

OUTCOME REPORT

Cost analysis of instant non-invasive and portable intracranial bleed detector in ambulance and different level of healthcare services

Health Technology
Assessment in India (HTAI)



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Dr Kuldeep Singh

Principal Investigator

Table of contents	Page number
List of tables	5
List of figures	6
List of abbreviations	7
Executive summary	8
Background	9-12
Gap analysis	13
Aim	13
Objectives	13
PICO	13
Methodology	14
Study design	14
Input parameters	14-17
Estimation of cost	18-22
Modelling	22-29
Budget Impact Analysis	29-30
Discussion	31
Assumptions	32
Limitations	33
Conclusion	34
Recommendations	34-35
References	36-37

List of tables

Table no.	Title	Page no.
Table 1	Clinical effectiveness of portable intracranial bleed detector	12
Table 2	Input parameters used in analysis	15
Table 3	Sensitivity and specificity for intra-cranial bleed detector used in analysis	16
Table 4	Cost parameters used in the analysis	19
Table 5	Unit cost of head CT at tertiary hospital	20
Table 6	Unit cost of intra-cranial bleed detector in ambulance	21
Table 7	Unit cost of intra-cranial bleed detector at CHC	21
Table 8	Unit cost of intra-cranial bleed detector at tertiary care	22
Table 9	Estimation of incremental cost of NIR at ambulance level	25
Table 10	Estimation of incremental cost of NIR at CHC level	26
Table 11	Estimation of incremental cost of NIR at tertiary level	28
Table 12	Estimation of incremental cost of NIR at different level of healthcare settings	28
Table 13	Budget impact analysis at Ambulance and CHC level	30

List of figures

Figure no.	Title	Page no.
Figure 1	Examination of the left frontal lobe using intra-cranial bleed detector	10
Figure 2	Measurement locations for scan using NIR technology for TBI patients	11
Figure 3	Estimated Sensitivity of intra-cranial bleed detector in India pooling included studies	17
Figure 4	Estimated Specificity of intra-cranial bleed detector in India pooling included studies	17
Figure 5	Decision tree model for TBI diagnosis	23
Figure 6	Decision tree model for TBI diagnosis at ambulance level	24
Figure 7	Decision tree model for TBI diagnosis at CHC level	26
Figure 8	Decision tree model for TBI diagnosis at Tertiary level	27

List of abbreviations

Abbreviations	Full form
BIA	Budget Impact Analysis
CEA Registry	Cost-Effectiveness Analysis Registry
CHC	Community Health Centre
CI	Confidence Interval
CT	Computed Tomography
EDH	Epi Dural Hematoma
EMBASE	Excerpta Medica dataBASE
GCS	Glasgow Coma Scale
ICH	Intra Cranial Haemorrhage
ICU	Intensive Care Unit
IVH	Intra Ventricular Haemorrhage
LMICs	Low- and Middle-Income Countries
MeSH	Medical Subject Headings
NIRS	Near-InfraRed Spectroscopy
NHS	National Health Service
NPV	Negative predictive value
PICOT	Population Intervention Comparator Outcome Time
PPV	Positive Predictive Value
RCT	Randomized Controlled Trial
TBI	Traumatic Brain Injury
TICH	Traumatic Intra Cranial Haemorrhage
SAH	Sub Arachnoid Haemorrhage
SDH	Sub Dural Hematoma
SR	Systematic Review

Executive summary

One of the rapidly escalating public health problems worldwide is attributed to traumatic brain injury (TBI) due to road traffic accidents. TBI is defined as “traumatically induced structural injury or physiological disruption of brain function as a result of an external force” by the United States Department of Defence. To identify intracranial haemorrhage (ICH), a head Computed Tomography (CT) scan is the preferred examination. However, the concerns for CT scans are limited access, increased radiation exposure, and an inappropriate burden on healthcare resources. Field triage can assist in identifying whether a patient has an intracranial hematoma and, if so, screen them for a CT scan referral. Accurate, user-friendly, and quick-to-use portable ICH detection technology can reduce the number of pointless CT scans while also signalling the urgent need for one in TBI patients. At the point of care, portable near-infrared spectroscopy (NIRS) instruments have been developed to diagnose TICH.

A Decision Tree model was utilized to assess the cost of an intra-cranial bleed detector, focusing on the cost per case detected across distinct healthcare settings: Ambulance, Community Health Center (CHC) and Tertiary Health Center. A Health system perspective was employed.

The unit cost of the intra-cranial bleed detector varied depending on the healthcare setting, with the lowest cost observed at tertiary centres, followed by CHCs and ambulances. The financial evaluation of integrating Near-Infrared (NIR) technology for intracranial bleed detection reveals distinct cost implications across different levels of the healthcare system. At the ambulance level, the incremental cost per patient is Rs 984.15, leading to a substantial annual budget impact of Rs 4,41,68,76,149.28 for equipping all ambulances in India. At the Community Health Centre level, while the incremental cost per patient is lower at Rs 360.90, the total annual budget impact amounts to Rs 1,87,77,37,556.97. This reflects the larger number of CHCs, making the overall financial requirement considerable but more distributed compared to the ambulance level. At the tertiary health care level, the incremental cost per patient is the lowest at Rs 289.78, indicating a more feasible integration within the existing infrastructure of tertiary care centres. These findings highlight the varying financial burdens and efficiencies of adopting NIR technology across different healthcare settings. Decision-makers must weigh these costs against the potential benefits of improved diagnostic capabilities, considering both the immediate financial impact and the long-term advantages of early and accurate TBI detection. Strategic planning and resource allocation are crucial to optimizing the deployment of NIR technology, ensuring it enhances patient care while managing costs effectively.

Background

One of the rapidly escalating public health problems worldwide is attributed to traumatic brain injury (TBI) due to road traffic accidents. TBI is defined as “traumatically induced structural injury or physiological disruption of brain function as a result of an external force” by the United States Department of Defence.¹ TBI is classified as a form of acquired brain injury that can be diagnosed within the first 24 hours of the injury or at the time of the accident. The Glasgow Coma Scale is a clinical indicator of acute brain damage (GCS). When TBI patients enter the emergency room, it is utilised as a diagnostic tool to evaluate their cognitive abilities.²

TBI has the highest incidence of all common neurological disorders and is a major public health concern. TBI is now recognised as both an acute and chronic disorder with long-term implications, including a higher risk of late-onset neuro-degeneration.³ According to the 2019 Global Burden study, about 90% of the 4 million injuries-related deaths worldwide happened in LMICs, and autopsy results indicate that a significant number of these deaths are attributable to TBI.⁴ An epidemiological shift from communicable, maternal, neonatal, and nutritional diseases to non-communicable diseases and injuries is linked to growing industrialization and changing demographics in LMICs. Over the next several years, it is anticipated that the burden of injuries in LMICs will increase. Because of the poor quality of quantitative research, the overall burden of TBI in India is unknown. Yet, some of them indicate that over a million trauma-related deaths occur there annually, with 50% of those deaths being connected to TBI. Although they make up less than 10% of cases, severe TBI cases are thought to incur annual global costs of \$400 billion.⁵ The survival and recovery rates are directly correlated with the time between the injury and the onset of treatment. Secondary brain injury may result from treatment delays.

