A single-center study about the safety, practicability and acceptance of *Vibwife One*, a new medical device to support delivering women in their mobilization: an interim analysis

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Introduction

"Vibwife One" is a new mattress that fits on delivery beds, designed to support the mobilization of laboring women. Different movements, adjustable in pace and intensity, can be chosen. Thus far, some data[1,2] have notably highlighted the positive impact of active mobilization during labor. "Vibwife One" (Fig.1) has never been tested in a clinical setting. Moreover, the aim of the study was to analyze its safety, practicability and acceptance in a low-risk population.

Methods

Fifty women with a minimum of 4 cm dilation were recruited during the first stage of labor. The first five women used the device for 10 minutes (group 1), the following 10 women for 20 minutes (group 2) and the remaining 35 women for 30 minutes (group 3). The women's vital signs, fetal heart rate monitoring using continuous cardiotocography (CTG), adverse events (AEs) and adverse device effects (ADEs) were recorded during and for 30 minutes post intervention. The women's pain intensity was recorded using the visual analog scale (VAS). Women's and medical staff's experiences on the device were evaluated. The study was approved by the ethics committee (EKNZ) and informed consent was obtained. An independent review board examined all AEs in relation to the study device.

Results

We report the interim analysis of the first 30 participants, included in group 1 - 3.

Thirteen of the 30 women experienced one or more AEs, which resulted in a total of 20 AEs. The AEs distribution is illustrated in Fig.1. Nineteen out of 20 AEs were rated as mild. For 18 of the 20 AEs, the review board rated the relation to the study device as unlikely or unrelated and no action had to be taken. One case of nausea and one case of suspicious CTG were considered to be potentially related to the study device. Both AEs were rated as mild and resolved without sequel.

There was one ADE in group 2. The shifting function could not be started, another function had to be chosen instead. The ADE did not result in any risk for the study participant.

Pain levels according to the VAS did not reveal any clear tendencies. However, 20 women had received PDA before the intervention. Women and midwives overall rated an excellent satisfaction with the product. (Fig.2, 3).

Figure 1: Occurrence of Adverse Events

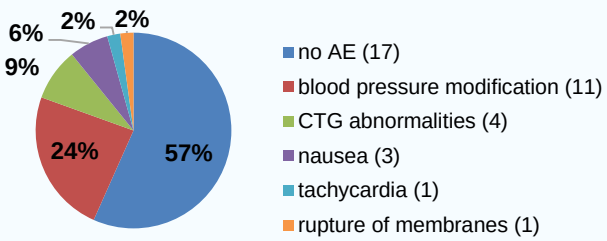


Figure 2: Participants' Questionnaire Results

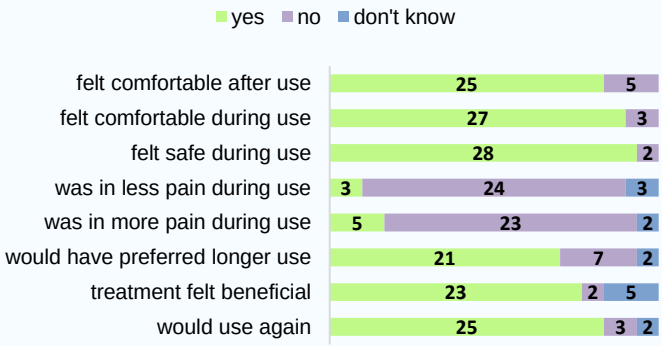
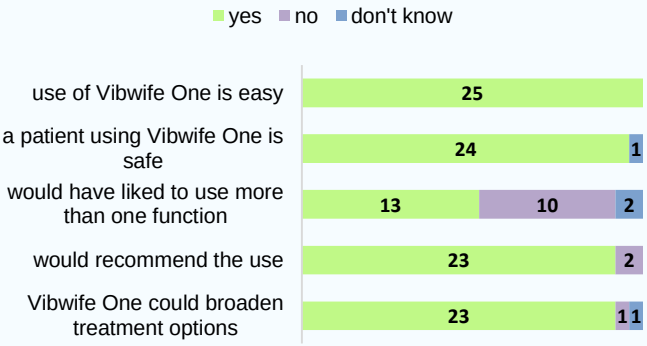


Figure 3: Midwives' Questionnaire Results



Five midwives used the device in two patients but answered only to one questionnaire

Discussion and Conclusion

The use of the medical device "Vibwife One" was estimated as safe for laboring low risk women and their fetuses. AEs were considered to be primarily related to the progression of labor. A study by Cohen et al. shows similar findings concerning blood pressure changes during the first stage of labor.[3] Given the positive feedback from participants, "Vibwife One" could be an interesting and potentially beneficial addition to obstetric practice.

Further information on the product is available at Stand 223.

1. LAWRENCE A, et al. . Maternal positions and mobility during first stage labour. Cochrane Database Syst Rev 2013.
2. IVERSEN ML, et al. Danish women's experiences of the rebozo technique during labour: A qualitative explorative study. Sex Reprod Healthc 2017.
3. COHEN J, et al. Blood pressure changes during the first stage of labor and for the prediction of early postpartum preeclampsia: a prospective study. Eur J Obstet Gynecol Reprod Biol 2015.