



Health technology assessment for uterine balloon tamponade devices in atonic post-partum hemorrhage management



POLICY BRIEF

Health Technology Assessment in India (HTAIn)
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SUMMARY

Free treatment is offered for pregnancy and related complications in public health facilities of India. Post partum hemorrhage (PPH) is the worldwide leading cause of preventable maternal mortality. Uterine Balloon Tamponade (UBT) is recommended for refractory atonic PPH management.

This policy brief addresses the policy question of determining the most cost-effective UBT device for atonic PPH management in India. The question was received by Department of Health Research, HTAIn.

Health technology assessment was undertaken using primary economic cost data across public healthcare levels, literature review and decision analytic model to compare the currently recommended Condom-UBT device with relatively low-cost Every Second Matters (ESM-UBT) and globally used Bakri balloon alternatives.

For atonic PPH management in India, It was found that Condom-UBT offered better value as compared to Bakri balloon. Though ESM-UBT presented as a more cost-effective alternative, evidence of clinical effectiveness available for the device was limited. Hence, decision making between ESM-UBT and Condom-UBT needs further evaluation.

RECOMMENDATIONS

- ESM-UBT is more cost-effective as compared to Condom-UBT, however incremental QALYs gained with ESM-UBT is minimal and results are associated with a decision making error probability of 0.44 across sensitivity analysis.
- Clinical effectiveness of individual UBT devices are sensitive parameters to cost-effectiveness results. Given the decision making uncertainty and limited availability of clinical effectiveness evidence for ESM-UBT device, cost-effective result for ESM-UBT must be viewed with due caution.
- Bakri balloon as compared to Condom-UBT is associated with higher costs and unfavorable health outcomes across analysis. Hence, Condom-UBT remains more cost-effective as compared to Bakri-UBT for atonic PPH management in India.
- To reduce decision making uncertainty around the choice of UBT device, comparative clinical effectiveness evidence generation for UBT devices in Indian context may be considered.

CONTEXT

PPH is defined as maternal blood loss of 500 ml or more within 24 hours after delivery. PPH affects nearly 3-6 percent off all women giving birth. India accounts for one-fifth of all global maternal deaths and PPH is the leading cause. Failure of uterus to contract i.e. uterine atony is the commonest type of PPH.

Management with UBT is recommended after failure of uterotonics in controlling PPH bleeding. UBT intervention is potentially life-saving, acts as a surgery avoiding step and can be used even in low-resource settings or while awaiting transfer of the patient to a higher center.

Multiple UBT devices, modified or specifically designed for PPH management are available. India currently recommends modified Condom-UBT for atonic PPH management in its public health facilities. With availability of low-cost alternatives such as ESM-UBT or the globally used Bakri balloon device, India is assessing cost-effectiveness of UBT devices to determine the most cost-effective UBT intervention for atonic PPH management in Indian public health settings.

POLICY OPTIONS

UBT	Cost	Clinical effectiveness#	Advantages
Condom-UBT	INR 128 Assembly components commercially available	92.3%	Inexpensive, Assembled using available resources, Modified versions are used to assess blood loss post insertion
ESM-UBT	INR 397 Commercially not available at present	95.3%**	Relatively inexpensive, Specifically designed for PPH use, All components needed for assembly available in a sterile pack, US-FDA approved device
Bakri Balloon UBT	INR 9,554 Commercially available at present	84.3%	Ready to use, Specifically designed for PPH use, Comes in a sterile pack, Has drainage outlet to measure ongoing blood loss, US-FDA approved device

Determined from literature review of 33 studies

** Evidence limited to 3 case-series studies

RESEARCH OVERVIEW

Health Technology Assessment was undertaken using the HATIn reference case to answer the given policy question. A decision tree model was built to estimate expected costs and consequences of using ESM-UBT or Bakri-UBT device as compared to standard care i.e. using condom-UBT intervention.

A hypothetical cohort of women accessing public health facilities after experiencing atonic PPH were run through the decision model. For input parameters, following steps were undertaken:

- Published literature was collated to assess clinical effectiveness of all three UBT devices. An extensive literature review including a systematic review for ESM-UBT was undertaken to assess clinical effectiveness of UBT devices.
- Primary health system costing was undertaken in four public healthcare facilities of Maharashtra, India representing three healthcare levels using facility level, HMIS and literature based event probabilities.
- Cost-effectiveness analysis was evaluated in terms of incremental cost-utility ratio (QALYs as recommended by reference case and DALYs), Net benefits, maternal deaths and surgeries averted with the intervention.

RESULTS

An estimated 59,962 women out of total 2,07,85,669 births in India in the year 2017-18 were eligible for UBT device insertion after failure of uterotonics in controlling atonic PPH bleeding.