Diagnosis of traumatic brain injury:

For patients with TBI to receive early treatment, a prompt and precise diagnosis of traumatic intracranial haemorrhage (TICH) is essential. To identify intracranial haemorrhage (ICH), a head Computed Tomography (CT) scan is the preferred examination. However, the concerns for CT scans are limited access, increased radiation exposure, and an inappropriate burden on healthcare resources.⁶ Thus, emergency medical services or the trauma department must swiftly triage trauma patients for additional testing and care. Field triage can assist in identifying whether a patient has an intracranial hematoma and, if so, screen them for a CT scan referral. Accurate, user-friendly, and quick-to-use portable ICH detection technology can reduce the number of pointless CT scans while also signalling the urgent need for one in TBI patients. At

the point of care, portable near-infrared spectroscopy (NIRS) instruments have been developed to diagnose TICH. The accuracy of these instruments has varied according to the TICH's type, volume, and depth.⁷

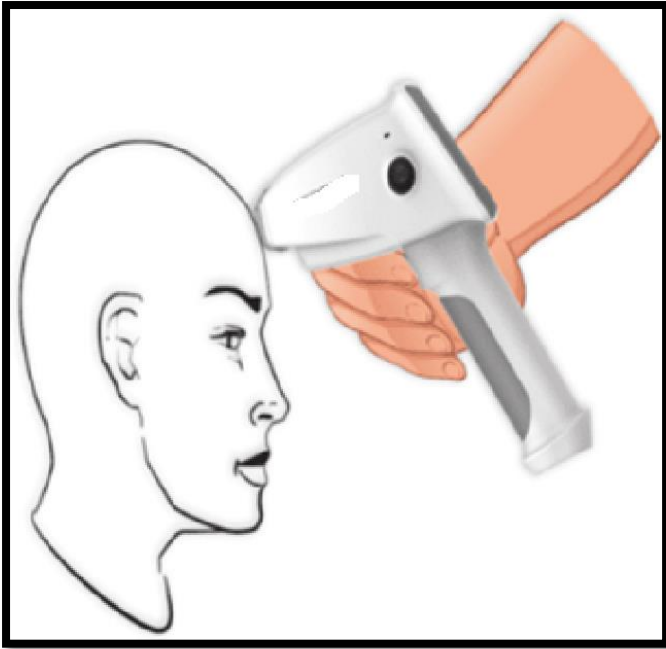


Figure 1: Examination of the left frontal lobe. The device is kept perpendicular to the lobe and then the button is triggered to initiate the scan

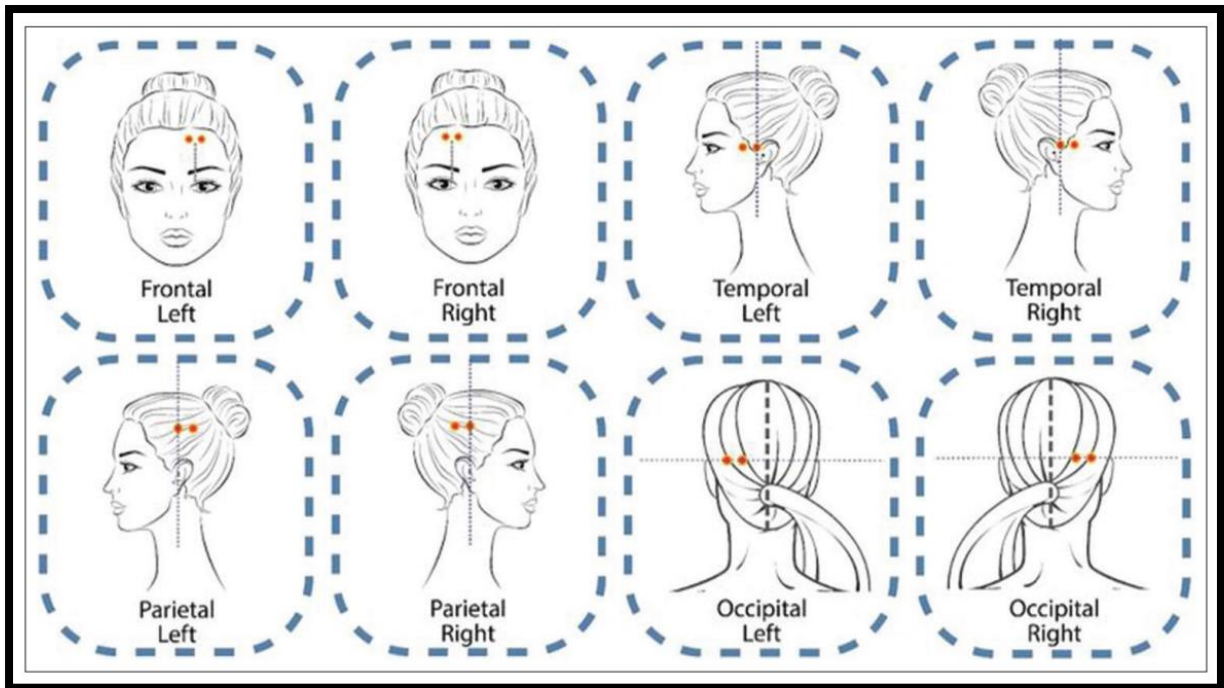
Working principle of near-infrared intracranial bleed detector- Instant, Non-invasive and portable device:

Adaptive machine learning offers an analytical benefit above straightforward ratio-metric analysis. This cutting-edge optical system driven by machine learning operates in the Near Infrared (NIR) part of the electromagnetic spectrum. NIR light can non-invasively identify an extravascular bleed since it can pass through the skull, brain, and scalp. The objective method of detecting intracranial bleeding involves placing NIRS probes on the scalp's surface and measuring the absorption. NIR light is emitted from one end of the probe, and as it interacts with different substances, including haemoglobin, it experiences scattering and absorption processes. The concentration of haemoglobin rises when hematomas are present. Therefore, in the absence of a hematoma, the extravascular blood absorbs more NIR light than the brain tissue.⁸

The fundamental idea behind using NIRS to detect hematomas is that tissue absorbs most of the near-infrared spectrum, and extravascular blood absorbs more of this wavelength than normal brain tissue because haemoglobin is more concentrated in hematomas. The NIRS's high

effectiveness is due to its non-invasive capacity to examine and penetrate the scalp, skull, and brain to a certain depth.⁷

Figure 2: Measurement locations for scan using NIR technology for TBI patients



With the use of machine learning and near-infrared technology, it is a tool that assesses TBI patients objectively and can detect intracranial bleeding in both pre-symptomatic and delayed haemorrhagic patients.

It is extremely safe for both pregnant women and infants to use repeatedly and simple for paramedic workers to use and understand. It is transportable and can be used for monitoring at the event site or by the patient's bed. It is clinically reliable and highly accurate in identifying an intracranial bleed.⁹

Table 1: Clinical effectiveness of Portable Intracranial Bleed Detector

Research article	Sample size	Population	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Brogan et al 2017 ¹⁰ (SR and meta-analysis)	8 studies included (N= 920)	extradural parietal haemorrhage, acute and chronic SDH, EDH, SAH, hematoma, contusion	78	90	77	90
Viderman et al 2021 ¹¹ (SR)	19 studies included (N= 2291)	-	90	77	10.8-100	35.7-100
Esmaili et al 2022 ¹² (Iran)	300	EDH, SDH, ICH, SAH, IVH	94.8	86.9	92.9	90.3
Shah et al 2023 ¹³ (India)	234	ICH, edema	95.7	97	-	-
Malik et al 2023 ⁸ (India)	521	Epidural, Subdural, Subarachnoid, Contusions/intracerebral heamorrhages	94.4	93.1	65.7	99.1
Shah et al 2023 ¹⁴ (India)	44	Epidural, Subdural, Subarachnoid, intracerebral heamorrhages	94.87	76.19	93.67	80
Shukla et al 2023 ⁷ (India)	158	Epidural, Subdural, Subarachnoid, intracerebral heamorrhages	96	85	91	93
Francis et al 2005 ¹⁵	71	EDH, ICH	77.8	100	100	93
Robertson et al 2010 ¹⁶ (USA/India)	319	Epidural hematoma, subdural hematoma, intracerebral hematoma, contusion, Subarachnoid hemorrhages	88	90.7	63.7	97.6
Trehan et al 2018 ¹⁷	100	ICH	58.5	42.9	65.5	35.7

Gap Analysis:

This medical device is designed to detect intracranial bleeds instantly, non-invasively, and portably. Unlike traditional methods involving invasive procedures or time-consuming imaging scans, this technology offers a swift and efficient solution for healthcare professionals in hospital settings, particularly for therapeutic cases where prompt detection is crucial. The device is designed to be user-friendly, with intuitive interfaces and simple operation, making it accessible to a wide range of medical personnel. Its implementation can improve patient outcomes and streamline treatment for conditions requiring urgent medical attention. While the initial investment in acquiring this device, it may represent a financial outlay, its potential to improve patient outcomes and streamline healthcare delivery can result in long-term cost savings for healthcare systems and payers. A cost analysis needs to be conducted to compare the use of infra-red technology with the current standard of care treatment process. This analysis can assess factors such as the direct costs associated with the device, the savings from reduced treatment delays and complications.

