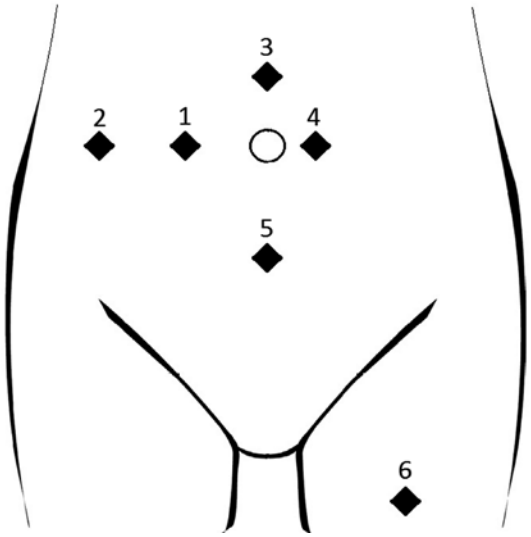

Fig. 1. Electrode placement over the abdominal wall

The KOMPOREL software is used for:

– filtering interference, including those from the maternal abdominal muscle,

– extracting and canceling the maternal electrocardiogram,

– detecting the fetal QRS complex and calculating fetal heart rate,

– identifying the P-QRS-T complex,

– determining T-wave amplitude in relation to QRS – T/QRS complex,

– calculating baseline fetal heart rate,

– determining the short-term and long-term variability,

– filtering and analysis of uterine electrical activity.

The statistical analysis was performed with STATISTICA 10 PL. The results are expressed as mean, standard deviation (SD), confidence interval (CI). In order to determine correlations among the studied parameters, a Pearson correlation analysis was carried out. A value of $p < 0.05$ was considered significant.

Results

The average signal loss in abdominal fECG monitoring in the study group was 32% (SD 25.26; CI 29.82–33.38). In the group of 601 pregnant women with normal pregnancies, mean signal loss was 30.38% (SD 25.02; CI 28.38–32.38). In the group of women (n = 91) with pregnancies complicated by intrauterine growth restriction and pregnancy induced hypertension, it was 31.44% (SD 25.12; CI 26.21–36.67), while the highest percentage of signal loss occurred in the group of woman threatening preterm labor (n = 81) – 40.86% (SD 25.4; CI 35.25–46.48). According to the FIGO criteria, the maximum acceptable level of signal loss determining the correct interpretation of the record is 20%. In the present study, over 46% (357/773) of total records met this criterion, yielding efficiency of at least 80%. According to DGGG guidelines, which are stricter, the maximum level of acceptable fetal signal loss is 15%. The percentage of correct recordings drops then to 39% (303/773).

Body mass index (BMI) was calculated in 687 patients. The values obtained ranged from 18.5 to 50.7 (mean 26.9; SD 4.31).

Assessing the relationship between signal loss, gestational age and patient's BMI, the following results were obtained:

– no correlation between the percentage of signal loss and gestational age was found (correlation coefficient r – 0.059; CI 0.129–0.0107; $p > 0.096$); scatter plots of signal loss in gestational week are shown in Fig. 2,

– no correlation between the percentage of signal loss and patient's BMI was found (correlation coefficient r – 0.005; CI – 0.079–0.069; $p > 0.892$); scatter plots of signal loss and BMI values are shown in Fig. 3.

Discussion

CTG, since the 60s of the last century, has become a standard non-invasive method in monitoring fetal well-being before and during labor. It was introduced in order to identify events that might result in complications such as hypoxic ischemic encephalopathy, cerebral palsy and perinatal death. The use of the method in clinical practice is still controversial, especially in terms of efficacy. A study conducted by Zimmer et al. on a group of 10,983 labors showed that continuous electronic fetal monitoring was not associated with a reduction in cesarean sections and an increase in neonatal Apgar score given to newborns [7]. Studies conducted by Alfirevic et al. proved that continuous monitoring of fetal heart rate during labor resulted in an increase of cesarean sections and instrumental vaginal deliveries but did not reduce neonatal mortality and the frequency of cerebral palsy [8]. The only noticeable advantage of this method was a reduction in neonatal seizures [9]. The major factor limiting the effectiveness and reliability of continuous electronic fetal monitoring might be the difficulty and variability in the interpretation of intrapartum cardiotocogram traces by obstetricians and midwives [9–11]. Therefore, methods for more accurate assessment of heart rate and intrauterine fetal well-being have been sought. An alternative to CTG may be the rapidly developing fECG.

