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Original Article

# Influence of the WOMAN trial on national wide standard operating procedures for treatment of postpartum hemorrhage

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ABSTRACT

*Background:* Postpartum hemorrhage is the leading cause of maternal death. Recently, the WOMAN trial showed that early administration of tranexamic acid leads to a reduced mortality due to bleeding. The aim was to study whether the results of the WOMAN trial have influenced the institutional standard operating procedures in treating postpartum hemorrhage.
*Methods:* We performed a paper-based survey during the German Perinatal Congress in 2017 located in Berlin. A total of thirteen questions covered the fields of incidence, training, and treatment of postpartum hemorrhage.
*Results:* 250 questionnaires were handed out to all participants of three different sessions during the congress. 72 questionnaires were returned, resulting in a return rate of 29%. 94% (n = 65) of all participants stated that they had implemented a standard operating procedure to treat postpartum hemorrhage prior to the WOMAN trial. 18 of these standard operating procedures were revised after the publication of the WOMAN trial, resulting in an early inclusion of tranexamic acid in 100% of all standard operating procedures.
*Conclusion:* We recognized a correlation between the publication of the WOMAN trial and the administration of tranexamic acid at an early time-point in all standard operating procedures of the participating institutions to treat postpartum hemorrhage. In all those clinics whose algorithms initially did not contain any tranexamic acid, it was supplemented. This resulted in a 100% implementation of tranexamic acid.



## Introduction

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality worldwide [1,2]. PPH-attributed mortality varies considerably depending on location and ranges between 7/100,000 in Western Europe and 1,570/100,000 in Central Africa [3]. This pronounced difference in mortality is most likely attributed to insufficient emergency management standards in cases of PPH [4–7].

The WOMAN trial (WT) showed that tranexamic acid (TXA) is an effective treatment option to reduce bleeding-associated maternal morbidity and mortality when used early in critical hemorrhages [8,9].

Further analysis of the results from the WT [8] and CRASH2-study [10] revealed the clinical relevance of treatment delay. Immediate treatment with TXA greatly improved survival odds. This survival benefit decreased by 10% every 15 min and after 180 min no further benefit was detected [11]. The easy application and effectivity when given as soon as possible, makes TXA a favorable treatment choice as part of emergency algorithms for PPH.

In order to improve outcome immediate and appropriate reaction is crucial in cases of PPH to avert lethal outcome. Therefore, repeated training in standardizing critical disease management is important, furthermore so since PPH is a multidisciplinary problem.

In cases of acute hemorrhage, clinicians are challenged with several diagnostic and therapeutic tasks at once. As such, simple algorithms with clear guidelines are crucial in coordinating emergency treatment and patient management.

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We performed a survey at the German Perinatal Congress in Berlin to evaluate whether algorithms are existing to tackle PPH and weather TXA was considered. Furthermore, we investigated the impact of the WT on algorithm updates with regard to the implementation of TXA to treat PPH in German obstetrical departments [8].

## Material and methods

Ethical committee approval was deemed unnecessary for this study. Written consent to analyze and publish the results was obtained from every participant.

### *Participants*

Participants were midwives and physicians with different levels of education and work experience who attended the German Congress for Perinatal Medicine in Berlin in 2017.

### *Questionnaire and survey design*

The questionnaire consisted of thirteen questions (Q) that covered data on hospital infrastructure (Q 1–3), level of education of the participant (Q 4), familiarity with the WT [12] and its results (Q 5) as well as statistical data on PPH at the respective hospitals (Q 6–7). The remaining questions (Q 8–13) focused on algorithm details and were applicable solely on the availability of PPH management algorithms at the participant's institution.

### *Data collection*

The survey was performed during three different sessions of the German Congress for Perinatal Medicine (www.dgpm2017.com). During 30$^{th}$ November 2017 – 2$^{nd}$ December 2017 a total of 250 questionnaires were handed out to every participant in the auditorium with the request, that only one questionnaire per hospital should be completed.

The consent of the participants was confirmed by completing the questionnaire. The questionnaire did not contain any personal information to ensure anonymity.

No approval by the institutional ethical review board was necessary.