Aim:

To assess the cost of instant non-invasive and portable intracranial bleed detector (NIR) per case detected for mild/moderate TBI patients.

Objectives:

- Cost estimation of instant non-invasive and portable intracranial bleed detector (NIR) in terms of per case detection for mild/moderate TBI patients.
- To assess the Budget Impact Analysis to introduce portable intracranial bleed detector (NIR) at CHC and Ambulance care.

PICO:

Population: Patients with mild to moderate head injury at emergency ambulance services, CHC level or Tertiary level

Intervention: Instant non-invasive and portable intracranial bleed detector (NIR) along with current standard of (in-hospital) care for patients with mild to moderate head injury

Comparator: Current standard of (in-hospital) care for mild to moderate head injury without using instant non-invasive and portable intracranial bleed detector (NIR)

Outcomes to be measured:

- Cost per case detected with using instant non-invasive and portable intracranial bleed detector (NIR) from health system perspective at different levels of healthcare

Methodology:

The Methodology of the study involves the following steps:

- I. Study setting and design
- II. Search for input parameters
- III. Estimation of costs
- IV. Modelling

I. Study Setting and design

Cost analysis of instant non-invasive and portable intracranial bleed detector in an ambulance and different level of healthcare services based on secondary data was done in the Indian context. Furthermore, relevant articles were also collected for a review to find the clinical effectiveness of the diagnosis method.

Perspective

A Health system perspective was employed.

II. Search for input model parameters

Parameters pertaining to the study were derived from published literature through systematic searches/targeted reviews as and where required. A literature review was done on various online search engines like PUBMED, EMBASE, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, NHS Economic Evaluation Database for systematic reviews, Meta-analysis, randomized clinical trials (RCTs), observational studies and CEA registry for economic evaluations using the MESH specific terms. The search strategy was developed using appropriate Boolean terms, MEDLINE via PubMed strategy and adapted as per the specific norms of each separate electronic database. The following input parameters were searched:

Table 2: Input parameters used in analysis

Input parameters	Probabilities	Source (reference)
Prevalence of TBI in India	0.92%	Adusumilli et al 2023, GBD data ¹⁸
Percentage of mild/moderate TBI patients in total TBI patients	51.42(mild)+26.28 (moderate) =77.7%	Singh et al 2018 ¹⁹
Prevalence of mild/moderate TBI patients in 1 lakh population	715	Calculated (920*77.7%)
No. of ambulances in India	17,000	Niti Ayog report 2021 ²⁰
Daily emergency call of ambulance in India	50,000	GVK EMRI data from the user department ²¹
Probability of TBI cases in ambulance	25%	GVK EMRI data from the user department ²¹
TBI patients seeking services at ambulance (per year)	264	Calculated (22 per month)
Number of CHCs in India	6,064	Rural health statistics 2021-22 ²²
Population catered by CHC	1,20,000	Rural health statistics 2021-22 ²²
Prevalence of mild/moderate TBI at CHC level	858	Calculated from CHC population= (715/1,00,000) *1,20,000
Population catered by tertiary hospital	13,48,138	Calculated by dividing population of a district by number of tertiary hospitals
Prevalence of mild/moderate TBI in tertiary care hospital	9,640	Calculated (715/1,00,000*13,48,138)
Probability of suspected TBI patients showing positive results in CT scan	24.60%	Maharjan et al 2017 ²³

The analysis of the sensitivity and specificity of the intra-cranial bleed detector was conducted by aggregating data from studies sourced from Indian literature. Specifically, three studies were selected for this evaluation, and the data was combined using Meta-XL software. The results of the pooled analysis revealed that the intra-cranial bleed detector demonstrated a high sensitivity of 95% with a confidence interval (CI) ranging from 93% to 96%. (Figure 3) This indicates that the detector is highly effective at correctly identifying patients with intra-cranial bleeding. Additionally, the pooled specificity of the detector was found to be 91%, with a confidence interval ranging from 80% to 99%. (Figure 4) (Table 3) Overall, these results

highlight the reliability of the intra-cranial bleed detector in clinical settings, particularly within the context of the studies analysed.

Table 3: Sensitivity and specificity for intra-cranial bleed detector used in the analysis

Input parameters	Base-case value	Lower limit	Upper limit	Source (reference)
Pooled sensitivity of intra cranial bleed detector	95.00%	93.00%	96.00%	Shah et al ¹⁴ , Malik et al ⁸ , Shukla et al ⁷ . (Calculated by using meta-XL)
Pooled specificity of intra cranial bleed detector	91%	80.00%	99.00%	Shah et al ¹⁴ , Malik et al ⁸ , Shukla et al ⁷ . (Calculated by using meta-XL)
True positive as per gold standard	0.246	0.246	0.246	Calculated
True negative as per gold standard	0.754	0.754	0.754	Calculated
Using NIR true positive	0.2337	0.22878	0.23616	Calculated
Using NIR true negative	0.68614	0.6032	0.74646	Calculated
Using NIR false negative	0.0123	0.00984	0.01722	Calculated
Using NIR false positive	0.06786	0.00754	0.1508	Calculated
Total NIR positive	0.30156	0.23632	0.38696	Calculated
Total NIR negative	0.69844	0.61304	0.89726	Calculated
CT positive patients of NIR positive	0.2337	0.22878	0.23616	Calculated
CT negative patients of NIR positive	0.06786	0.00754	0.1508	Calculated
CT positive patients of NIR negative	0.0123	0.00984	0.1508	Calculated
CT negative patients of NIR negative	0.68614	0.6032	0.74646	Calculated

Figure 3: Estimated sensitivity of intra-cranial bleed detector in India pooling included studies

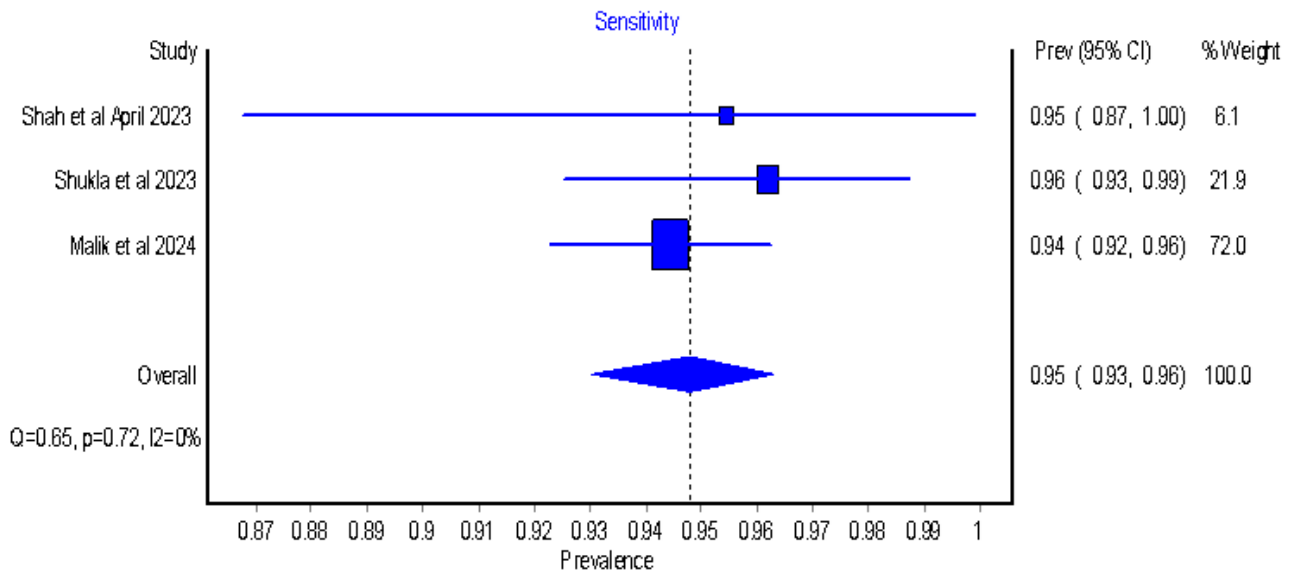
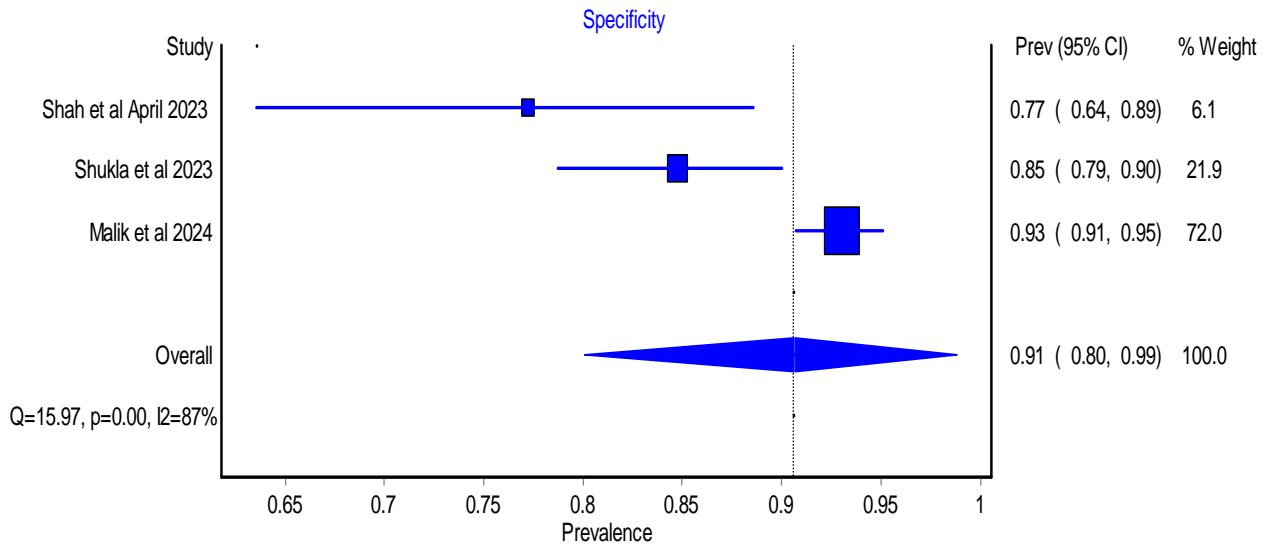


