Suction Tube Uterine Tamponade

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Conflict of interest

• No conflict of interest regarding suction tube uterine tamponade

• Developer of a ‘Safe Birth Tray’ device for postpartum blood loss assessment.
Postpartum Haemorrhage Treatment

• Most cases of PPH stop spontaneously
• Observational studies and clinical impressions of interventions for PPH are inherently over-optimistic
• Need Randomized trials to confirm effectiveness and safety
Treatment of PPH unresponsive to uterotonics

• Uterine Balloon tamponade widely used, based on compelling observational studies and clinical impressions (1)

• Two randomized trials found increased harm with UBT versus controls (2,3)
  
Alternative: Uterine Suction Tamponade

• Possible mechanisms of Uterine Tamponade devices:
  • Balloon: compression of bleeding site
  • Suction: contracts uterus to promote physiological haemostasis
  • Both: ? Mechanical stimulation of endogenous uterotonics eg Pg
Purpose-designed Suction Uterine Tamponade Devices

• Ram/Panicker: Stainless steel 12mm cannula (1,2)
  • Reported use in 40 vaginal, 15 CS cases of PPH
• Inpress (Jada®): 10 cases reported (3)
• Effective in 100%
  • 1. Ram H, Ram HS, Ram S, Panicker V. Vacuum retraction of uterus for the management of atonic postpartum hemorrhage. IOSR-JDMS 13 (11) 2014, 15-19
Treatment of PPH refractory to first line uterotonics: Summary

• Clinical experience and observational studies very compelling for:
  • Uterine balloon tamponade (Bakri, condom, Ellavi, etc)
  • Uterine suction tamponade (cannulae, Inpress)

• Randomized trials:
  • Balloon tamponade worse than no tamponade
  • No RCT of Uterine suction tamponade vs no tamponade

• Urgent need for further RCT evidence on both

  • Hofmeyr GJ. Time to test tamponade. BJOG. 2018 Apr;125(5):538-539. doi: 10.1111/1471-0528.14809
Uterine Suction Tamponade

• If found to be effective, purpose-designed devices would be unaffordable/inaccessible to most women globally
• We have identified an inexpensive (USD<1), widely available device suitable for uterine suction tamponade (Levin stomach tube), and assessed its functionality in a ‘proof of concept’ study at CS

Suction Tube Uterine Tamponade (STUT): Description of technique and report of 3 cases

• 3 Cases of profound PPH and maternal decompensation treated with STUT as ‘last resort’ prior to laparotomy

• Bleeding arrested without recourse to surgery.

FG36 Levin stomach tube (use 24-36) (MVA suction syringe used if no other suction source available)
Identifying PPH: Safe Birth Tray

- The wedge is tucked against the woman’s buttocks after the baby is born
- The first chamber overflows at 500ml to alert for PPH
- The second chamber holds 1500ml, and can be used temporarily to place the placenta during 3rd stage
- Convenient, keeps the bed linen clean
- Non-disposable (cost and environment saving)
Conclusions and planned research

• UST intuitively attractive option for uterine tamponade
• Levin suction tube appears to be suitable, inexpensive device (STUT)
• Pilot RCT in progress at several SA centers - STUT vs routine care (UBT)
References

- Dumont et al. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. BMJ Open. 2017 Sep 1;7
- Ram H, Ram HS, Ram S, 4Dr. Panicker V. Vacuum retraction of uterus for the management of atonic postpartum hemorrhage. IOSR-JDMS 13 (11) 2014, 15-19
Vacuum-Induced Hemorrhage Control - VHC

Andy Uchida, VP of R&D – Alydia Health
Marcela Smid, MD, MA,MS – University of Utah

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Disclosures

• Andy Uchida is an employee at Alydia Health, manufacturer of Jada.
• Marcela Smid is a PEARLE Site PI. While receiving no personal compensation, University of Utah was provided with research support as a Study Site by Alydia Health.
Vacuum-induced Hemorrhage Control (VHC) – Feasibility Study

First-in-Woman
- 10 subjects
- Cessation of PPH in 2 minutes without recurrence
- No related adverse events

Peer-Reviewed Publication
Sabaratnam Arulkumaran, MD, PhD, Jan Segnitz, MD, et al.
Jada® System

• All silicone construction
• Inflatable seal at external cervical os to enable vacuum formation throughout uterus
• Low vacuum -> 80 mmHg
Low Cost Jada – Design Goals

• Designed for lower resourced settings – anywhere cost is an issue
• Maintain performance of the Jada System
• Fewer components
• New cervical seal without inflation (syringe) or fluid
• Maintains vacuum in presence of collapsing tissue and clotted blood
PEARLE: Trial completed at 15 Sites

Mary D’Alton, MD
Study Principal Investigator
Chair Department of Obstetrics & Gynecology, Columbia University

Investigational Device – Limited by US Law to Investigational Use
The PEARLE Study: FDA Approved IDE Trial

Prospective, single arm, literature-controlled pivotal clinical trial

107 subjects

Primary effectiveness endpoint: Control of PPH = No non-surgical, second-line or surgical intervention to control uterine hemorrhage after Jada

Primary safety endpoint: Incidence, severity and seriousness of device-related AEs.

Subjects: After vaginal or c-section, have PPH related to atony and have failed uterotonics and massage.

Study Status: Enrollment and follow up complete: 107 enrolled; 103 (96%) subjects completed 6 wks of follow up.

Marketing application to FDA under review and manuscript in review at peer-reviewed Journal.

Clinicaltrials.gov: NCT02883673

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Reflections on PEARLE

• Jada System use / assessment by 17 investigators at University of Utah
• Impressions of use at University of Utah
Jada® System

• All silicone construction
• Inflatable seal at external cervical os to enable vacuum formation throughout uterus
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Thank You!

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