Uji klinis awal kelayakan alat inpress untuk mengatasi perdarahan pascasalin karena atonia uteri = Feasibility clinical investigation using the inpress device for the treatment of postpartum hemorrhage due to uterine atonia

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Abstrak

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 Latar Belakang
Perdarahan pascasalin adalah penyebab 25% kematian ibu diseluruh dunia, bahkan mencapai 60% pada beberapa negara. Sekitar 60-90% disebabkan oleh atonia uteri. Berbagai alat ditemukan dan digunakan seperti tamponade balon uterus, NASG (Nonpneumatic Anti Shock Garment), Bakri Balloon dan The Glenveigh Medical Complete Tamponade System namun memiliki efektifitas sekitar 65-87,5% dan potensi komplikasi. Oleh sebab itu diperkenalkanlah suatu metode baru untuk mengontrol perdarahan pascasalin.
Metode
Tujuan dari penelitian ini adalah untuk melihat keamanan, kemudahan dan efektifitas alat InPress mengatasi perdarahan pascasalin karena atonia uteri. Alat InPress menggunakan mesin vakum bertekanan rendah untuk menurunkan tekanan atmosfer dalam kavum uteri sehingga uterus menjadi kolaps dan membuat tamponade sehingga perdarahan berhenti. Selain itu secara fisiologis, dapat merangsang kontraksi uterus pascasalin yang normal dan retraksi uterus ke bentuk dan ukuran semula.
Hasil
Dari sepuluh subyek penelitian menunjukkan bahwa mesin vakum dengan cepat menciptakan tamponade yang efektif melalui balon pengunci yang berada di ostium uteri eksterna. Jumlah perdarahan yang dievakuasi dari kavum uteri sekitar 100-250 cc, tertampung dalam kanister. Uterus kolaps dan terjadi tamponade dalam waktu 1-2 menit sehingga perdarahan berhenti. Alat InPress dipasang selama minimal 1 jam dan maksimal 6,5 jam. Repair luka robekan perineum dan vagina dapat dilakukan dengan mudah saat alat InPress terpasang di dalam uterus. Pada sepuluh subyek tidak ada tindakan lanjutan untuk mengatasi perdarahan setelah alat InPress dipasang. Tidak ditemukan adanya kelainan pada uterus, serviks dan vagina pada saat dan sesudah pemasangan alat InPress.
Kesimpulan
Tamponade uterus yang berasal dari tekanan negatif mesin vakum terbukti aman dan efektif untuk mengatasi perdarahan pascasalin karena atonia uteri.
ABSTRACT
 Background
the Treatment of Postpartum Hemorrhage Due To Uterine
Atonia

Postpartum Hemorrhage (PPH) is responsible for +/- 25% of maternal mortality worldwide, reaching as high as 60% in some countries. Approximately 60-90% caused by uterine atonia. Many devices were invented and applied such as uterine balloon tamponade, NASG (Nonpneumatic Anti Shock Garment), Bakri Balloon dan The Glenveigh Medical Complete Tamponade System but the effectiveness only about 65-87,5% control hemorrhage and have potential complications. Therefor a new method to control PPH has been introduced.

Method

The purpose of this study was to demonstrate patient safety, device efficiency, and ease of use, as an overall Proof of Concept with a new device, the InPress Device, for the treatment of primary postpartum hemorrhage (PPH) due to atony.

The InPress device uses gentle vacuum force to lower the atmospheric pressure within the uterine cavity to collapse the uterus into and onto itself to stop hemorrhage through tamponade. It also stimulates normal postpartum uterine contractions, to effect hemostasis. In this hemostatic state the atonic uterus recovers, physiologically, and retracts down to its? normal hemostatic postpartum size.

Results

Results from our ten trial patients showed that: the vacuum created an immediate effective tamponade confined to the uterus by our seal situated at the external cervical ostium, 100-250 milliliters of residual blood were evacuated from the uterine cavity into the vacuum canister. The uterus collapsed and regained tone within 1-2 minutes, and hemorrhaging stopped, in all cases. The device stayed in place while vaginal and perineal lacerations, which occurred during delivery, were easily repaired. The device was left in for one-hour minimum up to 6,5 hours. There were no further operative procedures required to stop hemorrhaging in any of these cases. There was no abnormality of uterus, cervix and vagina while and after InPress procedur performed.

Conclusion

Vacuum induced uterine tamponade using physiologic force, is a safe and effective way to achieve rapid control of PPH due to atony.

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