The sensitivity and specificity of fetal emergency detection devices

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ABSTRACT

The prevalence of infant mortality rate in the world is still high, especially in Indonesia. One of the contributing factors to the high infant mortality rate is the delay in early detection of fetal emergency. Medical devices used in the health service at this time, cannot be reached by all pregnant women independently. The fetal emergency early detection device is designed like a Doppler to listen to the fetal heart rate, but it is equipped with LED lights and alarms that will light up when the fetal heart rate indicates an emergency. This study will analyze the sensitivity, specificity and acceptance rate of this fetal emergency detection device compared to Fetal Doppler as Gold Standard. This study is an experimental study, an experiment to determine the sensitivity and specificity of fetal emergency detection devices by comparing sensitivity and specificity with Fetal Doppler (Gold Standard) when used in pregnant women with >12 weeks pregnancy age. The results of this study showed that this fetal emergency detection tool has a sensitivity of 92%, and specificity of 67%, 88.7% of pregnant women receive fetal emergency detection equipment to be used as an early detection tool for fetal emergency because it is comfortable, practical, safe and flexible. The results of this study are expected to be used by the Department of Health as an alternative tool in improving maternal and child health care programs in health facilities as an effort to support the decrease in infant mortality.

Introduction

Infant Mortality Rate in Indonesia is still high from other ASEAN countries, compared to the target of Sustainable Development Goals (SDGs) in 2015 which is 23 per 1000 live births.[1,2] Infant Mortality Rate (IMR) in DIY since 2014 until 2017 is still high, in 2014 it was 405 cases and it dropped considerably in 2015 to 329 cases, then decrease until 278 cases in 2016, but again increase until 313 cases in 2017. From the 5 districts/cities in DIY, the highest cases of infant mortality rate were in Bantul District (108 cases).[3] Common causes of infant mortality were low birth weight baby and sepsis. In addition, other causes of infant mortality that are often found in DIY include direct factors namely asphyxia at birth due to long birth path, transverse location, and narrow pelvis. Indirect factors that are the caused of Infant Mortality Rate (IMR), one of them is delay in early detection for fetal emergency monitoring.[3]

The causes of infant mortality in Bantul in 2018 are 22 cases of low birth weight baby, 20 cases of congenital disorder, 14 cases of asphyxia, 7 cases of infection, and 45 cases caused by other factors, one of which is due to delays in early detection of fetal emergency.[4] Fetal emergency monitoring is an effort to determine the welfare of the fetus since in the womb that aims to detect any disorders related to fetal emergency and can determine the follow-up of the monitoring results. Early detection of fetal emergency must be done from the beginning of pregnancy, by conducting early detection, the classification allows the exposure of a disease

during pregnancy to be known earlier.[5] Devices for early detection that now exist in medical practice was Ultrasonography (USG), CTG and Doppler. Ultrasonography (USG) is a device that performed by displaying an image of the condition of the inside of the body. While Cardiotocography (CTG) is a tool used to monitor fetal heart rate and uterine contractions, when the baby is in the womb. Fetal Doppler is a diagnostic device that used to detect a fetal's heart rate using the principle of electromagnetic wave reflection. This tool is very useful for knowing the health condition of the fetus, and it is safe to use and non-invasive.[6]

The medical device has some disadvantages such as having to be done by health workers who are competent and understand about health in accordance with their authority, pregnant women must spend more time, money, and pregnant women who want to do the pregnancy services should take time to get the service, so it is less effective when used by pregnant women because not all pregnant women can do early detection of fetal emergency in health workers and can not use the device independently. So researchers have innovations to develop fetal emergency detection device that are practical, cheap, safe, and acceptable to the public, especially by pregnant women. This device has a high sensitivity and specificity that has the same function as fetal doppler device that are commonly used in health facilities. Fetal emergency detection alarm is an alternative device used for early detection and equipped with a series of hazard indicators composed of alarms and LED lights, so that when the alarm and lights turn on, it indicates the emergency of the fetus then there will be no delay to detect early fetal emergency and the mother apply it independently.

Material and method

This study is an experimental study, an experiment to find out the sensitivity and specificity of new device for early detection of fetal emergency by comparing the sensitivity and specificity of fetal emergency detection devices with Fetal Doppler (Gold Standard). The subject of this study was pregnant women with a gestasional age >12 weeks as many as 30 people in PMB Anastasia Darwati Bantul and carried out from April to June 2019. The variables of this experimental study are sensitivity, specificity, and acceptance test of the devices used for early detection of fetal emergency. The data collection technique in this study was conducted by observation of trials and questionnaires of the acceptance rate of fetal emergency detection devices in pregnant women.

