

Supplementary material

Improving maternal safety: Usability and performance assessment of a new medical device for the treatment of postpartum haemorrhage

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A. Assembly and usage procedures for the BAMBI device and the CBT solution and training modalities

The use procedure of BAMBI can be broken down into a series of tasks. Some tasks involve physical actions, while others imply the cognitive processing of perceptual inputs. The main steps are shown in Figure A.1.

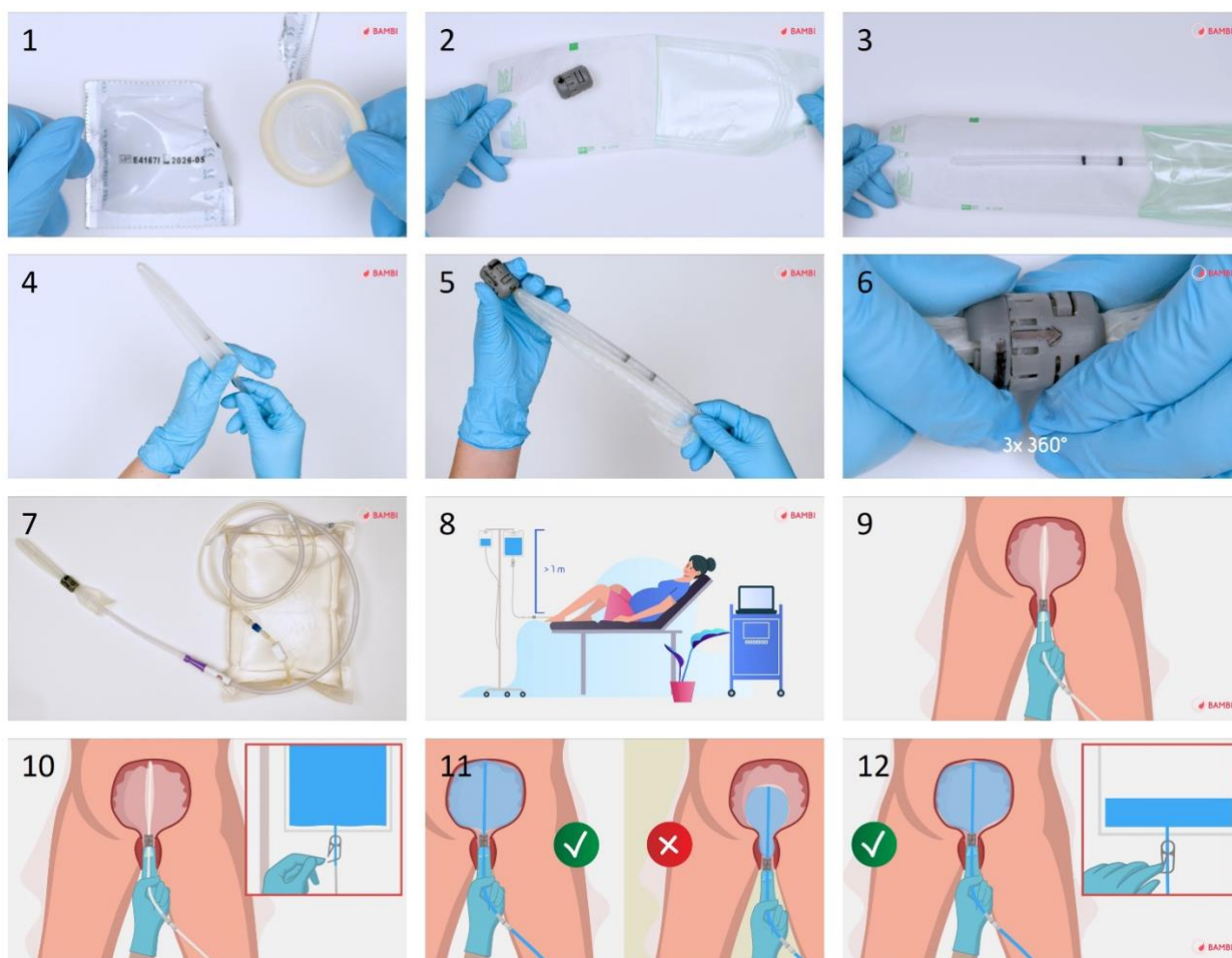


Figure A.1. Use procedure of the BAMBI device divided into tasks. All the pictures are extrapolated from our video used for the tests involving non-expert users.

