4.3.4. Historical, retrospective cohort study evaluation (n=666) comparing the effectiveness of CELOX™ PPH with balloon tamponade or medical therapy in patients with PPH.

Does the use of CELOX™ PPH for postpartum haemorrhage reduce the need for surgical therapy including hysterectomy? A databased historical cohort study.

Biele C, Radtke L, Kaufner L, Hinkson L, Braun T, Henrich W, Dückelmann AM. J Perinat Med. 2022; 50(8):1078-1086.

Retrospective cohort study (n=666)

- Assessment of the effectiveness of CELOX™ PPH in comparison with balloon tamponade, and medical therapy only
- Groups were compared in terms of therapy success, side-effects, and the primary outcome was the need for surgical measures (e.g., hysterectomy)
- No significant differences in the need for surgical therapy between groups.
- CELOX™ PPH group had significantly fewer hysterectomies compared to the balloon tamponade group.
- Following the introduction of CELOX™ PPH, the incidence of PPH-related hysterectomies was significantly reduced by 77.8%.
- No adverse events related to CELOX™ PPH
- CELOX™ PPH is easy to use and cost-effective compared to alternative devices.

Biele and colleagues (2022) reported a database-based, retrospective case-control study evaluation (n=666) comparing CELOX™ PPH with that of balloon tamponade and medical therapy (the use of uterogenic and/or haemostatic drugs) only. A total of 530 received medical therapy only, 51 balloon tamponade, and 85 CELOX™ PPH. The primary outcome of the study was the need for further surgical/radiological therapies (e.g., compressing sutures, selective devascularisation, (re-)laparotomy and hysterectomy). The secondary outcomes included duration of inpatient stay, admission to ICU, and inflammatory markers. There was no significant difference in the need for surgical therapy, but a significantly lower number of hysterectomies in the CELOX™ PPH group compared to the balloon tamponade group was reported (Figure 13). There were no significant differences in secondary outcomes and no adverse events related to CELOX™ PPH. Since the introduction of CELOX™ PPH, the number of PPH-related hysterectomies reduced significantly by 77.8% (7.8% vs. 0.0%, p=0.018) (Figure 15).

Back to Contents page

Figure 13. Hysterectomies due to PPH before and after the introduction of CELOX™ PPH

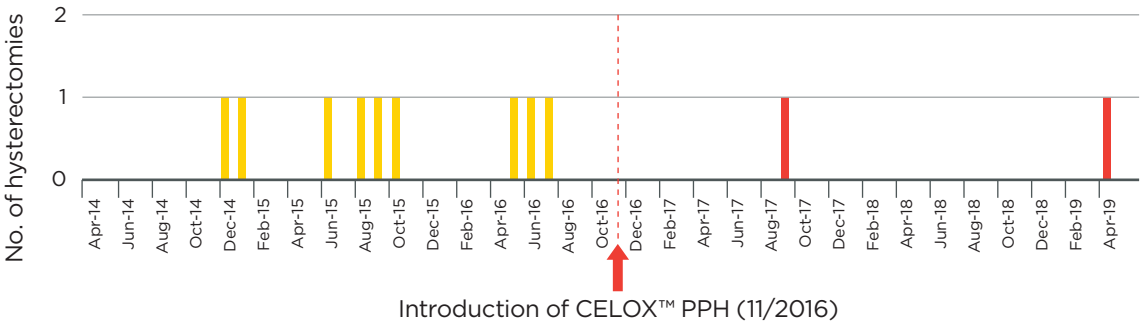
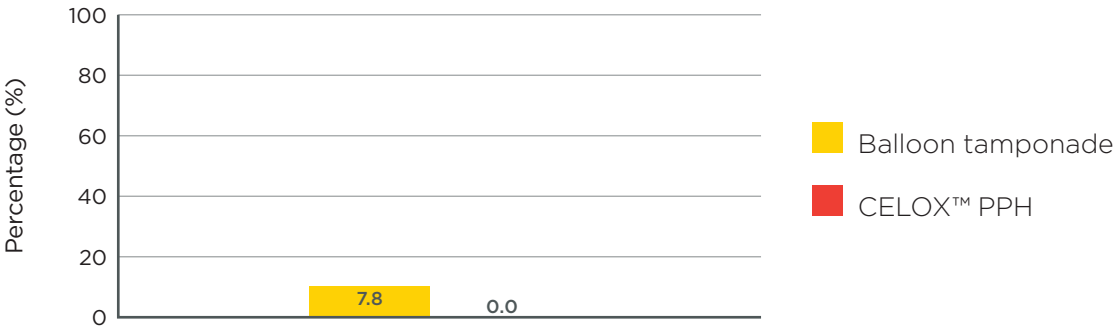


Figure 14. Percentage of patients requiring hysterectomy



Back to Contents page