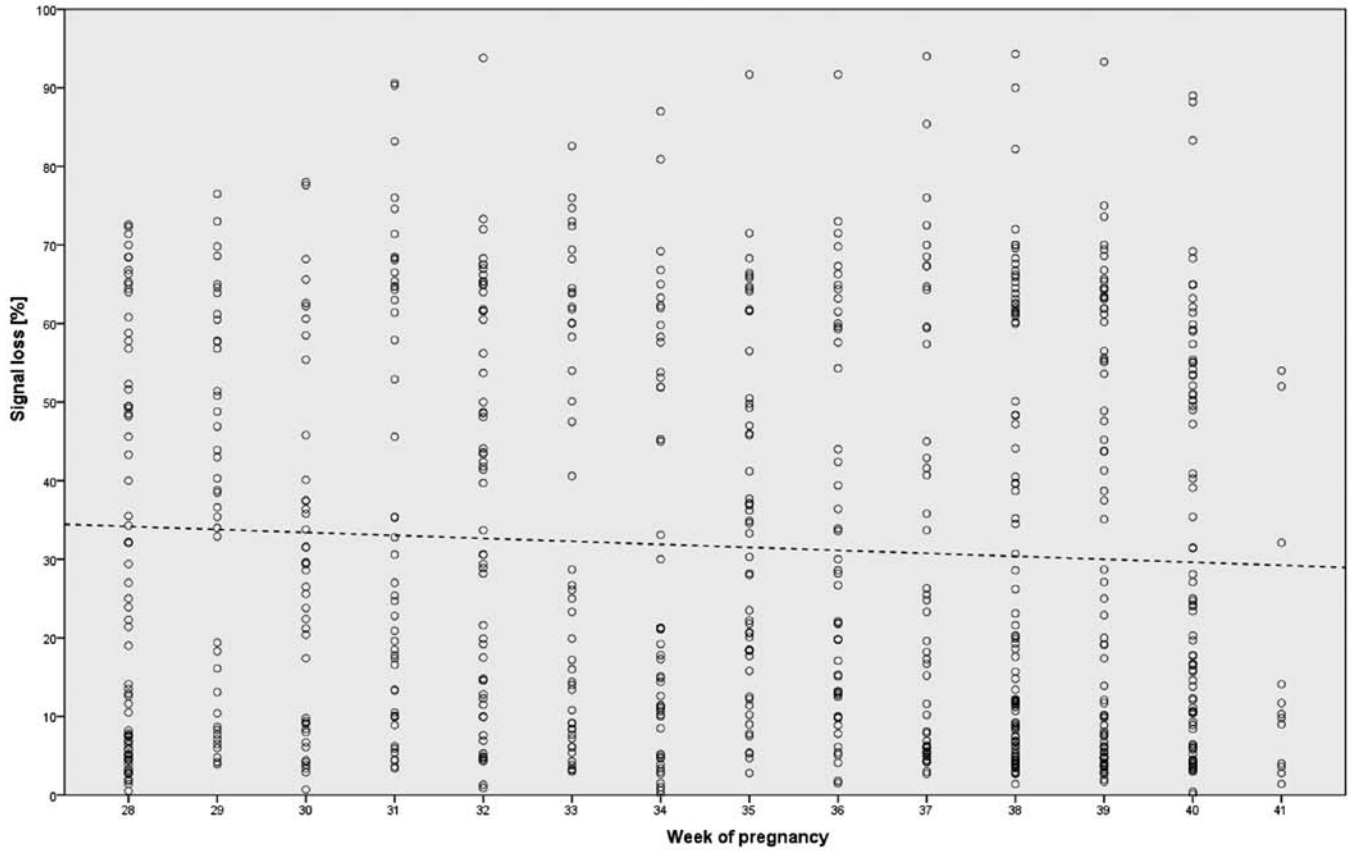

Fig. 2. Pearson correlation – signal loss vs. week of pregnancy: r – 0.059, CI – 0.129–0.0107, p > 0.096