These steps are:

1. open and remove the probe cover from its wrapper;
2. open the sterilisation pouch housing the connector;
3. open the sterilisation pouch housing the rectal probe;
4. insert the probe cover over the rectal probe and slide it to its entire length;
5. insert the connector making sure the arrow is pointing downward, and position the connector between the two lines on the rectal probe;
6. perform three complete 360° clockwise rotations of the upper part of the connector while keeping the lower part fixed to secure the probe cover to the rectal probe;
7. connect the rectal probe to the pre-filled saline bag;
8. hang the bag at least one meter above the patient;
9. insert the device into the patient's uterus (=manikin) through the vaginal canal until the probe touches the fundus of the uterus;
10. open the plastic clamp of the saline bag to fill the probe cover;
11. make sure to be into the uterus (the connector is no longer visible from the outside; check whether the device stops the bleeding, and it is not inflating into the vaginal canal instead; to prevent this from happening, push the probe cover toward the inside of the uterus with your hand while it is inflating;
12. check whether the bleeding has stopped; close the clamp of the saline bag only when the bleeding has stopped.

The three training modalities were designed to provide the same information about the correct use procedure of BAMBI. Further details of each modality are given below. The training was always conducted in Italian, as all the test participants were native Italian speakers.

- *Live training*

The live training session was conducted by the same experimenter for all the tests. The training was one-to-one, i.e., it was repeated identically for each participant. It consisted of a live explanation and practical demonstration of the entire procedure by the experimenter. The participant was allowed to ask questions about unclear steps of the procedure (e.g., "Could you show me this step again, please?"), but he/she was unable to perform practical tests.

- *Video training*

The participant was allowed to watch the video as many times as he/she wanted until he/she was ready for the test. The participant was not allowed to ask the experimenter any questions about the use of the device.

- *Paper IFU*

The English translated version of the paper IFU used as training modality for non-medical participants is reported in the Supplementary Material B. No time limit was set, so the participant was free to read the instructions as many times as he/she wanted, until he/she was ready for the test. The participant was not allowed to ask the experimenter any questions about the use of the device.

No standard procedure for the CBT solution is available, so medical users were left free to secure the probe cover to the rectal probe using sutures according to their medical experience. Steps 1, 3-4 and 7-12 (Figure A.1) are the same as the BAMBI procedure. Step 2 is absent. An example of how to connect the two parts is shown in Figure A.2. However, users can choose how many rounds and knots perform.

