EMERGENCY & CRITICAL CARE

These unmet clinical needs were identified following an 8-week clinical immersion that was conducted by a team in Emergency Medicine and Critical Care. The clinical immersion was conducted in high volume tertiary care centres in South India. We observed what's done and how it affects the provider, the patient, and the system. This was followed by a peripheral immersion to numerous primary, secondary and tertiary health care centres across India. The clinical needs found in the tertiary care hospital were validated in other large centres and new primary and secondary specific unmet needs were added on. At the end of 2 months of clinical immersion, the team had over 100 detailed observations with significant negative outcomes and 150 unmet clinical needs. These needs were then filtered using objective parameters, detailed below:

THE FILTERING PROCESS: 3 STAGES OF FILTERING

Level 1: The level 1 filter eliminated those needs which are redundant, pharmaceutical related or process related.

Level 2: This level of filtering focused on the severity of clinical condition (in the perception of observers and clinicians) as well as the epidemiology of the disease and the frequency of the negative outcome. This data was then validated by a comprehensive literature review of incidence and prevalence data. A scoring system of 1 – 3 – 5 was used through the process.

Epidemiology

Frequency of problem as per clinician (number of cases per month)

- < 5 patients per month=1
- 6-12 patients per month =3
- >13 patients per month =5

Frequency of problem as per observers (number of cases seen per month during the clinical immersion)

- < 2 patients per month=1
- 2-5 patients per month =3
- >5 patients per month =5

Criticality

- Short lasting, reversible: Not resulting in death, disability, hospitalization, or socioeconomic stress = 1
- Resulting in death, hospitalization >3 days, disability/ handicap (> 6 months), large financial burden to the patient/family = 5
- Needs in between 1 and 5 = 3.

Observed Epidemiology and criticality score: 3 (Frequency of clinician) + Frequency of observer + 3 (Criticality score)

Target patient population in a given year: We used data wherever available for India. However, in many cases due to the dearth of validated health statistics, certain assumptions had to be made using a combination of data from India and global epidemiological data.

- <100,000 patients/year = 1
- 100,000 – 500,000 patients/year = 3
- >500,000 patients/year =5

Secondary research based epidemiology and criticality score: Target patient population * Criticality score

Filter 2 score: Subjective epidemiology and criticality score + secondary research based epidemiology and criticality score

Level 3: The third level of filtering evaluated the technical complexity of the solutions available, the regulatory landscape and the buyer environment.

Number of predicates: This was made based on the solutions which currently exist as per guidelines and those being used in the Indian clinical setting. Both at prevailing practice as well as gold standards were considered.

- High number of predicates i.e. >5 = 1
- Medium number of predicates i.e. 1 to 5= 3
- No predicates = 5

Technical complexity of predicates: This filter considered the technology behind the solution as well as the expertise needed to implement it in current clinical practice. A medium complexity solution is rated the highest, followed by low complexity and lastly by a highly complex solution.

- High =1
- Medium =5
- Low =3

Regulatory and clinical trial complexity: This filter was based on the regulatory hurdles and clinical trials one would have to conduct for a particular solution. It was a judgment call based on the current predicates in the system and the classification of devices as per the Global Harmonisation Task Force classification (Class A - Low Risk, Class B - Low to Moderate Risk, Class C - Moderate to High Risk, Class D - High Risk)

- High (Class D) =1
- Medium (Class C) =3
- Low (Class A & B) =5

Buyer environment: This filter was based on the eventual buyer of a particular medical solution. This in turn depended on which level in the healthcare system the particular condition was treated. The peripheral immersion helped understand, more thoroughly, the referral system in India which defined this filter.

- High (Tertiary Care Centre) = 5
- Medium (Secondary Centre) = 3
- Low (Individual/Primary centre) = 1

Filter 3 score = Number of predicates score + Regulatory and clinical trial complexity score + Buyer environment score

Final Score= Filter 2 score + (Filter 3)/4

NEED SPECIFICATION DOCUMENTS

1. INTRA-CRANIAL PRESSURE MONITORING

BACKGROUND

The concept of intracranial pressure and volume, and the compliance of each component of the intracranial compartment as being related, was first proposed by the anatomist and surgeon Alexander Monro and his student George Kellie in the 18th century. It normally ranges between 7-15 mm Hg in adults, with pressures over 20 mm Hg considered pathological and pressures over 15 mm Hg considered abnormal. The causes of intracranial tension range from space-occupying lesions (tumors, abscesses, intracranial haemorrhage), cerebrospinal fluid (CSF) flow obstruction, anatomical malformations, cerebral edema (due to head injury, ischemic stroke with vasogenic edema, postoperative edema), increase in venous pressure, metabolic disorders, increased CSF flow production to idiopathic intracranial hypertension.[1]

OBSERVATION

A 65 year old female came to the Emergency department with altered sensorium, 4 episodes of generalised tonic clonic seizures, 2 episodes of loss of consciousness, urinary incontinence in the past 1 day, fever and earache associated with purulent discharge for the past 5 days, which was treated in a private clinic. Altered behaviour was also noted, including incoherent speech and loud chanting at night. She was a known case of hypertension and bronchial asthma on therapy. ENT consultants suspected a diagnosis of an Acute Otitis Media (middle ear infection) with intracranial complications in the form of meningitis. On examination, her blood pressure was found to be 146/64, with a pulse rate of 104. The patient was intubated and immediately moved to the ICU. An initial dose of antiepileptic medication was administered intravenously for the seizures. To reduce intracranial pressure, a lumbar CSF drainage procedure was planned. A CT scan was done that was interpreted by the radiologist, who concluded that there no signs of impending herniation. The lumbar procedure was done and pressure was released by draining 30ml of the cerebrospinal fluid. The neurologist, on following-up, observed that the patient had had a twitching in her eye and diagnosed seizures. The patient was having recurrent seizures but due to sedation it had been missed by the intensivists. A second anticonvulsant was added. Approximately 6-7 hours later, the patient began to develop clinical signs of herniation of the brain stem. An emergency CT scan was done which confirmed the herniation. The seizures continued and a 3rd antiepileptic was added. The initial CT was reinterpreted and confirmed the presence of bleeding within parenchyma of the brain but had been missed by the radiologist. The patient desaturated and expired due to respiratory insufficiency and cardiovascular collapse the next day.

PROBLEM STATEMENT

Raised intracranial pressure can lead to death or devastating neurological damage. The cerebral perfusion pressure is directly related to the mean arterial pressure and the intra-cranial pressure. Since the cranium (skull cavity) is a closed compartment, an increase in intracranial pressure with no rise in mean arterial pressure will reduce cerebral perfusion pressure (CPP) and cause cerebral ischemia (lack of blood flow to the brain). This can also lead to fatal complications due to compressing and causing herniation of the brainstem or other vital structures. Currently drugs are available to reduce intracranial pressure but the techniques for

monitoring intracranial pressure and, thus gauging the efficacy of therapy, are restricted to clinical examination, radiological estimations and fundal examination. There are high complexity techniques available, however these are not commonly done in tertiary healthcare settings. [1,2]

NEED STATEMENT

An accurate, safe and continuous (compared to CT & MRI) method to continuously monitor changes and trends in intra cranial pressure and cerebral compliance in patients with intracranial tension in the ICU in order to allow for prognostication without the risk of infection (associated with invasive measurement) in a tertiary care setting.