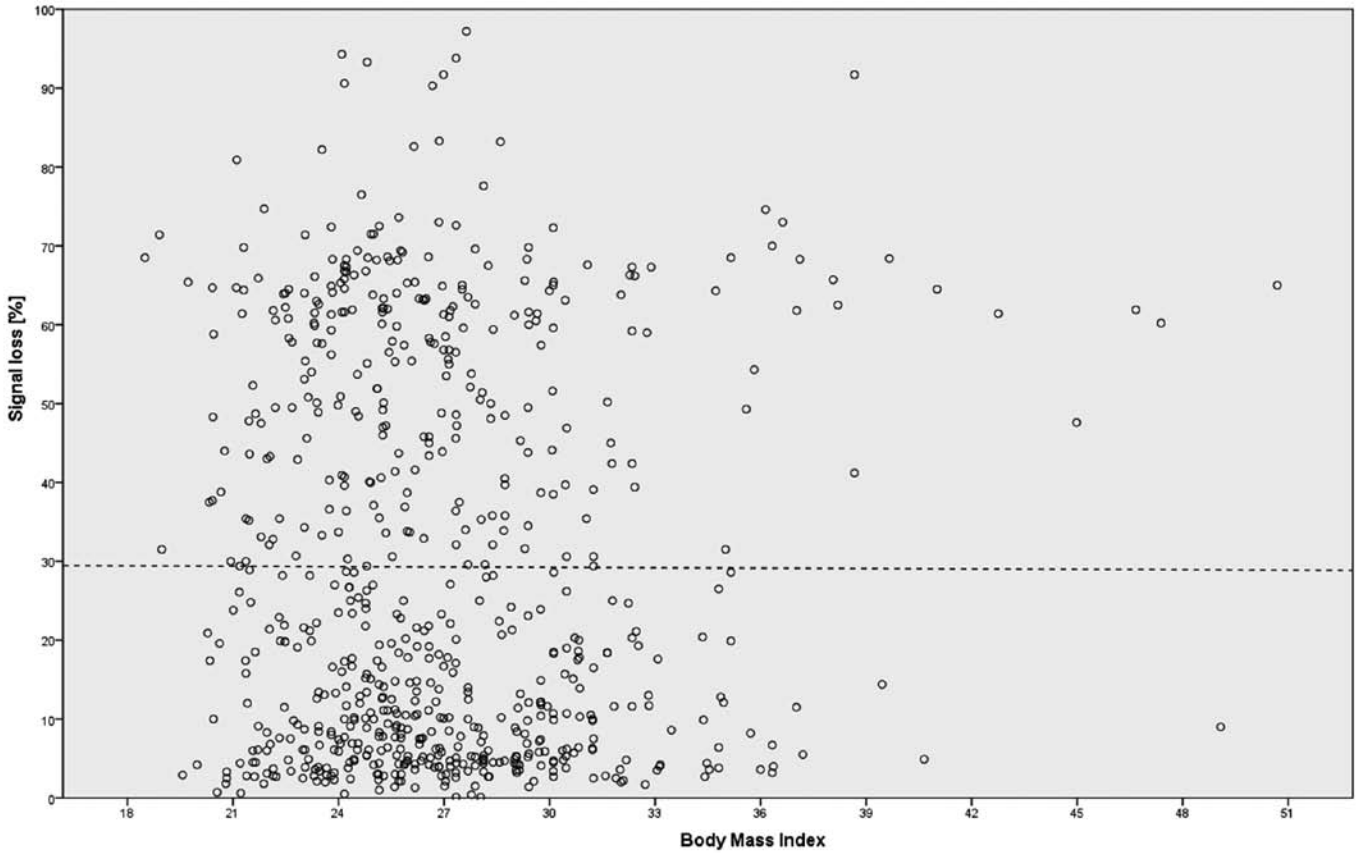

Fig. 3. Pearson correlation – signal loss vs. patient's BMI: r – 0.005; CI – 0.079–0.069; p > 0.892

The STAN monitoring system has been under development for many years. It provides a computerized analysis of ST interval of the fECG. The device is attached to the fetus by fetal scalp electrode. Unlike transabdominal fECG, it is an invasive method as it requires dilated cervix (sometimes instrumentally) and ruptured amniotic membranes, which increases the risk of intrauterine infection [12]. Salmelin et al., in a meta-analysis carried out in 2013, concluded that there is not enough scientific evidence that computerized ST analysis reduces the incidence of metabolic acidosis in newborns [13]. At the same time, it was shown that the incidence of cesarean sections and instrumental vaginal deliveries due to fetal distress did not change, regardless of the fetal heart rate monitoring method. However, there was a significant reduction in the number of fetal scalp pH testing.

In 1986 FIGO introduced the first recommendations for the nomenclature of changes in fetal heart rate recorded on cardiotocographic traces and guidelines for their interpretation. This helped to standardize maternity care [5]. Organizations such as the American College of Obstetricians and Gynecologists (ACOG), the National Institute of Child Health and Human Development (NICHHD), the Royal College of Obstetricians and Gynaecologists (RCOG), and the National Institute of Clinical Excellence (NICE) also undertook to introduce their own guidelines for the interpretation of CTG, though regarding mainly records during labor. However, their use is limited to the countries in which they were developed [14].

