Health Technology Assessment in India (HTAIn)

Cost-effectiveness of I.V tranexamic acid for treatment of postpartum hemorrhage

ICMR NIRRH
INDIAN COUNCIL OF MEDICAL RESEARCH | NATIONAL INSTITUTE FOR RESEARCH IN REPRODUCTIVE HEALTH

Policy Brief

Health Technology Assessment in India (HTAIn)
National Institute for Research in Reproductive Health - Mumbai

Post-partum haemorrhage

Post-partum haemorrhage (PPH) is one of the complications post delivery accounting for 6-7% of maternal mortality cases in India

Standard of care for management of primary PPH as per Indian guidelines includes supportive care, treatment with uterotonics, conservative interventions like uterine balloon tamponade followed by surgical interventions for refractory cases

About Tranexamic Acid (TXA)

TXA is an anti-fibrinolytic drug. It causes competitive inhibition of plasminogen activation. It reduces bleeding by inhibiting breakdown of fibrinogen and fibrin clots.

Recommendations

Addition of intravenous Tranexamic Acid for primary PPH management within three hours of birth is costeffective and is recommended for use in the Indian public health system with an additional dose if required after 30 minutes or within 24 hours if bleeding restarts

The 'Dakshata' checklist and 'LaQshya' (emergency drug tray) and other Indian guidelines should be updated with this recommendation.

Summary

Intravenous Tranexamic acid (TXA) use in all women with primary PPH is now recommended by the World Health Organization. This HTA answers the policy question of whether the Indian public health system should consider TXA intervention for all PPH management from a cost-effectiveness perspective.

The analysis suggests that from a disaggregated societal perspective, a per patient cost of INR 6,607 with a discounted health gain of 20.25 QALYs is associated with TXA intervention as compared to INR 6,486 incurred with 20.16 QALYs gained with standard care (i.e. without TXA).

At base-case, an ICUR value of INR 1,470 per QALY gained and 94.5% simulations favouring the intervention across sensitivity analysis, TXA addition for PPH management in the Indian context is cost-effective.

Approximately 389 maternal deaths, 177 surgeries, and 128 ICU admission per 1,00,000 PPH cases respectively in India can be averted with TXA intervention.

Budget impact analysis indicates an additional financial allocation of 2.3% for PPH management in case TXA intervention is considered.

Context and gap analysis

India's guidance note on PPH management follows the WHO 2012 guidelines

2012 WHO recommends using TXA only in refractory atonic or traumatic PPH cases within 3 hours of delivery. Based on this, there is no clarity in Indian guidelines over dosage or timing of administration [1]

'Dakshata' checklists and the 'LaQshya' guidelines to improve quality of care have no mention about use of TXA and is not part of the emergency tray [2]

This HTA will help in justifying whether India should adopt the latest WHO recommendation of adding IV TXA to all PPH cases by considering both clinical and cost-effectiveness perspectives.

Policy Brief

Aim and Objectives

This study aimed to address the policy question of whether India should consider adding IV tranexamic acid for all primary PPH case management in the Indian public health system.

Objectives

- **To estimate cost-effectiveness of addition of IV Tranexamic acid to standard care treatment in the Indian public health facilities.**
- **To assess budget impact of introducing tranexamic acid in the Indian public health program**

Methods and Approach

Decision analytic modelling approach was adopted to answer the given policy question

A decision tree model was designed based on Indian guidelines specific to public healthcare levels/facility accessed by women for childbirth

Perspective: **Disaggregated societal (includes health system plus out-of-pocket expenses for patients)**

Population**: Hypothetical cohort of 21 year old women accessing public facilities for PPH management**

Intervention**: IV TXA (100mg/ml/min) addition to standard care within 3 hours of birth**

Comparator**: Uterotonics, supportive care**

Outcome: **Cost per QALY gained, number of maternal deaths, surgeries and ICU admissions associated**

Analysis

Analysis was undertaken using HTAIn reference case manual.[3]

A life-time horizon was considered for analysis to account for associated health outcomes