FILTERING

Final score = 14

Rank = 1

MARKET POTENTIAL

Epidemiology: As per the Indian Injury Foundation, 1 million suffer from serious head injuries annually, which can potentially lead to intracranial tension. The annual incidence rate per 100,000 intracerebral and subarachnoid hemorrhage cases was found to be 10.1, and 4.2 respectively, resulting in about 100,000 and 40,000 cases per year.

Given that ICT was only treated in a critical care setting and its importance in determining prognosis and monitoring therapy it would be a valuable addition to augment CT and clinical examinations by the clinicians.

COMPETITIVE LANDSCAPE

CURRENT PRACTICE

ICP measurement: The importance of intracranial pressure and cerebral perfusion monitoring has been clearly delineated in various clinical trials. [1,2,3]

NON- INVASIVE METHODS [1]

Clinical examination: Headache, nausea, pupillary reactivity, Glasgow Coma Scale, vitals.

Fundoscopy:In a study of patients with head trauma, 54% of patients had increased ICP, but only 3.5% had papilledema on fundoscopic examination. Papilledema develops 1-5 days after an increase in ICP.[4] Other signs, such as pupillary dilation and decerebrate posturing, can occur in the absence of intracranial hypertension.[3]

Non contrast CT scan: Signs of brain swelling, such as midline shift and compressed basal cisterns, are predictive of increased ICP, but intracranial hypertension can occur without those findings.[3]

INVASIVE METHODS: [1]

External ventricular drain placement: This is a highly accurate technique for monitoring ICP. A catheter is placed in the lateral ventricle at the level of the foramen of Monro. EVD also allows for therapeutic relief of elevated ICP via CSF drainage. EVD requires skill and training for optimal placement. Risks include parenchymal hematoma and infection/ventriculitis. Obstruction of the drain requires replacement. Continuous monitoring requires nursing staff to be educated on EVD management.

Intraparenchymal fiberoptic catheter placement: This a technique of measurement of ICP without CSF diversion. It has a lower complication rate, lower infection rate, and no chance of catheter occlusion or leakage. Neurological injury is minimized due to the small diameter of the probe. Incorrect positioning of the transducer has less impact on errors of measurement. Drawbacks include the high expense and inability to calibrate it after placement.

The landmark Bolivia Trial which changed treatment protocol from invasive to clinical and radiological approach, specifically mentioned that the inadequacies of the invasive procedures were the focus on instantaneous values, rather than trends of intracranial pressure on cerebral compliance. This coupled with the risk benefit ratio taking complications of the catheter and procedure into account, led to these pressure monitoring techniques from being removed from the guidelines.

MEDICAL MANAGEMENT OF INTRACRANIAL TENSION

Sedation and paralysis: Routine paralysis of patients with neurosurgical disorders is not indicated; however, intracranial hypertension caused by agitation, posturing, or coughing can be prevented by sedation and non-depolarizing muscle relaxants. A disadvantage is that a neurologic examination cannot be conducted easily for close monitoring.

Hyperosmolar therapy: Mannitol is the most commonly used hyperosmolar agent for the treatment of intracranial hypertension. More recently, hypertonic saline also has been used in this circumstance

Hyperventilation: Hyperventilation decreases $PaCO_2$, which can induce constriction of cerebral arteries by alkalinizing the CSF. The resulting reduction in cerebral blood volume decreases ICP

Barbiturate coma: Barbiturate coma should only be considered for patients with refractory intracranial hypertension because of the serious complications associated with high-dose barbiturates, and because the neurologic examination becomes unavailable for several days

Steroids: Steroids commonly are used for primary and metastastic brain tumors, to decrease vasogenic cerebral edema. The CRASH trial [75] is a recently completed, large (>10,000 patients enrolled), placebo-controlled randomized clinical trial of methylprednisolone for 48 hours in patients with TBI. Administration of methylprednisolone resulted in a significant increase in the risk of death from 22.3% to 25.7% (relative risk 1.15, 95% confidence interval 1.07–1.24). This trial confirmed previous studies and guidelines that routine administration of steroids is not indicated for patients with TBI.

SURGICAL MANAGEMENT OF INTRACRANIAL TENSION

Resection of mass lesions: Intracranial masses producing elevated ICP should be removed when possible. Acute epidural and subdural hematomas are a hyperacute surgical emergency, especially epidural hematoma because the bleeding is under arterial pressure. Brain abscess must be drained, and pneumocephalus must be evacuated if it is under sufficient tension to increase ICP.

Cerebrospinal fluid drainage: CSF drainage lowers ICP immediately by reducing intracranial volume by allowing edema fluid to drain into the ventricular system. Drainage of even a small volume of CSF can lower ICP significantly, especially when intracranial compliance is reduced by injury.

Decompressive craniectomy: The surgical removal of part of the calvaria to create a window in the cranial vault is the most radical intervention for intracranial hypertension

IDEAL SOLUTION STATEMENT

A solution that offers non-invasive, continuous monitoring of the intracranial pressure and cerebral perfusion pressure without the risks of ventriculitis, meningitis and catheter closure.

NEED CRITERIA

MUST HAVE

- Continuous monitoring of intracranial pressure and cerebral perfusion pressure
- Should be more accurate than CT, fundoscopy and clinical examination
- Should have minimal risk of infection
- Should not be high skilled from measurement or maintenance perspective

NICE TO HAVE

- Should be non-invasive
- Should be easy enough for an intensive care nurse to measure and maintain
- Should be portable
- Should be reusable so that multiple patients can benefit

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2. ACUTE POISONING

BACKGROUND:

With the availability of a vast number of chemicals and drugs, acute poisoning is a common medical emergency in any country. The exact incidence of this problem in India remains uncertain, but it is estimated that about 10-15 million cases of poisoning are reported every year, of which, more than 50,000 die.

OBSERVATION:

A 24 year old woman presented with a history of attempted suicide by consumption of multiple substances two hours prior to presentation. She had three episodes of vomiting with blood and severe epigastric chest pain. On arrival into the Emergency Department, a venous line was established, an ABG was done that revealed evidence of metabolic acidosis. Clinicians believed this to be due to the vomiting. On more detailed history, the substances consumed could not be identified either from the patient or the caregivers present. Her bleeding parameters were normal (PT, INR) was normal. There were 2 episodes of vomiting thereafter, with evidence of bleeding in the form of streaks. She had no known comorbidities. On examination, she was pale with tachycardia. Her abdominal examination revealed a tender epigastrium. She had 2 further episodes of vomiting with blood in vomitus. An RT wash or activated charcoal was not used since the substance was unknown and it was beyond 30 minutes post consumption. Mucosal injury was present as reveealed by the endoscopy, which also showed tears at the lower esophageal sphincter. The patient went into respiratory failure and was intubated immediately and treated supportively in the ICU with monitoring including serial ABGs. A week later, the patient died in the ICU. On autopsy, a rodenticide was identified as the toxic substance.