### *Primary outcome variable*

- The primary endpoint of this survey was to evaluate if the WT would lead to changes in the algorithms treating PPH at German obstetric centers.

### *Secondary outcome variables*

- The time point of the tranexamic acid application according to algorithm
- The rate of obstetric centers with algorithms implemented to treat PPH
- Number of PPH (according to institutional definition)
- Number of training or medical education for PPH treatment
- Number of births
- Number of cesarean deliveries

### *Data collection and statistical analysis*

Results of the questionnaires were collected and stored in a Microsoft Excel (Microsoft Office 365, 2016) Database. The statistical analyses were performed using SigmaPlot 12 (Systat Software GmbH, Erkrath, Germany) and SPSS 22 (IBM Deutschland GmbH, Ehningen, Germany).

Chi-squared test and Fisher exact test were used to detect differences. Values were expressed as number (percent) or median (25th and 75th percentiles, IQR), as appropriate. The level of significance was set to $p < 0.05$.

## Results

72 of 250 questionnaires were returned giving a return rate of 29%. Two questionnaires were excluded from the analysis due to incorrect completion, resulting in 70 questionnaires for analysis (28%). Incomplete questionnaires were included in the further evaluation process.

All depicted results were grouped by the hospital level of supply (Normal obstetric centers n = 25 (36%); Perinatal centers n = 4 (6%); Level II perinatal centers n = 8 (11%); Level I perinatal centers n = 33 (47%)).

### *Familiarity with the WOMAN trial*

Overall 36% (n = 25) were familiar with the WT and its results, while 64% (n = 45) of the respondents were aware of it. Participants from perinatal centers constituted the only group in which the number of participants familiar with the trial was greater than those aware of it (3 vs. 1; 75% vs. 25%).

### *Algorithm updates and details*

PPH treatment algorithms were implemented in 94% (n = 65) of all participating hospitals. In four centers (6%; n = 2 obstetric centers and n = 2 level I perinatal centers) there were no PPH treatment algorithms available at the time of the survey. All perinatal (n = 4) and level II perinatal (n = 8) centers had an algorithm implemented.

The question if the results of the WT led to an update of algorithms was left unanswered by two out of 65 (3%) participants. In 45 (71%) cases there was no update and in 18 cases (29%) updates were carried out after the publication of the WT.

In 92% (n = 55) TXA was part of the algorithms before the WT results were released, while in 5 (8%) cases TXA was added newly after publication. After these updates, TXA was a component in all algorithms.

In 53% (n = 34) application of TXA was equally performed by anesthesiologists and gynecologist. In 25% (n = 16) application of TXA was performed by anesthesiologists and in 22% (n = 14) by gynecologists according to the implemented algorithms.

### *Birth rates*

The highest birth rate of >3.000/year was reached by Level I perinatal centers in twelve cases. The lowest birth rate of <500/year was reached in one case by a normal obstetric center. The remaining birth rates swayed between 1.000/year and 3.000/year. With increasing level of care, the average number of birth per year increased (Table 1).

### *Cessation rates*

Four categories from <20% up to <50% were available to choose from in the questionnaire. The lowest section rate was reached by obstetric centers in three cases (12%) and one (2%) level I perinatal center. Overall a rate of <30% was stated most (n = 38; 54%), followed by a rate of <40% (n = 25; 36%).

