June 2022

Refractory haEmorrhage Devices trial (RED trial)

PPH COP Annual meeting 2022

Fernando Althabe & Mariana Widmer
Human Reproduction Programme
World Health Organization

World Health Organization

human reproduction programme hrp
research for impact
UNDP · UNFPA · UNICEF · WHO · THE WORLD BANK

WHO recommendation on uterine balloon tamponade for treating PPH

UBT is recommended for the treatment of PPH due to uterine atony after vaginal birth in women who do not respond to standard first line treatment, provided that all of the following conditions are met:

- Immediate recourse to surgical intervention is possible if needed;
- A primary PPH first line treatment protocol (including the use of uterotonics, tranexamic acid, IV fluids and blood products) is available and routinely implemented;
- Other causes of PPH (retained placental tissue, trauma) can be reasonably excluded;
- The procedure is performed by health personnel who are trained and skilled in the management of PPH, including the use of uterine balloon tamponade; and
- Maternal condition can be regularly and adequately monitored for prompt identification of any signs of deterioration.

(Recommended in specific contexts)

WHO 2021

Research implications

In adequately resourced settings with good-quality PPH care:

- What is the comparative effectiveness of different types of UBT devices (including improvised or low-cost purpose-designed devices) in the reduction of PPH-related maternal morbidity and mortality?
- What is the comparative effectiveness of UBTs compared to other tamponade interventions (such as suction devices) in the reduction of PPH-related maternal morbidity and mortality?
- What is the safety and comparative effectiveness of different tamponade devices for the treatment of refractory PPH at caesarean section in the reduction of PPH-related maternal morbidity and mortality?
- What is the most effective modality for training and assuring competency in the use of UBT?

WHO 2021

RED trial aim

To evaluate the efficacy of different uterine tamponade devices for the treatment of refractory PPH, in well resourced settings

Ellavi® Balloon

- The Ellavi® balloon is a fully pre-assembled UBT device made of plastic that can be quickly filled up to 750 mL without expansion pressure.

- It can work with a free-flow mechanism through an open gravidity-fed system, or as a fixed volume UBT

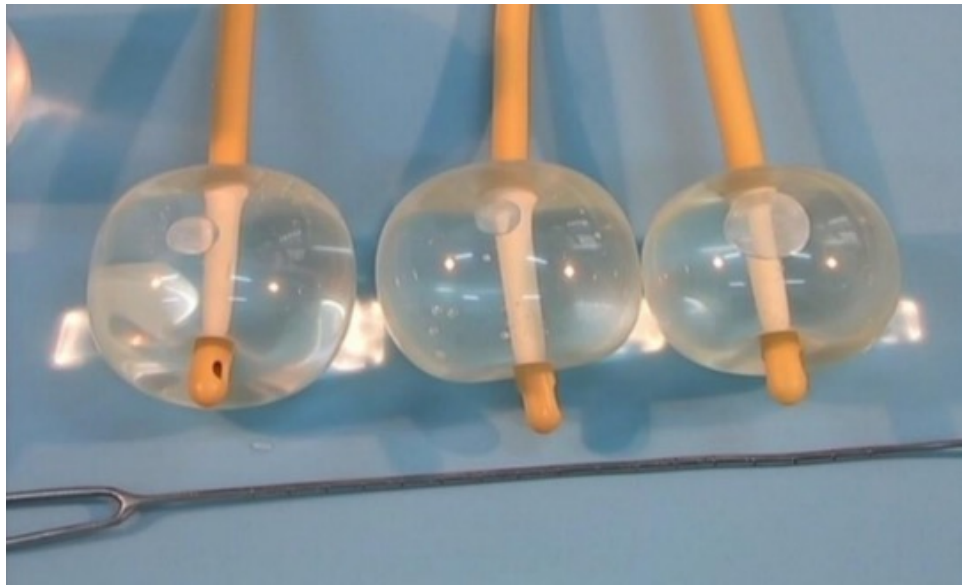
Suction Tube Uterine Tamponade (STUT)

