



सत्यमेव जयते

Health Technology Assessment in India Department of Health Research, MoHFW



Health Technology Assessment of Uterine Balloon Tamponade for Management of Postpartum Haemorrhage in India

SUMMARY

In the year 2015, there were an estimated 303,000 maternal deaths globally. Nearly 99 % of all maternal deaths occur in developing countries with more than half of them occurring in sub-Saharan Africa and one third occurring in South Asia. One of the top preventable and treatable causes of maternal death is post-partum hemorrhage. Operational Guidelines on Maternal and Newborn Health in India for management of PPH, guidance Note on PPH management and Dakshata Guidelines recommend use of intrauterine balloon tamponade for uterine atony cases or refractory bleeding cases when medical management fails. Various Uterine Balloon Tamponade devices available across the world includes condom uterine balloon tamponade device, ESM UBT, packed UBT devices like Bakri UBT. A decision tree model was used for a hypothetical cohort of women with atonic PPH in India. A primary costing study across five public health centers in Maharashtra centers was performed. The QALYs per woman in condom UBT, ESM UBT and Bakri UBT were 23.767, 23.769 and 23.763 respectively showing a very minute difference in QALYs.

Objective: To evaluate cost-effectiveness of Condom Uterine balloon device (that has been recommended in Govt. of India's guidelines for management of PPH) against ESM-UBT and Bakri uterine balloon tamponade techniques available for management of atonic type of postpartum hemorrhage.

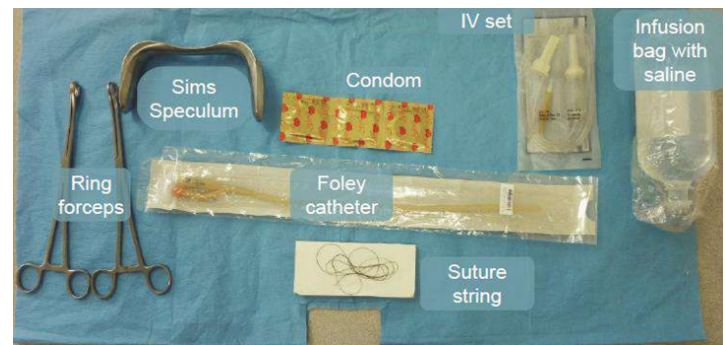
Recommendations:

- Analysing the net health benefits based on QALY, there is less than 0.1 difference between the Condom, Bakri & ESM-UBT alternatives; indicating the similarity in health benefits of the three UBTs. ICUR value of ESM UBT against Condom UBT shows that ESM UBT is only 42.8% cost-effective. Good quality efficacy data on ESM-UBT should be generated by doing RCTs in Indian settings, before any decision regarding the same is undertaken. Considering the above statements, decision-making regarding ESM UBT's introduction into the public health system must be made with caution.
- If ESM-UBT is considered for introduction, it should be noted that to gain the benefits estimated by the model, a universal coverage needs to be attained (100%) which currently seems to be very challenging given the current poor use of condom UBT in spite of being recommended in the Govt. of India Guidelines.

POLICY BRIEF

Need of the Study:

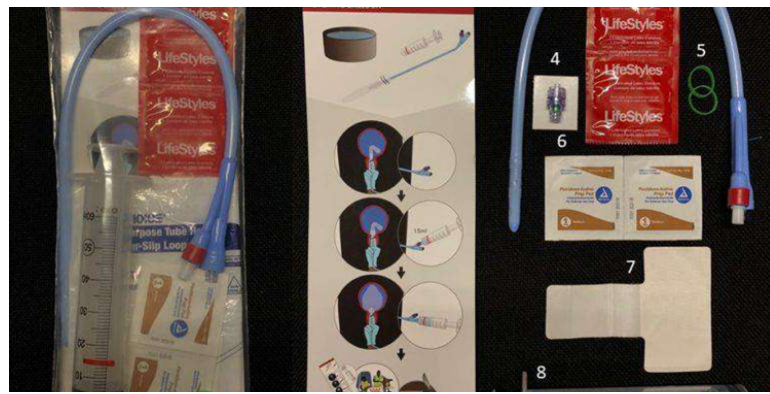
Given the availability of different types of uterine balloon tamponade and effectiveness of UBTs in management of PPH, the Indian government is keen on introducing a cost effective uterine balloon tamponade in the public health system. No studies describe cost effectiveness of uterine balloon tamponade in India.