**Table 1**
General survey results.

| | Normal Obstetric Center [n = 25; 36%] | | Perinatal Center [n = 4; 6%] | | Level II Perinatal Center [n = 8; 11%] | | Level I Perinatal Center [n = 33; 47%] | | Total [n = 70; 100%] | |
|---|---|---|---|---|---|---|---|---|---|---|
| Births/year [n, %] | | | | | | | | | | |
| <500 | 1 | (4%) | 0 | (0%) | 0 | (0%) | 0 | (0%) | 1 | (2%) |
| <1.000 | 13 | (54%) | 0 | (0%) | 0 | (0%) | 0 | (0%) | 13 | (20%) |
| <1.500 | 4 | (17%) | 1 | (25%) | 3 | (43%) | 6 | (18%) | 14 | (22%) |
| <2.000 | 5 | (21%) | 1 | (25%) | 4 | (57%) | 10 | (30%) | 20 | (32%) |
| <3.000 | 1 | (4%) | 2 | (50%) | 0 | (0%) | 5 | (15%) | 3 | (5%) |
| >3.000 | 0 | (0%) | 0 | (0%) | 0 | (0%) | 12 | (37%) | 12 | (19%) |
| Cessation rate [%] | | | | | | | | | | |
| <20% | 3 | (12%) | 0 | (0%) | 0 | (0%) | 1 | (2%) | 4 | (6%) |
| <30% | 17 | (68%) | 1 | (25%) | 5 | (63%) | 15 | (45%) | 38 | (54%) |
| <40% | 4 | (16%) | 3 | (75%) | 3 | (37%) | 15 | (45%) | 25 | (36%) |
| <50% | 1 | (4%) | 0 | (0%) | 0 | (0%) | 2 | (6%) | 3 | (4%) |
| Position | | | | | | | | | | |
| Midwife [n, %] | 1 | (4%) | 0 | (0%) | 1 | (17%) | 1 | (3%) | 3 | (4%) |
| Intern [n, %] | 6 | (25%) | 2 | (50%) | 1 | (17%) | 11 | (33%) | 20 | (30%) |
| Consultant [n, %] | 4 | (17%) | 2 | (50%) | 2 | (34%) | 1 | (3%) | 9 | (13%) |
| Senior Consultant [n, %] | 10 | (42%) | 0 | (0%) | 1 | (17%) | 20 | (61%) | 31 | (46%) |
| Chief Consultant [n, %] | 3 | (12%) | 0 | (0%) | 1 | (17%) | 0 | (0%) | 4 | (6%) |
| WOMAN Trial known? | | | | | | | | | | |
| Yes [n, %] | 7 | (28%) | 3 | (75%) | 2 | (25%) | 13 | (39%) | 25 | (36%) |
| No [n, %] | 18 | (72%) | 1 | (25%) | 6 | (75%) | 20 | (61%) | 45 | (64%) |
| PPH rate | 11 | (5/50) | 10 | (10/10) | 13 | (10/20) | 25 | (20/90) | 20 | (10/50) |
| Trainings for PPH | 1 | (1/2) | 5 | (1/6) | 2 | (1/2) | 2 | (1/3) | 1 | (1/2) |
| PPH algorithm? | | | | | | | | | | |
| Yes [n, %] | 22 | (92%) | 4 | (100%) | 8 | (100%) | 31 | (94%) | 65 | (94%) |
| No[n, %] | 2 | (8%) | 0 | (0%) | 0 | (0%) | 2 | (6%) | 4 | (6%) |

Data displayed as count [n] and percentage [%]. PPH rate and Training are depicted as median (IQR).

*PPH rate*

The lowest (n = 2/year) and highest (n = 300/year) rate with a median of 25 (IQR: 20/90) of PPH were reached in level I perinatal centers. Overall the median was 20 (IQR: 10/50).

*PPH training*

PPH training was performed up to six times a year (perinatal centers). Conversely, there were a number of hospitals without any training (n = 3 level I perinatal centers; n = 5 obstetric centers). The median rate of training per yeare was 1 (IQR: 1/2).

*Timepoint of TXA application*

Participants were able to choose between seven different time points of TXA application. Multiple answers were allowed. These time points are depicted in Table 2. Two out of seven time points were chosen by all participants. In 62% (n = 34) TXA was applied directly after administration of uterotonic agents and in 38% (n = 21) TXA was given within the diagnosis of PPH according to the institutional SOPs.

*Position / Level of education*

Midwives, interns, consultants, senior consultants and chief consultants were allowed to participate in this survey. The largest group was represented by 31 senior consultants (46%), followed by interns (n = 20; 30%), consultants (n = 9; 13%), chief consultants (n = 4; 6%) and midwives (n = 3; 4%). Level I perinatal centers (n = 33) and normal obstetric centers (n = 25) represented the hospitals with the most participants. In both cases, senior consultants made up the largest group of participants (Table 1).