Figure 4: Estimated specificity of intra-cranial bleed detector in India pooling included studies



III. Estimation of cost

Cost of instant non-invasive and portable intracranial bleed detector at different levels of healthcare-

1. Pre-Hospital Care (Ambulances):

In ambulances, this device could serve as a valuable pre-symptomatic screening tool for patients suspected of TBI. By enabling early detection of intracranial bleeding, it could potentially streamline triage and inform decisions about urgent care, which may lead to better patient outcomes and optimized use of emergency resources.

2. Community Health Centres (CHCs):

At CHCs, the detector could play a crucial role in swiftly identifying cases of TBI that require transfer to specialized neuro-facilities. This capability would help minimize the time from injury to appropriate neurosurgical intervention, thereby potentially improving patient prognosis by reducing delays in receiving specialized care.

3. Tertiary Centres:

In tertiary care centres, the detector could assist in reducing the time from patient arrival to the initiation of the first head CT scan. By providing preliminary insights into the presence of intracranial bleeding, it would help in managing high patient volumes, prioritizing cases for neuroimaging, and optimizing resource allocation, particularly during peak periods or emergencies. Additionally, it could be used for continuous monitoring of TBI patients post-surgery, potentially reducing the frequency of CT scans needed and thereby decreasing overall imaging costs.

The comprehensive cost evaluation of the intracranial bleed detector included several components:

- ✓ Capital Asset Cost: The initial investment required to acquire the device.
- ✓ Operating Cost: The ongoing expenses associated with the device's use.
- ✓ Consumable Cost: Costs related to any disposable items required for operation.
- ✓ Training Cost: Expenses related to training healthcare personnel to effectively use the device.

- ✓ Maintenance Cost: Costs for routine maintenance and servicing of the device to ensure its optimal performance.

These costs were assessed through a combination of secondary literature and expert opinions, providing a detailed understanding of the financial implications of implementing this technology at various levels of healthcare.

Table 4: Cost parameters used in the analysis

Input parameters	Base case value (INR)	Lower limit (INR)	Upper limit (INR)	Year 2024 cost (after inflation) (INR)	Source (reference)
Unit cost of delivering services at CHC	185	109	349	205.91	Chauhan et al 2022 ²⁴ & CHSI database ²⁵
Unit cost of delivering services at tertiary care hospital	304	223	433	338.36	Chauhan et al 2022 ²⁴ & CHSI database ²⁵
Unit cost of patient in treatment of minor head injury	7,800				Manmohan et al 2006 ²⁶
Unit cost of patient in treatment of moderate head injury	22,172				Manmohan et al 2006 ²⁶
Unit cost of patient for minor/moderate head injury	14,986			39,285.29	(7800+22172)/2 (Calculated using data from Manmohan et al 2006 ²⁶)
Unit cost of head CT at tertiary hospital	2,871			2,871.00	CHSI data ²⁵
Health system cost for referral of a patient to neurosurgery centre/ district hospital	1,001	801	1,201		Beena Nitin Joshi et al 2021 ²⁷ (We assumed lower limit for referral to district hospital and higher limit for referral to neurosurgery centre)
Health system cost for referral of a patient to neurosurgery centre	1,201			1,410.26	Beena Nitin Joshi et al 2021 ²⁷
Health system cost for referral of a patient to district hospital	801			940.57	Beena Nitin Joshi et al 2021 ²⁷
Health system cost of transport via ambulance	561.83	462.81	673.77	1,012.47	Prinja et al 2013 ²⁸
Treatment cost of mild/moderate TBI	3,672			3,811.57	Calculated (Unit cost of CT + Health system cost)

patient when CT is negative				
Inflation rate	5.50 %			https://www.worlddata.info/asia/india/inflation-rates.php ²⁹
Discounting rate	3%			Malaisamy Muniyandi et al 2022 ³⁰

Table 5: Unit cost of head CT at tertiary hospital (CHSI data)²⁵

CT cost breakup	Cost (INR)
HR	403.553
Space/building	198.08
Equipment	1322.07
Non-consumables	2.6
Consumables	896.19
Overheads	1.5
Image processing	47
Total cost	2871

Unit cost of intra-cranial bleed detector for ambulance, CHC and tertiary health centre:

- ✓ Number of mild/moderate TBI patients per year detected in ambulance is calculated as 264 (Table 2).
- ✓ Number of mild/moderate TBI patients per year detected in CHC is calculated as 858. (Table 2)
- ✓ Number of mild/moderate TBI patients per year detected in tertiary health centre is calculated as 9640 (Table 2)

The unit cost for intracranial bleed detector has been thoroughly analysed and detailed. This includes several key cost components: The health system annual cost (taken from Chauhan et al 2022²⁴), the consumables necessary for operating the detector, machine cost for purchasing the detector, annual training to ensure that healthcare professionals receive the necessary training to effectively operate the detector and interpret its results and the maintenance cost were provided by the user department.