Condom Uterine balloon tamponade (source: Jhpiego)



Bakri Uterine balloon tamponade (source: Cook Medical Products)



Every second matters Uterine balloon tamponade a) Every Second Matters for Mothers and Babies – Uterine Balloon Tamponade (ESM-UBT) package. b) ESM-UBT package made of 8 components: 1/Instruction card, 2/2-way Foley catheters (retention catheters), 3/Condom, 4/Check valve for injection site, 5/O-Rings, 6/Povidone-iodine prep pads, 7/Catheter Holder, and 8/Syringe.

Findings: Of total 2,07,85,669 births in India in the year 2017-18, by applying incidence of PPH and the effectiveness of medical management, we estimated that 59,862 women will require UBT. In this cohort, our model estimates the total costs, deaths, QALYs, DALYs and surgeries of each of the three decision trees as presented in Table 1.

Table 1: Results of the three decision trees in terms of costs and outcomes per woman

	Condom UBT	ESM UBT	Bakri UBT
Total costs in INR (Health system perspective)	₹ 3,858.54	₹ 3,786.29	₹ 13,635.45
Total costs in INR (Societal perspective)	₹ 13,671.77	₹ 12,096.06	₹ 22,300.75
Total QALYs	23.77	23.77	23.76
Total DALYs	0.22082	0.20291	0.28829

Table 2 shows the incremental costs and outcomes, for the two comparisons i.e. ESM UBT vs. Condom UBT and Bakri UBT vs. Condom Balloon. Primary and secondary outcomes are presented in Table 3

Table 2: Incremental costs and outcomes of the two comparisons in UBT per woman

	ESM UBT Vs. Condom UBT	Bakri UBT Vs. Condom UBT
Incremental costs (Health system)	-₹ 72.25**	₹ 9,776.91
Incremental costs (Societal perspective)	-₹ 1,575.71**	₹ 8,628.98
Incremental QALYs	0.00131	-0.004926
Incremental DALYs	-0.0179	0.0675

** Negative sign implies that the value of first comparator is lesser than the second one

Table 3: ICURs of the two comparisons of UBT (Societal perspective)

	ESM UBT Vs. Condom UBT	Bakri UBT Vs. Condom UBT
ICUR (QALYs)	-12,05,590	-17,51,769.25**
ICUR (DALYs)	88,009.28##	1,27,880.92

** Negative values indicate that either the numerator or denominator is negative
These values are positive because both numerator (Incremental costs) as well as denominator (Incremental outcomes) are negative

Table 4: Maternal deaths averted as compared to current scenario (cause specific MMR)

	Total Deaths as per model	Deaths averted (compared to current scenario**)
Condom UBT	283.00	10038.16
ESM UBT	280.03	10041.13
Bakri UBT	294.19	10026.97

** Current scenario specifies deaths due to current cause specific mortality in India i.e. PPH. The current scenario can have situations with varying use of different UBTs as no such specific information is currently available

References:

1) Maternal mortality [Internet]. [cited 2019 Jul 19]. Available from: <https://www.who.int/news-room/factsheets/detail/maternal-mortality>
 2) Sample Registration Survey. (2018). SPECIAL BULLETIN ON MATERNAL MORTALITY IN INDIA 2014-16. MMR India [Internet]. 2016; Available from: http://www.censusindia.gov.in/vital_statistics/SRS_Bulletins/MMR%20Bulletin-2014-16.pdf
 3) Balloon Tamponade for Atonic Primary Postpartum Hemorrhage - Tabular View - ClinicalTrials.gov [Internet]. [cited 2019 Jul 25]. Available from:<https://clinicaltrials.gov/ct2/show/record/NCT02430155>

