Evaluation of cognitive and functional status among survivors of sepsis in a tertiary care hospital in South India (CAFDASS)

A dissertation submitted in partial fulfilment of the rules and regulations for MD General Medicine examination of the Tamil Nadu Dr.M.G.R Medical University, Chennai, to be held in May 2020

Registration Number: 201711456

DECLARATION

This is to declare that this dissertation titled **"Evaluation of cognitive and functional status among survivors of sepsis in a tertiary care hospital in South India (CAFDASS)"** is my original work done in partial fulfilment of rules and regulations for MD General Medicine examination of the Tamil Nadu Dr. M.G.R. Medical University, Chennai to be held in May 2020

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CERTIFICATE

This is to certify that the dissertation entitled, **"Evaluation of cognitive and functional status among survivors of sepsis in a tertiary care hospital in South India (CAFDASS)"** is a bona fide work of Dr. George Abraham Ninan towards the partial fulfilment of rules and regulations for MD General Medicine degree examination of the Tamil Nadu Dr. M.G.R. Medical University, to be conducted in May 2020.

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https://www.slideshare.net/Aalisheer/a-rational-approach-to-fluid-therapy-in-sepsis20160403
https://arxiv.org/pdf/1609.07214
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670798/

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Contents

ABBREVIATIONS

APACHE	Acute Physiology and Chronic Health Evaluation
ARDS	Acute respiratory distress syndrome
BCRS	Brief Cognitive rating scale
DVT	Deep venous thrombosis
GCS	Glasgow Coma scale
ECOG	Eastern Cooperative oncology group
HDU	High dependency unit
HRQOL	Health related quality of life
ICU	Intensive care unit
IQR	Interquartile range
IRB	Institutional review board
MODS	Multiple organ dysfunction syndrome
MRS	Modified Rankin Score
OPD	Outpatient department
PaO2	Partial pressure of oxygen
QALY	Quality adjusted life years
QOL	Quality of life
RetroBCRS	Retrospective Brief Cognitive rating scale
SF-36	Short form health survey 36 questionnaire
SIRS	Systemic inflammatory response syndrome
STROBE	Strengthening Reporting of Observational studies Epidemiology
SOFA	Sequential organ failure assessment
WHO	World health organization
WHODAS-2	World health organization disability assessment schedule 2

List of tables:

List of Figures:

1. Introduction

Sepsis is a life-threatening state and continues to be a major challenge for health care institutions. Sepsis syndrome is a frequent cause of intensive care admissions and may even develop in patients admitted to the ICU for other reasons. There has been decrease in in-hospital mortality rate of patients admitted with sepsis from 27.8 percent during the period 1979 through 1984, to 17.9 percent during the period 1995 through 2000. Thus, despite favorable mortality outcomes, an accurate reflection of treatment success of a sepsis survivor depends on the person's ability to get back to normal life and activity. This not only depends on his physical function but also mental alertness and cognitive capabilities.

In this study we defined sepsis as is described below according the Sepsis 3 guidelines. Various scales have been used to measure the Health-related quality of life of the patients and in this study WHODAS-2 and BCRS questionnaire were used to assess function at first and subsequent follow up reassessment among survivors of sepsis at 3 months. Through this study we hope to estimate quality of life through cognitive and functional domains following a critical illness and to evaluate the risk factors which pre-dispose to worse outcomes

2. Aim

Aim of this study is to evaluate the cognitive Impairment and Functional Disability Among Survivors of Sepsis

3. Objective

3.1 Primary objective

Primary objective of this study is to measure the change in cognitive function and functional ability in survivors of Sepsis up to 3 months after discharge.

3.2 Secondary objective

Secondary objective of this study is to compare outcomes in both groups and identify factors which may have contributed to poorer outcome.

4. Review of literature

Sepsis is a life-threatening state and continues to be a major challenge for health care institutions across the globe. Sepsis syndrome is a frequent cause of intensive care admissions and may even develop in patients admitted to the ICU for other reasons. The incidence of sepsis in the USA was found to be 3.0 cases per 1000 population(1), with mortality being high, ranging from 29%(1) to 72% (2) in several studies, which in turn depends on several factors including severity of the sepsis, number organs affected, age and pre-existing comorbidities (2,3). Patients with sepsis are also at risk for complications such as acute lung injury and multisystem organ failure (4). These complications further increase the mortality and morbidity associated with the illness.

Incidence of sepsis has increased over the past few years (5) in spite of major advances in health and supportive care over the years. There has been several changes in guidelines for definition and management of sepsis which has led to decrease in in-hospital mortality rate from 27.8 percent during the period from 1979 through 1984, to 17.9 percent during the period from 1995 through 2000 (4)

Following first year after admission in hospital for sepsis, mortality rates remain high, and the sepsis-associated risk for dying persists up to 5 years after discharge(6). This shows that despite the acuteness of the disease process, mortality persists for a number of years (7). Patients who either admitted with sepsis or who develop severe sepsis during hospital stay commonly end up with prolonged stay in the ICU and hospital due to multiple organ dysfunction and later sepsis-related disabilities. (8)

Thus, using the in-hospital mortality or the frequently used 28-day mortality indices may not be the ideal way to measure outcome. The mortality and morbidity of sepsis survivors are not accounted with these measures.

4.1 Definition of sepsis

Sepsis exists on a continuum of severity ranging from infection and bacteremia to sepsis and septic shock, which can lead to multiple organ dysfunction syndrome (MODS) and death. The definitions of sepsis and septic shock have rapidly evolved since the early 1990s (9,10). The reported incidence of sepsis is increasing (11) likely to be reflected from the aging populations, increased comorbidities, greater recognition,(12) and, in some nations, reimbursement/insurance favoring coding (13).

It was in 1991, that the consensus conference by American college of chest physicians developed initial definition of sepsis that focused on the prevailing view at that time, that sepsis resulted from a host's systemic inflammatory response syndrome (SIRS) to infection.

Bone et al (14) describes SIRS to have two or more of the following:

- Temperature >38°C or <36°C
- Heart rate >90/min
- Respiratory rate >20/min or PaCO2 <32 mm Hg (4.3 kPa)
- White blood cell count >12 000/mm3 or <4000/mm3 or >10% immature bands

Systemic inflammatory response syndrome (SIRS) is an inflammatory process which was independent of its cause. This systemic inflammatory response can be seen following a wide variety of insults and includes, more than one of the above mentioned clinical / investigational manifestations the systemic response is seen in association with a number of clinical conditions. Apart from the infectious insults, noninfectious pathologic causes can include pancreatitis, ischemia, extensive trauma and tissue injury, hemorrhagic shock, immune mediated injury, and the exogenous administration mediators of the inflammatory process as tumor necrosis factor. The following diagram encompasses the above-mentioned salient points and helps to identify the subset sepsis is an overlap between infectious etiology with systemic inflammatory response syndrome. (14)

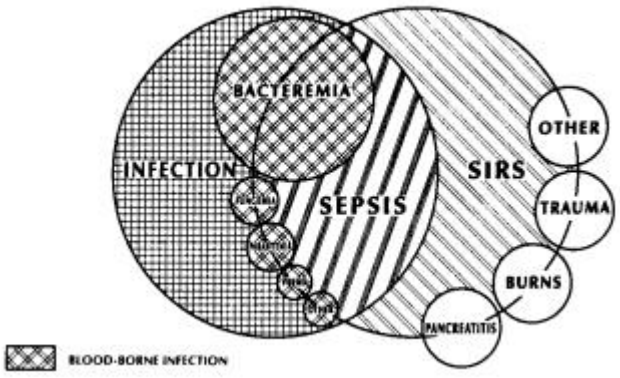

Figure 1 Sepsis as an overlap between infectious aetiology with systemic inflammatory response syndrome

Frequently SIRS is complicated by the development of organ system dysfunction, which includes clinical conditions such as acute lung injury, shock, renal failure. When more than one organ system was involved the term multiple organ dysfunction syndrome (MODS) was used.

From this consensus, it was gathered that sepsis when complicated by organ dysfunction was severe sepsis. This could progress to septic shock, which was defined as sepsis induced hypotension which persisted despite appropriate fluid resuscitation.

In 2001 a task force was set up after recognizing the limitations with these definitions. They attempted expanding the list of diagnostic criteria but could not offer alternatives because of lack of evidence(9). As a result of which the definitions of sepsis and septic shock remained unchanged for more than 20 years. However, they reviewed the strengths and weaknesses of the definition of sepsis and related conditions, while focusing on ways to improve them and to identify methodologies for increasing accuracy, reliability, and utility of the diagnosis of sepsis itself.

Apart from the clinical manifestations of systemic inflammation, which are protean, there are biochemical parameters of sepsis which may be more consistent. There have been studies which have detected elevated circulating levels of interleukin 6 (15), adrenomedullin (16), soluble CD14, soluble endothelial cell/leukocyte adhesion molecule 1, macrophage inflammatory protein 1α (17), extracellular phospholipase A2 (18),and C-reactive protein (19) in patients who meets the SIRS criteria proposed in 1992. This leads to possibilities of aided biochemical and immunological parameters, rather than clinical criteria alone, to identify the systemic inflammatory response.

There were limitations in the definition of SIRS as mentioned above. Task force set up in 2001 designed and set up an exhaustive list of possible signs of systemic inflammation in response to infection which are listed below. (9)

General parameters

Fever (core temperature >38.3°C)
Hypothermia (core temperature <36°C
Heart rate >90 bpm or >2 SD above the normal value for age
Tachypnea: >30 bpm
Altered mental status
Significant edema or positive fluid balance (>20 ml/kg over 24 h)
Hyperglycemia (plasma glucose >110 mg/dl or 7.7 mM/l) in the absence of diabetes

Inflammatory parameters

Leukocytosis (white blood cell count >12,000/µl)
Leukopenia (white blood cell count <4,000/µl)
Normal white blood cell count with >10% immature forms
Plasma C reactive protein >2 SD above the normal value
Plasma procalcitonin >2 SD above the normal value

Hemodynamic parameters

Arterial hypotension[b] (systolic blood pressure <90 mmHg, mean arterial pressure <70, or a systolic blood pressure decrease >40 mmHg in adults or <2 SD below normal for age)
Mixed venous oxygen saturation >70%[b]
Cardiac index >3.5 l min^{-1} m^{-2}[c,d]
Organ dysfunction parameters
Arterial hypoxemia (PaO_2/FIO2 <300)
Acute oliguria (urine output <0.5 ml kg^{-1} h^{-1} or 45 mM/l for at least 2 h)
Creatinine increase ≥0.5 mg/dl
Coagulation abnormalities (international normalized ratio >1.5 or activated partial thromboplastin time >60 s)
Ileus (absent bowel sounds)
Thrombocytopenia (platelet count <100,000/µl)
Hyperbilirubinemia (plasma total bilirubin >4 mg/dl or 70 mmol/l)

Tissue perfusion parameters

Hyperlactatemia (>3 mmol/l)
Decreased capillary refill or mottling

Figure 2 List of signs of systemic inflammatory response to infection developed by Sepsis Task force, 2001

This schema assisted experienced clinicians in looking for the physical and laboratory findings that could ascertain that an infected patient looked septic. It was imperative to identify symptoms and signs of early organ dysfunction and it was for this reason that findings such as hemodynamic instability, oliguria, arterial hypoxemia, coagulopathy,

and abnormal liver function tests were among the list of criteria. At the same time, it is also important to realize that none of the findings in above mentioned table was specific for sepsis. Hypotension could be caused by many conditions apart from sepsis, such as acute left ventricular failure secondary to myocardial infarction. Coagulopathy can be drug or toxin induced and is associated with many diseases, in addition to sepsis. This is where it becomes important for the practitioner to check off relevant boxes while making the diagnosis of sepsis such that only findings that cannot be explained by other etiology are included.

In 2001, task force designed by the international sepsis definition conference developed a classification scheme for sepsis (9). They called it **PIRO.** These stratified patients based on ***P****redisposing conditions*, the nature ***i****nsult*, nature and extent of host ***r****esponse*, and the degree of associated ***o****rgan dysfunction.*

Predisposition – Premorbid comorbidities have an immense impact on outcome in sepsis. It modifies both the disease process and even approach of therapy. The importance of genetic factors in determining the risk of mortality due to sepsis than in influencing the risk of death from other common conditions such as cardiovascular diseases was published by Gospodarowicz M in 1998 (20). Apart from the genetic factors, management of patients with sepsis and outcome from the same is also impacted by factors such as the premorbid health status and the reversibility of comorbid illnesses. It can also influence risks attributed for each of the different stages which includes infection, response, and organ dysfunction. This can benefit or be harmful which can be exemplified by the following. Immunosuppression may increase risk of infection and decrease the effect of inflammatory response and will have no direct

influence on organ dysfunction. Similarly, genetic polymorphism in *TNF2* allele may cause aggressive inflammatory which might decrease a risk of infection but increases the risk of extensive and harmful inflammatory response in case patient does get infected.

Infection - The location, extent and type of infection has significant impact on disease process and outcome. Randomized clinical trials for new antimicrobial agents as adjuvant therapy for of sepsis has shown that pneumonia and intra-abdominal source of infections were associated with higher risk of mortality. It also showed that secondary nosocomial bacteremia was associated with higher mortality than those of primary bacteremia at presentation which could be due to the virulence and antimicrobial resistance pattern of microbes in secondary infection (21). There is also evidence that host response to micro-organisms vary and this was demonstrated by Opal et al who showed clinical response to gram-positive organisms differs from that evoked by Gram-negative organisms (22). Studies conducted by Ziegler et al (23) and Wolter et al (24) wherein they used antibodies directed against endotoxin suggested that there is benefit in patients with Gram negative infection.

Response – Assessing, characterizing and treating the host response rather than infecting organisms have been the paradigm shift in treatment of sepsis. Various biological markers of response severity have been studied and have been mentioned above which include circulating levels of procalcitonin (25) interleukin 6 and many

others. The search for new mediators with epidemiological studies determining whether measurements of the compound will be useful clinically for assessing response or for staging severity of sepsis in patients and underway. The usefulness of these biological markers on deciding therapeutic options are also considered. For example, Bernard et al (26) used dysregulation of coagulation system as an indicator for making a decision about instituting therapy with activated drotrecogin, whereas hypotension as a marker of adrenal dysfunction can be useful for determining need for instituting treatment with hydrocortisone (27).

Organ dysfunction – One of the major determinants of prognosis associated with sepsis is the severity of organ dysfunction (28). Whether this severity of organ dysfunction can aid in therapeutic classification of sepsis is doubtful. However, evidence exists that neutralization of tumor necrosis factor which is an early mediator of the inflammatory cascade is better effective in patients prior to significant organ dysfunction (29), whereas activated drotrecogin provide additional benefit in patients with greater disease burden (30). Various organ failure scores have been developed which help quantitatively describe the degree of organ dysfunction developing and help in assessing the course of critical illness.

The potential of proposed PIRO system mainly lies in its ability to distinguish morbidity secondary to infection from morbidity secondary to *response* to infection. Tailored intervention to response and infection can be attained using this as basis as treatment to

response may adversely affect the ability of the body to contain an infection and conversely treatment targeting infection are unlikely to be benefit if the morbidity is driven mainly by host response. Premorbid status helps establish a baseline, while organ dysfunction keeps the prognosis at check.

The PIRO system proposed by the task force in 2001 was a work in progress and they advised it to be used adapted as a model and applied to practice. It will require evaluation of the natural history of sepsis to define variables that predict adverse outcomes and response to therapy.

Recognizing the need for redefinitions, the European Society of Intensive Care Medicine and the Society of Critical Care Medicine convened a task force in 2014 (10). It included 19 specialists from critical care, surgical, infectious disease and pulmonary specialists. With unrestricted funding and complete autonomy, the task force nominated cochairs and selected members according to scientific expertise in various fields of sepsis including epidemiology, clinical trials and basic sciences. The group engaged in discussions via 4 face-to-face meetings for a year duration till January 2015. Existing definitions were challenged, especially in light better appreciation of pathophysiology of sepsis and the availability of comprehensive electronic health record databases. They followed an expert consensus process, based on a current knowledge of sepsis, changes in organ function, biochemistry, immunology and circulation and forged updated definition for sepsis and criteria to be tested in the clinical field.

The previous use of 2 or more of the SIRS criteria to identify sepsis was unanimously decided by the task force to be not helpful. Components of the SIRS criteria including temperature, changes white blood cell counts and heart rate reflected the host response to “danger” which could be from infection or other insults. These did not necessarily imply a dysregulated response according to the task force. Construct validity encompasses two main domains, concurrent validity and discriminant validity. Churpek et al (31) showed that SIRS criteria present in many hospitalized patients, including those who never developed infection and also did not have any adverse outcomes. This highlighted the poor discriminant validity of the SIRS criteria. In addition to this, Kaukonen et al (32) showed that 1 in 8 patients admitted in intensive care centers in Australia and New Zealand with infection and features of new organ dysfunction did not meet the requisite minimum of 2 SIRS criteria, yet had their course of therapy complicated with significant morbidity and mortality, and highlighted the poor concurrent validity.

Organ dysfunction and severity has been assessed with various scoring systems which uses different variables. Differences in these systems have led to inconsistent reporting. The most widely used score in current practice is the Sequential Organ Failure Assessment (SOFA) (33) which is mentioned below.

Table 1 Components of SOFA score

Sofa score	0	1	2	3	4
Respiration Pao2/Fio2 or Sao2/Fio2	>400	<400 221-301	<300 142-220	<200 67-141	<100 <67
Renal Creatinine Urine output	<1.2	1.2-1.9	2.0-3.4	3.4-4.9 <500	>5 or <200
Liver bilirubin (mg/dl)	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12
Cardiovascular Hypotension	No Hypotens ion	MAP<70	Dopamine </=5 or Dobutamin e (any)	Dopamine >5 norepineph rine </=0.1	Dopamin e>15 or norepinep hrine>0.1
CNS (GCS)	15	13-14	10-12	6-9	<6
Coagulation (platelet counts)	>150	<150	<100	<50	<20

SOFA score was directly related with probability of mortality which was demonstrated by Vincent et al. (33). The score requires laboratory variables like platelet count, PaO2, bilirubin levels and creatinine level for full computation and it grades the severity by organ system. However, selection of cutoff values for the variables mentioned above were developed by consensus. SOFA scoring system is not known outside the critical care community.

Following the convention of task force, the third consensus definition of Sepsis was formed. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. With this definition they were able to emphasize the importance of non-homeostatic host response to infection. They highlighted the lethality associated with sepsis which was considerably larger than that of a straightforward infection. With this the need for urgent recognition as a life saving measure was emphasized. Organ dysfunction associated with infection was associated with mortality of 10% within hospital as already mentioned earlier. Hence prompt recognition and appropriate response was of immense importance. The earlier defined SIRS criteria as main pillar in definition of sepsis will only help in the diagnosis of infection. SIRS may just reflect an appropriate host response. Sepsis associated organ dysfunction indicates pathology more severe than infection with its inflammatory response alone. The task force explained that organ dysfunction was secondary to that cellular level defects which led to physiologic and biochemical abnormalities. Using

this concept, they disregarded the definition of severe sepsis as any sepsis should warrant higher levels of intensive monitoring and earl intervention.