- ✓ The unit cost of mild/moderate TBI case detected in an ambulance is **Rs 2,177.90**. (Table 6)

- ✓ The unit cost of mild/moderate TBI case detected in CHC is **Rs 748.09**. (Table 7)
- ✓ The unit cost of mild/moderate TBI case detected in tertiary health centre is **Rs 628.14**. (Table 8)

Table 6: Unit cost of intra-cranial bleed detector in ambulance

Budget head	Quantity	Cost (INR)	Unit cost (INR)	Annual cost (INR)	Reference
Health system cost	1	1,012.47	1,012.47	2,67,292.08	Chauhan et al 2022 ²⁴
Consumables	1	265.30	265.30	70,040.52	From user department
Machine cost	1	13,66,000	13,66,000	1,47,633.79*	From user department
Training cost Yearly	1	40,000	40,000	40,000.00	From user department
Maintenance yearly	1	50,000	50,000	50,000.00	From user department
Total cost	Rs. 5,74,966.39				
Device cost per mild/moderate TBI cases detected in ambulance	Rs. 2,177.90				

* Estimated through annualization

Table 7: Unit cost of intra-cranial bleed detector at CHC

Budget head	Quantity	Cost (INR)	Unit cost (INR)	Annual cost (INR)	Reference
Health system cost	1	205.91	205.91	1,76,670.78	Chauhan et al 2022 ²⁴
Consumables	1	265.219	265.219	2,27,557.90	From user department
Machine cost	1	13,66,000	13,66,000	1,47,633.79*	From user department
Training cost yearly	1	40,000	40,000	40,000.00	From user department
Maintenance yearly	1	50,000	50,000	50,000.00	From user department
Total cost	Rs. 6,41,862.48				
Device cost per mild/moderate TBI case detected in CHC	Rs. 748.09				

* Estimated through annualization

Table 8: Unit cost of intra-cranial bleed detector at tertiary health centre

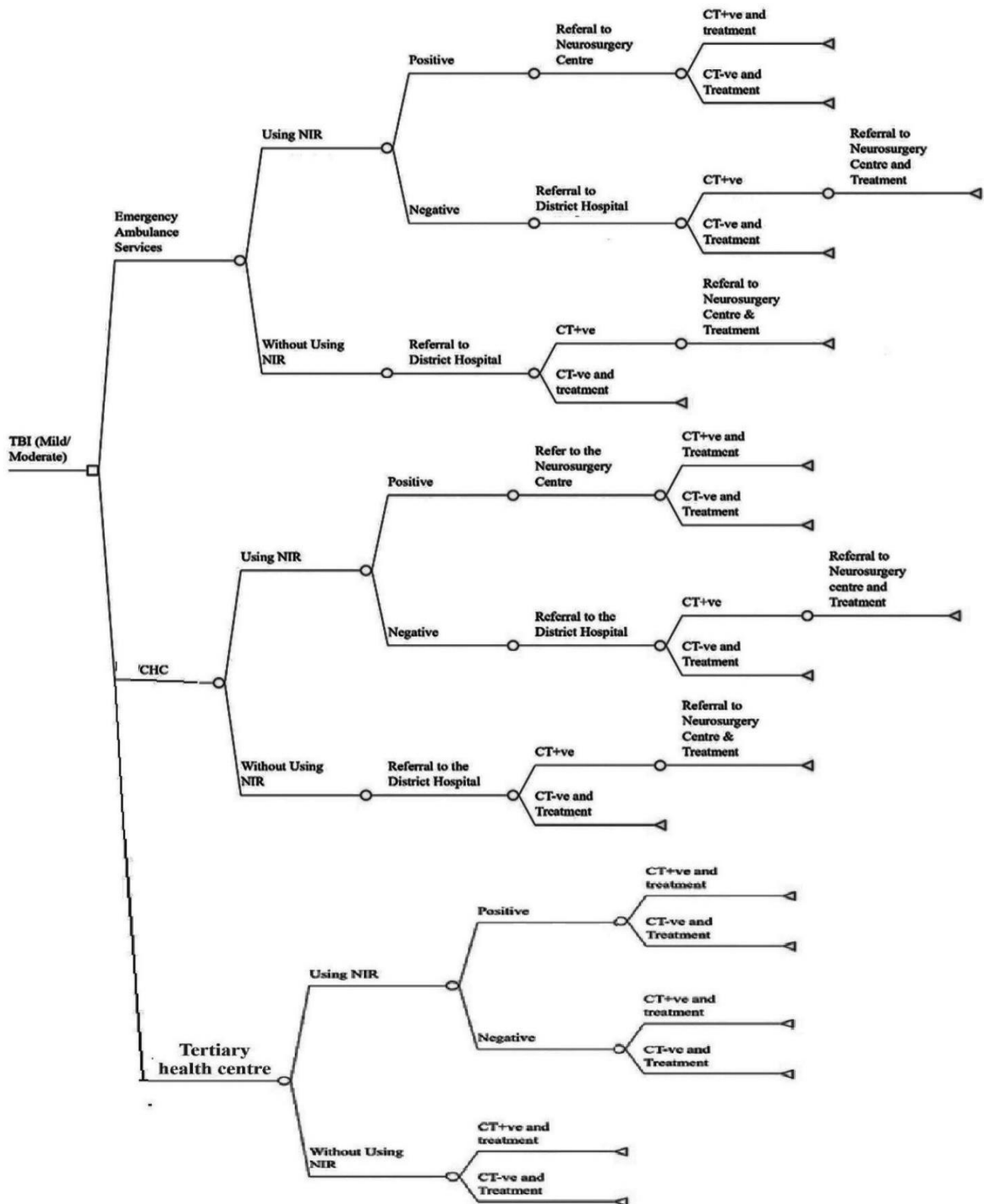
Budget head	Quantity	Cost	Unit cost	Annual cost	Reference
Health system cost	1	338.36	338.36	32,61,790.40	Chauhan et al 2022 ²⁴
Consumables	1	265.133	265.133	25,55,882.12	From user department
Machine cost	1	13,66,000	13,66,000	1,47,633.79*	From user department
Training cost yearly	1	40,000	40,000	40,000.00	From user department
Maintenance yearly	1	50,000	50,000	50,000.00	From user department
Total cost		Rs. 60,55,306.31			
Device cost per mild/ moderate case detected in tertiary centre		Rs. 628.14			

* Estimated through annualization

IV. Modelling

A Decision tree model was used focusing on the incremental cost per case detected across three distinct healthcare settings: Ambulance, CHC and tertiary health centre. (Figure 5) Utilizing pooled data from Indian studies, the detector's performance was evaluated with a sensitivity of 95% and a specificity of 91%. (Table 3) By analysing the incremental cost per case detected, the model helped in assessing the overall value of the detector and its impact on healthcare efficiency and patient care across various levels of the healthcare system.

Figure 5: Decision tree model for mild/moderate TBI patients at different levels of healthcare settings



Ambulance level: In a cost analysis comparing the use of NIR technology versus not using it in ambulances, we began with a cohort of 264 patients (There are 17,000 ambulances in India and daily emergency calls for ambulance are 50,000. Out of which probability of TBI cases is 25%). The evaluation focused on two scenarios: one where NIR technology is employed for diagnosing mild/moderate TBI and another where it is not. (Figure 6) The total cost of implementing NIR technology was calculated at Rs 40,30,827.70, whereas the cost of not using the technology was Rs 37,71,011.46. This resulted in a cost difference of Rs 2,59,816.24 between the two scenarios. To determine the incremental cost per patient for using NIR technology, this difference was divided by the cohort size, yielding an additional cost of **Rs 984.15** per patient. (Table 9)

