

### INTRODUCTION

#### Background

Hysterotomy is one of the key steps during Cesarean section (CS). It is often associated with increased bleeding which can obstruct the surgeon's field of visibility and therefore lead to increase complications.

#### Aim

to validate the safety and the efficacy of a new surgical device, called B-ReD (Bleeding Reduction Device), in reducing bleeding during hysterotomy by mechanical compression of peri-incisional uterine vessels.

INCLUSION CRITERIA	EXCLUSION CRITERIA
<ul style="list-style-type: none"> <li>- Women aged 18-45</li> <li>- Singleton pregnancy</li> <li>- Transverse hysterotomy</li> <li>- Informed consent</li> </ul>	<ul style="list-style-type: none"> <li>- Coagulation disorders</li> <li>- Use of salicylic acid &lt; 7 days prior to surgery</li> <li>- &lt; 34 weeks of gestation</li> </ul>

### STUDY DESIGN / METHODS

Pregnant women prior to CS were randomized in

- Control arm (A: without B-ReD) – Image 1
- Experimental arm (B: with use of B-ReD) – Image 2

CSs were performed by qualified senior surgeons

#### Primary and secondary outcomes

- Score assessment \*:
  - Visibility during the incision for the operator (Op)
  - Visibility during the incision for the assisting resident (Re)
  - Visibility without vs with use of the device on same patient for the Op (arm B)
  - Ease of technical performance for the Op
- Hysterotomy time
- Blood loss during hysterotomy \*\*

\* (scale 1 to 10 : with 10 optimal)

\*\* (collected by a gauze in grams)

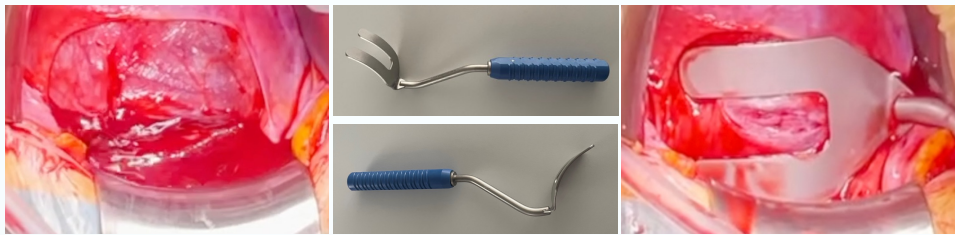
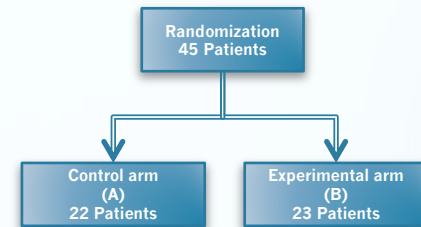


Image 1: Without B-ReD

B-ReD

Image 2: With B-ReD



### RESULTS

Outcome	Measurement	A : Control arm **	B : Experimental arm **	P-value
Hysterotomy time	Seconds	18.3 (±12.9)	21.5 (±14.6)	0.451
Hysterotomy related complications	Number of events	0	0	1
Blood loss during hysterotomy	grams	10.51 (±18.1)	1.40 (±2.64)	0.042
Visibility for Op	Score 1-10	7.70 (±2.29)	9.09 (±1.95)	0.033
Visibility for Re	Score 1-10	7.26 (±1.30)	9.27 (±1.83)	0.002
Visibility for Op without vs with B-ReD *	Score 1-10	NA	6.21(±3.17) without vs 8.57 (±2.31) with B-ReD	0.033
Op's comfort during hysterotomy	Score 1-10	8.3 (±2)	9.4 (±1.3)	0.025

Op: operator, Re: assisting resident, \*: same patient, \*\*: mean (±SD)

### CONCLUSIONS

B-ReD decreases blood loss during cesarean hysterotomy, increases the visibility for the operator as well as for the assisting resident and therefore facilitates Cesarean section, with no additional operative time nor complications.

B-ReD may be particularly helpful in teaching hospitals.