The task force recognized that there were no current clinical measures that encompassed the dysregulated host response. However, there were bedside findings and laboratory investigations results which was indicative of inflammation or organ dysfunction as noted by the 2001 task force (9). The third task force thus evaluated which of the clinical criteria would be best to identify patients likely to have sepsis. They achieved this objective by interrogating large data sets of hospitalized patients with presumed infection and assessing agreement among existing scores of inflammation (14) or organ dysfunction using SOFA (28,33). Then multivariable regression was used to study the variables proposed by the 2001 task force, which included 21 bedside and laboratory criteria (9). Seymour et al (10) studied 148 907 patients with suspected infection treated in hospital setting and assessed outcomes of hospital mortality and prolonged intensive care stay of 3 days or longer. They assessed predictive validity of both overall and across deciles of baseline risk as determined by age, sex, and comorbidity. Following analysis of the results of the study the task force recommended using a change in baseline of the SOFA score of 2 points or more to represent organ dysfunction. They laid down that the baseline SOFA score would be assumed to be zero unless the patient is known to have organ dysfunction before the onset of infection. They gathered that patients with presumed infection and a SOFA score of 2 or more had an overall mortality risk of 10% (10). The same study also identified a 2- to 25-fold increased risk of dying in patients with SOFA score of 2 or greater compared with patients with a

SOFA score less than 2. The SOFA score should be used to clinically characterize a septic patient and not as a tool for patient management. There are components of SOFA requiring laboratory investigations and may not immediately delineate dysfunction in all individual organ systems. However, SOFA has gained familiarity within intensive care setting and its relationship to mortality risk is well validated. The task force also noted a limitation that there are novel biomarkers to identify variables used in SOFA, but were refuted as these would require broader validation before they can be incorporated into criteria.

A clinical model was developed using multivariable logistic regression and identified that any 2 of the following three variables— Glasgow Coma Scale score of 13 or less, respiratory rate of 22 per minute or greater and systolic blood pressure of 100 mm Hg or less—offered predictive validity (AUROC = 0.81; 95% CI, 0.80-0.82) similar to that of the full SOFA score (10). This model was then subjected to multiple sensitivity analyses where in more simple assessment of mentation were undertaken. Using this they identified qSOFA score which could be calculated quickly and repeatedly and is mentioned below,

Quick Sepsis-related Organ Failure Assessment (qSOFA) criteria:

- Hypotension: SBP < 100mmHg
- Altered Mental Status
- Tachypnea: RR > 22/Min

It had the advantage of mot requiring interventional laboratory investigations. The task force hence suggested to utilize qSOFA criteria as a screening tool to prompt clinicians to further investigate for organ dysfunction, increase the frequency of monitoring, intensive care admission or early referral to centers with the same. The task force also noted that a positive qSOFA criteria should further prompt lookout for possible infection in patients not deemed infected.

Septic shock is defined as a subset of sepsis in which underlying circulatory and cellular metabolism abnormalities are profound enough to substantially increase mortality. The 2001 task force definitions described septic shock as "a state of acute circulatory failure." But this could not separate cardiovascular dysfunction from septic shock. The third task force hence had a wider view and also recognized the importance of cellular abnormalities. Septic shock was a more severe illness with a mortality rates reaching 40% as mentioned earlier. To encompass cellular level dysfunction the task force recognized the role of that serum lactate measurements and coupled this finding along with hypotension. Clinical criteria for septic shock were then developed with hypotension and hyperlactatemia rather than either alone as this ensured cellular dysfunction and cardiovascular compromise were given significant weightage and was also found to be associated with a significantly higher mortality. They used Delphi system for approval and this proposal was approved by the majority but with certain limitations.

The latest update on definitions and clinical criteria for sepsis was proposed in the above mentioned Third sepsis international sepsis guideline task force. Using qSOFA as a screening and SOFA score to facilitate earlier recognition, it was expected that more timely management of patients with would develop and this would help in reducing the mortality associated with the same. The new definition is designated Sepsis-3, with the 1991 and 2001 iterations being recognized as Sepsis-1 and Sepsis-2, respectively, to emphasize the need for future iterations.

4.2 Morbidity associated with sepsis

The mortality associated with sepsis, including severe sepsis and septic shock, has been demonstrated till now. However, this leaves the survivors who continue to die in the next few months after hospital discharge unaccounted for. The decrements in quality of life of patients following admission with sepsis over long-term will also be overlooked by following only mortality as end outcome of sepsis. Studies have been conducted through different patient population, varying severity of illness and across national borders, looking at the morbidity and quality of life among survivors, and although the magnitude varied from study to study, results were consistent within randomized controlled trials to observational trials. Meta-analysis conducted by Dowdy et al (34) showed the impact of an admission with Acute respiratory distress syndrome (ARDS) had on long term follow up. This study showed that ARDS survivors experience persistent quality of life decrements following discharge and the magnitude of this decrement, which was measured using questionnaire SF-36 as used in various studies,

amounted to mild to moderate limitation in physical functioning and it was less pronounced for mental health. These results have implicated the need for future clinical research studies as ARDS is just a prototype of severe critical illness, representing a multifactorial syndrome experienced by patients with prolonged ICU stay. Many studies conducted nowadays still tend to focus on shorter end points, at hospital discharge or typically at 28 days, especially for mortality. From conclusions gathered above it is becoming clearer that such short-term end points are not clear predictors of ultimate effect of these conditions, and is of no value without assessing quality of life and other measures which are seen on the rise, such as the incidence of cognitive dysfunction, post-traumatic stress disorder, critical illness polyneuropathy and chronic pulmonary dysfunction. The definition of long-term outcome is also dubious as there is no uniform definition for the same and many assume three to six months as a long enough time period wherein the functional and cognitive status remain stable. However, patients persist to be impaired longer after discharge. It is even interesting to note that, an acute admission with disease like sepsis showed similar decrease in quality of life measurements across varied scales, over the long-term, when compared to a chronic disease, such as chronic obstructive pulmonary disease or congestive heart failure (35). These findings can be extrapolated to sepsis, as it is the most common cause of an acute lung injury (11). There have been systematic reviews which have showed impairment in quality of life as long-term outcomes of patients following acute respiratory distress syndrome. At least 40% of patient with sepsis syndrome develop acute lung injury (36) and this overlap makes it difficult to delineate the extent to which long-term disability is the effect of sepsis, acute lung injury or both.

Now having established that sepsis survivors indeed have a diminished quality of life, it becomes imperative to establish the domains that are affected and the extent to which it is affected. Apart from the obvious physical disability, they are also at increased risk of new cognitive impairments as well as functional limitations later on in life. This was first demonstrated by Iwashyna et al (11) in the follow up of nation-wide cohort of severe sepsis survivors and assessing their physical, cognitive and functional well-being following discharge. This study reported that there was three times odds ratio for development of moderate to severe cognitive impairment following severe sepsis and furthermore, it was also independently associated 50% increase in new onset functional limitations in patients who previously had none or mild pre-existing limitations. These findings were significantly larger when compared to admissions after non-sepsis aetiology. Change in sleeping pattern, reduced ability to concentrate and fatigue are also previously described features in patients who have survived critical care therapy. These factors could also explain the slow return to work of critically ill patients following discharge. Studies have showed women returned to employment quicker than their male counterparts (37), which may be a reflection of the nature of the work undertaken by each gender.

There have been various theories on how sepsis results in decline of cognitive and physical function. Causal effect of sepsis resulting in motor weakness and later physical disability have been established through various studies which have showed critical

illness polyneuropathy and myopathy occurring as a result of hypoperfusion mediated and direct inflammatory degradation of neurons and muscle fibres (38,39). This when coupled with lack of physical therapy and prolonged bed bound status results in severe impairment in quality of life. The effect of the same hypotension and relative hypoperfusion on cognitive impairment due to brain injury have also been established (40,41). Apart from sepsis related hypotension, inflammation per say, which is the most important component in the pathophysiology of sepsis, has also been hypothesized to result in cognitive impairment in form of vascular dementia and Alzheimer disease (42). Sepsis have also been implicated in causing episodic inattention, an acute form of brain dysfunction or delirium (43). Apart from association with increased mortality during admission, delirium has also been associated with prolonged cognitive impairment in ventilated patients (44) and substantially increased cognitive decline among patients diagnosed with Alzheimer disease (45,46). Furthermore, patients who have survived severe sepsis have also been found to have an increased rate of depression after hospitalization (47). Thus sepsis alone may also have significant, unappreciated, long-term consequences secondary to deleterious effects on multiple organ systems, especially the CNS, which could be the by the pathogenetic mechanisms of the organism itself or the host's immune responses (48). Further biological research is clearly warranted to establish the pathophysiology of cognitive and functional decline, but the associations are evident through multiple studies showing similar results within the biological plausibility. Equally demanding is the need of clinical trials with sepsis directed therapy and better rehabilitation and how the impact on long-term cognitive and functional outcomes (49).

From data published in United States on incidence of dementia (50) and sepsis (1), nearly 20,000 new cases per year of cognitive impairment in the elderly may be attributable to sepsis. Thus, sepsis may just be a sentinel event in the lives of these families and the new persistent disability as a result of this insult is a an underrecognized public health problem with vicious insinuations on the patients, families and health care system. The burden of sepsis survivorship extends beyond caregiver time and also leads to depression, nursing home admission and even mortality (51,52). Langa et al (51) estimated that further 40 hours per week of informal care has to be provided by members of family for attending a severe cognitively impaired individual which is equivalent to an additional full-time job. Considering that onset of cognitive impairment in sepsis or its acceleration following an admission is preventable in many patients, as compared to Alzheimer disease and other forms of dementia, this additional burden on the society has to be addressed. This can be achieved by raising the standard of treatment of patients admitted with sepsis, including intensive care unit practices such as sedation management, and special emphasis on physical and cognitive rehabilitation.

4.3 Quality of life after sepsis

It is evident from this background that assessment of quality of life is an important outcome after critical illness (53,54). Even the converse has been proved to be significant. Poor quality of life prior to intensive care admission may even predict a worse outcome (55). This becomes important as providing intensive care treatment to patients who have poor prognosis is accompanied by a financial, physical and emotional

burden for patients and relatives. Furthermore, intensive care settings and resources are scarce in developing countries and there might be need in identifying those patients who will probably survive an admission which allows to make better use available resources (56). This decision making must extend beyond clinical experience and as the predictive value of this regard is limited (57). This has led to development of pre-admission health related quality of life assessment, which can be done with the single-item questionnaires such as SF-36 which included physical and mental domains. But the value in clinical practice of using such questionnaires and scoring system such as APACHE II score to provide useful predictive information is inadequate, because of the limitations to predict survival and mortality in each individual case.

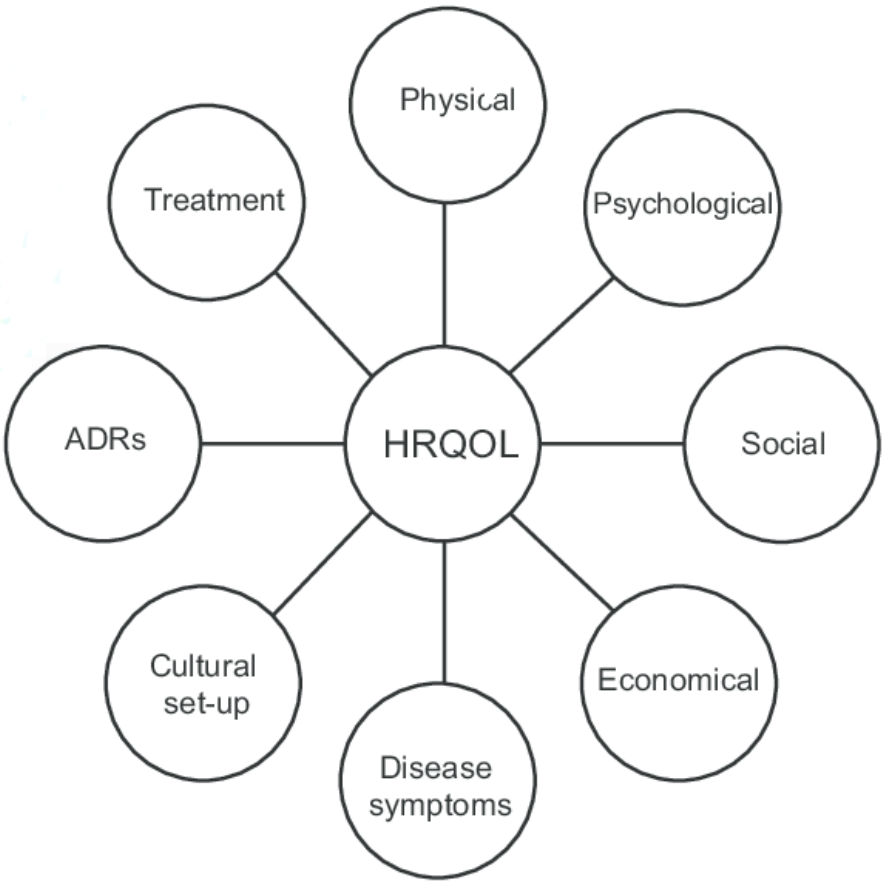

Figure 3 Factors affecting health related quality of life. Adapted from Patient-reported outcomes: A new era in clinical research - Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/figure/Factorsaffectinghqrl

Health related quality of life is an umbrella term encompassing multiple variables as shown above in figure 3. Most studies involving QOL in the patients admitted in intensive care unit (ICU) were studied within a period of 6 months to 1 year following hospital discharge (37,58,59). But again, an optimal time for assessment of long-term outcome and ideal questionnaire with which to measure QOL are still doubtful (60). This is because early assessment will be troubled with practical difficulties. Longer follow up results in increased loss of follow up and hence an assessment at 3 months sounds ideal in the evaluation of discharge related morbidity and this also paves the way for early intervention if warranted. Study done by Eddleston et al (37) showed that approximately 10% of the patients discharged following critical care admission had psychological derangements requiring specialist care. It was also noted that none had a relevant premorbid history and rates among female patents were numerically but not statistically higher than males.

A quality-adjusted life year (QALY) comprises length of life and QOL. The concept of QALY enables comparisons of the efficacies of different treatments and calculations of costs per one QALY. There are different ways to objectify the cost associated with the treatment provided and life years attained in the process. Most common scales used are cost effective analysis and cost utility analysis. Cost-effectiveness analysis measures benefits of treatments in terms of the number of years of lives saved. Cost-utility analysis measures treatments using a number of QALYs as a unit of efficacy (61).

Measuring QALY itself is a tedious process and can only be attained through various other indirect measurable indices. Physical and cognitive functioning are major determinants and various studies have used these domains to complement HRQL. In spite of the limitations assessing quality of life measures after a period of critical illness is gaining immense popularity. Various investigators have attempted variety of general outcome tools for studying the same and these include Nottingham Health Profile in conjunction with the Perceived Quality of Life questionnaire (France) (62), SF-36 (United Kingdom) (63) and Sickness Impact Profile (Netherlands) (64). Different tools used to measure and evaluate quality of life makes comparison between the studies difficult. Few of the tools rely largely on the functional status and give little attention to subjective satisfaction felt by the patients. Few questionnaires including SF-36 has been widely used and validated in various population, and there are more than 300 available studies from varied patient population groups including traumatic brain injury (65), critical care (63) and even patients following liver transplantation (66). In addition, one must not forget the practical difficulties faced while completing a QOL outcome questionnaire for previously critically ill patient as poor concentration, fatigue and manual dexterity are real entities causing troubling disabilities in communicating effectively.

4.4 Assessment of physical function

The World Health Organization (WHO) developed the International Classification of Functioning, Disability, and Health (ICF) with the aim to reach a universally accepted conceptual framework to define and classify disability (67,68). In the ICF, disability is described as *"a difficulty in functioning at the body, person, or societal levels, in one or*

more life domains, as experienced by an individual with a health condition in interaction with contextual factors" (69). With this biophysiological conceptual model of disability in mind ICF developed the World Health Organization Disability Assessment Schedule 2.0 (WHODAS-2) in 1998. There exists many other tools that were previously used to measure disability, such as the Functional Status Questionnaire, Functional Limitations Profile and Indexes of activities of daily living (ADLs) and a battery of other instruments which were established with focus on specific groups of population such as elderly (Late Life Function and Disability Instrument) and children (Functional Disability Inventory for children). However, they have not incorporated the biopsychosocial conceptual model developed by the ICF. WHODAS stands out with this respect and various studies have been performed to evaluate the metric properties of WHODAS-2 in different samples of population, such as arthritis (70), systemic sclerosis (71), psychotic disorders (72), stroke (73), ankylosing spondylitis (74), depression, patients in rehabilitation (75), among others. Health related quality of life of the patients have been measured by various questionnaires and most comprehensive one used is the Medical Outcome Survey Short Form-36 (SF-36) (59). There has also been other studies such as by Karlson et al which used the European Quality of Life 5-Dimensions (EQ)-5D assessment scale (76) to show a decline in function in sepsis survivors.

The WHODAS-2 contains 36 items on functioning and disability with a recall period of 30 days covering 7 domains: *Understanding and Communicating (6 items), Getting around (5 items), Self-care (4 items), Getting along with others (5 items), Life activities:*

household (4 items), Life activities: work/school (4 items), and *Participation in society (8 items)*. Response options go from 1 (no difficulty) to 5 (extreme difficulty or cannot do). WHODAS-2 scores are computed for each domain by adding the item responses (the score computation allows for up to 30% of missing items per domain) and transforming them into a range from 0 to 100, with higher scores indicating higher levels of disability.

The WHODAS-2, as designed for covering disability, measures the restrictions on daily life activities and social participation, while the Short form-36 Health Survey addresses patients physical and mental health. Study conducted by Garin et al (77) showed how the WHODAS-2 and the SF-36 measure different aspects of related concepts which are disability and HRQL, respectively and validated WHODAS-2 to measure disability better, which in turn reflects HRQL. This study confirmed the conceptual model of the WHODAS-2 and its ability to provide with good metric indices among patients with chronic conditions with very high reliability and also great ability to differentiate among known groups and adequate capacity to detect change over time. This supported the adequacy of the WHODAS-2 to measure disability in a wide range of mental and physical disorders. Feasibility of application of WHODAS-2 in critically ill patients was also suggested in this study by the low proportion of missing values which allowed easy completion for the wide range of patients. Majority of missing data was detected in the domain of activities attributed by work or school which could be explained by the proportion of patients neither working nor being students. However, the usage of best possible score in several domains raises the possible unsuitability of the

WHODAS-2 to differentiate among very low grades of disability. This was earlier shown by the high ceiling effect of the tool when applied to general population (78) but would hardly be a limitation when measuring disability in sample of patient population, but highlights the need for cautious handling of data. But this limitation would be overtaken by domain such as 'Participation in society' which merits comment. In the study conducted by Garin et al (77) no patient has the worst possible score in this domain which has been described as floor effect and represents the low ceiling effect. Implication of this result is that this domain is able to characterize a wide range of scenarios and is in fact reflective of the final common pathway in which disability is manifested in the societal context. WHODAS-2 is also able to detect differences between clinical-severity groups. Those patients with higher clinical severity were reported to have worse disability scores than those with mild clinical severity, with a large difference for most of the health conditions. Beside few domains where the discrimination ability was poor among severity ('Life activities household', 'Getting along with people' and 'Life activities work or school') WHODAS-2 was able to delineate the who were working at the time following admission from those who were not working due to their health condition.