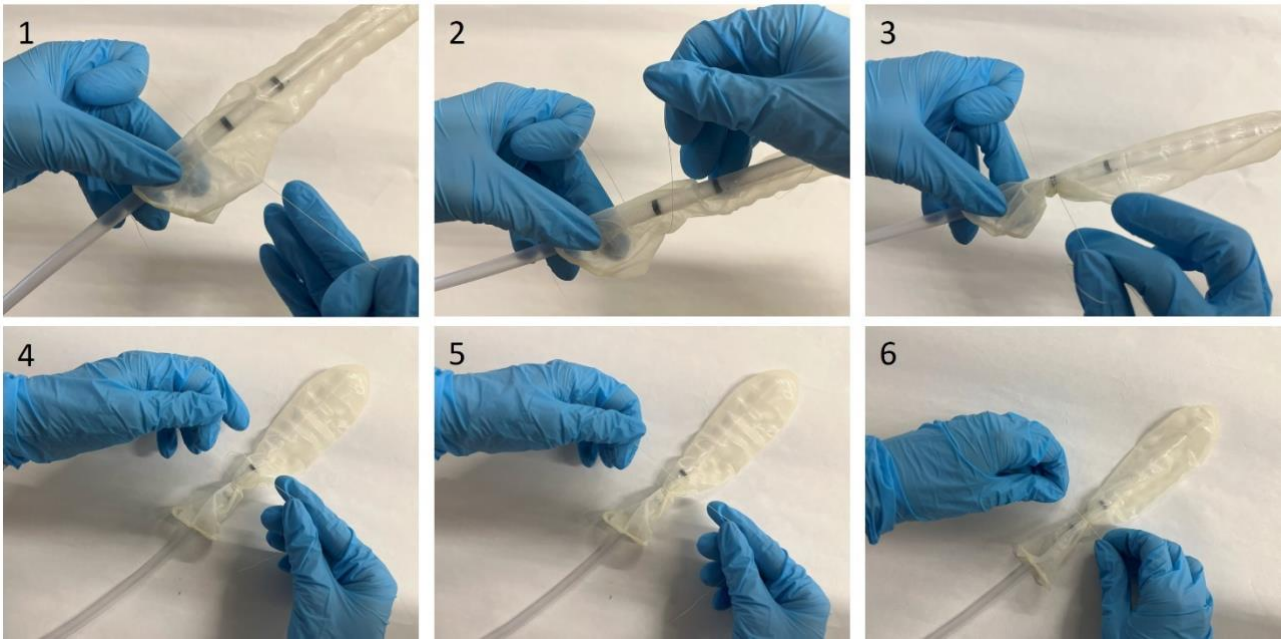
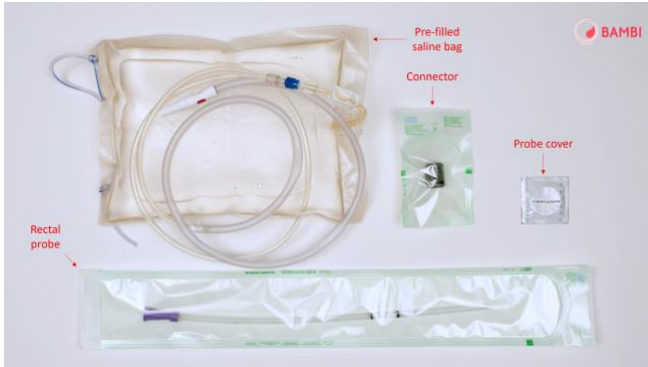


Figure A.2. Example of how to perform sutures knots in the CBT improvised solution.

B. Paper IFU

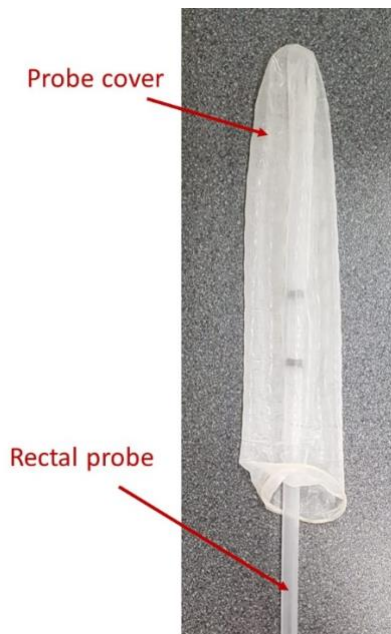
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Instruction for use – BAMBI kit
Kit components



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Step 1: Open and remove the probe cover from its wrapper (follow the perforated line, if any, to facilitate the opening). Insert the probe cover over the rectal probe and slide it to its entire length, making sure that the ends of the two components match.



