4.3.6. Clinical evaluation (n=65) of CELOX™ PPH in patients with severe PPH (including cases where risk of postpartum hysterectomy is high).

Uterine packing with CELOX™ PPH for control of postpartum Haemorrhage (PPH).

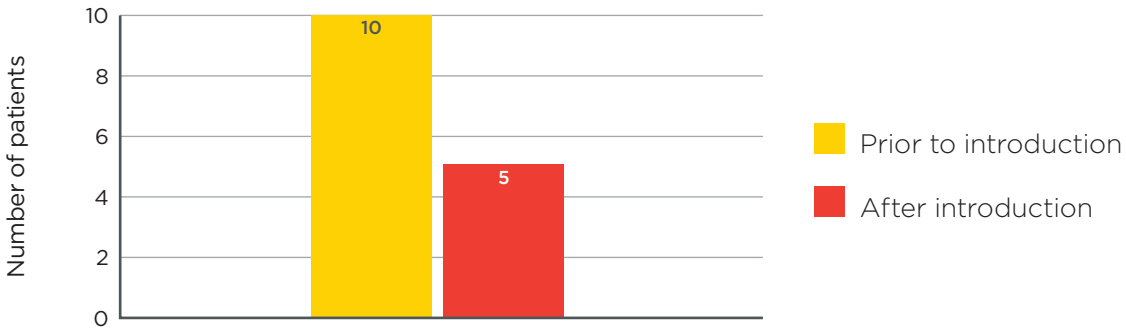
Maul H, Steinmacher S, Saade G, Gebauer G, Rolf N, Schmid B. Am J Obstet Gynecol. 2015; 212(1 Suppl 1):S358-S359. [poster presentation]

Case study series (n=65)

- Objective: to compare a 26 month period before and a 38 month period after the introduction of CELOX™ PPH in the treatment of PPH
- Women with PPH were treated by uterine packing with CELOX™ PPH through the hysterotomy in caesarean delivery, or transvaginally
- CELOX™ PPH is a viable option in the treatment of PPH
- After the introduction of CELOX™ PPH postpartum hysterectomies were significantly reduced (p=0.023)
- CELOX™ PPH can be safely used after both vaginal and caesarean section
- No complications related to CELOX™ PPH treatment were observed
- The use of CELOX™ PPH is inexpensive

In a cohort study of patients suffering from severe PPH, sixty-five women were treated with uterine packing with CELOX™ PPH via the hysterotomy in caesarean delivery, or transvaginally. 15036 consecutive births before and after the introduction of CELOX™ PPH (n=5498 vs. n=9538 deliveries) were analysed. The objective of the study was to compare the postpartum hysterectomies before and after the introduction of CELOX™ PPH (Maul et al, 2015). Compared with 26 months before, in the 38 months after introduction of CELOX™ PPH, the rate of postpartum hysterectomies was significantly reduced (10 vs. 5, p=0.023) (Figure 15). CELOX™ PPH was left in utero for up to 48 hours* (mean 20.63 hours). Maternal mortality after the introduction of CELOX™ PPH was zero.

Figure 15. Number of postpartum hysterectomies before and after introduction of CELOX™ PPH



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

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