Table: Decision tree costs and outcomes for three UBT devices (Per patient)

	Condom UBT	ESM UBT	Bakri UBT
Total costs in INR (Health system perspective)	₹ 3,209	₹ 3,135	₹ 13,430
Total costs in INR (Societal perspective)	₹ 6,340	₹ 6,266	₹ 16,563
Total QALYs (Discounted)	24.2017	24.2023	24.2002
Total DALYs (Discounted)	0.2141	0.1843	0.2936

Table: Incremental costs, outcomes and ICUR/ICER (QALY/DALY) for UBT comparisons

	ESM UBT Vs. Condom UBT	Bakri UBT Vs. Condom UBT
Incremental costs (Health system)	-₹ 74	₹ 10,222
Incremental costs (Societal perspective)	-₹ 74	₹ 10,223
Incremental QALYs	0.001	-0.002
Incremental DALYs	-0.030	-0.079
ICUR (QALYs gained)	-1,30,427	-67,60,076
ICER (DALYs averted)	-2,481	-1,28,614

This study was conducted by the regional resource hub for HTA at ICMR – NIRRH, Mumbai

RESULTS

Figure: Incremental cost-utility plane (QALYs gained) for UBT device comparisons

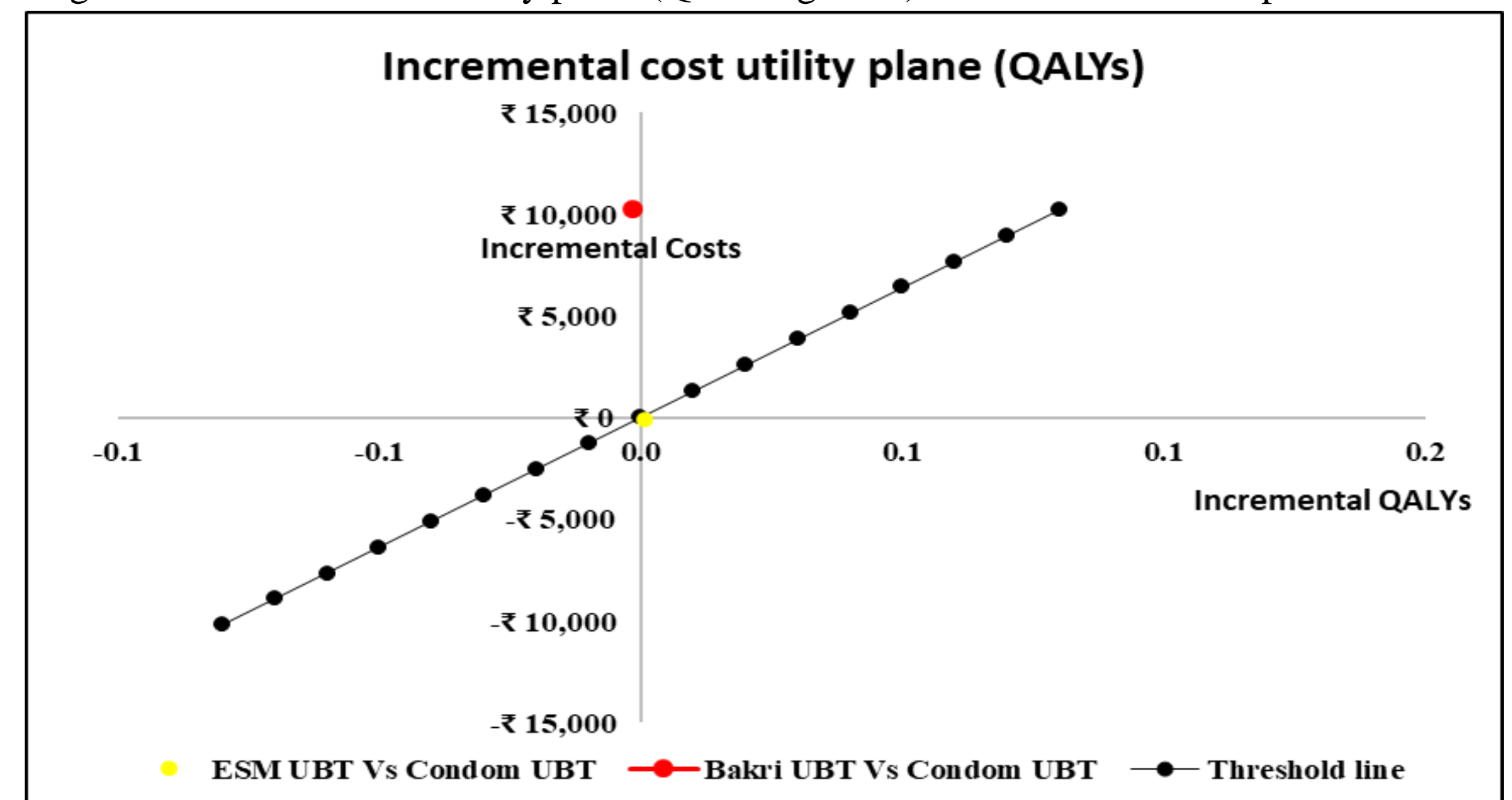
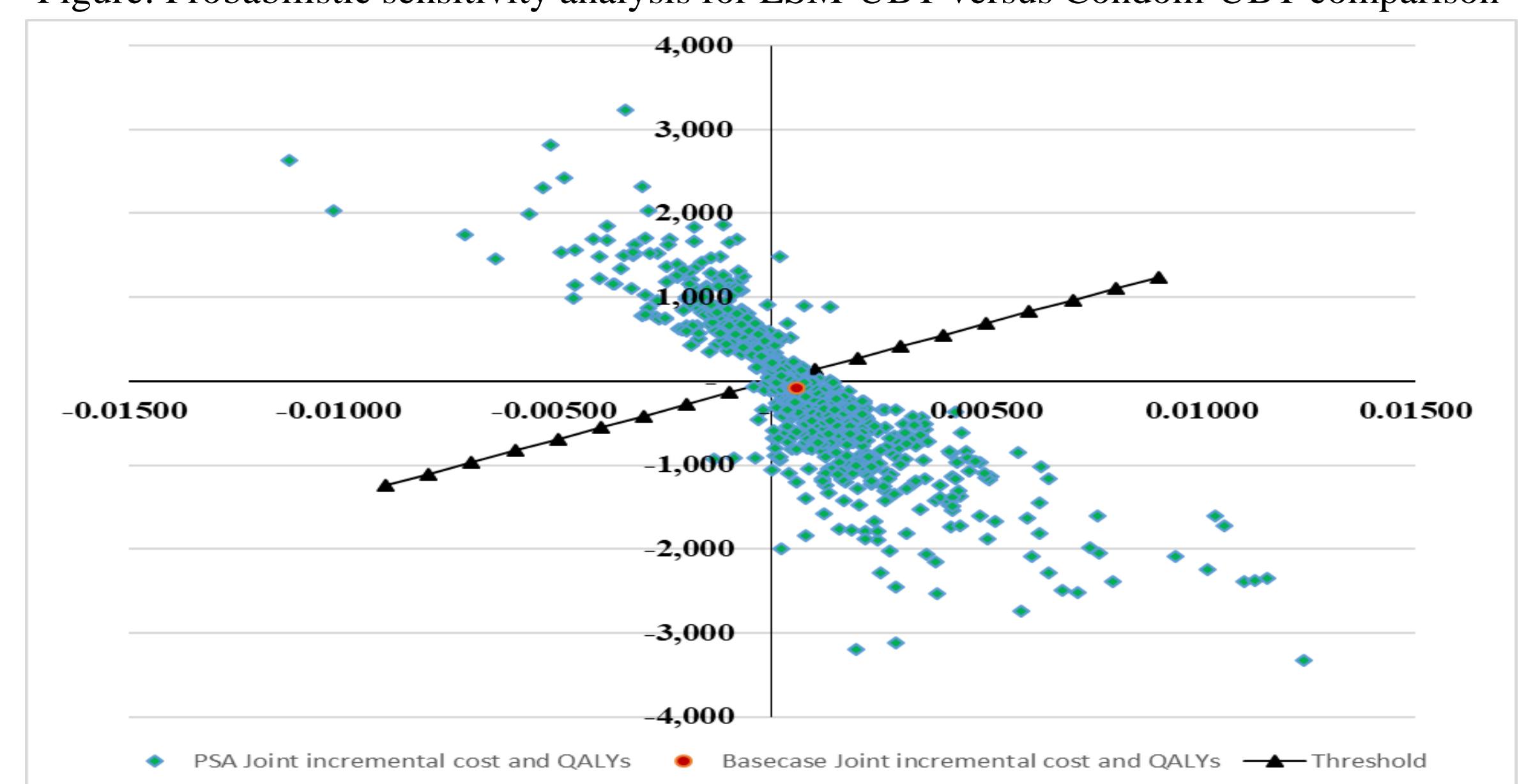


Figure: Probabilistic sensitivity analysis for ESM-UBT versus Condom-UBT comparison



- For ESM-UBT versus Condom-UBT, ICUR (QALY) of -1,30,427 INR/QALY gained indicates a cost-saving of INR 1,30,327 with a gain in 1 QALY if ESM-UBT is used instead of Condom-UBT device.
- For Bakri balloon versus Condom-UBT, ICUR (QALY) of -67,60,076 INR/QALY gained indicates expenditure of INR 67,60,076 INR with a loss in 1 QALY if Bakri balloon is used instead of Condom-UBT device.

Figure: Net benefits, surgeries and maternal deaths associated with UBT devices

	Net Health Benefit (QALYs)	Net Monetary Benefit (INR)	Total number of surgeries	Maternal deaths
Condom UBT	24.15	30,87,041	4,615	214
ESM UBT	24.15	30,87,187	2,817	214
Bakri UBT	24.07	30,76,624	9,411	216

CONCLUSION

ESM-UBT is cost-effective as compared to Condom-UBT, however is associated with decision making uncertainty with current available evidence. Introduction of ESM-UBT in the public health system must be made after due consideration.

Condom-UBT offers better overall value as compared to Bakri-UBT for atonic PPH management in India