Figure 6: Decision tree model for mild/moderate TBI diagnosis at ambulance level

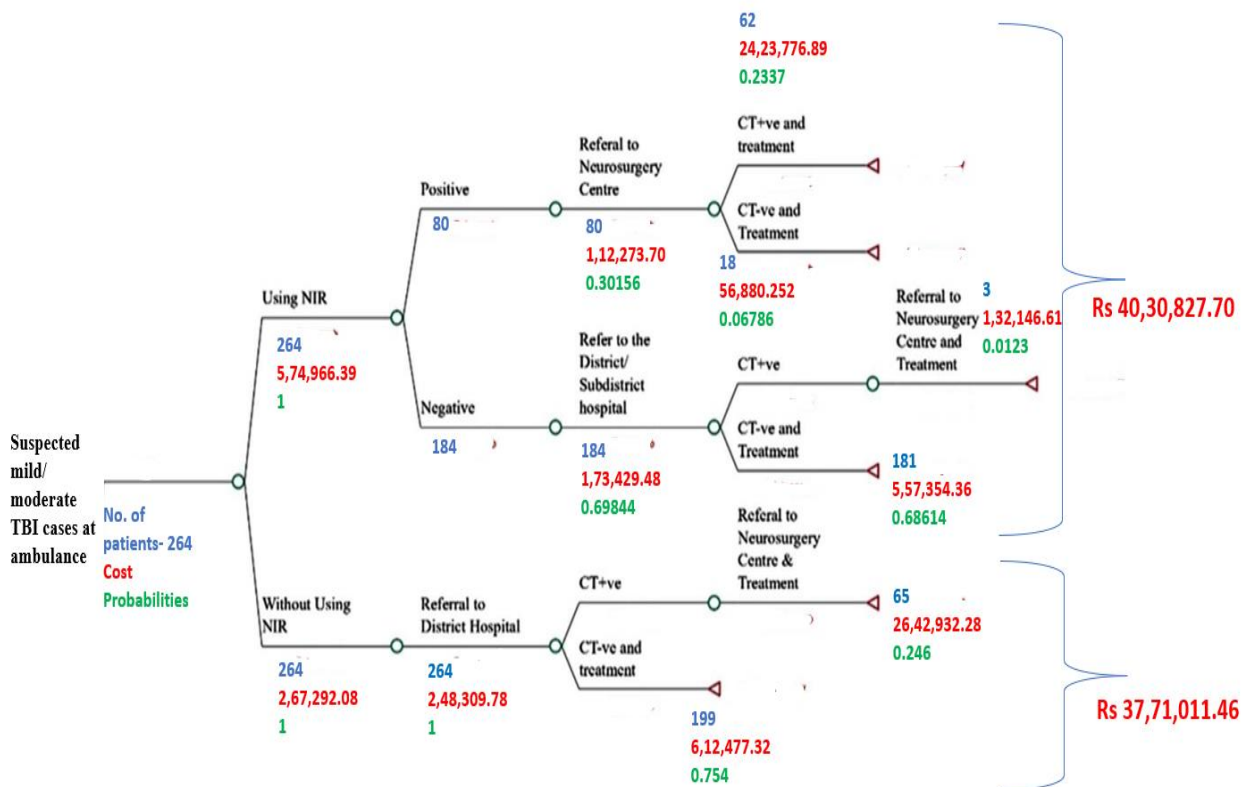


Table 9: Estimation of incremental cost of NIR at ambulance level

Parameters	Cost INR
Total cost of intervention	40,30,827.70
Total cost of comparator	37,71,011.46
No of patients	264
Incremental cost per patient	984.15

CHC level: At the Community Health Centre level, we analysed the financial implications of using Near-Infrared (NIR) technology for diagnosing mild/moderate TBI compared to not using it. We started with a cohort of 858 patients, based on the prevalence of mild to moderate TBI. Specifically, in India, the prevalence of TBI is approximately 0.92%, and 77.7% of these cases are classified as mild or moderate. This means that out of every 1,00,000 individuals, there are about 715 cases of mild or moderate TBI. Given that a CHC serves a population of 1,20,000, the expected number of mild or moderate TBI cases within this population is 858, as calculated by the formula $(715/1,00,000) * 120,000$. (Explained in table 2 with references)

In our evaluation, we compared two scenarios: one where NIR technology is used and one where it is not. (Figure 7) The total cost associated with using NIR technology was Rs 11,873,411.72, while the cost without using NIR technology was Rs 11,563,758.43. This resulted in a cost difference of Rs 3,09,653.29 between the two scenarios. To ascertain the incremental cost per patient for employing NIR technology, we divided this cost difference by the cohort size of 858 patients, yielding an additional cost of Rs 360.90 per patient. (Table 10)

Figure 7: Decision tree model for mild/moderate TBI diagnosis at CHC level

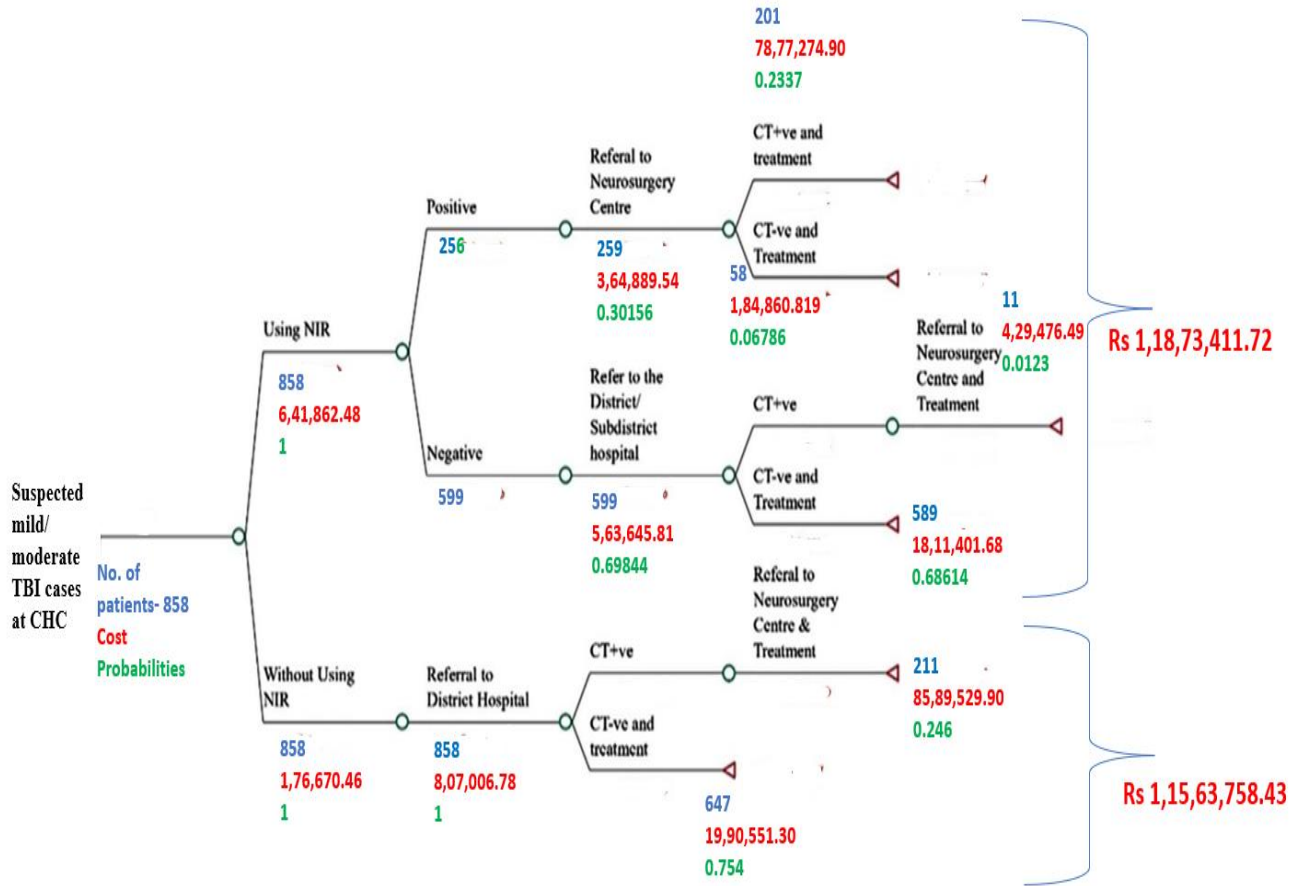


Table 10: Estimation of incremental cost of NIR at CHC level

Parameters	Cost INR
Total cost of intervention	1,18,73,411.72
Total cost of comparator	1,15,63,758.43
No of the patients	858
Incremental cost per patient	Rs 360.90

Tertiary level: At the tertiary center level, we conducted a comparison of using Near-Infrared (NIR) technology for diagnosing TBI versus not using it. The analysis was based on a cohort of 9,640 patients. This cohort size was derived from a detailed prevalence calculation. Specifically, in India, the prevalence of TBI is approximately 0.92%, with 77.7% of these cases being classified as mild or moderate. Based on data from two districts in Rajasthan—Jodhpur

and Jaipur—we estimated the number of mild or moderate TBI cases in a representative population. For Jodhpur, with a population of 16,25,325³¹ and three tertiary centers, the average population served per center is 5,41,775. For Jaipur, with a population of 43,09,000³² and two tertiary centers, the average population served per center is 21,54,500. The average of these two figures is 13,48,137.5. Using the prevalence of mild or moderate TBI (715 cases per 1,00,000), we calculated the expected number of cases in this average population by the formula $(715/1,00,000) * 13,48,138$, resulting in a cohort size of 9,640 patients.