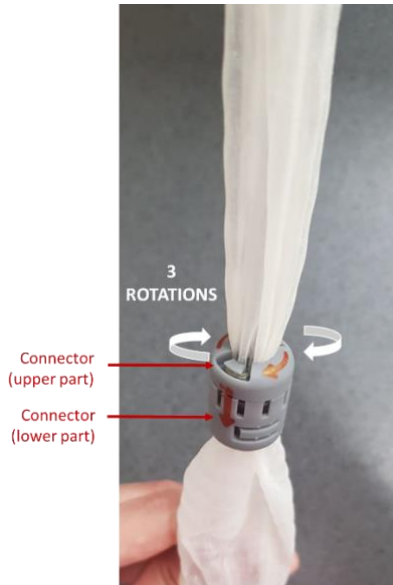
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Step 2: Insert the connector (Figure A) and slide it down following the direction of the arrow, positioning it approximately 10 cm from the tip of the probe cover. Position the connector between the two black lines on the rectal probe. The connector is positioned as shown in Figure B.



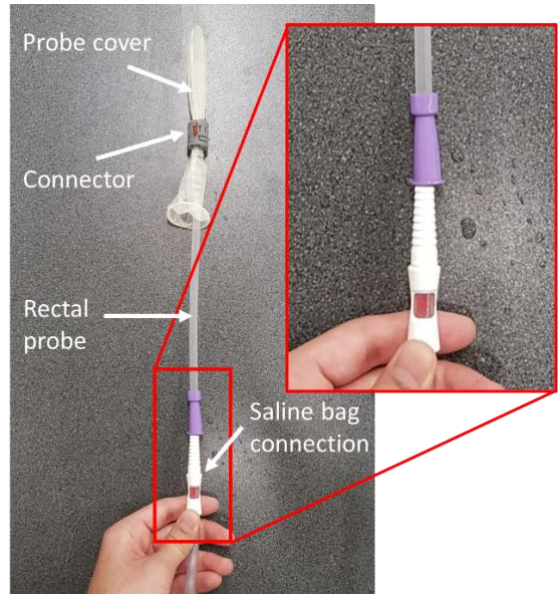
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Step 3: Perform 3 (three) complete 360° clockwise rotations of the upper part of the connector while keeping the lower part fixed to secure the probe cover to the rectal probe. Use the red lines at the arrow as a reference to see if the 360° rotation has been completed.



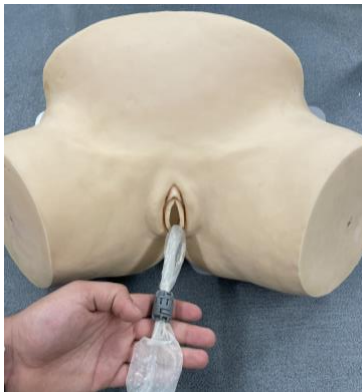
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Step 4: Connect the rectal probe to the pre-filled saline bag.

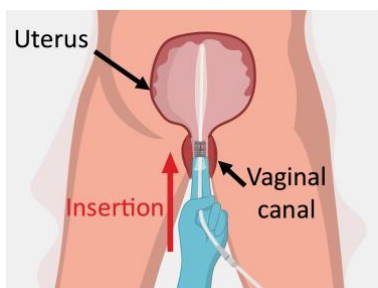


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Step 5: Insert the device into the patient's uterus as shown in Figure.

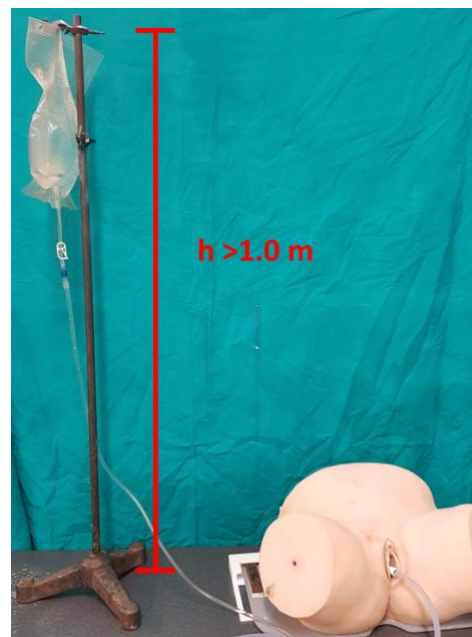


Step 6: Continue to insert the device into the uterus until the connector is no longer visible from the outside.