4.5 Assessment of cognitive function

For the cognitive domain of the patients, Brief Cognitive Rating scale (BCRS) was used. The Brief Cognitive Rating Scale (BCRS) as devised by Reisberg & Ferris in 1988 was used to assess functional and cognitive abilities in both normal aging and progressive

dementia. The BCRS is part of the Global Deterioration Scale Staging System which is composed of three separate rating scales that include the GDS, the Functional Assessment Staging (FAST; Reisberg, 1988), and the BCRS. The BCRS provides objective ratings of a number of domains that include various cognitive functions as well as functional abilities, mood, and behavior, and is made up of two parts. Part I includes ratings for Concentration, Recent Memory, Remote Memory, Orientation, and Functioning and Self Care, while Part II allows for ratings of Speech and Language Abilities, Motoric Capacities, Mood and Behavior, Praxis Ability, Calculation Ability, and Feeding Capacity. Each of the domains is rated on a 1–7 point scale that ranges from normal (rating of 1) to profound impairment (rating of 7). For each domain, a behavioral anchor is provided for each point on the rating scale. Ratings are completed based on interviews with the patient and an informant who is knowledgeable regarding the patient's day-to-day activities and functioning.

Functional status at baseline was determined from historical cognitive assessment of the survivor from reliable informant using RetroBCRS scale which was a close adaptation of BCRS (Brief Cognitive Rating scale). The RetroBCRS requires an expert interviewer and was more structured than the original BCRS, but keeping the originality of BCRS developed by Reisberg & Ferris. The RetroBCRS has been modified to drop axes that require test performance (praxis, attention, calculation and concentration) and to modify other axes based on insights derived from clinical experience. The RetroBCRS was administered and validated by Rockwood et al (79) in their study, after which they concluded that a score of 4 and above was suggestive of Alzheimer's

disease, which showed severe cognitive impairment. Scoring was graded to delineate cognitive impairment into Mild, Moderate and Severe for the purpose of this study. This helped ascertain the baseline cognitive status of the patients. Follow up functional status assessment was evaluated using BCRS scale. This allowed for comparison of cognitive status and helped measure decline in cognitive function.

Prevalence of moderate/severe cognitive impairment in the community which was attributed to age related factors alone after ruling out dementia and other etiology such as psychiatric illnesses, strokes and alcohol consumption was researched. Few studies have quoted prevalence ranging from 5.3% to 7.4% (11,80,81). The burden of neurodegenerative disease on family, health care institutes and society are increasing, and it places heavy demand for their long-term care. Among the long-term-care population aged 65 and over studies have reported that 86·9% have clinically diagnosable dementia compared to 20% of elderly who were people living at home (81). This again confirms the notion that majority of people with mild dementia are living at home and those with sever disability are institutionalized. Even mild cognitive impairment was associated with functional disability and them being residing at institutions highlights public-health concern. As shown in figure below, dementia has been associated with various risk factors.

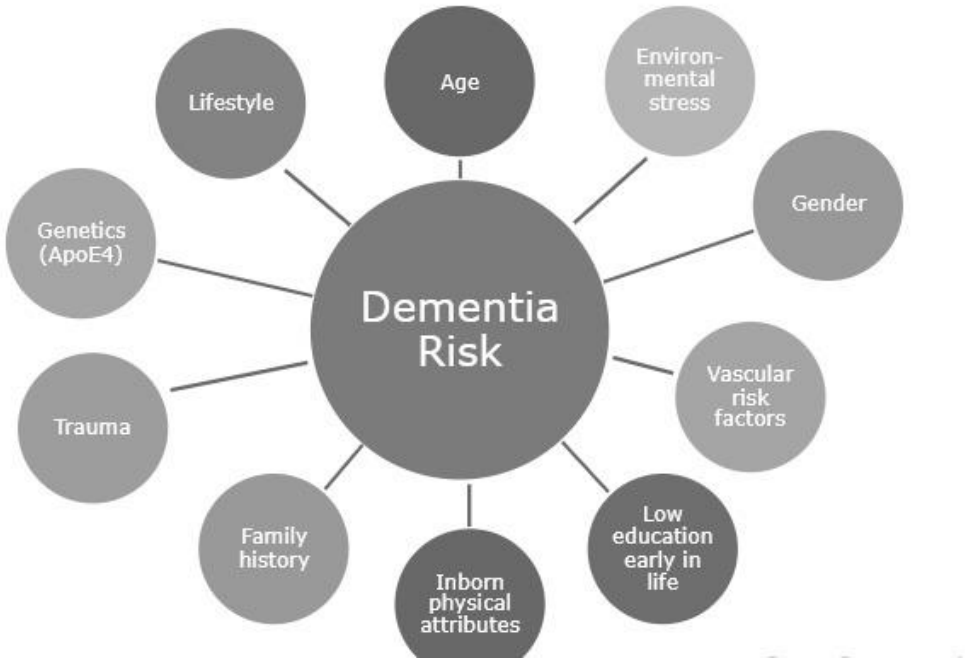

Figure 4- Risk factors for dementia- adapted from International journal of Alzheimer's disease 2010

Even though studies have shown that late life dementia is not attributed to ageing alone and underlying disease which promoted neurodegeneration has to be held responsible, age old belief of age-associated neurodegeneration cannot be prohibited. However, this belief may lead to mistaking and potentially overlooking modifiable vascular risk factors which are now known to cause a high proportion of late life cognitive impairment, and impairs the development and use of neuroprotective drugs. Nevertheless, less than severe than dementia, should be highlighted with importance in such situations as it may offer a chance for preventive intervention and help in reducing morbidity among the affected population. As mentioned previously regarding study conducted by Iwashyna et al (11) where in severe sepsis was found to be highly associated with progression to moderate to severe cognitive impairment with odds ratio

of 3.34, the profound impact of sepsis cannot be overlooked and should be given adequate weightage.

In this study we defined sepsis as is described below according the Sepsis 3 guidelines and performed BCRS and WHODAS-2 questionnaire which was administered to patient or closest reliable relative and followed the survivors at 3 months for re assessment. Through this study we hope to highlight the importance of decline in quality of life through cognitive and functional domains following a critical illness and to evaluate the risk factors which pre-dispose to worse outcomes and not consider short term goals as 28-day mortality alone as end points.

5. Methodology

5.1 Institutional review board approval

The study protocol was approved by the Institutional Review Board in April 2018 [IRB Min No. 11284 dated 04.04.2018] (IRB approval letter in Annexure 11.2). The study was funded by the Hospital research fund-Fluid research grant number 22 Z 559.

5.2 Study duration

The recruitment of participants took place between August 2018 and July 2019. All patients were followed up prospectively till October 2019.

5.3 Study design

This study is a prospective observational cohort study of patients admitted and discharged with a diagnosis of sepsis. STROBE checklist was used for designing the study and reporting the outcome (Annexure 11.8)

5.4 Study setting

All patients above 18 years of age admitted in medical intensive care unit, high dependency unit and medical wards, who satisfy the Sepsis definition according to Sepsis 3 guidelines were eligible for the study. Informed consent was taken from the patients or close relatives, at admission, as many of the patients were critically ill and unable to give consent. The patients were followed up throughout hospital stay and survivors were followed up after discharge. Baseline data consisting of demographic data, co-morbid illness, premorbid functional status, source of infection, presence or absence of septic shock, acute respiratory distress syndrome, acute kidney injury, altered mentation, need for mechanical ventilation, dialysis, cardiac dysfunction, arrhythmias, organism identified and antibiotic susceptibility pattern, antibiotic used, potential risk factors for acquisition of infection were collected. Lab parameters used to assess severity of illness were also collected. SOFA score was calculated at admission and change in SOFA >2 was used to guide diagnosis if this was not clear at the time of admission. Data on duration of mechanical ventilation, duration of ICU stay, duration of hospital stay, complications during hospital stay (nosocomial infections, critical illness polyneuropathy, procedural complications, bed sores, cardiac arrest, tube block, stroke, DVT, PE, Acute coronary syndromes, arrhythmias) etc. were collected. Their contact details for further follow up were also collected during this period. Survivors were called for follow up evaluation at 3 months by an OPD visit.

Baseline evaluation was done prior to discharge from hospital. At this time the WHODAS 2 and the RetroBCRS questionnaires were administered. WHODAS 2 assessment is informant based and helps to assess the functional capabilities of the patient at baseline. RetroBCRS, which is also devised and validated for a close informant, provides apt cognitive status of the patient and helps to identify mild/moderate/severe cognitive impairment based on score obtained. Based on validated studies a score more than or equal to 20 corresponds to severe cognitive impairment. Score of less than 5 is considered normal, 6 to 10 is considered Mild cognitive impairment, and 11 to 19 is considered as Moderate cognitive impairment.

Phone reminders for follow up was given and patients were requested to review for follow up after 3 months in OPD. During this visit WHODAS 2 and BCRS questionnaires were administered. WHODAS 2 was preferably ascertained from patient unless disabled to do so, in which case close relative was interviewed. BCRS score was also be ascertained from the patient at this visit and score was delineated into mild/moderate/severe cognitive impairment based on validated constructs. This data was compared to baseline data obtained to evaluate functional and cognitive decline among survivors of sepsis. Data pertaining to return to work, duration of loss of work, return to original work, morbidity and mortality was also collected. Data from the study was used to determine if there were any persisting long-term impairment in patient's functionality or the change in quality of life from previous level.

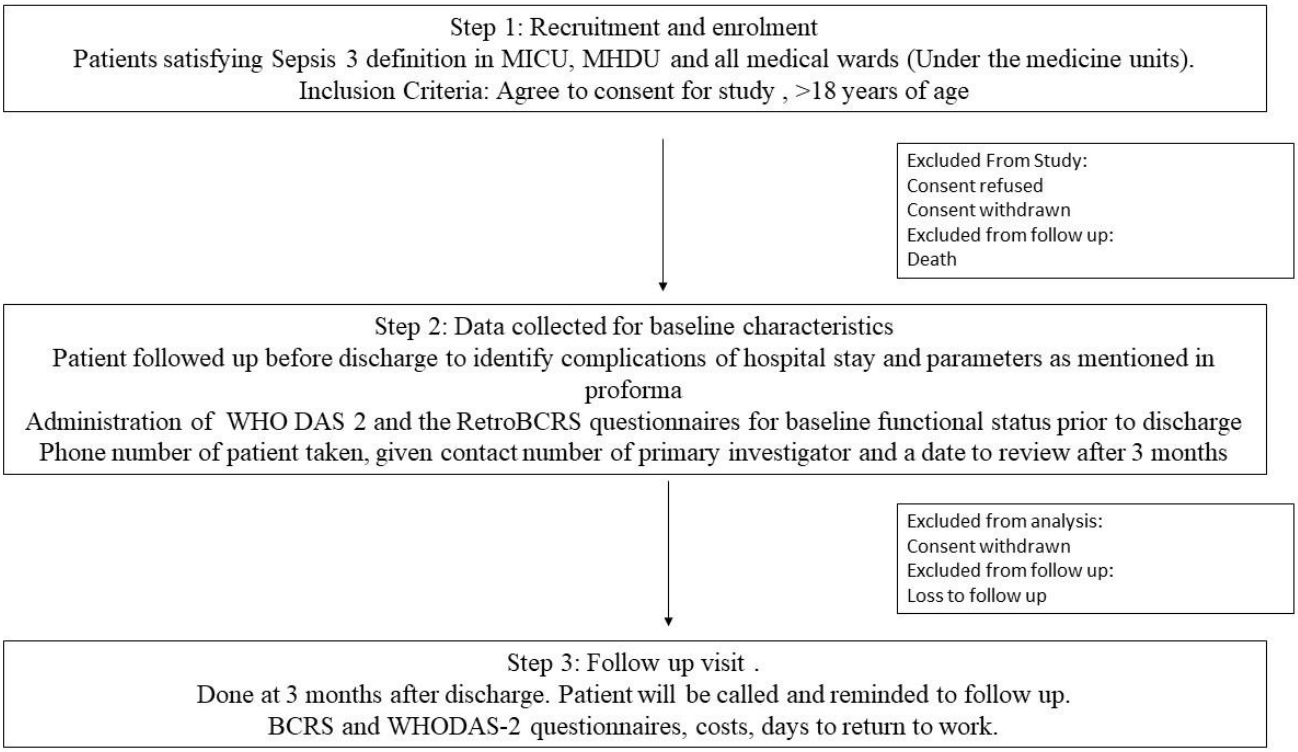

Figure 5: Algorithm for the study

5.5 Study participants

We recruited patients diagnosed with sepsis and following were the inclusion and exclusion criteria.

Inclusion criteria:

1. Age more than 18

2. All in-patients admitted in medical ICU, medical HDU and all medical wards, who presented to hospital satisfying the Sepsis definition adapted from Sepsis 3 guidelines.

3. Patients informed consent is necessary

4. Willing for follow up

Exclusion criteria:

1. Age less than 18

2. Patients who do not provide consent

3. Terminal malignancy with ECOG performance >3

4. Previous stroke with MRS score greater than or equal to 3

5. Patients diagnosed with Dementias – Alzheimer's, FTD, Vascular dementia, CBD, Multiple sclerosis, Cerebral palsy, psychiatric illnesses such as depressive symptoms as defined by DSM V or are on anti-depressant / anti-psychotic medications.

6. Patients who have primary CNS pathology as etiology of sepsis.

7.Physical disabilities preventing self-mobility, status post BKA/AKA/Hip arthroplasty.

8. Congestive cardiac failure with cardiogenic shock

5.6 Diagnostic criteria for sepsis and definition of baseline and follow up

We used Sepsis-3 guidelines for diagnosis of sepsis and excluded patients based on the exclusion criteria mentioned above. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection and organ dysfunction can be identified as an acute change in total SOFA score > 2 points consequent to the infection.

Table 2:Components of SOFA score

Sofa score	0	1	2	3	4
Respiration Pao2/Fio2 or Sao2/Fio2	>400	<400 221-301	<300 142-220	<200 67-141	<100 <67
Renal creatinine urine output	<1.2	1.2-1.9	2.0-3.4	3.4-4.9 <500	>5 or <200
Liver bilirubin (mg/dl)	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12
Cardiovascular Hypotension	No Hypotension	MAP<70	Dopamine </=5 or Dobutamine (any)	Dopamine >5 norepinephrine </=0.1	Dopamine >15 or norepinephrine>0.1
CNS(GCS)	15	13-14	10-12	6-9	<6
Coagulation	>150	<150	<100	<50	<20

Baseline function was defined as the status of the patient prior to the current episode of illness, which was assessed retrospectively at the time of discharge from hospital from the patient itself or immediate caregiver.

Follow up of the patients were done at 3 months following discharge and their functional status was assessed at that point in time using questionnaires from the patient itself or immediate caregiver.

5.7 Consent for participation

All patients who fulfilled the inclusion criteria were provided with the study Information sheet (Annexure 11.4). After they had read the same and the study explained, those willing gave written informed consent (Annexure 11.5). This was obtained in the regional language that the patient was conversant.

5.8 Sample size calculation

Based on the literature the proportion of severe cognitive dysfunction in the community ranged from 5.3% (49) to 7.4% (80). The required sample size to show the change of 10% Neurocognitive decline after 3 months post sepsis as shown by Iwashyna et al (11) using 80% power and 5% level of significance was found to be 150 subjects. Accommodating the 10% dropout, this study proposed to take around 170 subjects.

Sample Size calculation:

Table 3 : Hypothesis testing for sample size calculation

Hypothesis Testing for Single Proportion				
Population Proportion	0.06	0.05	**0.05**	0.05
Sample Proportion	0.106	0.1	**0.106**	0.106
Power (1- beta) %	80	80	**80**	90
Alpha error (%)	5	5	**5**	5
1 or 2 sided	2	2	**2**	2
Required sample size	248	185	**150**	215

Formula

$$n = \frac{\left\{Z_{1-\alpha/2}\sqrt{P_o(1-P_o)} + Z_{1-\beta}\sqrt{P_a(1-P_a)}\right\}^2}{(P_a - P_o)^2}$$

Where,

P_0 : Population proportion

P_a : Sample proportion

α : Significance level

$1-\beta$: Power

5.9 Data Sources/measurement:

The following variables were collected from the patients and relatives via questionnaire:

- Demographic data (Name, age, occupation, etc.)
- Contact details and Address
- BCRS, RetroBCRS, WHODAS-2 questionnaires

The following variables were taken from the clinical workstation:

- Basic blood investigations for calculation of SOFA score
- Chest X ray, ECG and blood investigation to evaluate for co morbidities including Blood borne virus status of the patient
- Culture reports for etiology of sepsis

The variables taken from ICU records, progress records and discharge summaries:

- For data on diagnosis of hospital acquired pneumonia, nosocomial infections, duration of ventilation and type of ventilation, use of inotropes, duration of stay in hospital and ICU

The following methods of assessment were used:

- Questionnaire and direct interviews

5.10 Bias

1) Selection Bias: All cases will be similar, as we will be all Sepsis cases that come to ICU or wards in one year. Non-respondent bias is a possibility with very sick patients or well patients not following up.

2) Information Bias: Information will be gathered the same way for all patients with Sepsis, irrespective of their severity.

3) Confounding: We have tried to include all possible variables that we believe will affect the long-term outcome. This allows for stratification to be done in the analysis. Unfortunately, we are not able to accurately describe the level of support for disabilities provided after hospital care. We will only be able to indirectly asses it by the BCRS and WHODAS-2 questionnaires.

5.11 Parameters

Demographic data and data required for study was collected using forms and questionnaires from the patients at admission, prior to discharge and at 3 months follow up. Standardized WHODAS-2, RetroBCRS and BCRS questionnaires were employed for the same as mentioned above and other details were recorded in clinical research sheet prepared for the same (Annexure 11.3)

Table 4: Variables assessed in study and point of assessment

Sex	+		
Duration of hospital stay		+	
Duration of stay in ICU		+	
Aetiology of sepsis		+	
SOFA score	+		
qSOFA score	+		
Requiring Dialysis		+	+
Addictions	+		
Comorbidities*	+		
Effort tolerance (MMRC/NYHA)	+	+	+
BMI	+		+
Modified Kuppuswamy scale	+		+
Marital status	+		+
Type of ventilation		+	
Duration of ventilation		+	
Steroid use		+	
Hospital Bill		+	
WHODAS-2		+	+
RetroBCRS		+	
BCRS			+
Return to work			+
Duration of return to work			+
Complications **		+	+

*Co-morbidities: Diabetes Mellitus, Hypertension, Dyslipidemia, Coronary Artery Disease, Chronic Heart Failure, Chronic kidney disease, Chronic Liver Disease, Stroke in past, Peripheral arterial occlusive, Hypothyroidism, Long term steroid use, Valvular heart disease, Tuberculosis in Past, Atrial Fibrillation, HIV infection, Bronchial Asthma, Obstructive airway disease, Physical Activity

**Complications of hospital stay: VAP (ventilator associated pneumonia), Central line related blood stream infection (CRBSI), Critical Illness polyneuropathy (CIPN), Acute coronary syndrome, Catheter associated urinary tract infection, Bed sores, Stroke, Deep venous thrombosis

5.12 Statistical Methods:

The data entry will be done by using EPIDATA software. Descriptive statistics will be used, such as number and percentage for categorical variable and Mean and SD or median with inter quartile range (IQR) for all the continuous variables. To evaluate before and after the cognitive function and physical functional ability in survivors of sepsis, Paired t test will be used. The cognitive function score will be categorized into Severe\Moderate and others. However, Histogram will be done for continuous variables such as duration of hospital stay and SOFA score, to study the distribution. If the histogram suggests normal distribution, independent t-test will be applied, and if the distribution is non-normal, Mann-Whitney U test will be used to compare between groups. To study the association between variables and outcome in cognitive function (Severe\Moderate vs Others), hypertension, long term steroid use, etiology of sepsis, Coronary Artery Disease, Chronic Heart Failure, Chronic kidney disease etc., chi-square test will be used. The variables that were significant at 5% level of significance at the bivariate analyses will be considered as potential variables for multivariable logistic regression analyses. P value at 5% level significance will be considered as statistical significance. Analysis will be carried out using SPSS software 16.0 version.

