

4.3.9. Case studies: use of CELOX™ PPH in patients with (n=4) life-threatening obstetric bleeding.

Uses of CELOX™ PPH for treating different forms of serious obstetrics haemorrhages.

Carles G, Dabiri C, Mchirgui A, Saoudi EO, Hcini N, Pouget K, Seve B, de Matteis B. J Gynecol Obstet Hum Reprod. 2017; 46(9):693-695.

Case study series (n=4)

- Four cases where CELOX™ PPH was used to treat severe obstetric haemorrhage
- Two chitosan variants, in powder and CELOX™ PPH form, were used*
- In all four cases, chitosan effectively resolved the severe obstetric haemorrhage
- Treatment with CELOX PPH was inexpensive, and required no training

Carles et al (2017) reported the application of CELOX™ PPH or chitosan powder* to treat life-threatening obstetric bleeding. Two cases of significant obstetric bleeding treated with the application of CELOX™ PPH were described. In the first case, a 35-year-old woman in her 10th pregnancy presented at the emergency room in early labour. After an emergency caesarean delivery, the patient displayed extensive bleeding and haemodynamic instability. Despite transfusions, haemodynamic sutures, and compression of the pelvis the patient continued to bleed from the edge of the cervix and within the pelvic cavity. Upon packing of the pelvic cavity with CELOX™ PPH the bleeding stopped completely within five minutes of application. CELOX™ PPH was removed, without difficulty, during surgery two days later**. In a second case, a 25-year-old woman presented with spontaneous labour at 40 weeks. The labor proceeded without complications, resulting in spontaneous delivery of the baby, facilitated by the administration of a 10 IU of oxytocin via intravenous injection. The patient then displayed abnormal bleeding, but no abnormalities were found upon examination. Despite administration of an additional 10 IU of oxytocin via intravenous injection and a one-hour intravenous infusion of a sulprostone ampoule, blood loss continued, and it was decided to pack the uterus with CELOX™ PPH. Bleeding stopped immediately upon application of the gauze. CELOX™ PPH was removed the day after delivery, by simply pulling it out of the uterine cavity. Another case involved a patient in late pregnancy with preeclampsia. As her preeclampsia worsened during labor, she received a combination of urapidil and magnesium sulfate. Vacuum extraction was performed due to abnormal fetal heart rate during the second stage of labor. An intravenous injection of 5 IU

*CELOX™ PPH gauze is the only product approved for use in cases of uterine PPH

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

oxytocin aided delivery, and though the placenta initially appeared complete, the patient experienced significant postpartum bleeding, estimated at over 2 liters of blood loss. Examination revealed extensive, bleeding vaginal tears that resisted traditional haemostatic measures. Chitosan powder* application and gauze compression for five minutes effectively stopped the bleeding. There was no further vaginal bleeding, and haemostatic tests returned to normal within two days.

4.3.10. Case report: use of CELOX™ PPH in combination with balloon tamponade for management of PPH.

Application of CELOX™ PPH in combination with intrauterine balloon tamponade for postpartum Haemorrhage treatment – Case report of a novel “uterine sandwich” approach.

Seidel V, Braun T, Weizsäcker K, Henrich W. Int J Surg Case Rep. 2018; 48:101-103.

Case report (n=1)

- Presentation of a case of PPH where a novel “uterine sandwich” (a combination of CELOX™ PPH and intrauterine balloon tamponade) used to halt blood loss
- The novel treatment strategy was effective at stopping further blood loss
- The use of the “uterine sandwich” prevented the need for more invasive second stage intervention

CELOX™ PPH has been used in a patient with PPH using a “uterine sandwich” approach using a combination of CELOX™ PPH with an intrauterine balloon tamponade to prevent blood loss (Seidel et al, 2018). At about 35 weeks a planned caesarean section delivered three healthy boys. However, within 2.5 hours the uterus became atonic and filled with blood. As it was the first pregnancy for the woman, a fertility preserving strategy was preferred. CELOX™ PPH was inserted, and an intrauterine balloon tamponade was added to the uterus. Bleeding was stopped after the additional insertion of the balloon. No further surgical intervention was necessary.

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