

The Efficacy And Safety Of Hemcon[®] Guardacare[®] XR Surgical Following Surgical Repair In Management Of Postpartum Bleeding Due To The Multiple Vaginal Lacerations.

Baron J . Md^{1,3}, Kesus R. Md^{1,3}, Yaniv S^{1,3}. Md, Regev A^{2,3}. Md, Dvir A^{2,3}.
Sherf M.³ Md. Novack V^{2,3}. Md, Phd, Wiznitzer A^{1,3}. Md



The Department Of Obstetrics And Gynecology¹,
And The Soroka Clinical Research Center²,
Soroka University Medical Center³,
Be'er-sheba, Israel

Poster presented at Soroka Medical Center OBGYN Congress, Israel, on January 12, 2012.

MMF-200 Rev 1 03/12

The Efficacy And Safety Of Hemcon® Guardacare®XR Surgical Following Surgical Repair In Management Of Postpartum Bleeding Due To The Multiple Vaginal Lacerations.

Baron J. Md^{1,3}, Kesus R. Md^{1,3}, Yaniv S^{1,3}. Md, Regev A^{2,3}. Md, Dvir A^{2,3}. Sherf M.³ Md. Novack V^{2,3}. Md, Phd, Wiznitzer A^{1,3}. Md

The Department Of Obstetrics And Gynecology¹, And The Soroka Clinical Research Center², Soroka University Medical Center³, Be'er-sheba, Israel

Background

The most common injury during labor is vaginal tearing that occurs as the fetal head passes through the vagina. Between 63%-88% of vaginal birth will need a repair of the perineum with sutures.

Occasionally, the vagina is very edematous and fragile, and suturing could be difficult and frustrating due to oozing of blood from the vaginal tissue. Current management of cervical and vaginal tears has not changed much over the years, and includes assessment of injury, surgical repair and if needed packing bandage.

Objective

To assess the safety and efficacy of the HemCon® GuardaCare®XR Surgical compared to standard bandaging in subjects with post partum hemorrhage as a result of cervical and vaginal lacerations. The primary endpoint was a cessation of bleeding at 30 minutes after insertion of the device.



Materials and Methods

Product - HemCon® GuardaCare®XR Surgical

Provides the medical professional a flexible solution to quickly stop a range of bleeding from oozing to severe arterial within minutes, minimizing blood loss and reducing costs and risks associated with transfusions.

Methods

This study was designed as a prospective, randomized trial. Patients were 1:1 randomized to compression with either regular or HemCon pad. Exclusion criteria were: Subjects undertaking anticoagulation treatment; Pre-existing coagulopathy; Massive uncontrolled bleeding requiring blood transfusions/urgent vascular surgery; Systolic blood pressure <90mmHg; Shellfish allergy. The following data were compared between the two groups: cessation of bleeding at 30 minutes, 3 hours and 6 hours.

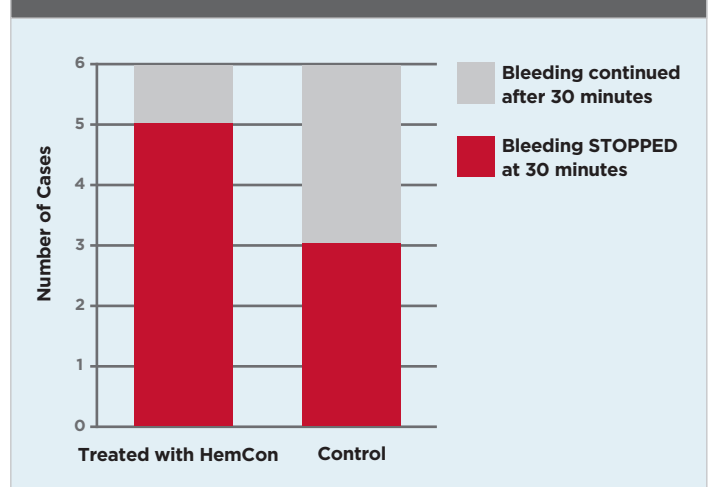
Results

- We enrolled 12 women with second degree cervical and vaginal laceration tears, requiring bandaging. Average age was 23.0±4.6 years.
- The average weight of newborn was 3060±653 gr. Mean number of perineal tears was 2.5±0.8. Mean number of sutures per woman was 2.9.
- Bleeding cessation at 30 minutes was successful in five out of six patients treated with HemCon, and three of six treated with standard bandaging.
- In HemCon group all bleeding were stopped at 3 hours as compared to three in the control group.
- No adverse events were reported in the intervention group.

MATERNAL AND FETAL CHARACTERISTICS AND INTRAPARTUM COMPLICATIONS

	HemCon N=6	Control N=6
Age, mean±SD, years	28.3±3.3	28.5±6.0
Ethnicity (Arab) ²	2(33.3)	4(66.7)
Gravidity, median	2	1
Parity, median	1	0
Newborn weight, mean±SD, (gr) ²	3126±671	2993±690
Induction, n (%)	1(16.7)	1(16.7)
Episiotomy, n (%)	2(33.3)	3(50)
Number of tears, n(%)	One	1(16.7)
	Two	3(50)
	Three	1(16.7)
	Four	1(16.7)
Number of sutures, mean±SD	4.0±2.73	1.8±1.3
Suture length, mean±SD	3.8±2.16	3.0±1.22

CESSATION OF BLEEDING AT 30 MINUTES



PATIENTS WHO CONTINUED TO BLEED AFTER 30 MINUTES

Patient Number	Treated With	Bleeding Stopped At	Massive Bleeding	Needed Surgical Treatment
1	Standard	6 hours	No	No
2	Standard	6 hours	Yes	Yes
3	HemCon	3 hours	No	No
4	Standard	>6 hours	No	No

Conclusion

- Treatment of vaginal tears with HemCon® GuardaCare®XR Surgical was safe and efficacious in achieving hemostasis at 30 minutes following the surgical repair.
- Larger study to assess the efficacy of HemCon® GuardaCare®XR Surgical in treatment of 1st degree vaginal tears without surgical intervention is underway.