6. Results

In this study, 150 patients who were discharged following diagnosis of sepsis were followed up for 3 months. 20 patients were lost to follow up and total number of patients included in the study was 130. All 130 patients had data with regard to baseline characteristics along with baseline WHODAS 2 and RetroBCRS questionnaire and follow up WHODAS 2 and BCRS questionnaire after 3 months.

6.1 Demographics:

Mean age of patients included in the study was 57.18 years with standard deviation of ± 15.67 years. Patient age ranged from 20 years to 87 years and age distribution has been described in the bar graph below. 44% of the patients were elderly with age more than 60 years.

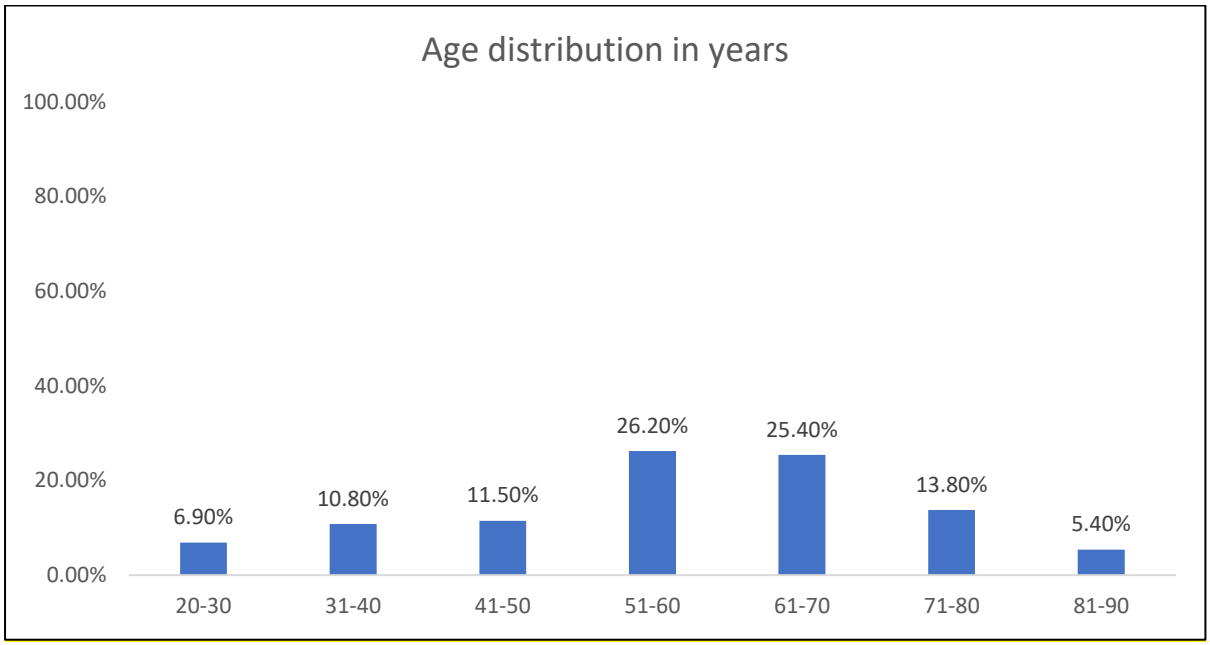

Figure 6: Age distribution of study population

Males and females were equally represented in the study population. Only patients from South India were included in the study to allow ease of follow up after 3 months and 86.2 % of the patients were from Tamil Nadu.

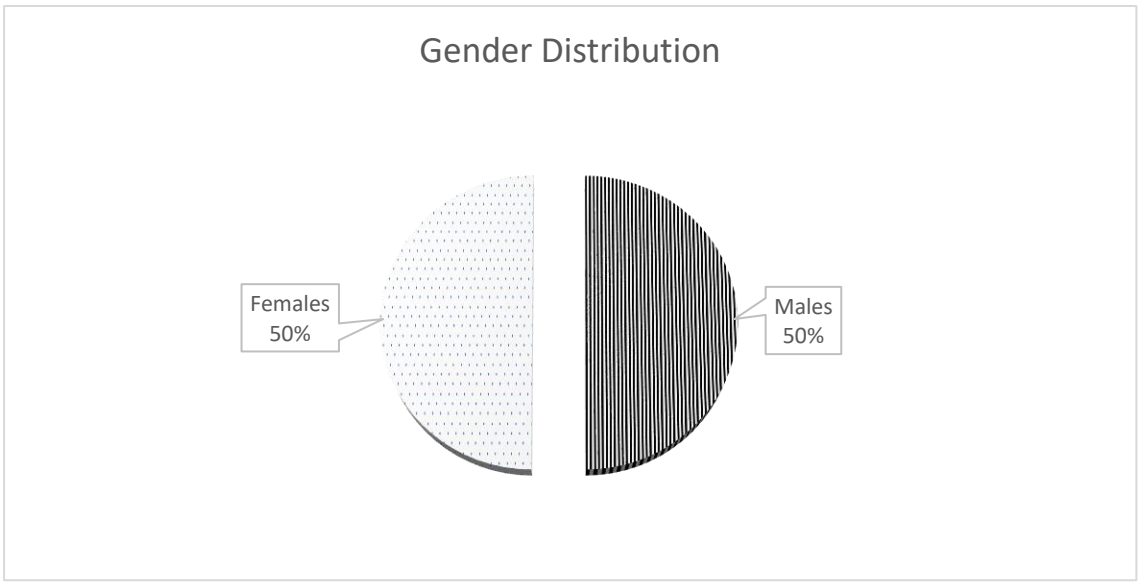

Figure 7: Gender distribution of the study population

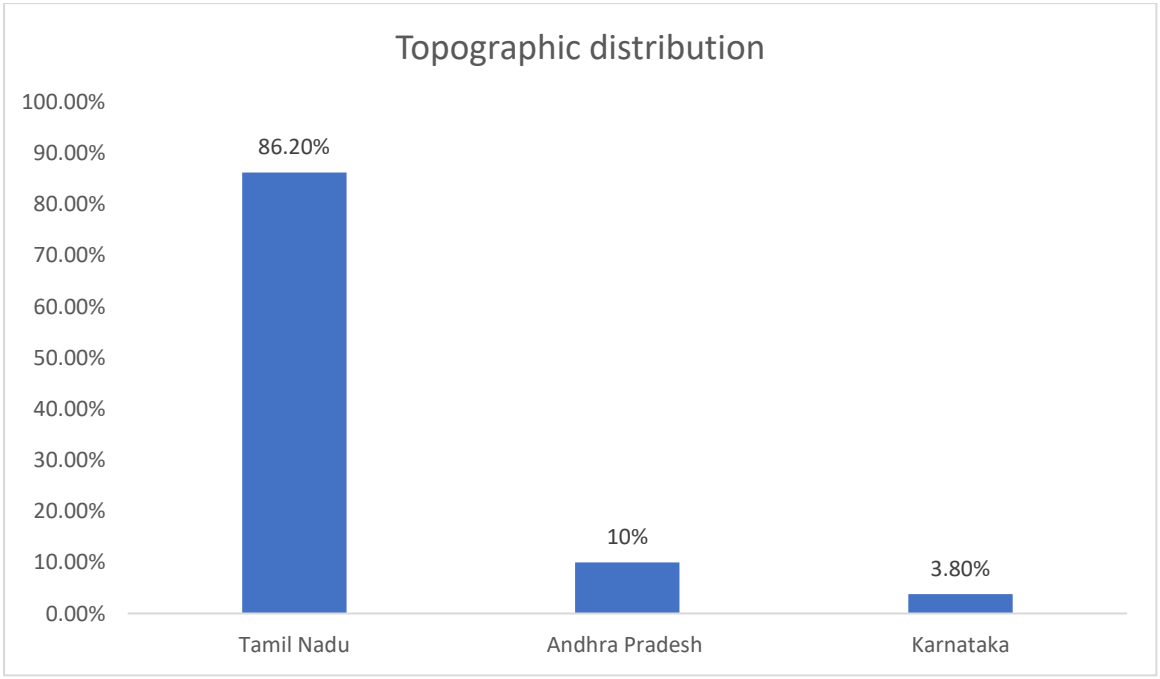

Figure 8: Topographic distribution of the study population

86.2% of the patients were married and were living with spouses while 12.3% of the patients had been widowed. 14.6% of the patients admitted were dependent on spouse or immediate family members for activities of daily living at baseline.

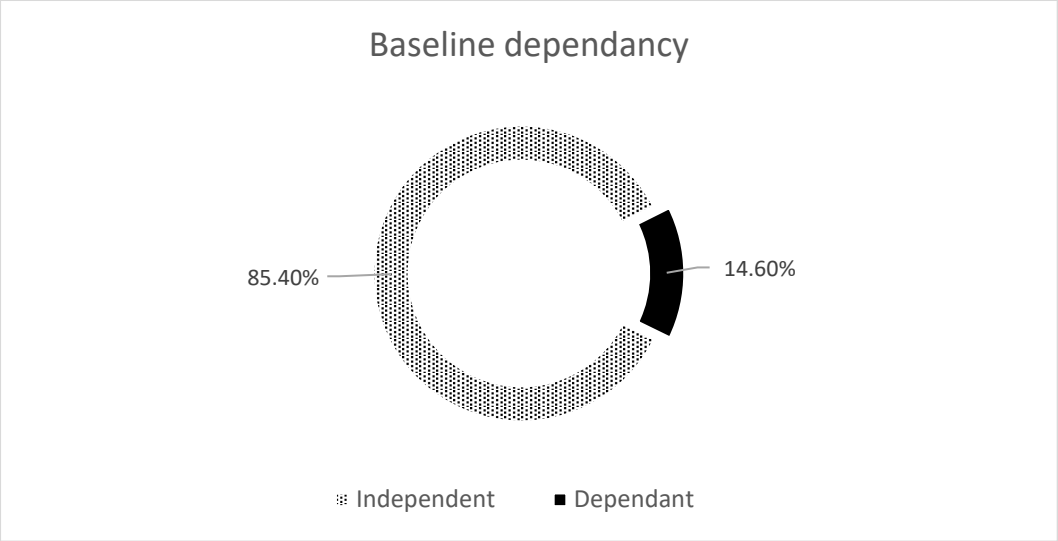

Figure 9: Dependency on activities of daily living at baseline

Mean body mass index of the patients was 24 with standard deviation of ± 3.26. Following table demonstrates the distribution of patients according to their body mass index for Asian population.

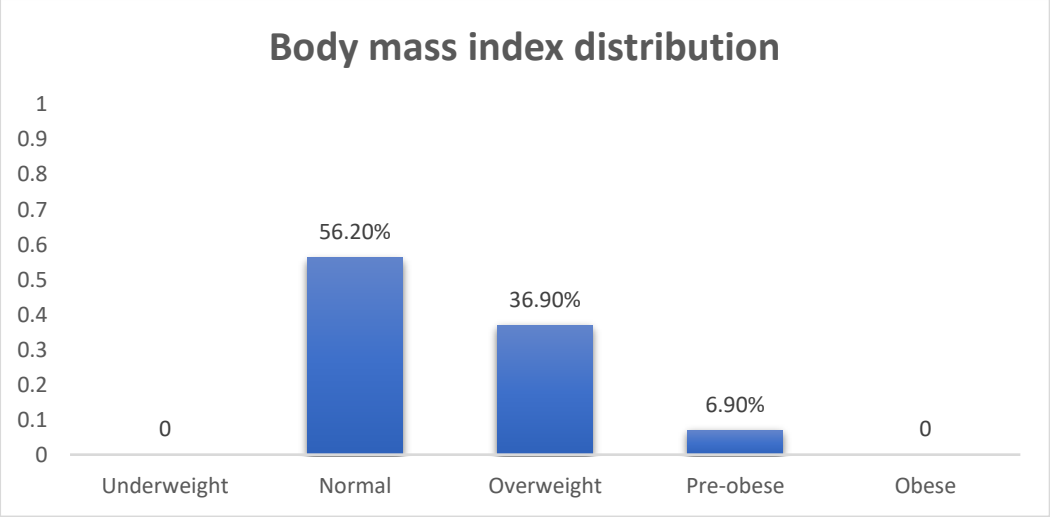

Figure 10: Body mass index distribution of the study population at baseline

Baseline socioeconomic score of the patient's family was calculated using Modified Kuppuswamy scale. Mean Socioeconomic score was 19.03 with standard deviation of ± 3.26, and ranged from lowest score of 8 to highest score of 27. Distribution according to socioeconomic score has been depicted in bar graph below.

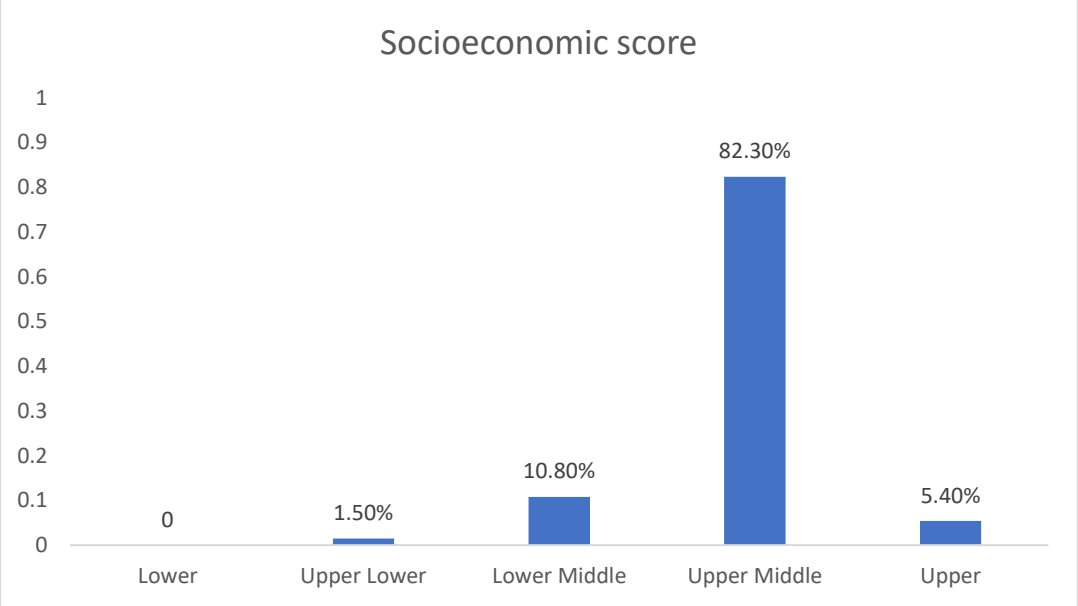

Figure 11: Socioeconomic score distribution of study population at baseline

Almost all the patients (96.9%) were admitted from Accident and Emergency department and only 3.1% of patients admitted had presented to medicine outpatient department. 81% of the patients were admitted into Medicine general wards and the remaining was admitted into intensive care unit / High dependency units.

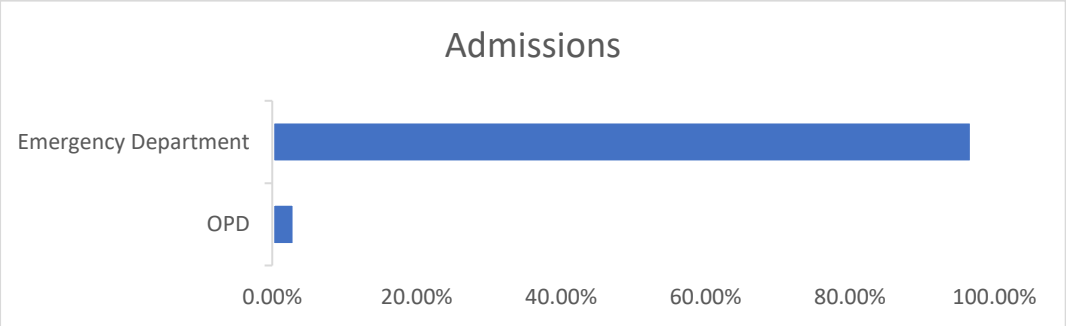

Figure 12: Distribution of study population based on route of admission

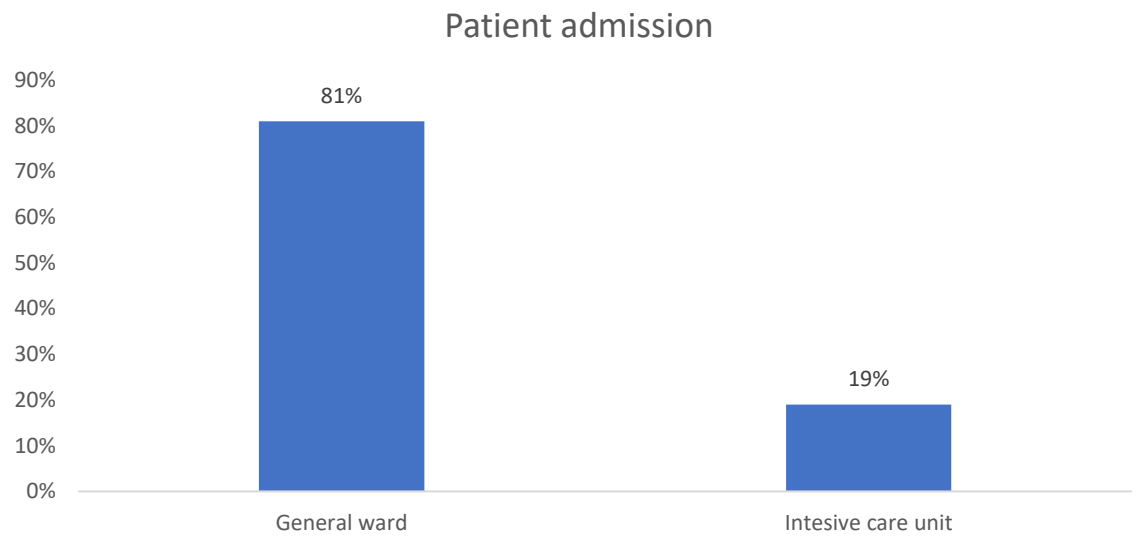

Figure 13: Distribution of study population based on intensive care versus ward admission

Mean duration of hospital stay was 8.27 ± 3.75 days and ranged from minimum of 3 days to a maximum of 30 days. Distribution of patients based on duration of stay is depicted below as bar graph. Among the patients admitted in intensive care unit, mean duration of stay was 4 days before which they were shifted back to the ward.