In our evaluation, we compared two scenarios: the use of NIR technology and its absence. (Figure 8) The total cost associated with using NIR technology was Rs 12,25,45,448.36, while the cost of not using the technology was Rs 11,97,51,932.45. This produced a cost difference of Rs 27,93,515.91 between the two scenarios. To determine the incremental cost per patient of using NIR technology, we divided this cost difference by the cohort size of 9,640 patients, resulting in an additional cost of Rs 289.78 per patient. (Table 11) This comprehensive analysis highlights the financial impact of incorporating NIR technology at the tertiary care center level, providing a clear picture of the additional cost incurred per patient when employing this diagnostic tool.

Figure 8: Decision tree model for mild/moderate TBI diagnosis at tertiary level

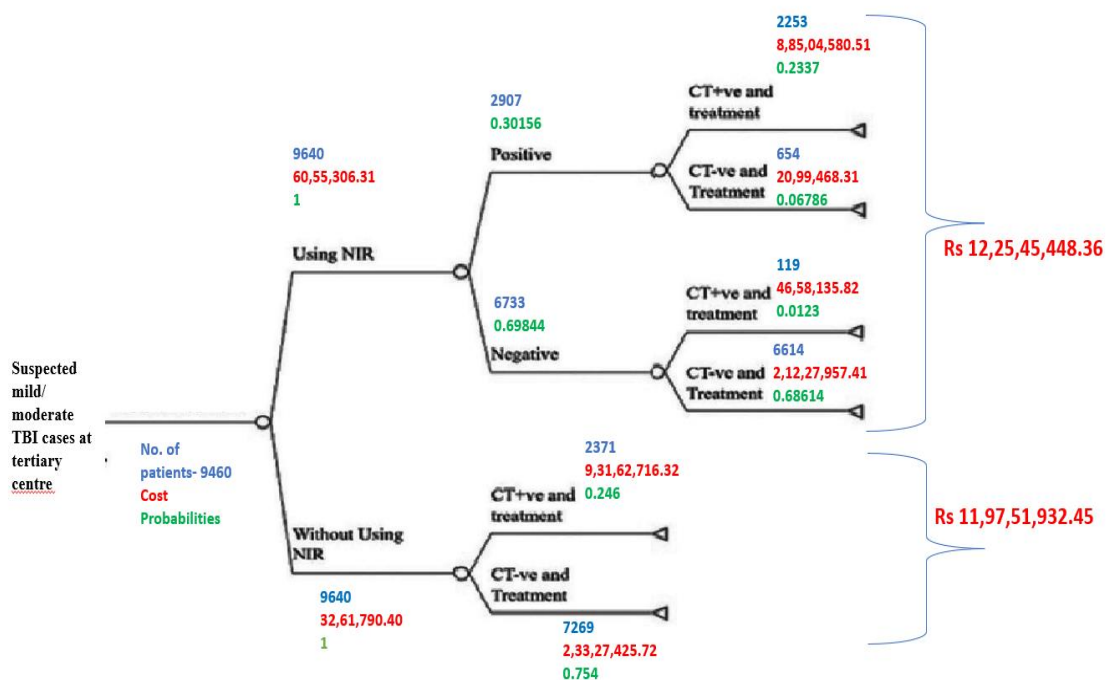


Table 11: Estimation of incremental cost of NIR at tertiary level

Parameters	Cost INR
Total cost of intervention	12,25,45,448.36
Total cost of comparator	11,97,51,932.45
No of patients	9,640
Incremental cost per patient	289.78

Table 12: Estimation of incremental cost of NIR at different levels of healthcare settings

Parameters	Cost INR
Incremental cost per patient at ambulance	984.15
Incremental cost per patient at CHC	360.90
Incremental cost per patient at tertiary health care	289.78

Overall, the decision tree analysis reveals notable differences in the cost of the intra-cranial bleed detector across various healthcare settings. At the ambulance level, the incremental cost per patient is the highest at Rs 984.15. In contrast, at the CHC level, the incremental cost per patient is significantly lower at Rs 360.90. This reduction suggests that implementing NIR technology in CHCs is cheaper. Finally, at the tertiary health care level, the incremental cost per patient is the lowest at Rs 289.78. Tertiary care centres benefit from better infrastructure and economies of scale, allowing them to absorb the costs of advanced technologies more efficiently. The decreasing cost from the ambulance to the tertiary care level indicates improved cost efficiency and resource allocation in higher-level care settings. For decision-makers, this analysis underscores the importance of considering these cost variations when planning the deployment of NIR technology, suggesting a feasible integration in ambulance, CHCs and tertiary centres where the technology's benefits can be maximized at a lower cost per patient.

Budget Impact Analysis

A Budget Impact Analysis (BIA) was conducted for both ambulance and CHCs to estimate the national cost of implementing an intra-cranial bleed detector. Table 13 provides a comprehensive breakdown of the BIA for implementing intra-cranial bleed detectors in ambulances and CHCs with costs expressed in Indian Rupees.

At the ambulance level, the budget impact analysis reveals a significant financial implication of adopting NIR technology for detecting intracranial bleeds. For a population of 264 patients requiring such detection, the cost of standard care is Rs 37,71,011.46. In contrast, the cost of implementing the new NIR device amounts to Rs 40,30,827.70, resulting in an incremental cost of Rs 2,59,816.24. With a total of 17,000 ambulances across India, the annual budget impact for incorporating NIR technology nationwide at the ambulance level is substantial, reaching Rs 4,41,68,76,149.28 in the first year.

At the CHC level, the budget impact analysis shows a different scale of financial implications. For a population of 858 patients needing intracranial bleed detection, the cost of standard care is Rs 1,15,63,758.43. The cost of integrating the new NIR device in CHCs is Rs 1,18,73,411.72, resulting in an incremental cost of Rs 3,09,653.29. With 6,064 CHCs across India, the total annual budget impact for adopting NIR technology at the CHC level amounts to Rs 1,87,77,37,556.97 in the first year.

Overall, the analysis demonstrates that the initial costs of implementing NIR technology are high at both the ambulance and CHC levels. This detailed cost assessment highlights the need for careful consideration of budgetary constraints and financial planning when integrating new diagnostic technologies into different levels of the healthcare system.

Table 13: Budget impact analysis at ambulance and CHC level

Budget impact at ambulance level		
1	Population at ambulance level requiring intracranial bleed detection	264
2	Cost of standard of care for intracranial bleed detection at ambulance level	Rs 37,71,011.46
3	New near-infrared device for intracranial bleed detection at ambulance level	Rs 40,30,827.70
4	Incremental cost of near infrared device for intracranial bleed detection at ambulance level	Rs 2,59,816.24
5	Total Number of ambulances in India	17,000
6	Total Budget Impact Analysis of India at ambulance level (annual cost for India) cost at first year	Rs 4,41,68,76,149.28

Budget impact at CHC level		
1	Population at CHC requiring intracranial bleed detection	858
2	Cost of standard of care for intracranial bleed detection in CHC	Rs 1,15,63,758.43
3	New near-infrared device for intracranial bleed detection in CHC	Rs 1,18,73,411.72
4	Incremental cost of near infrared device for intracranial bleed detection in CHC	Rs 3,09,653.29
5	Total number of CHC's in India	6,064
6	Total Budget Impact Analysis of India at CHC level (annual cost for India) cost at first year	Rs 1,87,77,37,556.97

Discussion

The integration of NIR technology for detecting intracranial bleeding presents significant implications for healthcare systems, especially in addressing traumatic brain injury caused by road traffic accidents. NIR technology offers several advantages over traditional methods, including its non-invasive nature, portability, and ability to also be used in pre-hospital settings. The sensitivity (95%) and specificity (91%) of the NIR device indicate its potential for detection of intracranial haemorrhages, which can improve patient outcomes by facilitating timely intervention and reducing unnecessary CT scans. This is crucial given the high incidence and potentially severe outcomes associated with TBI, particularly in low- and middle-income countries (LMICs) where the burden of such injuries is substantial.³³

The cost analysis reveals that the incremental cost per patient for using NIR technology varies considerably across different healthcare settings. At the ambulance level, the cost is notably higher than at Community Health Centres and tertiary health centres. This higher cost at the ambulance level is primarily due to the additional costs associated with equipping a large number of ambulances nationwide. Trauma patient triaging or classification is mainly carried out in hospital environments. However, there is a growing need for field-deployable systems that can detect intracranial hematomas in prehospital settings, such as ambulances, without requiring expert data interpretation. The potential benefits of NIR technology in ambulances, such as improving triage accuracy and optimizing emergency care, justify the investment, especially in scenarios where timely intervention is critical for patient outcomes.