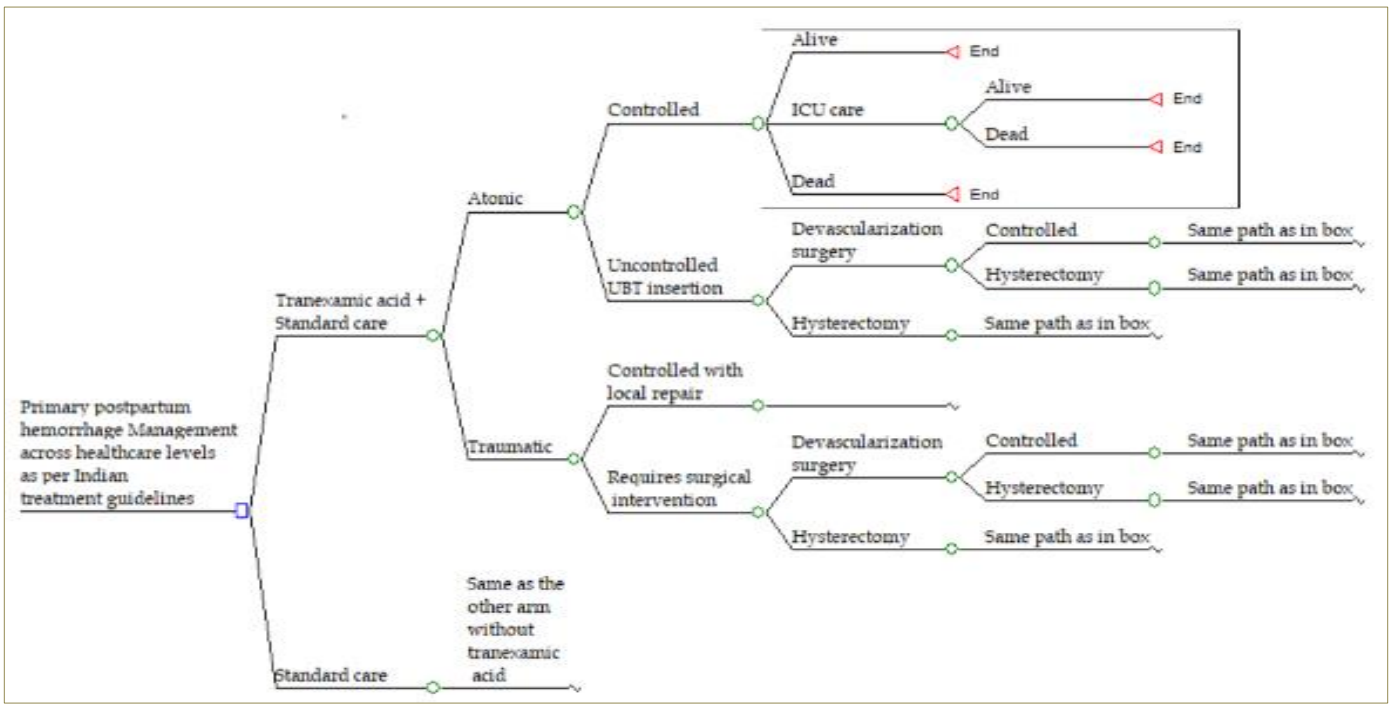
Clinical and epidemiological input parameters were obtained from WOMAN trial study and literature relevant to the Indian context.[4]

Health system cost data was obtained from a primary bottom-up micro-economic costing exercise undertaken across public healthcare levels in India.

Sensitivity analysis was undertaken

Budget impact was analysed for a 5 year period using phased bottom-up uptake of intervention from primary to tertiary care level