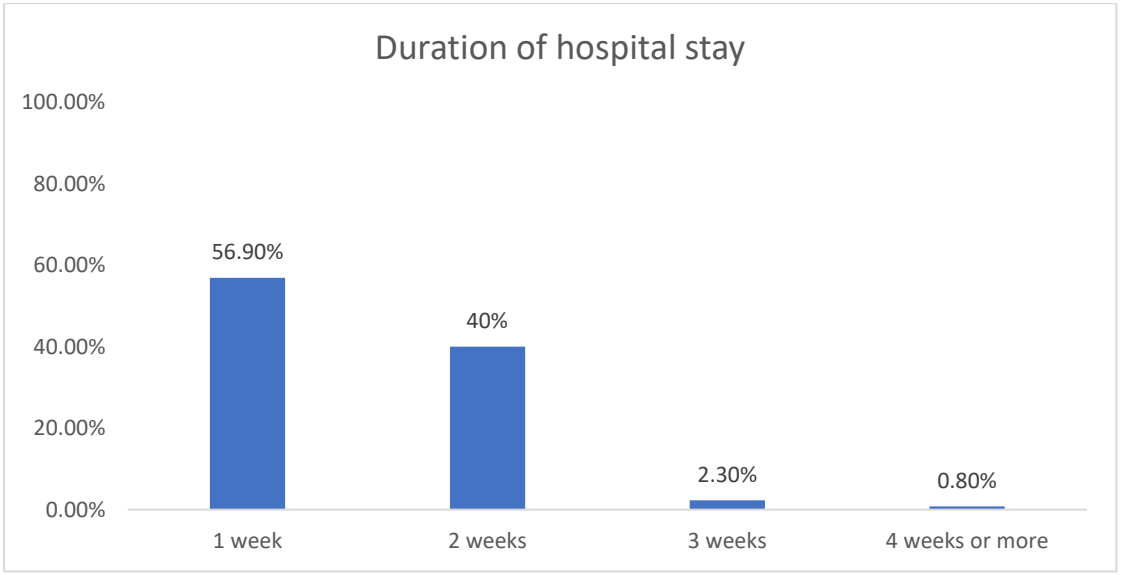

Figure 14:Distribution of study population based on duration of hospital stay

6.2 Baseline characteristics:

Baseline comorbidities of the population is outlined in table below:

Table 5: Baseline characteristics of the study population

CHARACTERISTIC	VALUE
Age (mean, SD, years)	57.18 ± 15.67
Gender (male: female)	1:1
Diabetes Mellitus (%)	60.8%
Hypertension (%)	55.4%
Dyslipidemia (%)	13.8%
Coronary artery disease (%)	10%
Chronic Kidney disease (eGFR<60ml/min/1.73m2, %)	9.2%
Chronic Liver disease (%)	1.5%
Obstructive airway disease (%)	23%

Among the study population, 60.8% of them were diabetics with mean duration of diabetes being 162 ± 64 months, ranging from 1 month to 30 years duration. The mean HbA1c of the diabetics is 9.04 ± 1.97 mg% and 35.4% of them is on various forms of insulin for diabetic control.

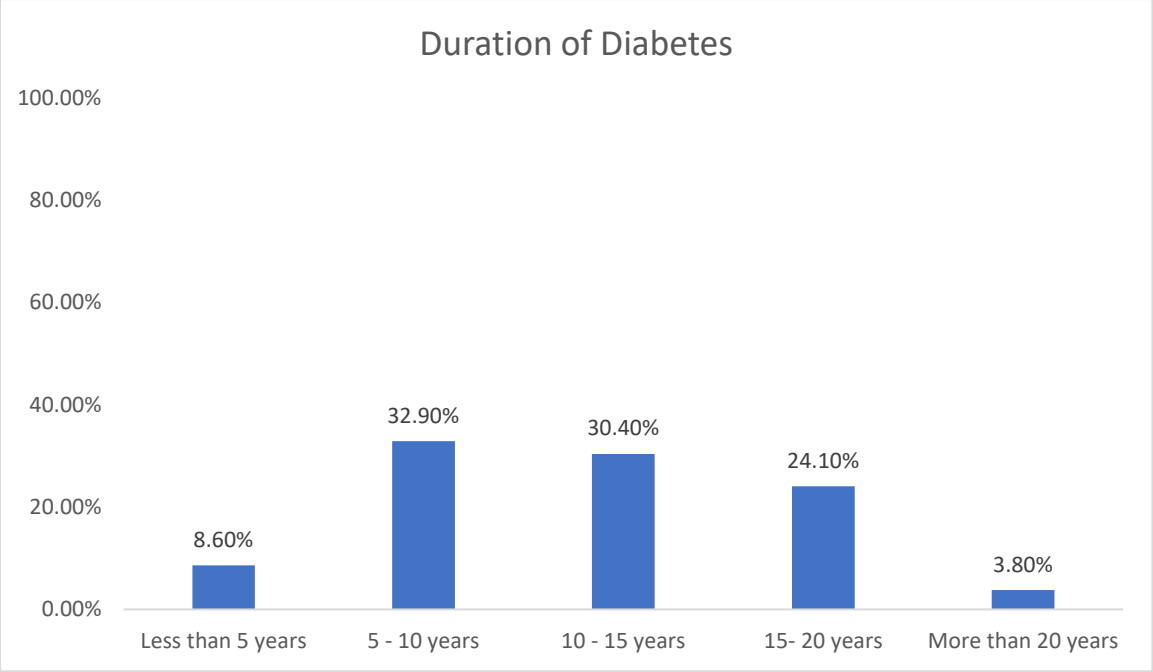

Figure 15:Distribution of diabetic patients based on duration of diabetes

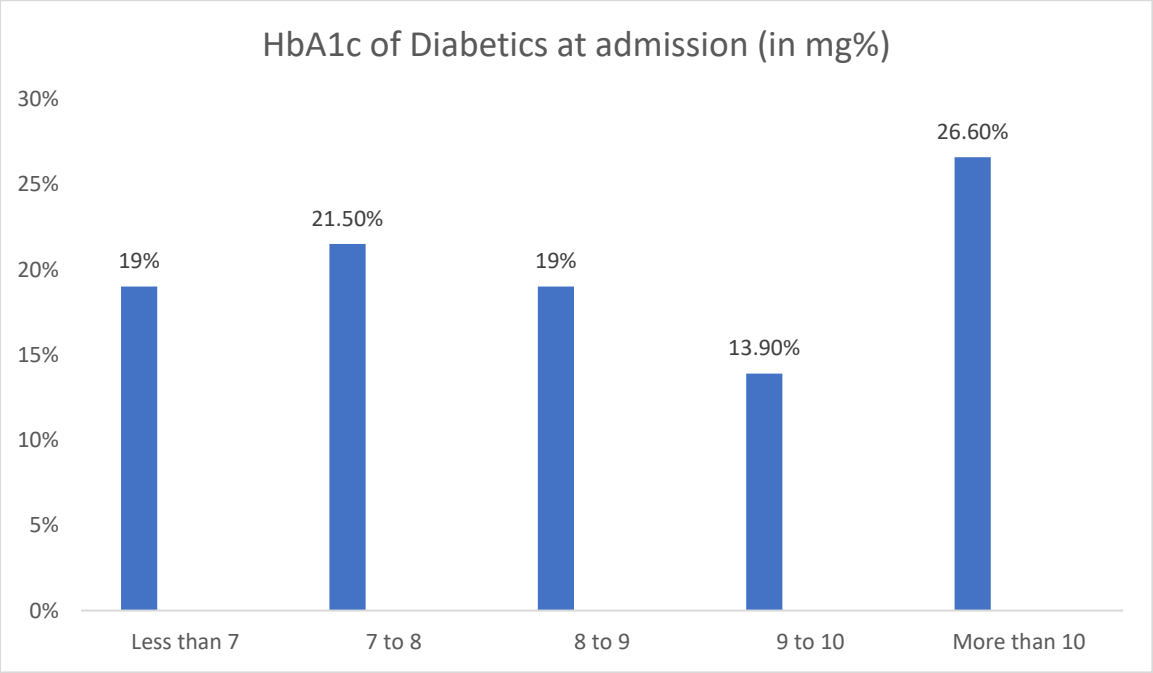

Figure 16:Distribution of diabetic patients based on HbA1c value

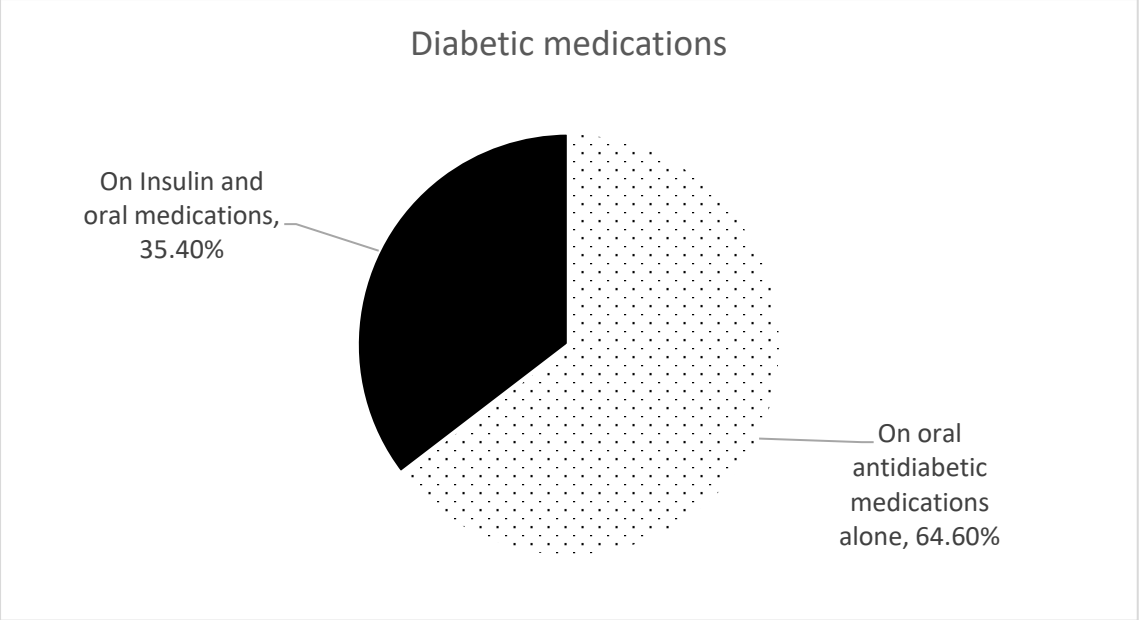

Figure 17: Distribution of diabetic population based on anti-diabetic medications

Among the study population, 55.4% were hypertensives and average duration of hypertension was 178 ± 69.6 months. Duration of hypertension at admission is depicted in graph below.

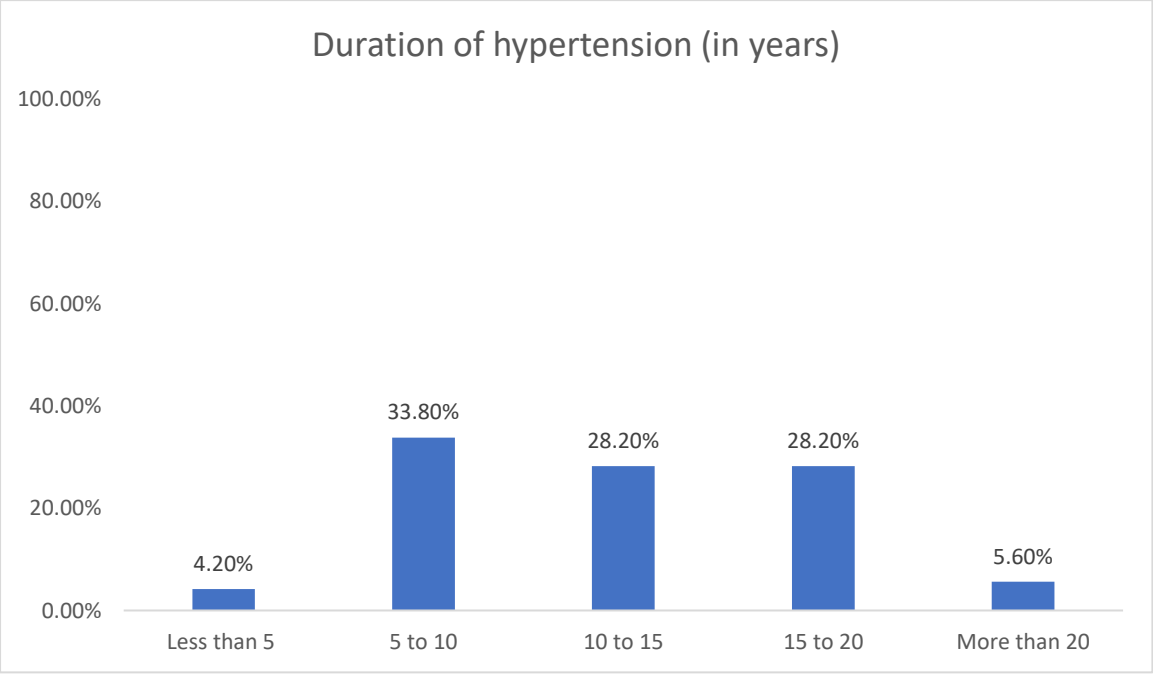

Figure 18: Distribution of patients based on duration of hypertension

Only 13.8% of the study patients were diagnosed with dyslipidemia and all of them were either on dietary modifications therapy or lipid lowering agents.

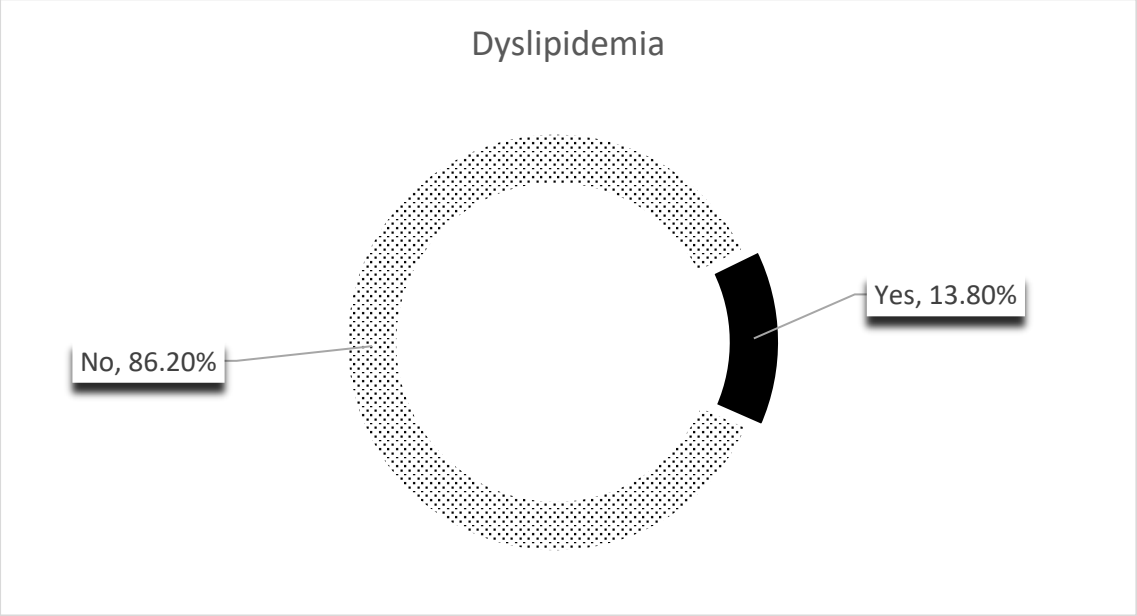

Figure 19: Distribution of study population based on presence of dyslipidaemia

Among the study population, 10% was known to have coronary artery disease and 3.1% had previous history of diagnosed acute coronary syndrome which was intervened with interventional or thrombolytic therapy. However, 90% had normal systolic left ventricular function prior to admission.

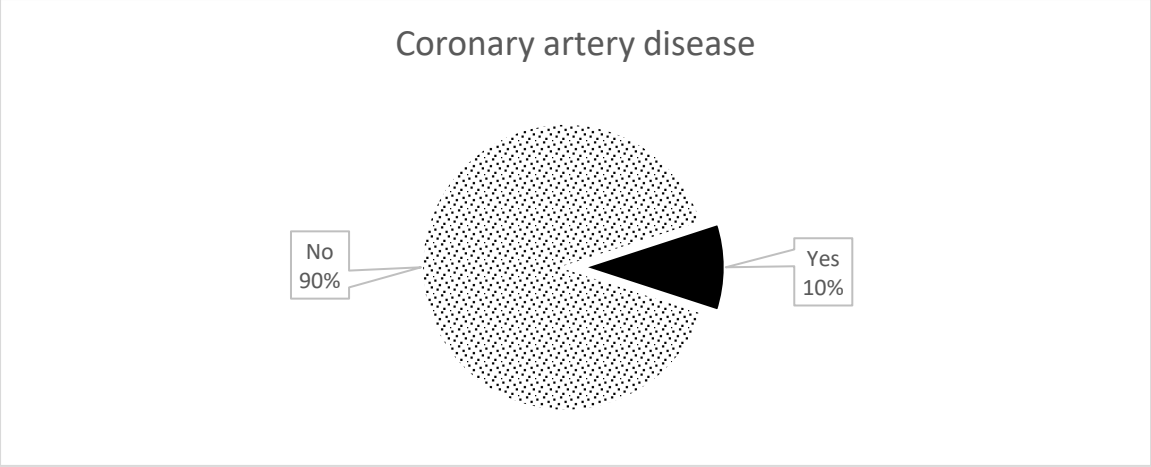

Figure 20: Distribution of study population based on presence of coronary artery disease

Among patients with known heart failure, average duration of the same was 8.5 years and mean ejection fraction was 45.7 ± 5.7 %. Distribution of heart failure according preserved, mid-range and reduced ejection fraction is shown below.

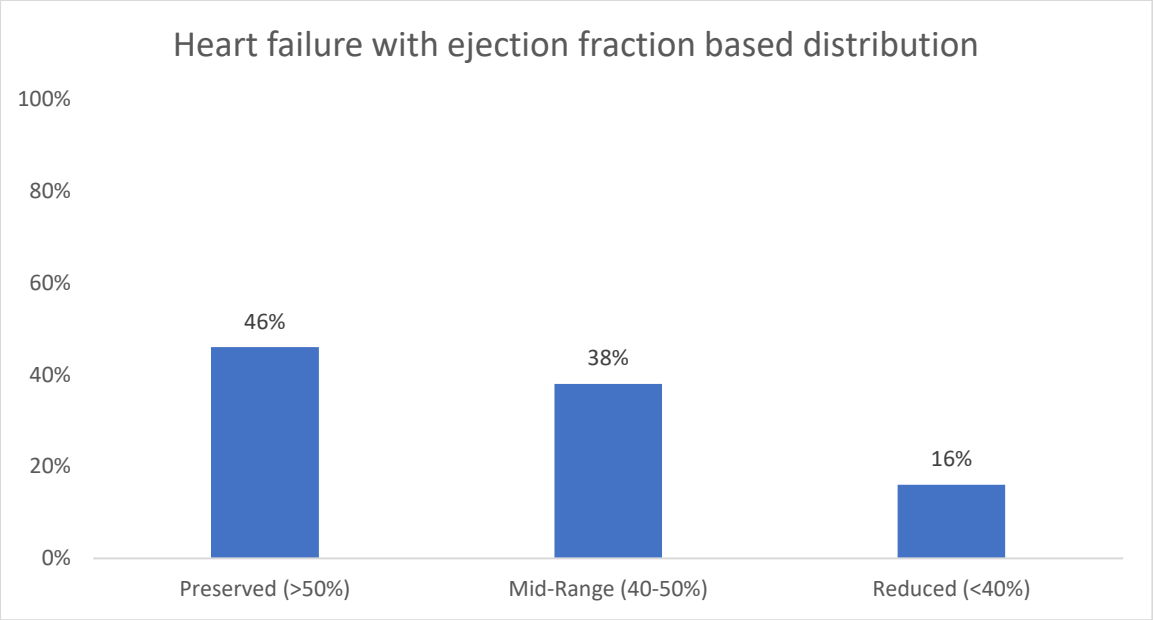

Figure 21: Distribution of heart failure patients based on severity of ejection fraction

9.2% of the study population was previously diagnosed with chronic kidney disease with estimated glomerular filtration below 60ml/min/1.73m2 according to abbreviated Modification of Diet in Renal Disease (MDRD) criteria. Average duration since diagnosis was 7 years and none of the patients were on maintenance hemodialysis. Only 2 (1.5%) of the patients included in the study were known to have underlying chronic liver disease and they had underling portal hypertension. 3 patients (2.3%) had previous cerebrovascular accident and Modified Rankin score of all patients were 3 or less. Only 1 patient had underlying rheumatic heart disease and was diagnosed with underlying moderate mitral regurgitation with atrial fibrillation and was on anticoagulant medications.