NEED STATEMENT

An accurate, accessible method to conduct a toxicology screen (as compared to inaccessible, prolonged individual substance screening tests) for specific classes of toxic substances with inherent toxicity to complement history and examination and allow for prognostication and immediate management, to avoid mortality in a tertiary emergency healthcare setting.

FILTERING

Final score = 14

Rank = 2

MARKET POTENTIAL

Epidemiology: 10-15 million cases reported per year in India with a mortality approximated at 50,000 per year. Nearly 10%–25% of emergency room registrations as per an Indian study by Sharma et al are poisoning-related.[2]

Criticality: Every case of acute poisoning or substance abuse is treated as an emergency on presentation regardless of the substance, especially until the patient is stabilised.

COMPETITIVE LANDSCAPE

Identification of poison: The dictum is to try to identify the agent but never delay therapy. The key aspects to be identified include nature of substance, degree of exposure and time since exposure.

Clinical examination: Danger signs are evaluated clinically to identify type of poison and prognosis so that treatment can be started immediately.

Physical properties of substance: Smell or colour can be recognised for some substances but that's the exception rather than the rule.

Toxidromes: These are clinical and lab findings that can point toward a class of drugs to aid further management. However, it is often confounded by the fact that the accuracy is not high given that it depends on multiple factors such as amount of toxin exposure, time since exposure, confounding by exposure to multiple substances

Toxicology screen: Lab test for specific poisons have the limitations of prolonged turnaround time, high costs (Rs 5,000 to 10,000), inaccessibility since they are only specific, specialised labs that conduct these tests, and a specimen collected too early or too late may have little clinical correlation with the results. Also, established cut off levels of toxicity have not been determined for many toxins, which makes the interpretation of test results very difficult.

As per the guidelines, the initial screening should rule out or detect the presence of the high risk substances for the purpose of management and prognostication. These are:

- Anticonvulsant
- Carbon monoxide
- Digoxin
- Iron
- Lead
- Lithium
- Methhemoglobin
- Paracetamol
- Heavy metals
- Salicyclates
- Theophylline
- Toxic alcohols

IDEAL SOLUTION STATEMENT

An accurate and affordable screening solution to detect the consumption of high risk poisons in an emergency healthcare setting even if the patient presents beyond one hour of consumption.

NEED CRITERIA

MUST HAVE

- Accurately identify the high risk poisons
- High turnaround time (<30 minutes)
- Should not be confounded by time or quantity of ingestion/exposure

NICE TO HAVE

- Should be easy to conduct
- Should be low cost
- Most common substances abused should be identifiable
- Should be a bedside examination

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3. VENTILATOR ASSOCIATED PNEUMONIA

INTRODUCTION

Ventilator-associated pneumonia (VAP) is pneumonia that develops 48 hours or longer after mechanical ventilation is given by means of an endotracheal tube or tracheostomy. Ventilator-associated pneumonia (VAP) results from the invasion of the lower respiratory tract and lung parenchyma by microorganisms. Intubation compromises the integrity of the oropharynx and trachea and allows oral and gastric secretions to enter the lower airways.[1]

OBSERVATION

A 47 year old male was the victim of a road traffic accident. He was riding a motorcycle which collided with a car. He immediately lost consciousness and one episode of Vomiting immediately after the accident. He was taken to a local hospital and administered first aid. Due to lack of ICU beds and the need for care at a higher centre, the patient was transferred to the emergency department. On presentation, his heart rate was 104 beats per minute, blood pressure was 170/90 mm of Hg and oxygen saturation was 84%. The distal pulses of the left leg were absent. GCS score was 10/15. Pupils bilaterally were 2 mm. The patient was intubated based on his GCS score and poor respiratory effort. He was then admitted to the ICU and started on ventilatory support. 3 days post admission a decision was taken to extubate the patient. During attempted extubation, there was inadequate respiratory effort by the patient and led to the aspiration of regurgitated gastric content. The extubation failed and he was reintubated in 15 minutes. 2 days after reintubation the patient had an X-ray due to dropping saturation rate, fever and pulmonary opacities were noticed which were diagnosed as ventilator associated pneumonia. The patient deteriorated post the failed extubation and remained in the ICU for 7 days due to the pneumonia, being treated with IV antibiotics and supportive therapy, before being successfully extubated and discharged from the ICU to the ward.

CURRENT PROBLEM

Ventilator-associated pneumonia (VAP) is a type of pneumonia that develops 48 hours or longer after mechanical ventilation is given by means of an endotracheal tube or tracheostomy. Ventilator-associated pneumonia (VAP) results from the invasion of the lower respiratory tract and lung parenchyma by microorganisms. Intubation compromises the integrity of the oropharynx and trachea and allows oral and gastric secretions to enter the lower airways. The incidence of VAP in India is 20-40% among intubated patients. It is the second most common nosocomial infection and increases a patient's hospital stay by approximately 7-9 days as well as hospital costs by an average of $40,000 per patient. Intubation increases the risk of VAP 3-21 fold and the crude mortality rate can range from 27-76%!

NEED STATEMENT

An effective way (compared to the current nursing protocol) to prevent aspiration of gastric content in intubated (short and long term) patients (including patients on general anesthesia/sedatives) in a tertiary care setting.

FILTERING PROCESS

Final Score: 14

Rank: 3

MARKET POTENTIAL

In India, there are nearly 5.5 million ICU patients annually, of which more than 50% (>2.7 million) are intubated. Most of these patients (~2 million) are on long-term intubation (>48 hrs.). The incidence rate of VAP is ranges from 20 - 40%, indicating that >600,000 individuals develop VAP during long-term intubation. Most importantly, the mortality rate for VAP is >40%, resulting in ~240,000 deaths annually. The target market for a potential solution is the >2 million ICU patients on long-term ventilation. Currently there are about 34,000 ventilators in the country, expected to grow to 50,000 by 2018. The bulk of these ventilators (~75%) are concentrated at roughly 1,500 tertiary care hospitals [2][3][4][5].

The following table provides a snapshot of the market as of 2014[2][3][4][5]:

Target Patient Pool India	2014	2015	2016	2017
Number of Patients in ICU	54,02,897	54,83,940	55,66,199	56,49,692
Growth in ICU Patients	1.30%	1.50%	1.50%	1.50%
% who are intubated (total)	50%	50%	50%	50%
# of Intubated Patients (total)	27,01,448	27,41,970	27,83,100	28,24,846
% Intubated - Long Term (>48 Hours)	70%	70%	70%	70%
# of Long Term Intubated Patients (>48 hours)	**18,91,014**	**19,19,379**	**19,48,170**	**19,77,392**
% Incidence Rate of VAP	31%	31%	31%	31%
# Incidence of VAP	**5,92,770**	**6,01,661**	**6,10,686**	**6,19,847**
Mortality Rate Attributable to VAP	42%	42%	42%	42%
Mortality due to VAP	**2,46,335**	**2,50,030**	**2,53,781**	**2,57,588**

COMPETITIVE LANDSCAPE - AVAILABLE TREATMENT OPTIONS

Sr.No.	Predicates	Continuous Suctioning	Auto Lavage and Mouth Wash	Compatible with any ETT	Record and Display data	Alarm for suction port block	Sensing amount of secretions
1	Manual Suctioning	✘	✘	✘	✘	✘	✘
2	CASS ETT	✔	✘	✘	✘	✘	✘
3	PneuX PY™ VAP prevention system	✔	✘	✘	✔	✔	✘

Currently VAP is prevented in intubated patients though buccal and oro-pharyngeal suctioning as well as the cuff of the ET tube. Manual suctioning by nurses is done by nurses in the ICU.