Diagrammatic representation of the model



Policy Brief

Results

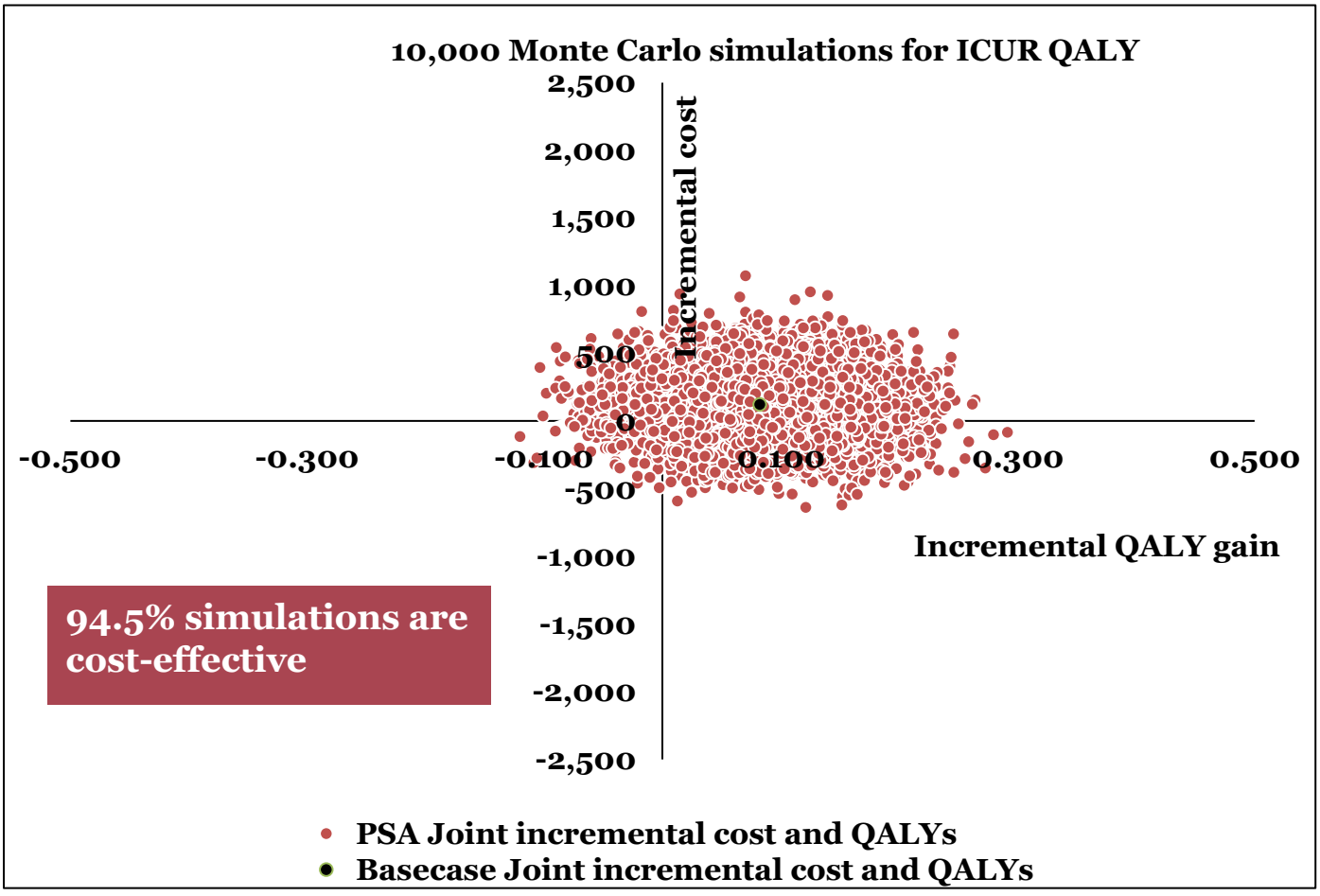
For an estimated annual cohort of 5,10,915 women who experience primary PPH in Indian public health facilities, a disaggregated societal cost of INR 6,607 is incurred per patient for PPH management with an associated gain of 20.25 discounted QALYs. Similarly, management without TXA i.e. current standard of care treatment results in a societal cost of INR 6,486 per patient with a gain of 20.16 QALYs.

Addition of TXA results in a marginally higher cost incurred but is also associated with marginally better health outcomes and thus at an ICUR value of INR 1,470 per QALY gain is cost-effective.

For the above cohort, this intervention is likely to prevent 389 maternal deaths, 177 surgeries, and 128 ICU admissions per 1,00,000 PPH cases. These outcomes as shown in the table below favor addition of TXA to the Indian public health system.

	TXA+SOC	SOC	Increment /Averted with TXA
Health system cost per patient	INR 5,934	INR 5,782	INR 152 (increment)
Societal cost per patient	INR 6,607	INR 6,486	INR 121 (increment)
Total surgeries (for annual cohort)	19,387	20,293	905 (averted)
Total number of ICU admissions	27,181	27,836	655 (averted)
Total number of maternal deaths	13,923	15,913	1990 (averted)

The study findings were robust across sensitivity analysis. Probabilistic sensitivity analysis suggested that 94.5% simulations across 10,000 Monte Carlo simulations favored IV TXA addition as a cost-effective intervention indicating low error probability.



Policy Brief

Budget Impact Analysis

This analysis aimed to assist policy makers in predicting the financial consequence of adoption and diffusion of this intervention at the national level.

Uptake of TXA intervention was considered to be bottom-up in nature with implementation assumed to take place from primary level care in the first year to addition of secondary and tertiary levels in subsequent years respectively.

Budget impact analysis suggested an incremental cumulative increase in financial allocation by 2.3% over a five-year period to that currently allocated for management of primary PPH in Indian public health settings.

Conclusion

Addition of intravenous Tranexamic Acid for primary PPH management within three hours of birth with an additional dose if required after 30 minutes or within 24 hours if bleeding restarts can be considered in the Indian public health settings from a cost-effectiveness perspective

Indian policy guidance, training manuals and facility checklists on PPH management have to be updated to reflect this recommendation if accepted

References

1. *Guidelines- MH :: National Health Mission.* *https://www.nhm.gov.in/index1.php?lang=1&level=3&sublinkid=839&lid=377. Accessed 18 Nov 2019*
2. *DAKSHATA Implementation Package :: National Health Mission.* *https://www.nhm.gov.in/index1.php?lang=1&level=3&sublinkid=838&lid=449. Accessed 18 Nov 2019*
3. *HTA in India Manual. https://htain.icmr.org.in/index.php/documents/*
4. *Shakur H et al., (2017) Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage : an international, a double-blind, placebo-controlled RCTl. The Lancet 389:2105–2116*