Table 5: ICURs (QALYs) and Net Benefit with UBT alternatives

	Societal Costs	QALYs	Net Health Benefit (QALYs)	Net Monetary Benefit (INR)
Condom UBT	₹ 13,671.77	23.767	23.67	₹ 32,77,376.36
ESM UBT	₹ 12,096.06	23.769	23.68	₹ 32,79,133.05
Bakri UBT	₹ 22,300.75	23.763	23.60	₹ 32,68,065.30

Table 6: Annual Deaths and surgeries averted, monetary savings in different coverage scenarios

	ESM UBT Deaths	Condom UBT Deaths	Deaths averted by ESM UBT	ESM UBT surgeries	Condom UBT surgeries	Surgeries averted by ESM UBT	Costs saved due to reduced surgeries
100% Coverage	280	283	3	2808	3919	1111	₹ 85,61,377
50% coverage	656	658	2	31335	31891	556	₹ 42,84,542
20% coverage	882	883	1	48452	48674	222	₹ 17,10,734

Table 4 shows maternal deaths averted due to intervention. ICURs are mentioned in the table 5. Annual deaths and surgeries averted, monetary savings are mentioned in Table 6.

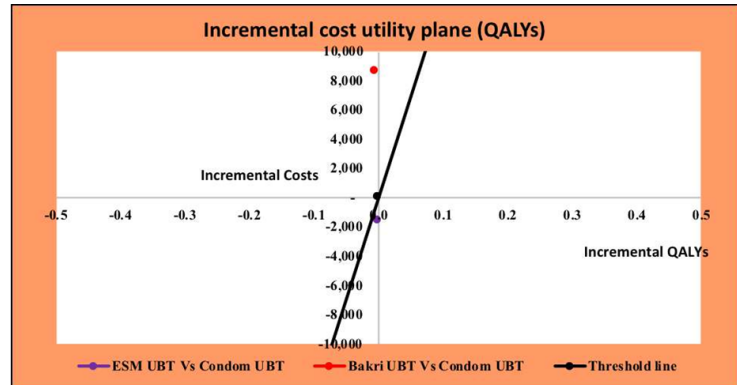


Figure 1: Incremental cost utility plane (QALYs)

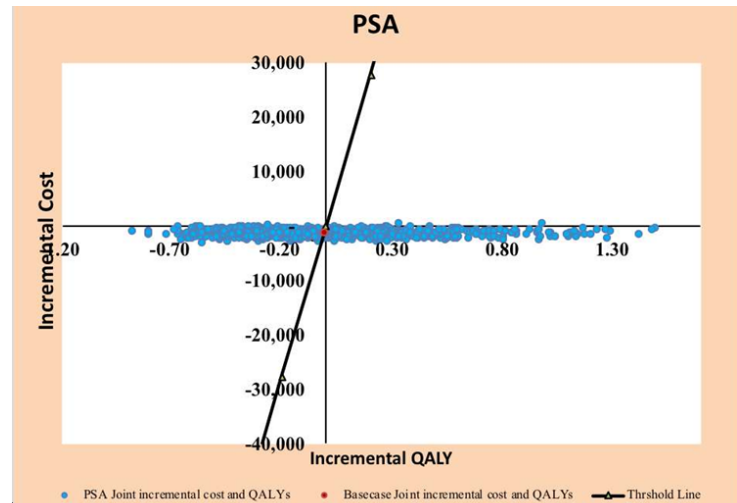


Figure 2: Cost-effectiveness plane showing Probabilistic sensitivity analysis

Budget impact analysis shows that annual additional budget required for introduction of ESM UBT into India's public health system is estimated to be 0.004 % of the total health budget and 0.005% of the total maternal and child health budget.

Conclusion:

Clinical effectiveness data available for ESM-UBT is currently limited to a few case studies. ICUR values suggest ESM-UBT to be cost-effective as compared to condom UBT, but probabilistic sensitivity analysis shows that only a 43% probability that ESM-UBT are cost-effective given the uncertainties. Decision making for introducing ESM-UBT should be made with caution.

Acknowledgement:

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