- STUT uses negative pressure to promote uterine contraction and haemostasis.
- A wide-bore (FG24 to FG36) Levine suction tube considered an inexpensive, widely available device suitable for uterine suction
- Connected by suction tubing to an adjustable electronic suction pump,
- The suction pressure needed is between 100 and 200mmHg

Hofmeyr BJOG 2020

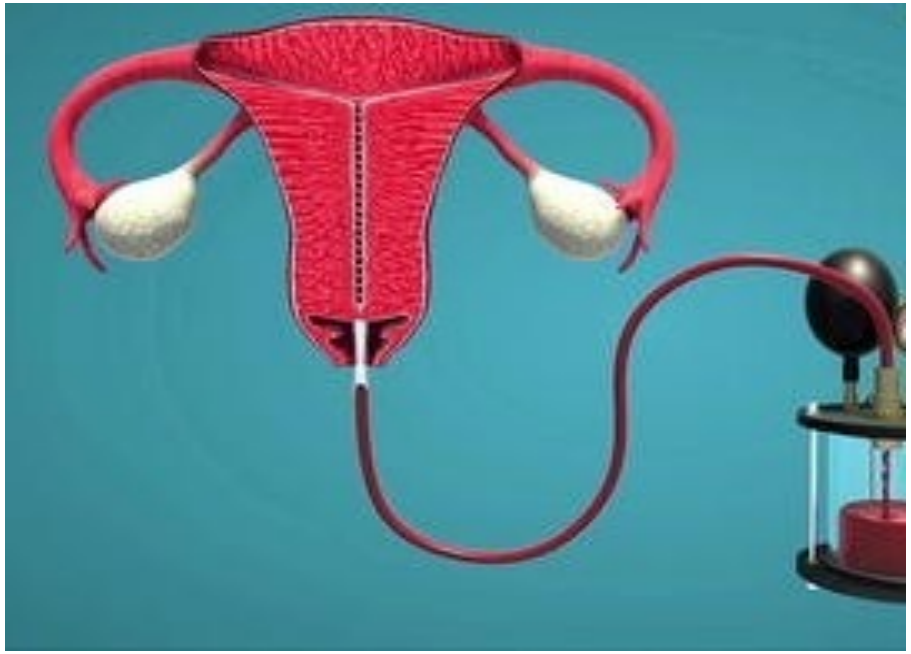
Foley catheter balloon

- Intrauterine single-balloon and double-balloon tamponades
  - Single Foley 30 Fr
  - A combination of Foley 30Fr and Foley 20 Fr*
  - Standard of care in Vietnam



*was created by Dr Nguyen Khanh Trang Huynh and co-workers at Hung Vuong Hospital, Ho Chi Min City, Vietnam