Result and discussion

The characteristics of pregnant women in PMB Anastasia Darwati Bantul are in the 2nd trimester and 3rd trimester of pregnancy (table 1). Fetal Heart Rate (FHR) can already be heard using Fetal Doppler and fetal emergency detection devices since 12 weeks of pregnancy age. According to Romauli (2015), Fetal heart rate can be heard with laenec stethoscope in weeks 17-18 in obese people and is relatively slower. Meanwhile, when using ultrasonic stethoscopes (Doppler), fetal heart rate can be heard earlier, around the 12 weeks.[7,8] The results of this study showed that pregnant women were >12 weeks pregnancy age. As many as 30% of pregnant women with 12-23 weeks pregnancy age, 47% of mothers with 24-36 weeks, and 23% mothers with >36 weeks pregnancy age.

Table 2, showed that fetal emergency detection device used in the community for early detection of fetal emergency has a sensitivity of 92% and specificity of 67%. From the data, it was concluded that this device is able to detect fetal emergency in pregnant women who have fetal emergency is true fetal emergency by 92% and who do not experience fetal emergency is true around 67%. This means that when it is is applied to pregnant women using Fetal Doppler as

Gold Standard, this fetal emergency detection device could showed the results that the fetus was in fetal emergency condition more properly compared to the results of the examination by Fetal Doppler.[5]

Table 1. Frequency distribution of study subjects based on regnancy age
at PMB Anastasia Darwati Bantul in 2019

Gestational age	Frequency	Percentage (%)
12- 23 weeks	9	30
24-36 weeks	14	47
>36 weeks	7	23
Total	**30**	**100**

Table 2. Test results of sensitivity and specificity of fetal emergency detection device
compared to Fetal Doppler

Condition	Resul (fetal emergency)		Total
	Yes	No	
Emergency	22 (a)	2 (b)	**24**
Normal	2 (c)	4 (d)	**6**
Total	**24**	**6**	**30**

Table 3. The test results of acceptance rate of pregnant women to fetal emergency detection
devices

Variable	Total Answers Agree (n=30)	Percentage	Total Answers Disagree (n=30)	Percentage
Comfort	27	90%	3	10%
Practicality	25	83%	5	17%
Safety	30	100%	0	0%
Flexibility	28	93%	2	7%
Average	**27,5**	**88,7%**	**3,3**	**11,3%**

This facts indicated that this device can effectively be used for early detection of fetal emergency in pregnancy. However, this fetal emergency detection device is still has the same function as Fetal Doppler which is to detect Fetal Heart Rate (FHR). The difference is in the hazard indicators in this device that the Fetal Doppler does not have. The creation of this fetal emergency detection device is in line with the findings of previous researchers, namely by Christian Johann Doppler who examined one of the applications of the doppler effect found and used in the health sector. In the medical practice, doppler is used to detect tissues or organs such as the heart or bloodstream. These sound waves penetrate the body and hit the boundaries between tissues, for example between fluids, blood and muscles and bones.[6]

In the acceptance tests that already done on 30 research subjects, 27 mothers said the fetal emergency detection device was convenient when used for early detection of fetal emergency, and 3 of them expressed discomfort because they felt amused in the mother's abdomen. There is no subject to suggest that this device causes pain or heat. 25 subjects asumed that fetal emergency detection devices are practically to used, and 5 of them asumed that the way of use needs to be thorough in detecting the position of the back of the fetus so that it can be heard fetal heart rate.

All subjects said no one felt electric shock or heat when using a fetal emergency detection device, it safe during the pregnancy both for the mother and for the fetus. A total of 28 subjects

asumed that flexible use means that this tool can be used wherever the mother is and under any conditions, including health conditions, economic conditions, and 2 subjects stated that this tool cannot be used while traveling and in busy conditions because the mother feels more comfortable checking with health workers directly so if a fetal in emergency condition it can be immediately get medical action and no delays.

Conclusion

The fetal emergency detection device that is used by pregnant women has high sensitivity and specificity. The sensitivity is 92% and specificity is 67% when compared to the Fetal Doppler (Gold Standard). This device can show fetal emergency condition in pregnant women where the fetus is truly in a good condition and that there is no fetal emergency result is truly not in emergency condition. In its implementation, this device can be easily accepted by the community with an acceptance rate of 88.7%. This device can be an early device for a fetal emergency by the community, especially in pregnant women it can be used independently, easy, safe, and practical. The results of this study are expected to be an alternative device by the Ministry of Health in improving maternal and child health care programs in health facilities to help in reducing infant mortality rate.

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