These measures are included in ICU cost to the patient which ranges from approximately 15000-50,000 INR per day.

A few Endotracheal Tubes have suctioning ports built in to remove the secretions. The nurse to patient ratios in most Indian ICUs is poor leading to the infrequent and inadequate suctioning. The Cost of these new advanced ET tubes puts it out of the reach of most patients.

IDEAL SOLUTION STATEMENT

An ideal solution shall remove secretions from three different locations where there is maximum pooling of secretions where:

- Subglottic space
- Oral cavity
- Oro nasal pharynx
- It shall fit onto any existing ET tube.

The solution shall automatically sense the pooling of secretions and start the suctioning system. It will monitor for suction tube blockage and give out alarm on sensing blockage.

It shall have arrangement to perform regular lavage and antimicrobial mouthwash.

It shall record, store and display the amount of secretions at any particular time.

NEED CRITERIA

MUST HAVE

- Secretion to be removed from 3 locations:
    - Subglottic region
    - Oral cavity
    - Naso oral pharynx
- Adopt to existing ET tube.
- Not cause aspiration of the lungs.
- Not allow pooling beyond 1 ml.
- Not cause any additional injury to the vocal chords or the mucosa besides the injury already caused during existing ETT insertion.
- Raise an alarm within 5 seconds of suction tube blockage.

NICE TO HAVE

- Monitor and record the amount of secretions.
- Lavage the oral and tracheal channels.
- Used with any external suction system.
- Auto clear the suction tube in case of a blockage.

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4. CENTRAL LINE COMPLICATIONS

INTRODUCTION

Central venous access allows the placement of various types of intravenous (IV) lines to facilitate the infusion of fluids, blood products, and drugs to obtain blood for laboratory analysis. Significant morbidity and mortality can result from complications that occur at the time of catheter insertion and include vascular, cardiac, pulmonary, and placement complications. These complications can cause a significant healthcare burden in cost, hospital days, and patient quality of life [2][3].

OBSERVATION

A 38-year-old male with Chronic Kidney Disease (CKD) was presented to the Emergency Department (ED) with nausea and vomiting. His BP was 90/50, an arterial blood gas (ABG) test demonstrated hypokalemia and metabolic acidosis and the patient was immediately started on Intravenous(IV) fluids, IV Emset and IV Pan. His blood pressure started to climb and he was admitted to the Intensive Treatment Unit (ITU) for monitoring. In the ITU the vomiting continued and a decision was made to start a central line at night. The doctor prepped for the procedure and while infiltrating the right internal jugular vein the carotid artery was perforated. Pressure was applied to the vessel to try and control the bleeding while the BP kept falling. While trying to rectify the bleed the patient developed a pneumothorax leading to desaturation. The patient was rushed to the Intensive Care Unit (ICU) but expired a few hours later.

CURRENT PROBLEM

The central line is used to replenish the fluid at faster rate but it also associates with serious complications which poses a high risk of mortality. The patient developed pneumothorax due to the central line needle, which further led to desaturation and resulted in mortality.

NEED STATEMENT

A safer way (compared to central line mechanical complication) to replenish fluid in patients with hypovolemic shock where peripheral IV line is not sufficient in order to avoid complications (procedure related: pneumothorax, arterial rupture and pulmonary embolism) in a tertiary care setting.

FILTERING PROCESS

Final Score: 14

Rank: 4

MARKET POTENTIAL

Overall complication rates range up to 15%, with mechanical complications reported in 5-19% of patients, infectious complications in 5-26%, and thrombotic complications in 2-26%. These complications are all potentially life-threatening and, invariably, consume significant resources to treat [1].

Total number of patient in ICU setting in a year in India: 5 million. Mostly all the patients in an ICU have a central line put for monitoring. Assuming a conservative 50% of them need a central line, leads to 2.5 million cases. Overall complication rates range up to 15%, thus implying up to 375,000 cases annually. Thus, accessible patient pool is at minimum 2.5 million a year.

COMPETITIVE LANDSCAPE

The Seldinger technique is the most commonly used method of gaining central venous access. It was initially described in 1953 by Seldinger as a vascular access method for percutaneous arteriography. Although the Seldinger technique requires multiple sequential steps, intravascular access can be rapidly and reliably gained once these steps are mastered.

The cost of the equipment is approximately INR 4,000-5,000.

IDEAL SOLUTION STATEMENT

The ideal solution to this problem should be an easier and faster way to replenish fluids in a patient without causing any mechanical complications or infections and occlusions. It would be ideal to be able to use the central line procedure without the use of ultrasound if mechanical complications such as pneumothorax and arterial rupture can be avoided.

NEED CRITERIA

MUST HAVE

- High rate of fluid replacement comparable to Central Venous Catheter.
- Lesser and quicker steps as compared to Seldinger Technique.
- Remove occurrence of CVC borne infections and mechanical complications.

NICE TO HAVE

- Ease of use to perform procedure without ultrasound.

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5. GASTROINTESTINAL PERFORATION & SEPTIC SHOCK

BACKGROUND

Definitions have not changed greatly since 1914, when Schottmueller wrote, “Septicemia is a state of microbial invasion from a portal of entry into the blood stream which causes sign of illness.” The old definition of sepsis was the presence of infection in conjunction with the systemic inflammatory response syndrome (SIRS). The new 2016 definition, also called Sepsis-3, eliminates the requirement for the presence of systemic inflammatory response syndrome (SIRS) to define sepsis, and it removed the severe sepsis definition. Sepsis is defined as life-threatening organ dysfunction due to dysregulated host response to infection, and organ dysfunction is defined as an acute change in total Sequential Organ Failure Assessment (SOFA) score greater than 2 points secondary to the infection cause. Septic shock: Subset of sepsis in which underlying circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone.

OBSERVATION

A 34 year male was admitted in the emergency department with a history of fever for 2 days and abdominal pain for 1 day associated with nausea, vomiting and fever with chills and rigors. The patient was initially admitted to a local hospital and was diagnosed with duodenal perforation on ultrasound and CT. In view of impending septic shock and due to a lack of ICU facilities the patient was immediately referred to the tertiary care center. On arrival the patient was intubated due to respiratory instability and a FAST ultrasound scan was done which revealed free fluid in the abdomen. Due to dropping blood pressure a central line was established and inotropes provided for circulatory support. In view of the low platelet count and the planned surgery, 8 bags of platelets were transfused. An exploratory laparotomy was planned and performed. During surgery a 0.5 X 0.5 cm (25 sq mm) D1 perforation was found and repaired with "Modified Gralam's patch", peritonitis was present with purulent collection of 150 - 200 ml and flakes in the lower intestine and large bowel. 3 drains were placed in the subhepatic, the pelvic & the subphrenic regions. 2 bags of blood were transfused during surgery. Post operatively the patient was transfered to the ICU for monitoring and support. After surgery, the patient devoloped complications of sepsis in the form of Acute kidney injury, acidosis and hyperkalemia (high potassium level in blood). The nephrologist advised for immediate dialysis but it was discontinued due to hemodynamic instability. The patients condition worsened and his blood pressure continued dropping as did his oxygen saturation levels. 2 cycles of CPR had to be administered on the second day post operatively and the patient was declared dead thereafter

NEED STATEMENT

A more effective way to manage patients with gastrointestinal perforation to prevent the onset of septic shock in a tertiary healthcare setting.