**Table 2**
PPH algorithm survey results.

| | Normal Obstetric Center [n = 22; 34%] | | Perinatal Center [n = 4; 6%] | | Level II Perinatal Center [n = 8; 12%] | | Level I Perinatal Center [n = 31; 48%] | | Total [n = 65; 100%] | |
|---|---|---|---|---|---|---|---|---|---|---|
| Update of algorithm after WT? | | | | | | | | | | |
| Yes [n, %] | 8 | (38%) | 2 | (50%) | 3 | (38%) | 5 | (17%) | 18 | (29%) |
| No [n, %] | 13 | (62%) | 2 | (50%) | 5 | (62%) | 25 | (83%) | 45 | (71%) |
| TXA in PPH algorithm | | | | | | | | | | |
| Yes [n, %] | 31 | (100%) | 8 | (100%) | 4 | (100%) | 22 | (100%) | 65 | (100%) |
| No [n, %] | 0 | (0%) | 0 | (0%) | 0 | (0%) | 0 | (0%) | 0 | (0%) |
| TXA new in algorithm after WT? | | | | | | | | | | |
| Yes [n, %] | 2 | (11%) | 0 | (0%) | 1 | (13%) | 2 | (7%) | 5 | (8%) |
| No [n, %] | 16 | (88%) | 4 | (100%) | 7 | (87%) | 28 | (93%) | 55 | (92%) |
| TXA application by | | | | | | | | | | |
| Gynaecologist [n, %] | 5 | (23%) | 2 | (50%) | 2 | (25%) | 5 | (17%) | 14 | (22%) |
| Anaesthesiologist [n, %] | 2 | (9%) | 2 | (50%) | 3 | (38%) | 9 | (30%) | 16 | (25%) |
| Both [n, %] | 15 | (68%) | 0 | (0%) | 3 | (38%) | 16 | (53%) | 34 | (53%) |
| Time of TXA application | | | | | | | | | | |
| With PPH diagnosis [n, %] | 7 | (37%) | 1 | (25%) | 3 | (38%) | 10 | (42%) | 21 | (38%) |
| After uterotonics [n, %] | 12 | (63%) | 3 | (75%) | 5 | (62%) | 14 | (58%) | 34 | (62%) |

WT = Woman Trial; TXA = tranexamic acid Data is depicted as count and percentage.

## Discussion

The aim of the present study was to evaluate the influence of the WT results on algorithms to treat PPH in Germany. Therefore, a paper-based survey was performed during the German Perinatal Congress 2017 in Berlin. Results showed that 18 of 63 SOPs were updated after the publication of the WT and resulted in an inclusion of TXA in 100% of all SOPs at an early time-point. Therefore, our data revealed a correlation between publication and implementation of TXA.

Our results show that prior to publication of the WT TXA was included in 55 algorithms (=92%). These results are in accordance with a survey performed previously that found an implementation rate of TXA in treatment algorithms of 80% [13].

After publication of the WT; 18 algorithms (=29%) had been updated, and in five cases (=8%) TXA was a recent addition. At the time of our survey, TXA was part in 100% of all algorithms. It has to be assumed, that the cognizance of TXA usage for PPH treatment increased after the publication of the WT results, leading to increased TXA implementation.

A meta-analysis by Gayet-Ageron et al. [11] from WT [12] and the CRASH-2 trial [10] cohorts, including 40,138 bleeding patients showed, that early administration of TXA after diagnosis of severe bleeding was associated with a significantly improved survival rate. The survival benefit decreased by 10% every 15 min. After 180 min. no further benefit was detected [14]. This led to the recommendation of early administration of TXA. Within the scope of the survey, 8 possible application times for TXA could be selected [1= Not received; 2= On diagnosis; 3= After uterotonics; 4= After tamponade; 5= After fibrinogen; 6= After RBC; 7= After B-Lynch; 8= After hysterectomy]. Application was early in all cases, i.e. after diagnosis or application of uterotonics (see Table 2). This reflects the high relevance of the TXA which has meanwhile found comprehensive coverage in algorithms. However, the optimal dose of TXA for PPH treatment is still unclear. Therapeutic dosages may vary from 2.5 to 100 mg/kg and different regimes have been suggested [8,15]. The TRACES trial comparing 1 g TXA vs. 0.5 g TXA vs. placebo in hemorrhagic caesarean delivery, and is still recruiting patients. First results are expected for February 2019 [16].