According to the FIGO criteria, fetal heart rate recording can be considered possible to interpret and reliable if signal loss during the examination does not exceed 20%. Among the available methods of fetal heart rate monitoring, magnetocardiography seems to be the most precise. In their studies, Crowe et al. as well as Stinstra et al. showed nearly 100% efficacy of fetal magnetocardiography in registering the electrical activity of the heart of the fetus [15, 16]. In comparison to transabdominal fECG, the electrical activity of the maternal heart and the presence of vernix did not affect the quality of the obtained recording [17]. However, due to the high cost of the equipment and conditions under which it operates, this method is not widely used in the assessment of fetal intrauterine well-being [18]. High efficacy can be also obtained in recordings of fetal electrical activity of the heart using electrodes placed on the presenting part of the fetus. The average signal loss of fECG in this method usually does not exceed 10%, although Bakker et al. achieved an average efficacy in the second stage of labor at less than 80% [19, 20]. In the studies in which researchers evaluated the quality of the signal recorded during intrapartum cardiotocography, the signal loss ranged between 15 and 40% [19, 21].

In the published literature, the authors did not find any reference to the quality description of the signal obtained during the recording of transabdominal electrocardiograms of the fetus in the antepartum period. In the studies conducted to date, researchers have focused mainly on the description of the efficacy of this method during labor.