FILTERING

Final score = 13.5

Rank 5

MARKET POTENTIAL

A single center study done in India over 5 years showed 4711 admissions during the study with 282 admissions with severe sepsis. ICU mortality, hospital mortality, and the 28-day mortality were 56%, 63.6%, and 62.8%, respectively. Median APACHE II score on admission was 22 (interquartile range 16–28) and median length of ICU stay was 8 days. Severe sepsis attributable mortality was 85%.[2]

In the United States, the incidence of severe sepsis is estimated to be 300 cases per 100,000 population. Extrapolating the data to India it would amount to approximately 350,000 cases per year. Septic shock is associated with a mortality, approaching 50%. The cumulative burden of organ failure is the strongest predictor of death, both in terms of the number of organs failing and the degree of organ dysfunction.

COMPETITIVE LANDSCAPE

The general principles guiding the treatment of infections are 4-fold: control the infectious source, eliminate bacteria and toxins, maintain organ system function, control the inflammatory process.

Surgical management: Operative management depends on the cause of perforation. Perform urgent surgery either on patients not responding to resuscitation or following stabilization and maintenance of adequate urine output. All necrotic material and contaminated fluid should be removed and accompanied by lavage with antibiotics (tetracycline 1 mg/mL).

Decompression of distended bowel via a nasogastric tube.

Drainage tube insertion.

Systemic antibiotic therapy: Metronidazole is typically used in combination with an aminoglycoside to provide broad gram-negative and anaerobic coverage.

Intensive care with hemodynamic, pulmonary, and renal support: Aggressive fluid resuscitation to treat intravascular fluid depletion should be instituted. Pressor agents are avoided if possible. Fluid administration requires frequent monitoring of blood pressure, pulse, urine output, blood gases, hemoglobin and hematocrit, electrolytes, and renal function.

Nutrition and metabolic support.

Inflammatory response modulation therapy.

IDEAL SOLUTION STATEMENT

An ideal solution should:

- Prevent the progression to septic shock.
- Control the inflammatory cascade within the abdomen.
- Can be initiated in the emergency department prior to surgery to augment recovery prior to definitive surgical management.

NEED CRITERIA

MUST HAVE

- Must have a mechanism of action that acts immediately
- It must control the inflammatory cascade that leads to organ failure in septic shock
- Must be amenable with general anesthesia

NICE TO HAVE

- Avoids the need for surgery altogether
- Simple enough to use for any healthcare professional
- Must be accessible to all since most cases are due to late entry to the healthcare setting

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6. BURN MANAGEMENT

INTRODUCTION

Resuscitation begins with the assessment and stabilization of the person's airway, breathing and circulation. If inhalation injury is suspected, early intubation may be required. This is followed by care of the burn wound itself. People with extensive burns may be wrapped in clean sheets until they arrive at a hospital. As burn wounds are prone to infection, a tetanus booster shot is given if an individual has not been immunized within the last five years.

OBSERVATION

A 35 year old male was brought to the emergency department with partial thickness burn in the frontal section (front side of body) in an ambulance. The accident was a result of a gas cylinder explosion. The family members sustained burn injuries, including the wife and a 10 year old child. The child was managed directly in the pediatric emergency ward.

Initial assessment of Airway, Breathing, Circulation, Disability, Exposure (ABCDE [1]) was done with inspection of the burn site injury to assess the intensity of burn and the patient condition. The patient had sustained 45% second degree burns on his face, hand, chest and legs [2]. On examination the patient was found to be oriented to time, place and person. His blood pressure was 140/90 mmHg with a pulse rate of 130 beats per minute and 98% of saturation at room atmosphere oxygen.

A central line was planned and executed with no adverse outcome to correct his hemodynamic instability. He was started on ringer lactate as per the Parkland Formula [3]. The burn wounds were debrided and cleaned. Clindamycin was applied on burn wounds for paraffin dressing. Post dressing, the patient was admitted to the ICU. A collagen dressing was planned to be performed the next day by the plastic surgeon. Post ICU admission, the patient developed hypovolemic shock. The patient was immediately intubated and started on inotropic support. The patient also developed associated infections. Despite measures taken in the ICU, the patient desaturated and developed respiratory failure and expired the following morning. Infection and fluid loss leading to Hypovolemic shock was identified as the primary cause of death.

CURRENT PROBLEM

Severe burn patients need immediate attention to reduce the complications due to the burn site infection and fluid loss. Despite the fluid replacement and paraffin dressing, the patient developed infection and went into shock and died.

NEED STATEMENT

A more effective way (than paraffin gauze with clindamycin ointment) to emergently manage burn wounds in patients with burns to avoid infection and fluid loss to allow for repeated inspection and to avoid sepsis, shock & mortality in a tertiary healthcare setting.

FILTERING PROCESS

Final score = 13.5

Rank = 6

MARKET POTENTIAL

According to the WHO, in India, over 10 lakh people are moderately or severely burnt every year. Along with adult women, children are particularly vulnerable to burns. Burns are the 11th leading cause of death in children aged between 1 - 9 years and are also the fifth most common cause of non-fatal childhood injuries [6]. 75% of all deaths are currently related to sepsis from burn wound infections or other infection complications [7]. The burn care market is expected to reach USD 2.33 billion by 2021 from USD 1.68 billion in 2016, at a CAGR of 6.8% from 2016 to 2021[8]. However, the high cost of burn care treatments and products is the major factor challenging the growth of this market.