In the present study, mean PPH incidence might vary between 10/year (perinatal center) and 25/year (perinatal center level II). Increasing PPH rate in centers with an advanced level of care has been shown to be attributed to an increased rate of high-risk pregnancies and is therefore concurring with our results [13].

In 94% (n = 65) of all hospitals, algorithms are used for the standardized treatment of PPH. The efficacy of algorithms, particularly in emergency situations to elicit a structured response, minimize complications and to perform highly efficient care is undisputed [17–19]. The recently published survey by Kaufner et al. revealed an implementation of algorithms in 85% of all participating German obstetric centers and is thereby concurrent with our findings [13]. PPH treatment using algorithm-based therapy is widespread. The importance of this process, especially in emergency situations, is recognized by the high prevalence of algorithms in medical care.

Appropriate algorithms should be updated accordingly and interdisciplinary training performed at regular intervals helps doctors to be prepared for emergency situations [20,21]. Eight (11%) hospitals did not have a regular training implemented. All other remaining hospitals (n = 64, 90%) carried out one to six trainings yearly. Over the years, different training methods, such as hands-on and video training were used to improve management of PPH. Nilsson et al. found mobile media-based training as effective as hands-on training [22]. These training methods are especially useful in developing countries where rural institutions are difficult to reach for conventional training. In general, virtual simulation and team training improved response times among clinically experienced community labor and delivery teams, thus strengthening the professional competency [23,24].

The cesarean delivery are increasing worldwide [25]. With increasing level of support from normal obstetric centers to perinatal level I centers, cessation rates and the number of births increased (s. Table 1). These results are in line with the results of Kaufner et al. representing a comparable study population [13].

There is however, very little information on treatment algorithms for PPH [19]. A review of the literature [26] and comparisons between different guidelines [27] did not focus on TXA, rather on prevention, diagnosis, and treatment, and were published before the WT. The only survey performed in Germany by Kaufner et al. covered the period from October 2014 to February 2015 and evaluated the hemostatic management in postpartum hemorrhage and included 533 German obstetric centers. Return rate (29%) was comparable to ours (28%), and percentage distribution of participating institutions regarding their level of care were in line with our results (Level 1: 47% vs. 43%; 11% vs. 11%; 6% vs. 14%; 36% vs. 33%). Due to the publication date, the influence of the WT on TXA implementation was not investigated.

Our study has several methodical limitations. The validity of our surveys is low, because results depend on the subjective answers from the participants. Additionally when using paper-based questionnaires, there is the possibility, that more than one questionnaire is used per institution. Computer-based surveys could minimize this bias. Furthermore, the participants were a diverse group with varying levels of education. Hence, the interpretations of the results need to be considered with caution. The total of 70 questionnaires represents only a portion of all obstetric centers in Germany.

## Conclusion

The Woman Trial and further analysis showed a reduced mortality when TXA was administered at an early time-point during management of postpartum hemorrhage. This study is investigating the influence of the WOMAN Trial results on national algorithms to treat PPH and revealed a correlation between publication and implementation of TXA. It seems that the results of the WOMAN Trial led to an implementation of TXA in all algorithms examined in this survey.

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## Conflict of interests / Disclosures

The authors state that there were no conflicts of interest.

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## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.jogoh.2019.01.010.

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## Glossary

*BC:* Blood count
*BGA:* Blood gas analysis
*FFP:* Fresh frozen plasma
*HR:* Heart rate
*I.U.:* International units
*Lyo-FFP:* Freeze-dried plasma
*PPH:* Postpartal hemorrhage
*PPSB:* Prothrombine complexe
*RBC:* Red blood concentrates
*RR:* Blood pressure
*TC:* Thrombocyte concentrates
*TEG 6s:* Hemostasis analyzer
*TXA:* Tranexamic acid
*WT:* Womantrial