

4.3.5. Clinical evaluation (n=98) of CELOX™ PPH in patients with PPH.

Use of CELOX™ PPH in 98 cases of severe postpartum haemorrhage—a multicenter registry analysis.

Von Beckerath AK, Maul H, Gebauer G, Abdel-Kawi AF, Rolf N, Saade G, Bader W, Kusnierczak D, Berger R, Kienast C, Kienemund J, Schmid B. Am J Obstet Gynecol. 2016; 214(1 Suppl 1):S269. [poster presentation]

Multicentre registry analysis study (n=98)

- Assessment of the potential side effects of CELOX™ PPH, and to assess if the use of CELOX™ PPH reduces the rate of postpartum hysterectomies
- Women with PPH were treated in accordance to guidelines with the addition of uterine packing using CELOX™ PPH
- After the introduction of CELOX™ PPH the rate of postpartum hysterectomies reduced from 0.18% to 0.05% (p=0.0183)
- No adverse events were observed or reported
- CELOX™ PPH is cost-effective and easy to use

The study examined the effectiveness of CELOX™ PPH in managing persistent bleeding PPH cases, involving ninety-eight women, where standard medical uterotonic interventions had failed. The objective of the multicentre CELOX™ PPH registry analysis was to report on potential side effects of CELOX™ PPH and to assess if the use of CELOX™ PPH reduced the rate of postpartum hysterectomies (von Beckerath et al, 2016b). After the introduction of CELOX™ PPH the rate of postpartum hysterectomy was significantly reduced (0.05% vs. 0.18%, p=0.018) (Figure 14). Two patients experienced uncomplicated pregnancies following treatment with CELOX™ PPH, and there were no instances of maternal mortality after the introduction of this medical intervention. Elevated levels of C-reactive protein (CRP) and leukocytes (WBC) were observed in patients who received CELOX™ PPH. Approximately 10% of patients developed a fever; however, none displayed any indications of sepsis. Please note that the gauzes were removed 24 hours after insertion, with a permissible window of up to 6 additional hours*.

*CELOX PPH is approved and indicated for use with a maximum insertion time of up to 24 hours

Figure 16. Rate of hysterectomy before and after introduction of CELOX™ PPH

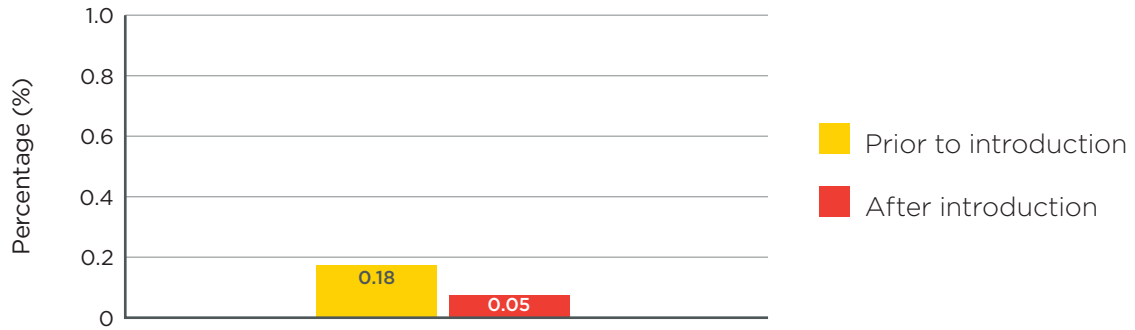


Figure 14. Hysterectomies due to PPH before and after the introduction of CELOX™ PPH