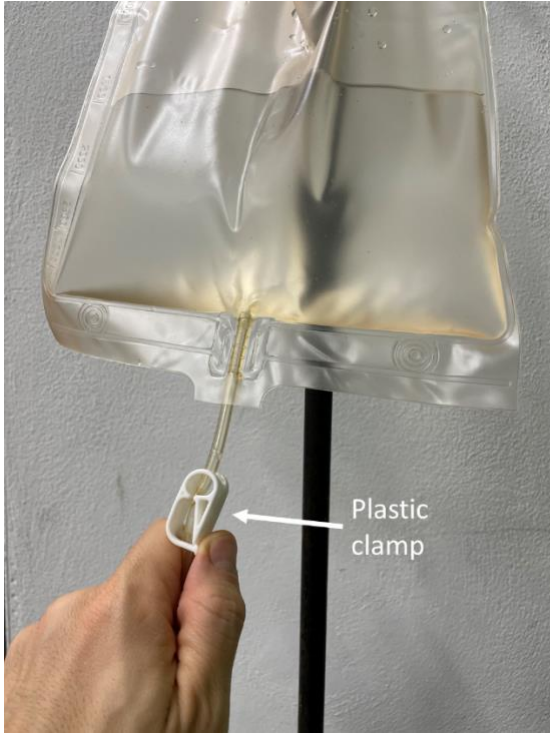
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Step 7: Hang the bag at least one meter above the patient using the stand.



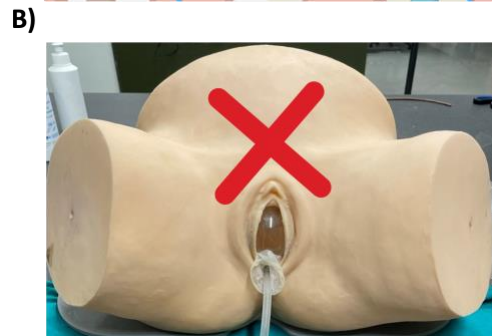
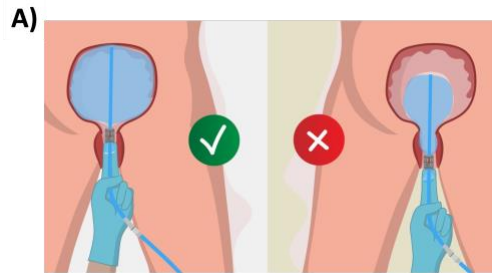
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Step 8: Open the plastic clamp of the saline bag to fill the probe cover.



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Step 9: Check whether the device stops the bleeding inside the uterus (as shown in Figure A, left), and it is not inflating into the vaginal canal instead (as shown in Figure A right and B). To prevent this from happening, push the probe cover toward the inside of the uterus with your hand while it is inflating. Close the clamp of the saline bag only when the bleeding has stopped.



C. Additional tables

Table C.1. Descriptive statistics of the three continuous variables (SUS score, assembly and manoeuvre time), divided for the different analyses. Mean (M) and standard deviation (SD) were used for normal distributions, while the median (Q2) and the interquartile range (IQR) were used for non-gaussian data.