Among the study population 16.1% consumed alcohol and 24.6% abused tobacco by smoking cigarette / beedi. Among those who consumed alcohol, mean units consumed per day was 2.23 and average number of days consumed in a week was 2.47. Among smokers, median pack years smoked was 20 years with interquartile range from 2 years to 40 years.

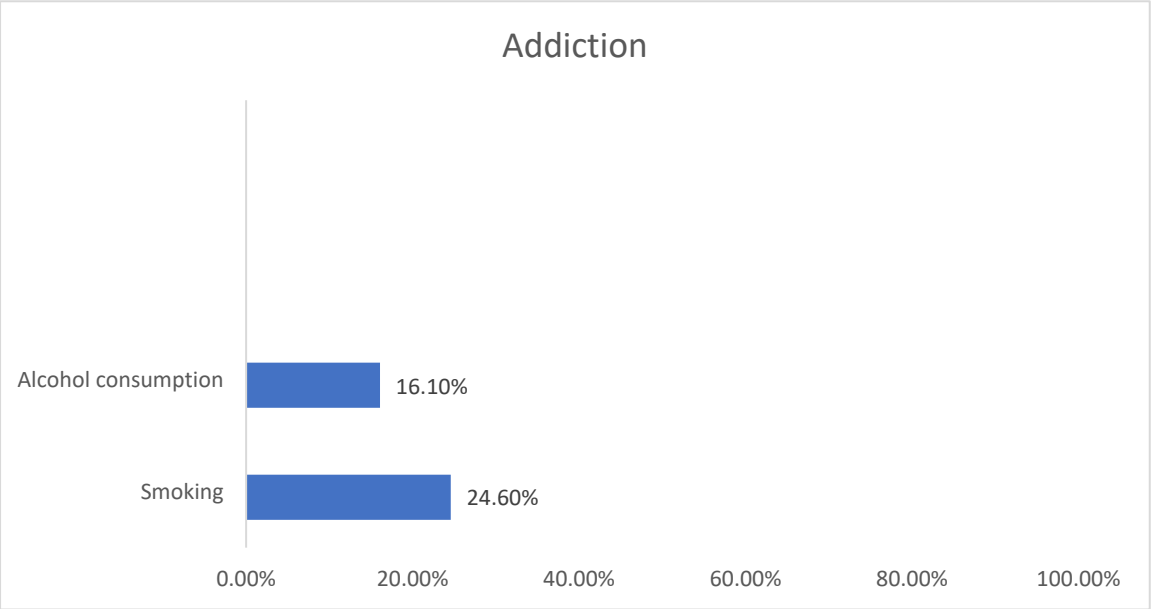

Figure 22:Distribution of population based on addictive habits

One patient had past history of pulmonary tuberculosis 5 years ago which was treated with first line anti tuberculous medication and was cured. One patient was diagnosed previously to be retroviral positive and was on Anti-retroviral therapy with last CD4 count of 293.

23% of the study population was diagnosed with obstructive airway disease, majority (83%) being chronic obstructive airway disease. Median duration of obstructive airway disease was 10 years with interquartile range of 1 year to 30 years.

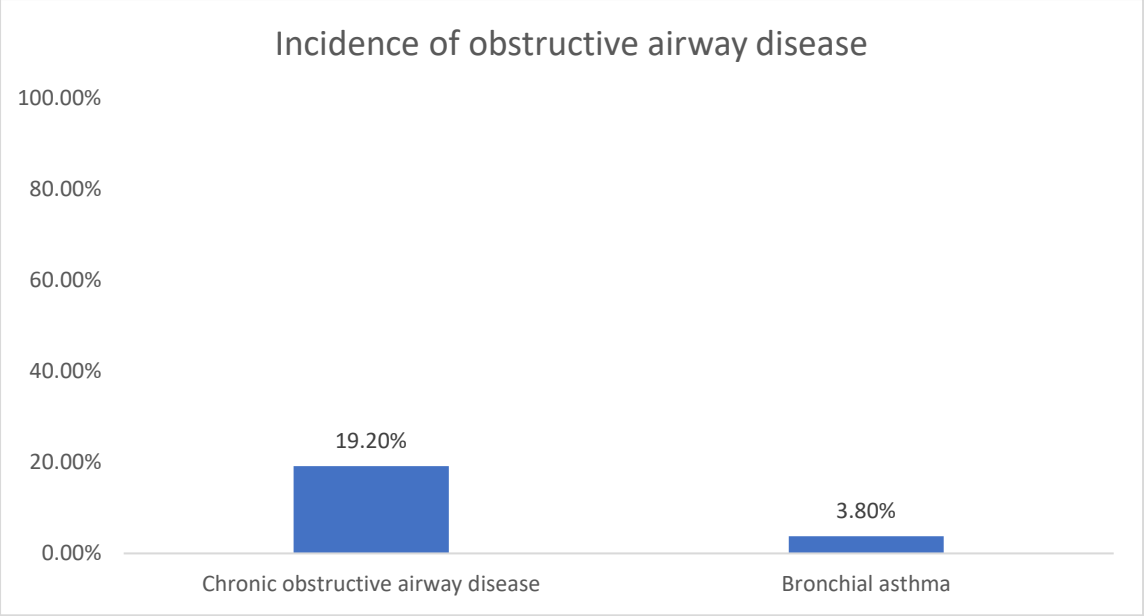

Figure 23: Distribution of study of population based on incidence of obstructive airway disease

6.3 Sepsis Related data:

Mean duration of fever prior to presentation is 5.2 ± 2.3 days, interquartile range from 1 to 10 days. Number of days of fever prior to presentation is depicted is bar graph below.

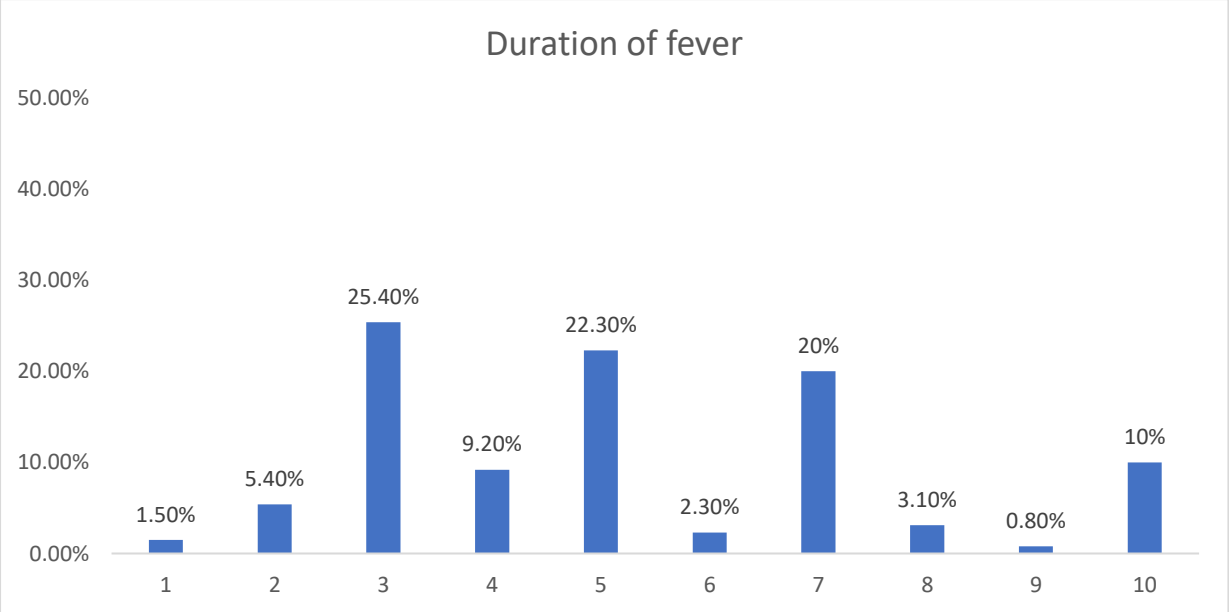

Figure 24: Distribution of study population based on duration of days of fever

The most common source of sepsis was of genitourinary origin which accounted for 50.8% of all admissions followed by pulmonary origin, which was 30%.

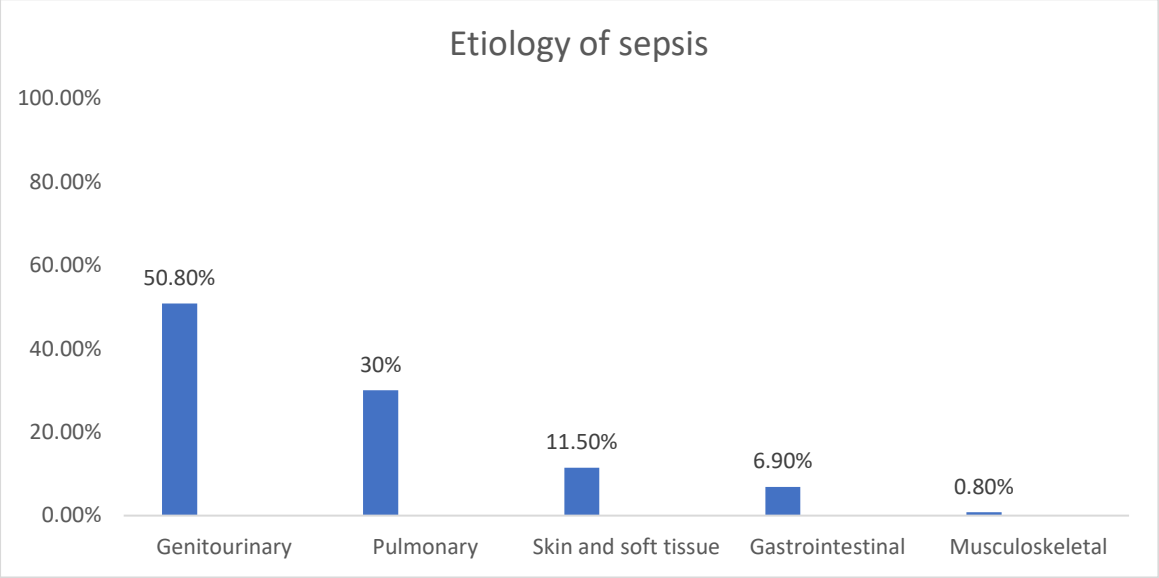

Figure 25: Distribution of study population based on aetiology of sepsis

Only 63% of the admitted patients had organism isolated in blood or other relevant culture source. Amongst this the most common organism was E. Coli (45.4%), followed by Streptococcus (6.2%). All the organisms isolated in cultures are depicted in graph below.

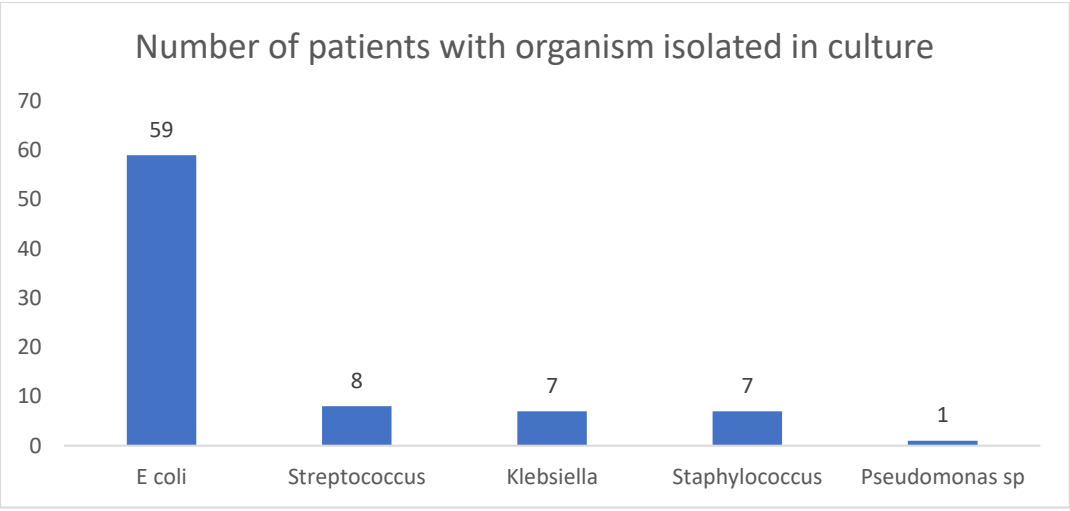

Figure 26: : Distribution of patients based on organism identified in culture

All the isolates of Streptococcus were pan sensitive and the antibiotic sensitivity of other isolated organisms is shown below:

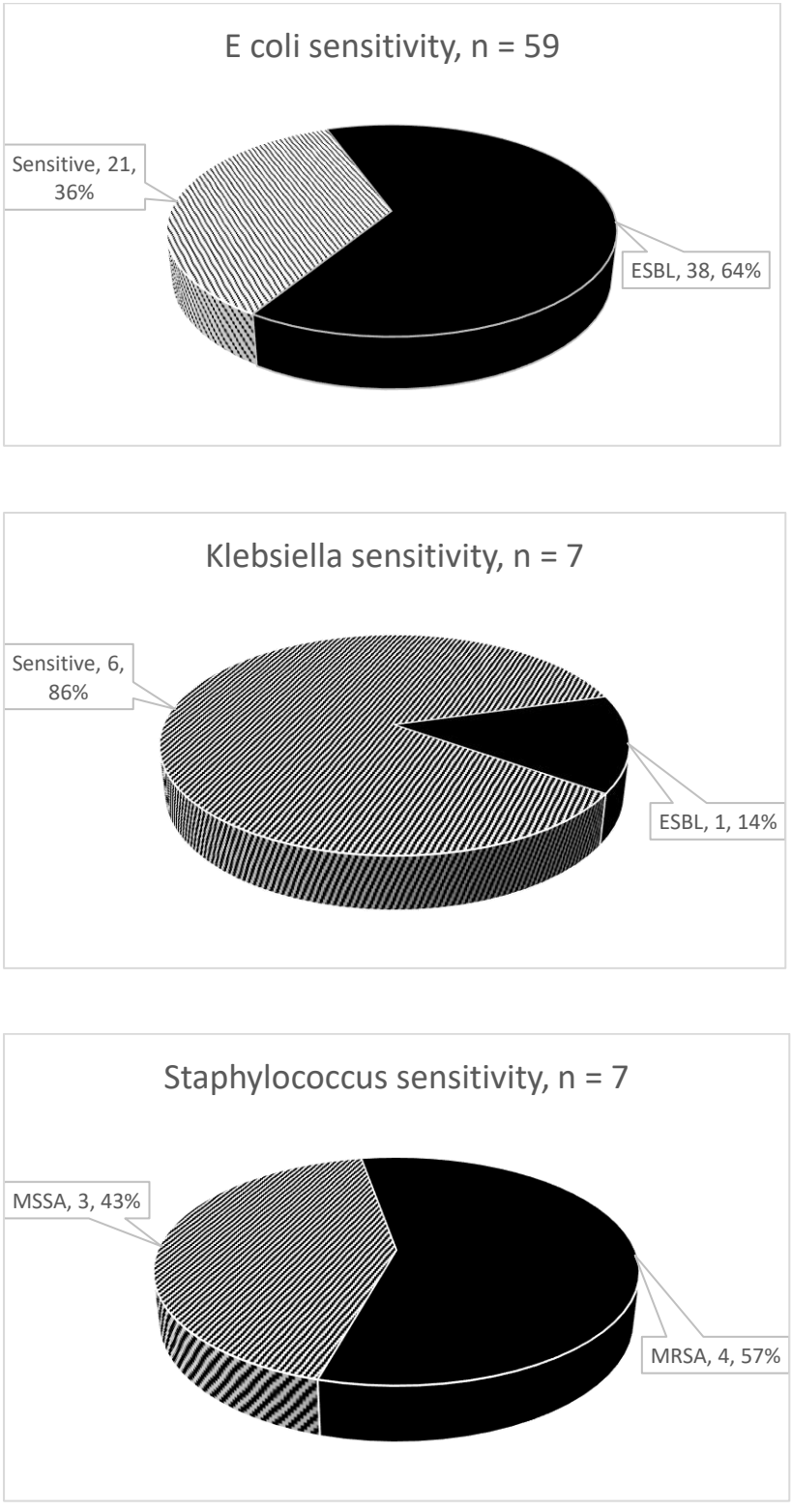

Figure 27:Distribution of antibiotic resistance pattern of isolated organisms

96% of the patients included in the study had SOFA score equal to or more than 2. The remaining 5 patients were included in view of isolation of organism in blood culture. Mean SOFA score of the patients at admission is 3.9, ranging from lowest score of 2 to maximum score of 10. SOFA score distribution of patients at admission is shown below.

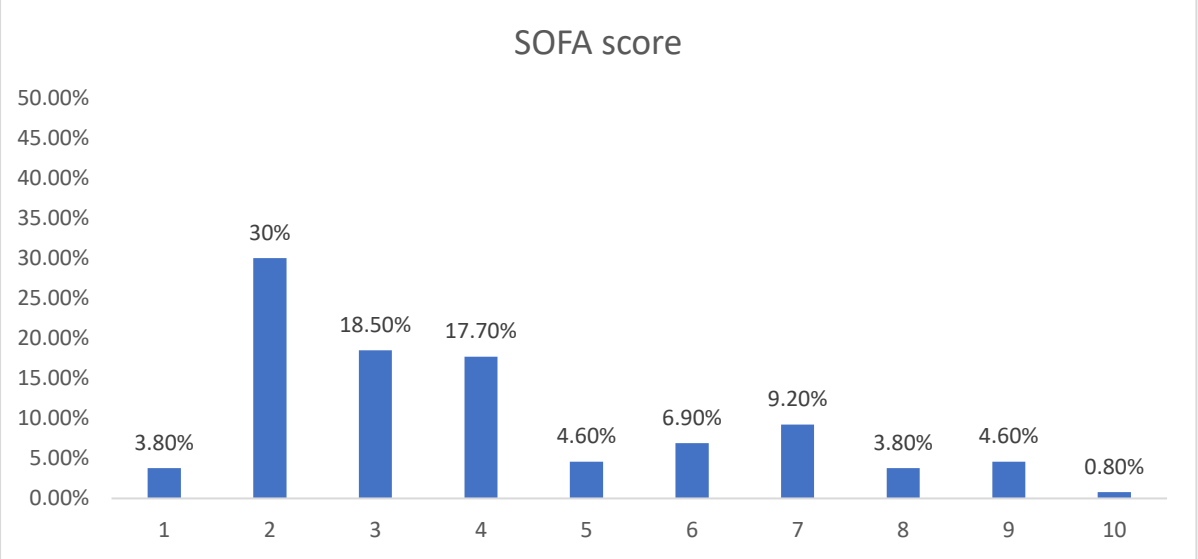

Figure 28: Distribution of study population based on SOFA score

The most common organ dysfunction is acute renal dysfunction (83.1%) closely followed by Acute respiratory distress syndrome (82.3%).