At the CHC level, the cost per patient represents a more manageable financial burden compared to ambulances, the total annual budget impact remains significant due to the higher number of CHCs. This setting offers a strategic opportunity for integrating NIR technology, as CHCs often act as crucial referral points for more specialized care. The ability to promptly identify patients requiring further neuroimaging could enhance patient management and reduce delays in treatment, potentially leading to better overall outcomes.

The least incremental cost per patient is seen at tertiary health centres. The lower cost per patient at this level can be attributed to the established infrastructure and economies of scale that tertiary centres benefit from. These centres are equipped to handle large patient volumes and can integrate new technologies more efficiently. Moreover, the use of NIR technology in tertiary centres could streamline diagnostic processes, reduce the need for repetitive CT scans, and improve patient throughput during peak times. Testing this device in the intensive care unit

(ICU) could be valuable to determine whether periodic NIRS measurements can effectively monitor the progression of cerebral hematomas after surgery.

While NIRS technology is not designed to replace CT scans, it can be useful in situations where CT scans are not available. It offers a non-invasive way to examine deep tissues and provides hospital-grade diagnostic capabilities directly at the point of care.

Furthermore, this technology has undergone comprehensive safety evaluations, including EMI/EMC and biocompatibility testing, in line with medical device regulations. It uses non-ionizing near-infrared (NIR) light, safer for biological tissues than ionizing radiation like X-rays or CT scans. The safety of pulsed light source follows the IEC 60825-1 laser safety standard, classifying it as a Class 1C laser product, meaning no protective eyewear, warnings, or interlocks are needed. The device includes a laser exposure warning label for safety information. It complies with US FDA exposure guidelines, ensuring safety for pregnant women, newborns, and vulnerable populations. These strict measures, including protective engineering controls, make this device safe for use in pregnancy.

Assumptions

- For health system cost for referral of a patient to neurosurgery centre/ district hospital, we assumed lower limit for referral to district hospital (Rs 801) and higher limit for referral to neurosurgery centre (Rs 1,001) and then the cost was inflated as outlined in table 4. This approach ensures that the model reflects realistic cost differences between initial and specialized care settings, thereby offering a more precise evaluation of the financial impact of patient referrals within the health system.
- In the decision tree modelling, several assumptions were made regarding patient referral pathways based on NIR technology screening results. Specifically, it was assumed that if a patient was tested positive for TBI using NIR technology, they would be directly referred to a neurosurgery centre for specialized treatment. This direct referral process is intended to expedite access to advanced care for those identified with potential TBI, potentially improving outcomes by reducing delays in treatment. Conversely, if a patient tested negative for TBI with NIR technology, the model assumed a two-step referral process. Initially, these patients would be referred to a district hospital for further evaluation and management. If the district hospital's assessment indicated the need for advanced care, they would then be referred to a neurosurgery centre. This sequential referral approach is designed to ensure that

patients who do not show signs of TBI still receive appropriate medical attention, while avoiding unnecessary direct referrals to specialized centres unless deemed necessary.

In the scenario where NIR technology is not used, the referral pattern was modelled as a straightforward pathway: all patients would first be directed to a district hospital for initial evaluation. Based on the district hospital's findings, those requiring specialized care would then be referred to a neurosurgery centre. This traditional referral pathway reflects a more gradual approach to patient management, where initial assessments are conducted at a local level before escalating to specialized care if required.

These assumptions were integral to evaluating the incremental cost and impact of incorporating NIR technology into the decision-making process, aiming to assess whether the technology's direct referral capabilities offer any advantages over traditional referral patterns in terms of cost.

- The analysis assumes stable patient volumes and healthcare settings as described. Changes in patient volume or healthcare infrastructure could affect the incremental cost per case and overall budget impact.
- The budget impact analysis assumes consistent national costs and does not account for regional variations in healthcare spending or device implementation. Additionally, it presumes that all ambulances and CHCs would be equipped uniformly, which might not be practical in diverse regions.

Limitations

- The sensitivity and specificity of the product are currently not sufficient to fully replace CT scans. While it can be a valuable complementary tool, its performance does not yet meet the high standards required for standalone diagnostic use. Its primary role is to support and enhance the diagnostic process, particularly in scenarios where CT scans may not be readily available, thereby providing preliminary information that can guide further imaging and treatment decisions. However, for definitive diagnosis and treatment planning, CT remains the gold standard. Future improvements in the product's sensitivity and specificity could enhance its utility, but for now, it is best utilized alongside CT scans to optimize patient care.
- There is no pertinent data on the effectiveness of NIR technology on mortality and morbidity reduction and increase in quality of life in patients with TBI. This absence of evidence highlights a critical gap in our understanding of the technology's clinical effectiveness. To address this, it is essential to conduct prospective studies that evaluate

the efficacy of NIR technology in improving patient outcomes for those with TBI. Such studies should focus on measuring how the use of NIR technology influences survival rates, recovery trajectories, and overall health status in TBI patients. By systematically investigating these outcomes, future research could provide valuable insights into whether NIR technology can contribute to significant reductions in mortality and morbidity, thus guiding its integration into clinical practice and informing healthcare decision-making.

Conclusion

The financial evaluation of integrating Near-Infrared (NIR) technology for intracranial bleed detection reveals distinct cost implications across different levels of the healthcare system. At the ambulance level, the incremental cost per patient is Rs 984.15, leading to a substantial annual budget impact of Rs 4,41,68,76,149.28 for equipping all ambulances in India. At the Community Health Centre level, while the incremental cost per patient is lower at Rs 360.90, the total annual budget impact amounts to Rs 1,87,77,37,556.97. This reflects the larger number of CHCs, making the overall financial requirement considerable but more distributed compared to the ambulance level. At the tertiary health care level, the incremental cost per patient is the lowest at Rs 289.78, indicating a more feasible integration within the existing infrastructure of tertiary care centres. These findings highlight the varying financial burdens and efficiencies of adopting NIR technology across different healthcare settings. Decision-makers must weigh these costs against the potential benefits of improved diagnostic capabilities, considering both the immediate financial impact and the long-term advantages of early and accurate TBI detection. Strategic planning and resource allocation are crucial to optimizing the deployment of NIR technology, ensuring it enhances patient care while managing costs effectively.

After thoroughly reviewing the documents submitted by the innovators, we have concluded that our results are unlikely to change. This is primarily because their cost-effectiveness analysis heavily relies on assumptions, which undermines its reliability. Furthermore, their analysis lacks a valid comparator, making it difficult to draw meaningful conclusions.

While their focus is on evaluating the device as a standalone solution, our approach incorporates a comprehensive perspective by considering the integration of the device with CT scan technology. This distinction is critical because the combined usage of the device with CT scan aligns more closely with real-world clinical scenarios and provides a more robust framework for assessing overall cost-effectiveness and utility.

Without addressing the integration with CT scans or providing a valid comparator, their analysis fails to account for important factors that influence both the economic and practical feasibility of implementing the device in a healthcare setting. Hence, our conclusions remain unchanged.

Recommendations

- **NIR technology cannot replace CT scans but can complement it.** While CT scans remain the gold standard for detailed imaging for TBI patients, the detector can provide an initial, non-invasive assessment of intracranial bleeding. Its role is to enhance early detection, streamline triage, and prioritize cases for CT imaging.
- In ambulances, this device could act as a crucial pre-symptomatic screening tool for suspected TBI patients. By enabling early detection of intracranial bleeding, it may streamline triage, guide urgent care decisions, and improve patient outcomes while optimizing emergency resource use.
- At CHCs, the detector can quickly identify TBI cases needing transfer to specialized neuro-facilities, minimizing the time to neurosurgical intervention and potentially improving patient outcomes by reducing delays in specialized care.
- In tertiary care centres, the detector can speed up head CT initiation by detecting intracranial bleeding early, optimize patient triage, and reduce imaging costs through fewer CT scans for post-surgery monitoring.

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