| | | #1 Medical users (BAMBI and CBT) analysis | | | | #3 Medical and non-medical users (BAMBI, live) analysis | | | | #5 Medical (CBT) and non-medical users (BAMBI, live) | | | | | |
|---|---|---|-------------|-------|--------|---|-------|-------|-------|--|-------|-------|-------|-------|-------|
| | | M | SD | Q2 | IQR | M | SD | Q2 | IQR | M | SD | Q2 | IQR | | |
| #1 Medical users (BAMBI and CBT) analysis | SUS-score | BAMBI | 93.92 | 4.78 | | | | 94.44 | 8.33 | | | 58.33 | 33.33 | | |
| | | CBT | 62.15 | 24.23 | | | | 94.44 | 13.89 | | | 94.44 | 13.89 | | |
| | Assembly time | BAMBI | | | 40.00 | 10.00 | | | 40.00 | 10.00 | | | | | |
| | | CBT | | | 60.00 | 22.50 | | | 70.00 | 25.00 | | | | | |
| | Manoeuvre time | BAMBI | 74.06 | 8.61 | | | | | 74.06 | 8.61 | | | | | |
| | | CBT | 85.00 | 24.43 | | | | | 98.00 | 12.07 | | | | | |
| #2 Non-medical users (BAMBI) analysis | SUS-score | live | | | 94.44 | 13.89 | | | 94.44 | 8.33 | | | 58.33 | 33.33 | |
| | | paper | | | 83.33 | 11.11 | | | 88.89 | 13.89 | | | 88.89 | 13.89 | |
| | | video | | | 91.67 | 8.33 | | | 40.00 | 10.00 | | | 60.00 | 12.87 | |
| | Assembly time | live | 64.00 | 15.14 | | | | | 80.00 | 20.00 | | | 79.89 | 19.42 | |
| | | paper | 86.43 | 12.77 | | | | | 74.06 | 8.61 | | | 87.06 | 25.13 | |
| | | video | 83.00 | 16.34 | | | | | 99.19 | 12.77 | | | 99.19 | 12.77 | |
| | Manoeuvre time | live | | | 100.00 | 15.00 | | | | | | | | | |
| | | paper | | | 90.00 | 15.00 | | | | | | | | | |
| | | video | | | 110.00 | 10.00 | | | | | | | | | |
| | #4 Medical and non-medical users (BAMBI) analysis | SUS-score | medical | | | 94.44 | 8.33 | | | 94.44 | 8.33 | | | 58.33 | 33.33 |
| | | | non-medical | | | 88.89 | 13.89 | | | 88.89 | 13.89 | | | 88.89 | 13.89 |
| | | Assembly time | medical | | | 40.00 | 10.00 | | | 40.00 | 10.00 | | | 60.00 | 12.87 |
| non-medical | | | | | 80.00 | 20.00 | | | 80.00 | 20.00 | | | 79.89 | 19.42 | |
| Manoeuvre time | | medical | 74.06 | 8.61 | | | | | 74.06 | 8.61 | | | 87.06 | 25.13 | |
| | | non-medical | 99.19 | 12.77 | | | | | 99.19 | 12.77 | | | 99.19 | 12.77 | |
| #6 Medical (CBT) and non-medical users (BAMBI) analysis | SUS-score | medical CBT | | | 58.33 | 33.33 | | | 58.33 | 33.33 | | | 58.33 | 33.33 | |
| | | non-medical BAMBI | | | 88.89 | 13.89 | | | 88.89 | 13.89 | | | 88.89 | 13.89 | |
| | Assembly time | medical CBT | 60.00 | 12.87 | | | | | 60.00 | 12.87 | | | 60.00 | 12.87 | |
| | | non-medical BAMBI | 79.89 | 19.42 | | | | | 79.89 | 19.42 | | | 79.89 | 19.42 | |
| | Manoeuvre time | medical CBT | 87.06 | 25.13 | | | | | 87.06 | 25.13 | | | 87.06 | 25.13 | |
| | | non-medical BAMBI | 99.19 | 12.77 | | | | | 99.19 | 12.77 | | | 99.19 | 12.77 | |

Table C.2. Contingency tables of the three dichotomous variables (procedure correctness, tamponade effectiveness, and uterine positioning), divided for the different analyses. The p-value of the χ^2 test for proportions is also reported.