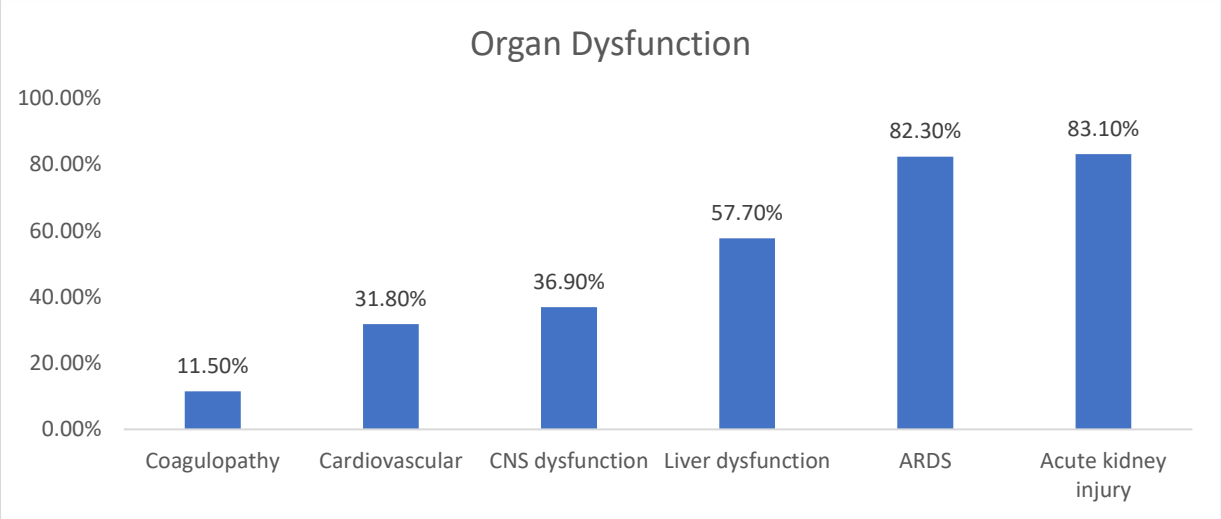

Figure 29: Distribution of patients of based on organ system dysfunction

Among patients with respiratory dysfunction, 23% of them required assisted ventilation during hospital stay in the form of invasive or non-invasive ventilation. 7 patients (5.4%) required mechanical ventilation which was deescalated into non-invasive ventilation and then to room air and 23 patients (17.7%) required non-invasive ventilation alone. Mean duration of non-invasive is 3.14 days and invasive ventilatory days is 3.57 days. Duration of requirement of ventilatory assistance are shown below.

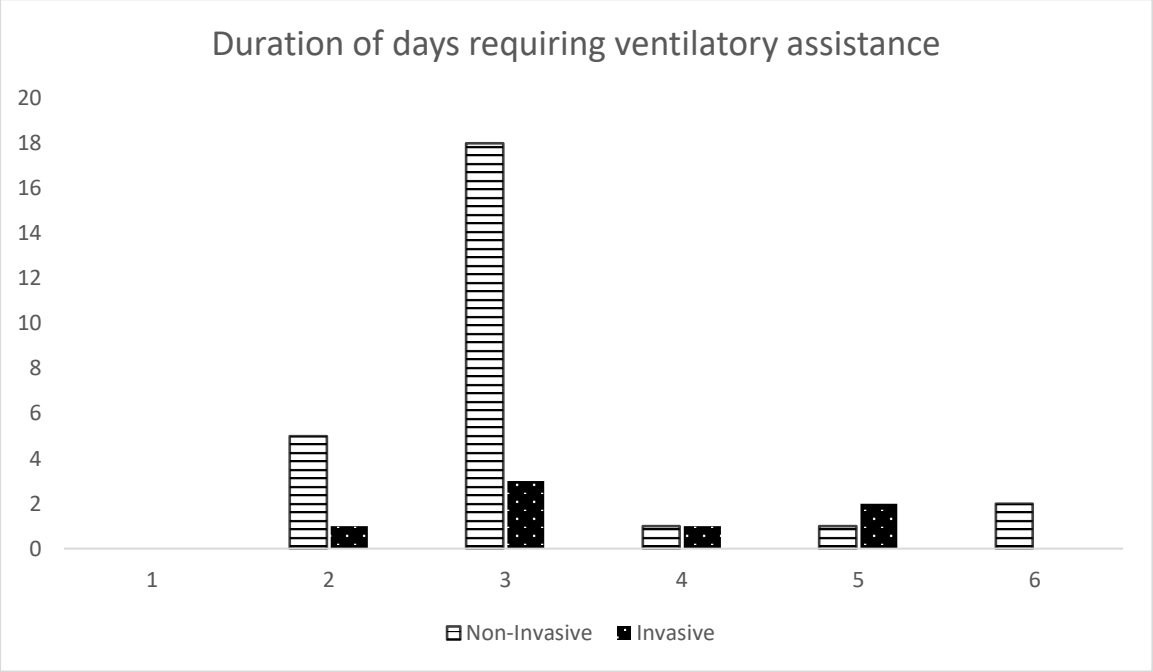

Figure 30: Distribution of population based on duration of days requiring ventilatory assistance

83.1% of the patients had acute renal dysfunction. Only 3.8% of them were oliguric and only 3 patients (2.3%) required dialysis in hospital stay. Acute kidney injury classified according to Acute Kidney Injury Network (AKIN) is shown below.

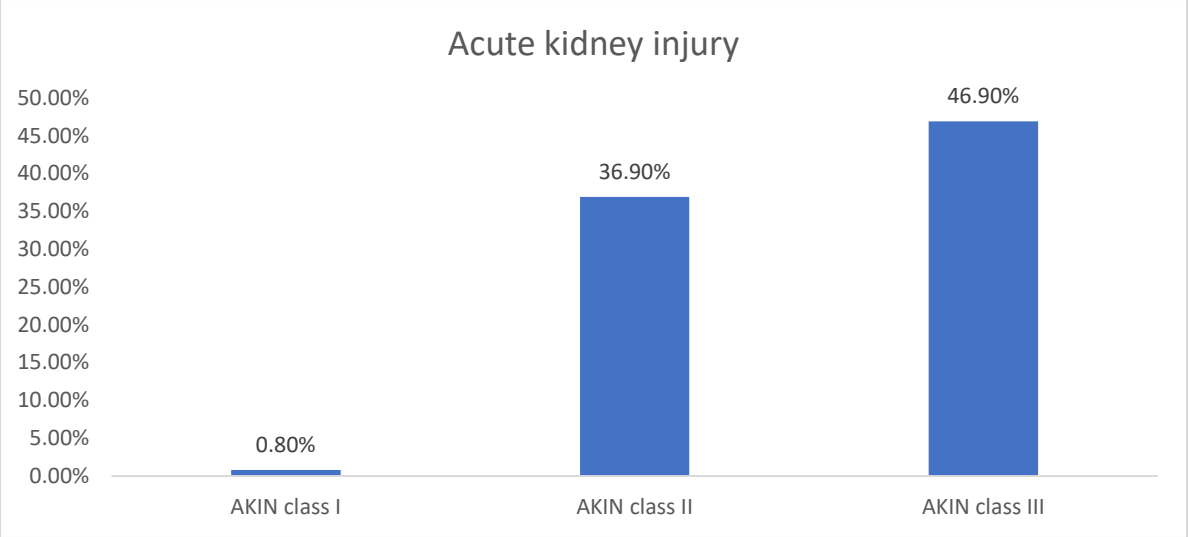

Figure 31: Distribution of study population based on grade of acute kidney injury

36.9% had altered sensorium at admission with Glasgow Coma Score (GCS) score of less than 15 indicating central nervous system dysfunction. Median GCS score was 15 and interquartile range was from 11 to 15. Distribution of GCS score at admission is shown below.

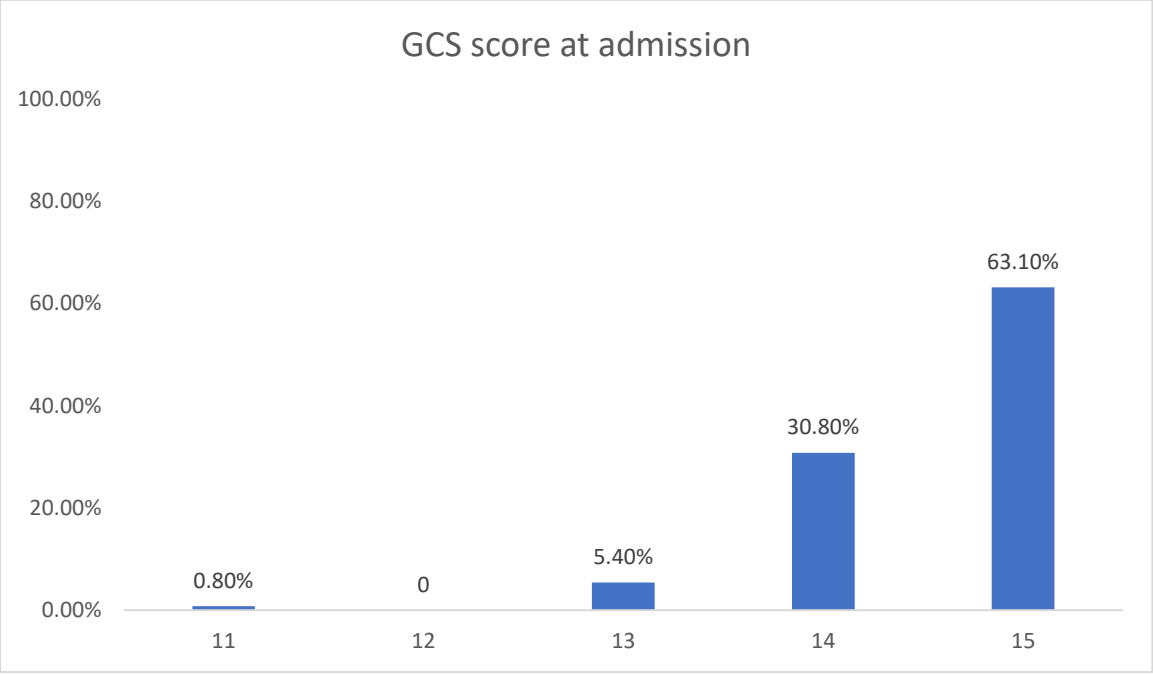

Figure 32: Distribution of study population based on GCS at admission

11.5% of the admitted patients had coagulopathy which was evidence by low platelet counts and deranged bleeding parameters. Only 1 (0.8%) patient had clinically significant bleeding and was transfused blood and blood products during hospital admission. Average platelet count of patients with coagulopathy is 65,600 /mm3 and distribution is as follows.

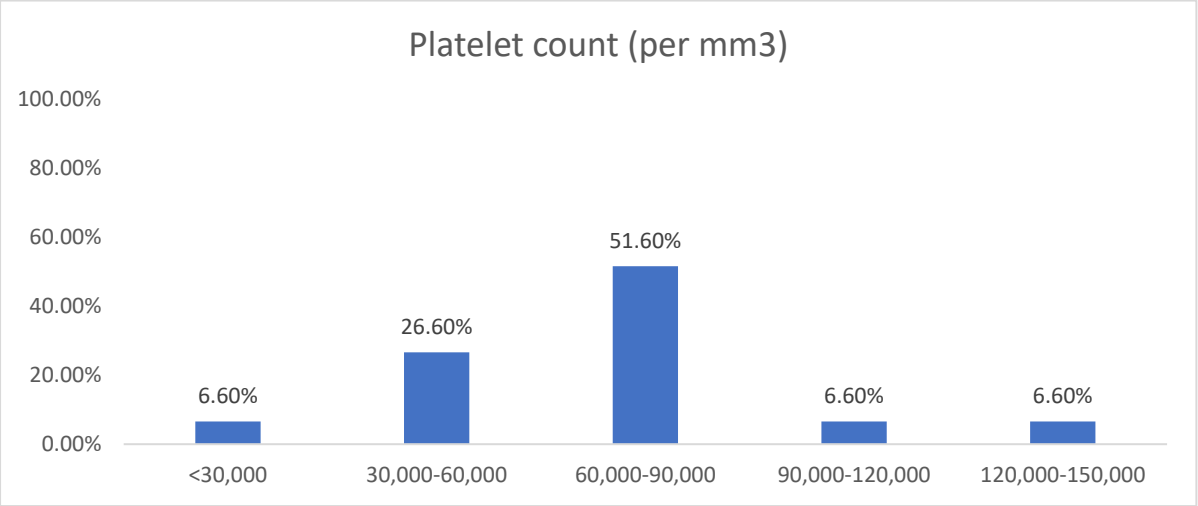

Figure 33: Distribution of study population with coagulopathy based on platelet counts levels

During hospital stay, half the patients received steroids according to sepsis protocol. Average cumulative dose of steroid received by the patients is 749mg of Hydrocortisone during the entire hospital stay, which approximates 200mg daily for mean duration of 4 days.

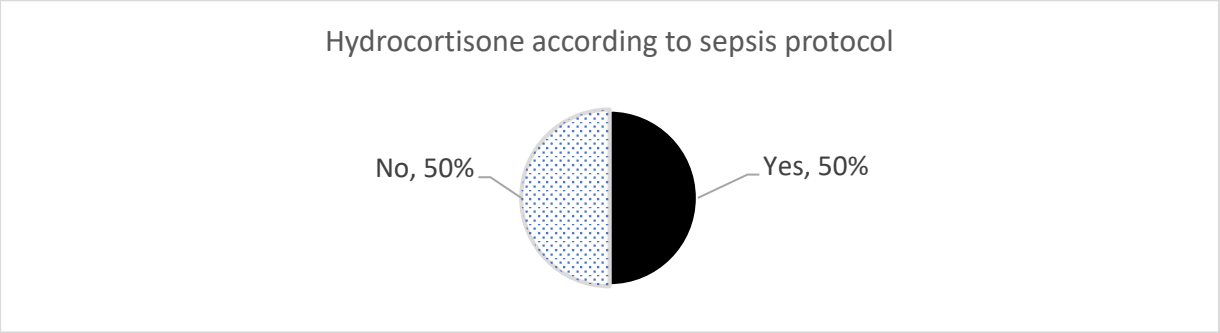

Figure 34: Distribution of study population based on administration of hydrocortisone according to sepsis protocol

5.3% of the patients had hospital acquired infection during their admission. The distribution of infection is depicted below.

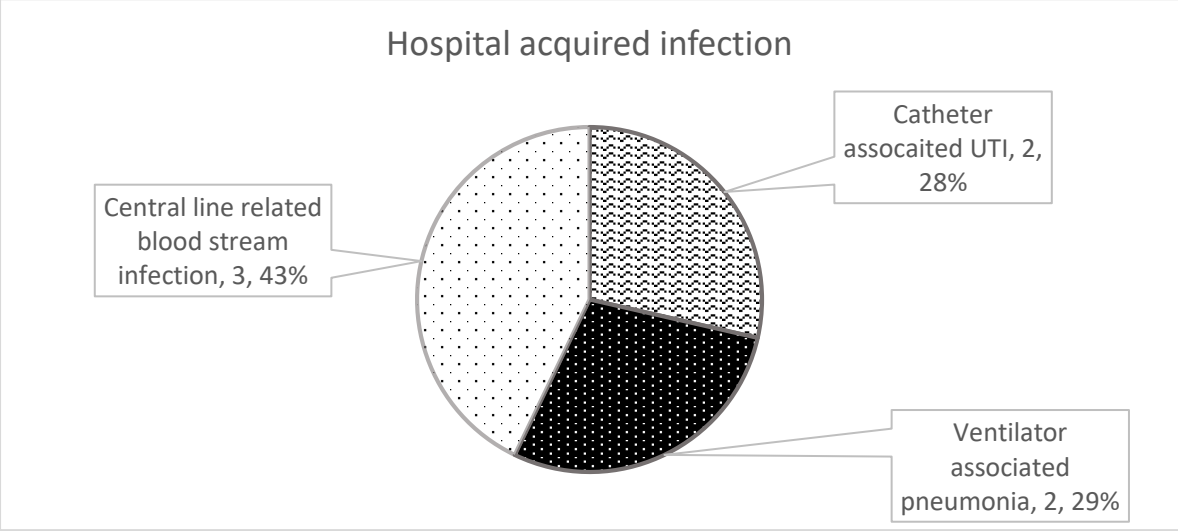

Figure 35: Distribution of patients with hospital acquired infection based on source of infection

Organism isolated from both patients with ventilator associated pneumonia was Acinetobacter baumanii and was carbapenem resistant. Both the organisms isolated from catheter related urinary tract infection was E coli and was Extended spectrum Beta lactamase inhibitory organism. Organism isolated from central line related blood stream infection is shown below.

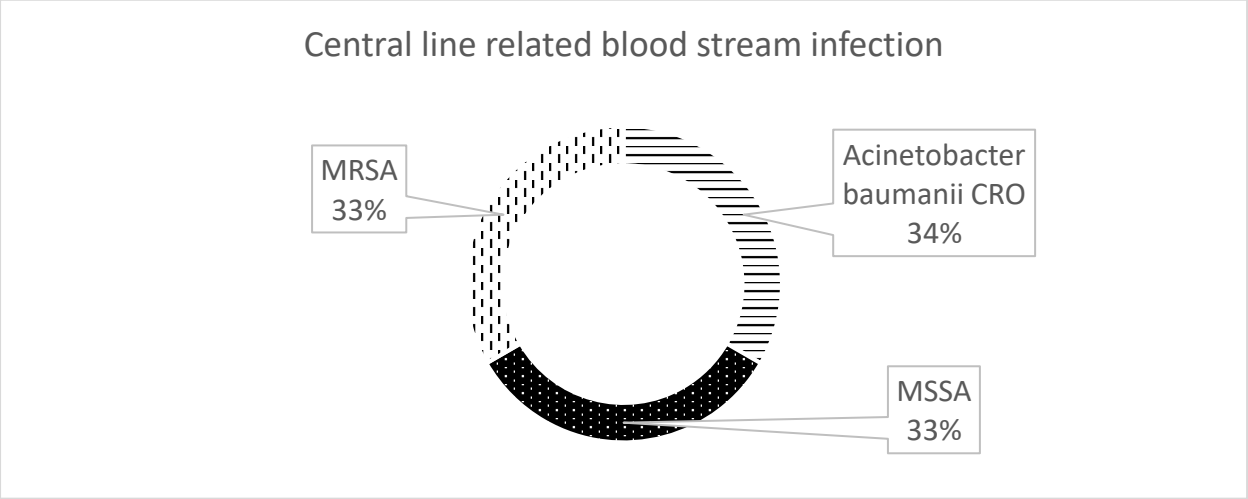

Figure 36: Distribution of patients with central line-based blood stream infection based on organism isolated

The incidence of other hospital stay related complications is depicted below in graph. 4 patients (2 with provoked deep venous thrombosis and 2 with newly detected atrial fibrillation) were started on oral anticoagulation with Vitamin K antagonists. Acute coronary syndrome in hospital was Non-ST elevation Myocardial infarction and was managed with dual anti-platelets and anticoagulation for 5 days. The most common complication was bed sore and occurred in 6.1% of the study patients prior to discharge. The next most common complication was critical illness neuropathy and was managed with physiotherapy.