COMPETITIVE LANDSCAPE

Type	Description	Actions	Indications/use	Precautions/contra-indications	Cost
Alginate/ carboxy-methyl cellulose (CMC)	Alginates are a natural wound dressing derived from algae and seaweed These may be combined with CMC gelling fibres Dressings made from CMC alone are known as Hydrofiber	Absorbs fluid Promotes autolytic debridement Moisture control Conforms to wound bed	Moderate to high exudate	Do not use on dry wounds Use with caution on friable tissue (may cause bleeding)	Approx. Rs 200-300 per sq. inch
Foam	Generally made from a hydrophilic polyurethane foam	Absorbs fluid Moisture control Conforms to wound bed	Moderate to high exudate May be left in place for 2–3 days	Do not use on burn wounds with minimal exudate	Approx. Rs 100 -150 per sq. inch
Honey	Wound dressing incorporating medical-grade honey	Antimicrobial	Sloughy, low to moderate exudate wounds and/or evidence of local infection	May cause 'drawing' pain (osmotic effect) Known sensitivity	Approx. Rs 100-150 per sq. inch
Hydrocolloid	Opaque dressing made of gel-forming components. Dressings are biodegrade able, non-breathable (occlusive) and adhere to the skin	Absorbs fluid Promotes autolytic debridement	'Difficult-to-dress areas', such as digits, heel, elbow, sacrum	Do not use on highly exuding burns May cause maceration May cause hyper	Approx. Rs 120-180 per sq. inch

				granulation	
Hydrogels	Hydrophilic polymer dressing	Moisture control Promotes autolytic debridement Cooling	Sloughy wounds	Do not use on highly exuding wounds or where anaerobic infection is suspected May cause maceration	Approx. Rs 50 per gram
Low-adherent	Wound contact layer or dressing with silicone or lipo-colloid matrix	Protects new tissue growth Atraumatic to peri wound skin Conformable to body contours	Low or minimal exudate	Known sensitivity to silicone	Approx. Rs 200-300 per sq. inch
Polyhexanide (PHMB)	Antiseptic impregnated dressing	Antimicrobial	Low to high exuding wounds Clinical signs of local infection	Known sensitivity to PHMB	Approx. Rs 50 per ml
Polyurethane film	Semi-permeable dressing	Moisture control Breathable bacterial barrier Transparent (allows visualisation of wound)	Low exudate May be left in place for 2–3 days	Should not be used in infected or heavily exuding burns	Approx Rs 50 per sq. inch
Silver	Topical preparations including SSD cream, impregnated dressings and paste Combined presentation with foam and alginates/CMC for increased absorbency	Antimicrobial	Clinical signs of local infection Low to high exudate	Some may cause discolouration Known sensitivity Discontinue after 2 weeks if no improvement and re-evaluate	Apprx Rs 3000-4000 per sq. inch

IDEAL SOLUTION STATEMENT:

An ideal solution should have following:

- Prevent fluid loss and balance dehydration
- Prevent infection
- Able to use in emergency situation in the hospital
- Allow for visual inspection
- Speedup the healing procedure

NEED CRITERIA

MUST HAVE:

- Protect against infection
- Maintain a moist wound environment
- Contour easily
- Non-adherent to protect delicate skin
- Retain close contact with the wound bed
- Painless on application and removal

NICE TO HAVE:

- Limit the number of dressing cycles required
- Allow visual inspection without removing the dressing.

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7. ENDOTRACHEAL TUBE DISLODGEMENT

INTRODUCTION

Endotracheal intubation is a medical procedure in which a tube is placed into the windpipe (trachea) through the mouth or nose. In most emergency situations, it is placed through the mouth. Whether the patient is conscious or unconscious, they will be given medication to make it easier to insert the tube. An endotracheal tube is needed to mechanically ventilate a patient (or breathe through a machine). Each breath is pushed into the endotracheal tube and into the lung.

OBSERVATION

A 65 year old patient was admitted in the emergency department in critical condition with complaint of respiratory distress and low saturation [1]. Post admission, the patient went into an arrest. Immediate measures were taken and CPR [2] (Cardiopulmonary Resuscitation) was initiated, the patient was stabilised after 4 sets of CPR. Post stabilization the patient was intubated for respiratory support and admitted in ICU. A physical examination showed a bulge on the right lower rib section. CT examination revealed small fluid deposit at right lower lobe of lung pleural space. Pleural tap [3] was then planned to remove the fluid deposit and executed without any sign of adverse incident. But post procedure, the patient saturation dropped rapidly. An emergency X-ray was done to identify the lung condition which then showed 75% (approx.) collapse of the right lung. During the pleural tap procedure the needle accidently punctured the lung causing pneumothorax leading to lung collapse. A chest tube was placed to drain the pneumothorax. The patient condition again worsened the next morning with a visible asymmetry at the left side of the chest. The chest asymmetry was noticed by the morning shift doctor during the patient handover round. X-ray showed that the ET [4] (Endotracheal) tube was dislodged and moved distally in the esophagus causing the collapse of the left lung. An emergency extubation was executed followed by re-intubation. X-Ray was done to confirm the correct placement of ET tube. The patient had to undergo chest physiotherapy course and post 6 hours the lung recovered to normal condition. The additional induced chest problems have also added to the cost and an additional day of stay in the ICU.

PROBLEM STATEMENT

ET tubes act as a critical bridge in maintaining the respiratory support to a patient on a ventilator, despite the fixing function of the ET tube, it had dislodged and caused serious acute morbidity, with mortality risk to the patient.

NEED STATEMENT

An effective way to fix the ET tube in a patient to avoid dislodgement and avoid further complications of desaturation & respiratory distress in a tertiary healthcare setting.

FILTERING

Final score = 13.5

Rank = 7

MARKET POTENTIAL

Surgical procedures, including minimally invasive surgeries, across the world are expected to grow by 30% to 40%. These procedures involve the use of anaesthesia in various orthopaedic, cardiovascular, respiratory, neurology, and cosmetics-related procedures. This will lead to an increasing demand for anaesthesia disposable devices such as anaesthesia ETTs [8].

COMPETITIVE LANDSCAPE

The second generation of supraglottic airway devices[9] are already in market with products like I-gel and LMA ProSeal and are widely used with standard ET tubes. A feature based comparison was done to analyse the available devices as listed in below table.

Product	Secure technique	Reliability	Position Indicator	Cost (INR)	Affordability
I-gel	Cuff	Medium	Marking	3,000	Low
LMA ProSeal	Pressure	Medium	Marking	13,000	Low
Standard ET tube	Pressure	Low	Marking	50-300	Only option
Additional secure devices	External	Low	Nil	100-150	Not popular

IDEAL SOLUTION STATEMENT

An ideal solution should have following:

- Must secure the airway support from any undesired movement
- Prevent dislodgement due to routine patient movement
- Easy to intubate and prevent any intubation related trauma
- Visible indication for intubated tube depth measure

NEED CRITERIA:

MUST HAVE:

- Must secure uninterrupted airway long term support
- Must secure from any dislodgment
- Must have an eye catching visible indicator to easy check
- Avoid any device inflected trauma
- Should cost under INR 2000

NICE TO HAVE:

- Cost around INR 500
- Alarm system for any unintended dislodgement

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8. DETECTING SEIZURES IN A PARALYZED & SEDATED PATIENT

INTRODUCTION

Seizures are a relatively common occurrence in the ICU. A seizure may be the first indication of a central nervous system (CNS) complication or the result of overwhelming systemic disease. Seizures in the setting of critical illness are often difficult to recognize and require a complex diagnostic and management strategy. Delay in recognition and treatment of seizures increases the risk of morbidity and mortality; thus, the rapid diagnosis of this disorder is mandatory.

OBSERVATION

A 65 year old female came to the Emergency Department with altered sensorium], 4 episodes of generalised tonic clonic seizures , 2 episodes of loss of consciousness, urinary incontinence in the past 1 day, fever and ear ache associated with purulent discharge for the past 5 days treated in a private clinic. The patient was intubated and immediately moved to the ICU on sedatives and a muscle relaxant. On day 2 in the ICU, the neurologist on follow up, observed that the patient had twitching of her eyes and diagnosed seizures. The patient was having recurrent seizures - but due to the muscle relaxants and the sedatives, it was missed by the intensivists. A second anti-convulsant was added on. The seizures continued and a 3rd antiepileptic was added. The patient developed herniation of the brain stem following a lumbar tap on day 1 in the ICU and on day 3 desaturated and expired due to respiratory insufficiency and cardiovascular collapse.