Other vacuum devices

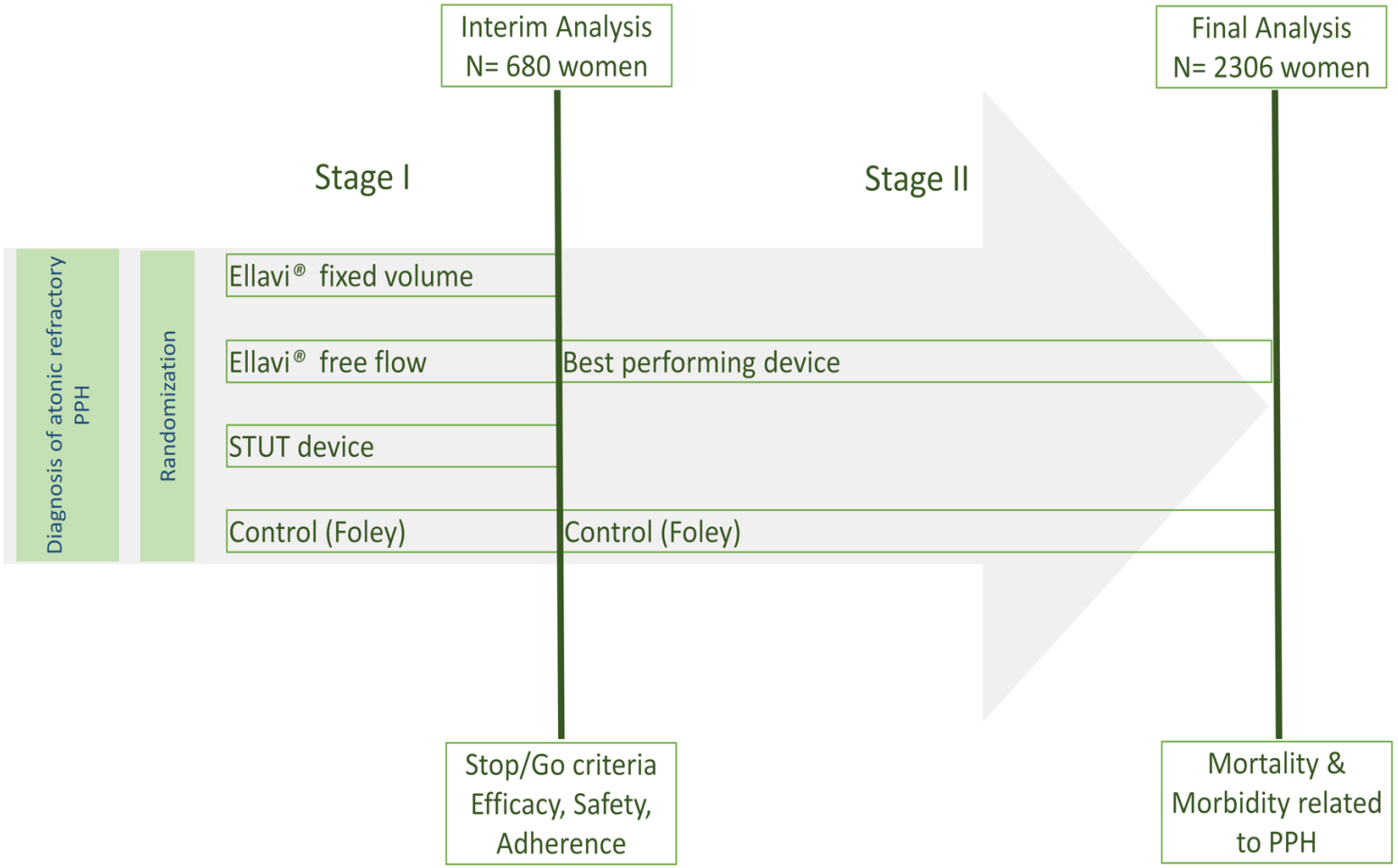


Panicker, T.N.V. Panicker's Vacuum Suction Haemostatic Device for Treating Post-Partum Haemorrhage. J Obstet Gynecol India 67, 150–151 (2017)

Panicker 2017, Dalton 2021

RED trial design

Adaptive, hospital-based, multicentre, multi-arm, multi-stage (MAMS), individually randomized active-controlled superiority trial



Trial setting

Two large maternity referral hospitals in Ho Chi Min City, Vietnam:

- Hung Vuong Hospital (PI Dr Hoang Thi Diem Tuyet

- Tu Du Hospital (Dr Le Quang Thanh)

Trial participants

Women will be eligible for the trial if they:

- have a vaginal birth
- experience PPH likely to be caused by uterine atony, not responding to first-line treatment with uterotonic drugs
- require further treatment to control the bleeding according to the birth attendant's opinion
- provide written informed consent at admission in labour

Primary Outcome

- The proportion of women with the composite outcome of:
  - invasive surgical procedures, or
    - laparotomy for compressive sutures
    - Laparotomy for uterine artery ligation
    - Laparotomy for hysterectomy
  - mortality related to PPH, or

Thank you!!!

Questions or clarifications?