| | Procedure correctness | | | | χ^2 test p | |
|---|-----------------------|-------------------------|-----|-------|-----------------|-----------------|
| | Yes | No | All | | | |
| #1 Medical users (BAMBI and CBT) analysis | BAMBI | 17 | 0 | 17 | 0.001 | |
| | CBT | 7 | 10 | 17 | | |
| | All | 24 | 10 | 34 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | BAMBI | 17 | 0 | 17 | 0.001 | |
| | CBT | 7 | 10 | 17 | | |
| | All | 24 | 10 | 34 | | |
| | | Uterine positioning | | | | χ^2 test p |
| | Yes | No | All | | | |
| BAMBI | 16 | 1 | 17 | 0.001 | | |
| CBT | 6 | 11 | 17 | | | |
| All | 22 | 12 | 34 | | | |
| #2 Non-medical users (BAMBI) analysis | | Procedure correctness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | live | 15 | 0 | 15 | 0.343 | |
| | paper IFU | 13 | 2 | 15 | | |
| | video | 14 | 1 | 15 | | |
| | All | 42 | 3 | 45 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | live | 15 | 0 | 15 | 0.343 | |
| | paper IFU | 13 | 2 | 15 | | |
| video | 14 | 1 | 15 | | | |
| All | 42 | 3 | 45 | | | |
| | Uterine positioning | | | | χ^2 test p | |
| Yes | No | All | | | | |
| live | 9 | 6 | 15 | 0.910 | | |
| paper IFU | 9 | 6 | 15 | | | |
| video | 10 | 5 | 15 | | | |
| All | 28 | 17 | 45 | | | |
| #3 Medical and non-medical users (BAMBI, live) analysis | | Procedure correctness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 17 | 0 | 17 | 1.000 | |
| | non-medical | 15 | 0 | 15 | | |
| | All | 32 | 0 | 32 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 17 | 0 | 17 | 1.000 | |
| | non-medical | 15 | 0 | 15 | | |
| | All | 32 | 0 | 32 | | |
| | Uterine positioning | | | | χ^2 test p | |
| Yes | No | All | | | | |
| medical | 16 | 1 | 17 | 0.016 | | |
| non-medical | 9 | 6 | 15 | | | |
| All | 25 | 7 | 32 | | | |
| #4 Medical and non-medical users (BAMBI) analysis | | Procedure correctness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 17 | 0 | 17 | 0.555 | |
| | non-medical | 42 | 3 | 45 | | |
| | All | 59 | 3 | 62 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 17 | 0 | 17 | 0.555 | |
| | non-medical | 42 | 3 | 45 | | |
| | All | 59 | 3 | 62 | | |
| | Uterine positioning | | | | χ^2 test p | |
| Yes | No | All | | | | |
| medical | 16 | 1 | 17 | 0.006 | | |
| non-medical | 28 | 17 | 45 | | | |
| All | 44 | 18 | 62 | | | |
| #5 Medical (CBT) and non-medical users (BAMBI, live) analysis | | Procedure correctness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 7 | 10 | 17 | 0.001 | |
| | non-medical | 15 | 0 | 15 | | |
| | All | 22 | 10 | 32 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 7 | 10 | 17 | 0.001 | |
| | non-medical | 15 | 0 | 15 | | |
| | All | 22 | 10 | 32 | | |
| | Uterine positioning | | | | χ^2 test p | |
| Yes | No | All | | | | |
| medical | 6 | 11 | 17 | 0.160 | | |
| non-medical | 5 | 10 | 15 | | | |
| All | 11 | 21 | 32 | | | |
| #6 Medical (CBT) and non-medical users (BAMBI) analysis | | Procedure correctness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 7 | 10 | 17 | 0.001 | |
| | non-medical | 42 | 3 | 45 | | |
| | All | 49 | 13 | 62 | | |
| | | Tamponade effectiveness | | | | χ^2 test p |
| | Yes | No | All | | | |
| | medical | 7 | 10 | 17 | 0.001 | |
| | non-medical | 42 | 3 | 45 | | |
| | All | 40 | 13 | 62 | | |
| | Uterine positioning | | | | χ^2 test p | |
| Yes | No | All | | | | |
| medical | 6 | 11 | 17 | 0.057 | | |
| non-medical | 28 | 17 | 45 | | | |
| All | 34 | 28 | 62 | | | |