CURRENT PROBLEM

The patient had multiple episodes of seizures which were missed by an intensivist due to a lack of obvious physical signs and symptoms. This missed diagnosis was because the patient was ventilated and sedated. An EEG can be used, but continuous EEG monitoring devices are not available in most hospitals, and at the moment most healthcare professionals cannot interpret an EEG outside of the neuroscience specialists.

NEED STATEMENT

An accurate way for a non-neurologists to detect seizures in sedated and paralyzed ICU patients to prevent permanent neurological damage in an ICU setting.

FILTERING PROCEDURE

Final score = 13.5

Rank = 8

MARKET POTENTIAL

All patients on sedatives and muscle relaxants run the risk of having seizures that go undetected and thus incur the possibility of permanent neurological damage. In children, absent seizures are more common than in adults. Non-convulsive seizures are common during continuous EEG monitoring in critically ill children and were seen in 44% of patients in a study by Jette et. al..

Multiple studies confirm the importance of prolonged EEG monitoring in critically ill children as a means to detect non-convulsive seizures. [1] Epilepsy product global sales are expected to rise to $5.4 billion by 2022[2]. Although the market is extremely owned by pharmaceuticals, but the high risk during sedation still remains an unanswered requirement and recent devices have shown a shift in the market trend [3].

COMPETITIVE LANDSCAPE

In India the EEG machines approved for medical use can range from Rs. 150,000 for fixed devices to Rs. 120,000 for portable devices. However, the interpretation is also a problem since a neurologist is required at the moment.

There are a few solutions available to consumers and researchers in non-clinical settings such as Neurosky that is an EEG headset available for Rs 7,000. However, most of these devices are either unreliable or aren't clinically tested, and thus cannot be used in ICU settings for continuous monitoring.[4]

IDEAL SOLUTION STATEMENT:

An ideal solution should be at least as accurate and reliable as an EEG in identifying a seizure in a paralyzed patient in an ICU, while being easy to use with results interpreted by a non-neurologist.

NEED CRITERIA:

MUST HAVE:

- At least as accurate and reliable as an EEG in identifying a seizure in a paralyzed patient in an ICU
- Easy to use and interpretable by a non-neurologist
- Must alert clinicians in case of an episode

NICE TO HAVE:

- Can be used in adults and infants
- Non-Invasive

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9. DIAGNOSING MINUTE INTRACRANIAL HEMORRHAGE

INTRODUCTION

Intracranial hemorrhage (ICH, intracranial bleeding) is a serious medical emergency, accounting for more than 10% of stroke cases.[1] It is important to diagnose the bleeding early to minimize permanent-morbidity and mortality. CT and MRI scans are the current techniques to diagnose it. In many cases, bleeding can be extremely focused and minute, resulting in the misdiagnosis by the radiologist using the available scanning techniques.

OBSERVATION

A 65 year old female came to the Emergency department with altered sensorium, 4 episodes of generalized tonic clonic seizures, 2 episodes of loss of consciousness, urinary incontinence in the past 1 day, fever and ear ache associated with purulent discharge for the past 5 days treated in a private clinic. Altered behavior was also noted, including incoherent speech and chanting loudly at night. She was a known case of hypertension and bronchial asthma on therapy. ENT consultants suspected a diagnosis of an Acute Otitis Media (middle ear infection) with intracranial complications in the form of meningitis. On examination her blood pressure was found to be 146/64, with a pulse rate of 104. The patient was intubated and immediately moved to the ICU. An initial dose of antiepileptic medication was administered intravenously for the seizures. To reduce intracranial pressure, lumbar CSF drainage procedure was planned. A CT scan was done too, and was interpreted by the radiologist to have no signs of impending herniation. The lumbar procedure was done and pressure was released by draining 30ml of the cerebrospinal fluid. The neurologist on follow up observed that the patient had had a twitching of her eye and diagnosed seizures. The patient was having recurrent seizures but due to sedation they was missed by the intensivists. A second anti-convulsant was added on. Approximately 6-7 hours later the patient began to develop clinical signs of herniation of the brain stem. An emergency CT scan was done which confirmed the herniation. The seizures continued and a 3rd antiepileptic was added. The initial CT was reinterpreted and confirmed the presence of bleeding within parenchyma of the brain but was missed by the radiologist. The patient desaturated and expired due to respiratory insufficiency and cardiovascular collapse the next day.

CURRENT PROBLEM

Intracerebral hemorrhage is a medical emergency, demanding immediate treatment as it can cause severe brain dysfunction or lead to mortality. Currently, imaging tests such as CT, MRI or Cerebral Angiography are performed to confirm the symptoms found in neurological examinations. Interpreting the CT, usually conducted as the first test to confirm the hemorrhage, can be challenging when there is minute bleeding and often, the timely and correct diagnosis can be missed leading to complications.

NEED STATEMENT

An accurate way to detect minute abnormalities (bleeding, ischemic changes) in the brain that are missed on CT and MRI for accurate diagnosis and management at a tertiary care setting.

FILTERING PROCESS

Final score = 13

Rank = 9

MARKET POTENTIAL

Incidence of intracerebral haemorrhage is 12-15 cases per 100,000 per year through the world, and mortality is higher in ICH cases (approx. 50%) as compared to ischemic stroke.[2] Population based studies have shown that most patients present with small ICH can be easily saved with prompt medical care. Quick diagnosis and management plays crucial role in preventing the case from worsening.

COMPETITIVE LANDSCAPE

Computed Tomography (CT) scan: CT scan creates images of the brain using X-ray technology, and can confirm bleeding along with assessing other evidence of trauma to the head. CT is the most commonly performed technique in the emergency evaluation of patients with suspected or known ICH. [3] A CT machine can cost INR 50Lakh - 1.5Crore in Indian settings depending upon which versions are being used and per scan, the amount charged to patient can vary from Rs. 3,000 – 8,000.

Magnetic Resonance Imaging (MRI) scan: An MRI scan helps the doctor see the brain more clearly to better identify the cause of the bleeding. MRI is increasingly being performed in the emergency department to evaluate brain injury extent, and has been shown to be more sensitive than CT in the detection of small foci of intracranial haemorrhage.[4] In most Indian settings, an MRI scan can cost around 8000-10000 INR. An MRI machine can cost between 1.5-2.5 Crore INR and per scan cost to patient can be anywhere between 1,500 – 25,000 INR, depending upon the body part being tested and the area in which the test is conducted.

IDEAL SOLUTION STATEMENT

Ideally, the minutest of bleeding should be detected in the brain by performing the diagnostic test. The solution should be non-surgical and easily interpretable by a radiologist.