Cohen et al. compared the accuracy and reliability of 3 methods used for heart rate detection: transabdominal fECG, cardiotocography, and monitoring with fetal scalp electrode. The study group consisted of 75 laboring women. All the pregnancies included in the study were of > 37 weeks' gestation. The mean value of signal loss in transabdominal fECG did not exceed 17% (success rate 83.4% ± 20.1%). During the first stage of labor, mean signal loss was 13.6% (success rate 86.4% ± 21.1%), and 24.8% in the second stage of labor (success rate 75.2 % ± 19.2%) [22]. Reinhard et al. conducted a study on 144 laboring women in order to assess the fetal heart rate signal quality of abdominal fECG. The signal loss in the first and second stages of labor was 4.3% and 19.8% with a median success rate 95.7% and 80.2%, respectively [23]. Considering the FIGO criteria, in the Reinhard's et al. study group, the percentage of patients having fECG signal loss below 20% during the first and second stages of labor was 78.5% and 46.9%, respectively. Signal loss below 15% (DGGG guidelines) occurred in 73.3% and 36.7% of women in the first and second stages of labor, respectively. These results show the poor quality of the recordings, particularly in the second stage of labor. In a Cohen et al. paper, corresponding calculations were not provided. Both Cohen et al. and Reinhard et al. used the Monica AN24 (Monica Healthcare, Nottingham, UK) fECG monitoring system. Clifford et al. evaluated the accuracy and fidelity of the E-TROLZ physiologic monitoring platform for measuring fetal heart rate and fetal electrocardiogram morphology, especially ST segment changes [24]. Data was recorded from 32 laboring women with the use of 29 electrodes placed over the maternal abdomen. This made it possible to obtain records with a mean value of signal loss below 11% (success rate 89.9%). The results of the above-mentioned studies are summarized in Table 1.

In the present study, the mean success rate of registered fECG was 68.4% (SD 25.26; CI 66.62––70.18). According to the FIGO and DGGG recommendations, an acceptable fetal signal loss was obtained in 46% and 39% of the recordings, respectively. In the studies conducted by Taylor et al. and Chia et al., poorer success rates in the recording of fECG signals in pregnancies during the period

Table 1. Signal loss in abdominal fECG monitoring in different studies

Author	Fuchs et al.	Cohen et al.	Reinhard et al.	Gari et al.
n	773	75	144	32
BMI (range)	26.9 (18.5–50.7)	32.6 (25–40.2)	29.8 (20.6–49.5)	30.4 (21.7–45.1)
Monitoring system	KOMPOREL	Monica AN24 Monitor	Monica AN24 Monitor	E-TROLZ
success rate μ (%)				
Antepartum recording	68.4%; n-773	n/a	n/a	n/a
Intrapartum recording	n/a	83.4% 20.1%; n-75	n/a	89.9%; n-32
First stage of labor	n/a	86.4% 21.1%; n-72	95.7%; n-135	n/a
Second stage of labor	n/a	75.2%; n-41	80.2%; n-98	n/a

μ – arithmetic mean; n – number of pregnant/laboring women, n/a – not applicable.

between 27 and 32 gestational weeks was reported [25, 26]. It concerned both an increased percentage of signal loss of electrical heart activity of the fetus and a reduced quality of various registered cardiac waveforms. This is presumably caused by the layer of *vernix caseosa*, which begins to form intensively on the entire body of the fetus at this stage of pregnancy. As the pregnancy advances, the mass of the cardiac muscle increases, the fetus grows and matures, and gaps appear in the vernix covering the body of the fetus. The above-mentioned factors contribute to increased quality of the fECG. In the present study, the average signal loss in pregnancies between 28 and 32 weeks' gestation was 29.9%. In contrast to the results of the above-mentioned authors, that value is lower than that obtained in the present study on pregnancies between 33 and 42 weeks' gestation (37.1%).

Reinhard et al. did not show correlation between a patient's BMI and the signal loss of abdominal fECG registered with the use of electrodes placed over maternal abdomen. Also in the present study, which was conducted on a 5-fold larger research group (144 vs. 773) this correlation was not demonstrated (r – 0.005; CI 0.079–0.069; $p > 0.892$). In the case of intrapartum electrocardiography, Solum et al. showed an inverse relationship between patient's BMI and the quality of the fECG signal [27].

The authors concluded that the average signal loss in abdominal fECG monitoring in our study group was 32%. Low fECG signal quality may constitute a potentially limiting factor of the described fetal heart monitoring system. No relationship between fECG signal quality, week of pregnancy and patient's BMI was proved.

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