NEED CRITERIA

MUST HAVE:

- Ability to diagnose the minutest of intracranial bleedings
- Easy to interpret
- Quick to diagnose
- Non-surgical method
- Cost to the patient should be under INR 8,000

NICE TO HAVE:

- Portable
- Non-invasive method
- Cost to the buyer should be within INR 10 lakhs
- Any trained technician should be able to perform the scan
- Cost to the patient under INR 5,000

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10. PLEURAL EFFUSION & THORACOCENTESIS

INTRODUCTION

A pleural effusion is an abnormal collection of fluid in the pleural space, usually resulting from excess fluid production and/or decreased lymphatic absorption. It is the most common manifestation of pleural disease, and its etiologies range in spectrum from cardiopulmonary disorders and/or systemic inflammatory conditions to malignancy[1].

OBSERVATION

A 65-year-old patient was admitted to the emergency department with complaints of respiratory distress and low oxygen saturation. The patient was critical and immediately after admission went into cardiac arrest. CPR (Cardiopulmonary resuscitation) was initiated and the patient was stabilized after 4 sets of CPR. Post stabilization the patient was intubated for respiratory support and admitted to the ICU. A physical examination revealed a swelling on the right anterior inferior thorax. A CT scan revealed a fluid collection adjacent to the right lower lobe of the lung in the pleural space. A pleural tap was planned to remove the fluid and executed without any adverse incident. Post-procedure the patient's saturation dropped rapidly. An emergency X-ray was done to identify the lung condition and revealed a collapse of right lung. It was inferred that during the pleural tap procedure the needle accidently went too deep, beyond the pleura, causing a tension pneumothorax and the subsequent pressure lead to lung collapse. A chest tube was placed to drain the pneumothorax. The patient's condition worsened the next morning with visible asymmetry on the left side of chest. On follow up, an X-ray determined that the ET (Endotracheal) tube was dislodged and moved distally into the esophagus causing the collapse of the left lung. An emergency extubation was executed followed by re-intubation. The pneumothorax induced by the chest tube placement led to increased cost to the patient and additional days in the ICU.

CURRENT PROBLEM

Tapping the pleural effusion is one of the fastest ways to provide immediate relief. But the chest tube if inserted beyond the optimum depth can penetrate through the pleura and cause a tension Pneumothorax. Although an ultrasound guided procedure reduces the incidence compared to a blind one, pneumotharoax remains one of the complications and is a clinical emergency.

NEED STATEMENT

A safer way (ensuring accurate position and optimum depth) to tap pleural effusion in order to avoid the development of a pneumothorax in patients in a tertiary healthcare setting.

FILTERING SCORE

Final score = 13

Rank: 10

MARKET POTENTIAL

Pleural effusion is a common presentation in any emergency setting. It may be transudative or exudative. Transudative pleural effusion are seen in Congestive heart failure, Cirrhosis (hepatic hydrothorax), Atelectasis, Hypoalbuminemia, Nephrotic syndrome, patients receiving dialysis etc. [1]

Exudative pleural effusions are seen in tuberculosis, malignancies, Pulmonary embolism, Collagen-vascular conditions (such as rheumatoid arthritis, pancreatitis and trauma). [1]

The numbers though not available for the disease state in India can be inferred to be high. For example India has far more cases of tuberculosis than any other country in the world - about 2.79 million new cases each year and accounts for nearly one third of prevalent cases globally[2] and is a significant cause of pleural effusion, seen in 23.5% of TB patients.[3] Thus approximately 660,000 new cases per year are seen in the Indian setting.

Pneumothorax is seen in 11% of chest tube placements (Thoracentesis) [4,5] thus if applied to the tuberculous pleural effusions alone would work out to approximately 66,000 complications every year.

The other complications include Hemothorax (0.8%), Laceration of the liver or spleen (0.8%), Diaphragmatic injury, and Empyema.

COMPETITIVE LANDSCAPE

Thoracentesis: Therapeutic thoracentesis is used to remove larger amounts of pleural fluid to alleviate dyspnea and to prevent ongoing inflammation and fibrosis in parapneumonic effusions. Three key factors are to be kept in mind. Remove fluid during therapeutic thoracentesis with a catheter, rather than with a needle, introduced into the pleural space. Various specially designed thoracentesis trays are available commercially for introducing small catheters into the pleural space. Alternatively, newer systems using spring-loaded, blunt-tip needles that avoid lung puncture are also available. Second, close monitoring of oxygenation is important. Third, removing only moderate amounts of pleural fluid to avoid re-expansion pulmonary edema and to avoid causing a pneumothorax. Removal of 400-500 mL of pleural fluid is often sufficient to alleviate shortness of breath. The recommended limit is 1000-1500 mL in a single thoracentesis procedure. The tube itself costs less than Rs. 500 and the procedure is generally inexpensive. However, Ultrasound guidance and manometers as mentioned in the guidelines are not available in all clinical settings.

Tube thoracostomy (chest tube): Complicated parapneumonic effusions or empyemas require drainage by tube thoracostomy. Traditionally, large-bore chest tubes (20-36F) have been used to drain the thick pleural fluid and to break up loculations in empyemas. However, they are not always well tolerated by patients and are difficult to direct into the pleural space. Small-bore tubes (7-14F) inserted at the bedside or under radiographic guidance have been demonstrated to provide adequate drainage.

Pleural drain: For recurrent pleural effusions a drain may be inserted.

Pleurodesis: Pleurodesis (also known as pleural sclerosis) involves instilling an irritant into the pleural space to cause inflammatory changes that result in bridging fibrosis between the visceral and parietal pleural surfaces, effectively obliterating the potential pleural space.

The most common procedure in India is thoracocentesis but for the other procedures as well, when indicated, additional radiographic expertise and equipment is uncommon. This tends to lead to a higher rate of complications as compared to the West.

IDEAL SOLUTION STATEMENT

The ideal solution should be an easier way to tap a pleural effusion by going to the optimum depth in the thoracic cavity, drain the optimum amount of fluid while monitoring the patient. Given the frequency of the problem in India, the solution should be implementable at lower healthcare settings as well. Although in the current referral network the vast majority of pleural effusions will be dealt with in the tertiary care centers.

NEED CRITERIA

MUST HAVE

- Ensure that only the pleural cavity is accessed and no further
- Ensure that the right amount of fluid is aspirated
- Avoid infections and mechanical complications
- Should not require additional complex equipment such as ultrasound and manometers

NICE TO HAVE

- Indicated in both transudative and exudative pleural effusions
- Low skill requirement and clinicians at lower healthcare center should be able to perform the procedure.

REFERENCES

1. Karkhanis, Vinaya S., and Jyotsna M. Joshi. "Pleural effusion: diagnosis, treatment, and management." Open access emergency medicine: OAEM 4 (2012): 31.
2. https://www.tbfacts.org/tb-statistics-india/
3. Zhai, Kan, Yong Lu, and Huan-Zhong Shi. "Tuberculous pleural effusion." Journal of thoracic disease 8.7 (2016): E486.
4. Complications Associated with Thoracocentesis· Michael G. Seneff, M.D.; R. WiUiam Conoin~ M.D.; Louis H. Gold, M.D. and Richard S. Irwin, M.D., F.C.C. CHEST/90/1/JULY. 1986.