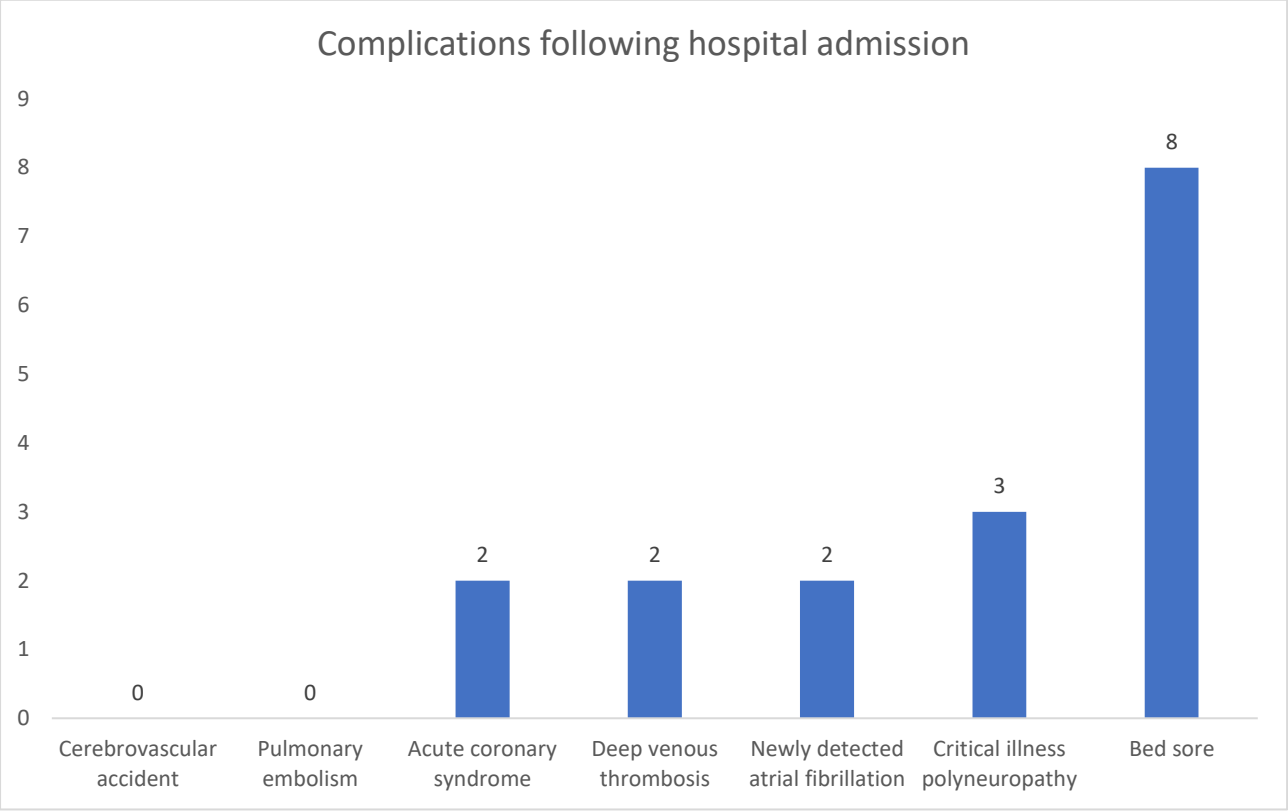

Figure 37: Distribution of study population with hospital acquired complications

10% of the patients admitted underwent procedures during hospital admission which was directed towards source control of sepsis. The procedures underwent are shown below.

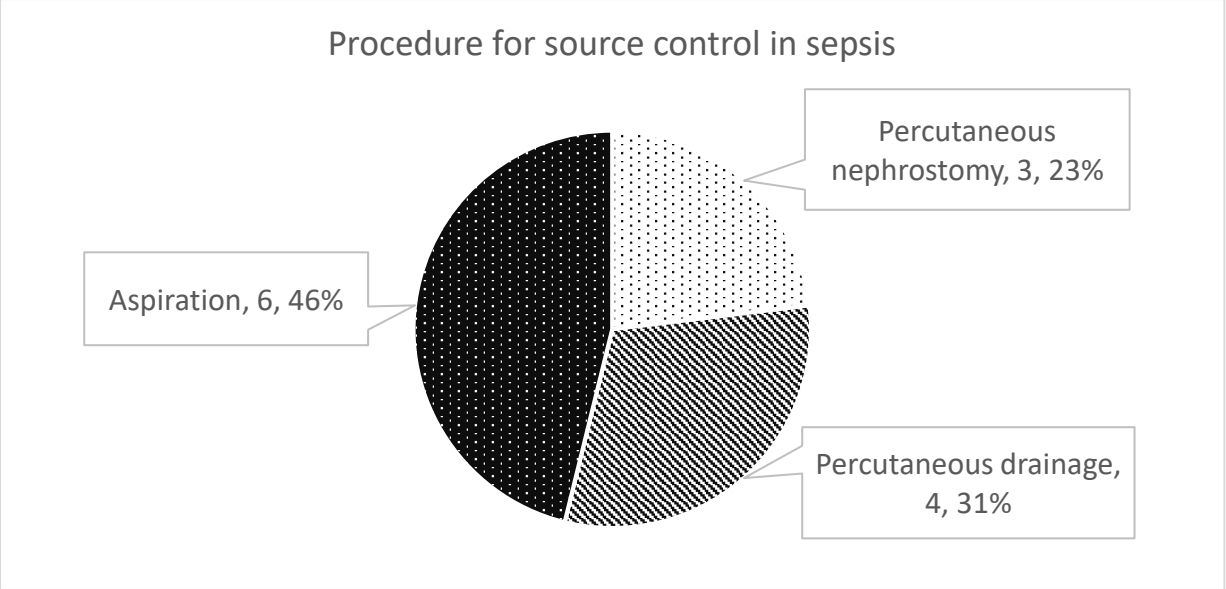

Figure 38: Distribution of study population who underwent procedure for source control of sepsis

6.4 3-month follow up data:

Apart from administration of questionnaires at follow up visit, data regarding change in baseline demographics and return to work was also gathered. Among the working section of the study population it was noted that only 81.9% returned to work after 3 months of discharge and majority returned to work after one month of discharge. Duration of absence from work is represented below.

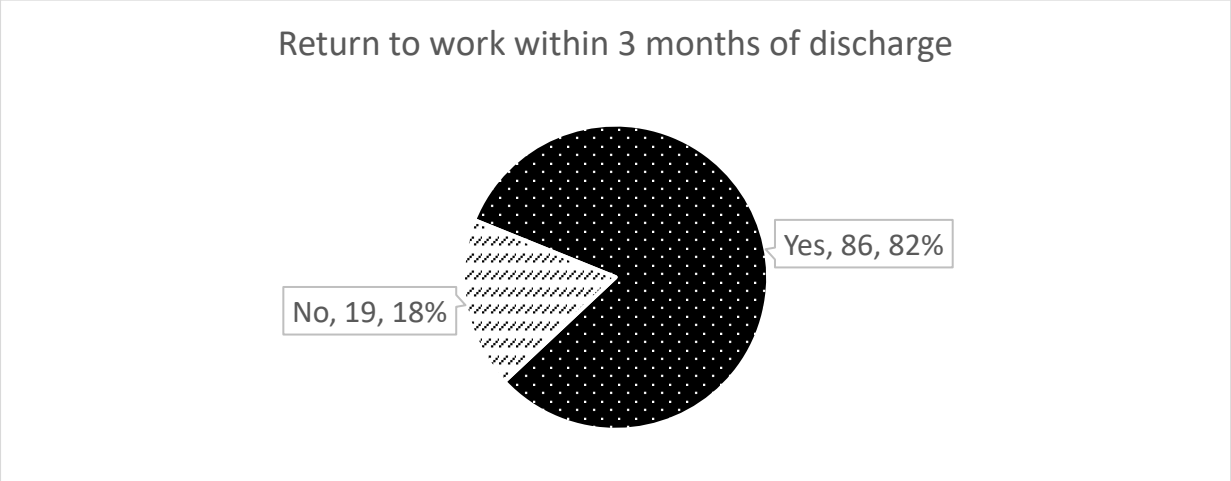

Figure 39: Distribution of study population-based return to work at 3 months following discharge

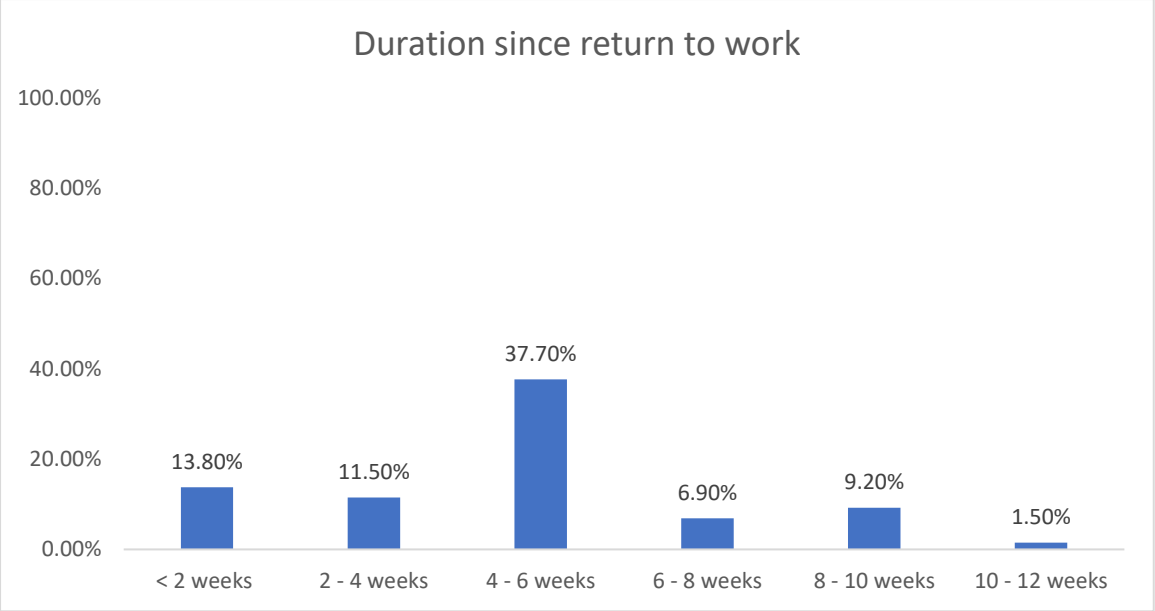

Figure 40: Distribution of patients based on time taken for return to work following discharge

New body mass index and dependency on immediate family members at 3 months follow up was also evaluated and was compared to baseline prior to admission in the hospital. There was a decrement in mean body mass index of the population from baseline to 3 months follow up as shown below.

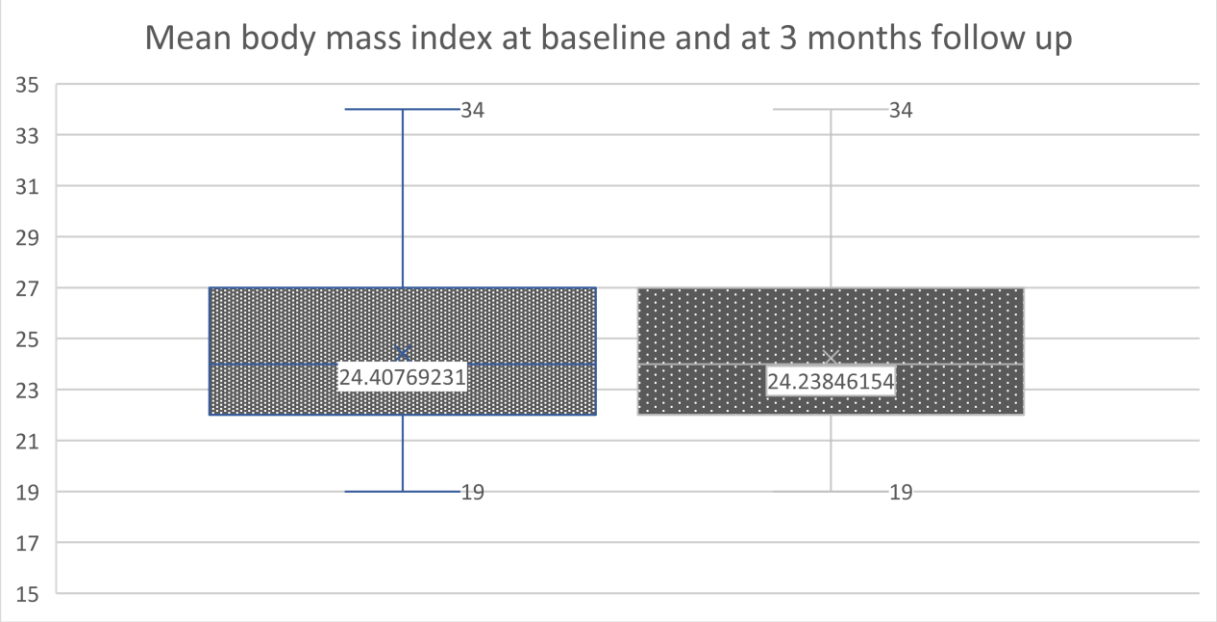

Figure 41: Box and whisker plot comparing mean, median, standard deviation and range of body mass index of study population at baseline and at 3 month follow up

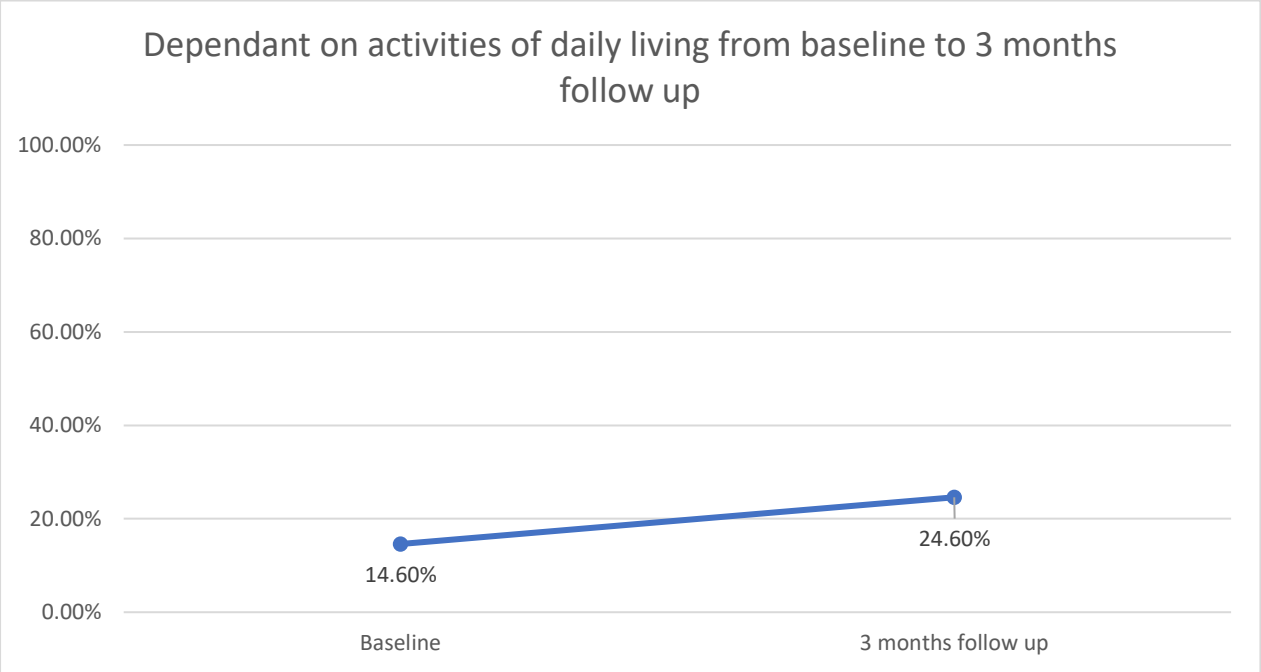

Figure 42 : Line Graph showing increase in dependency in activities of daily living from baseline to 3 months follow up

6.5 WHODAS-2 and BCRS:

WHODAS-2 and RetroBCRS questionnaires were administered at baseline and WHODAS-2 and BCRS questionnaire was administered at 3 months follow up visit.

Baseline mean WHODAS-2 score was 56.32 ± 19.8 and mean WHODAS-2 at 3 months follow up was 74.29 ± 29.1 as depicted in box and whisker plot below. This corresponds to 31.9% increase in mean WHODAS-2 score from baseline to 3 months follow up. Mean score of each individual domains of the scoring was also compared from baseline to 3 months and depicted in plot below.

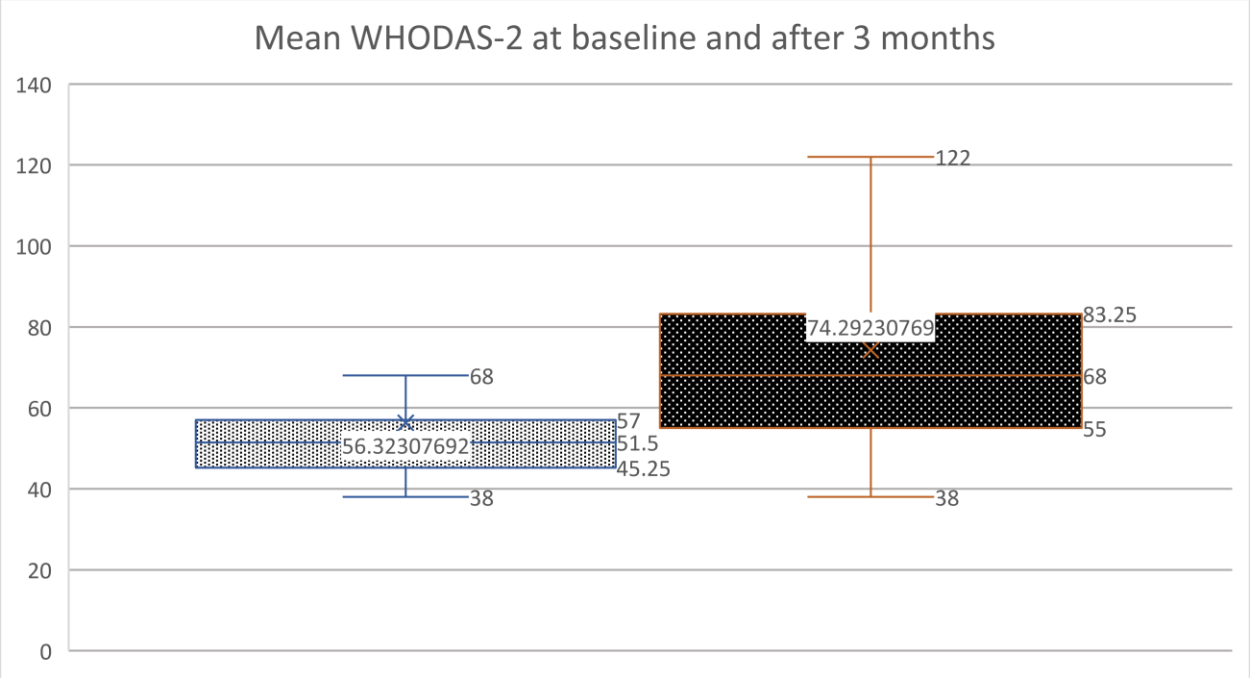

Figure 44: Box and whisker plot showing mean, median, IQR and range of WHODAS-2 score at baseline and at 3-month follow up

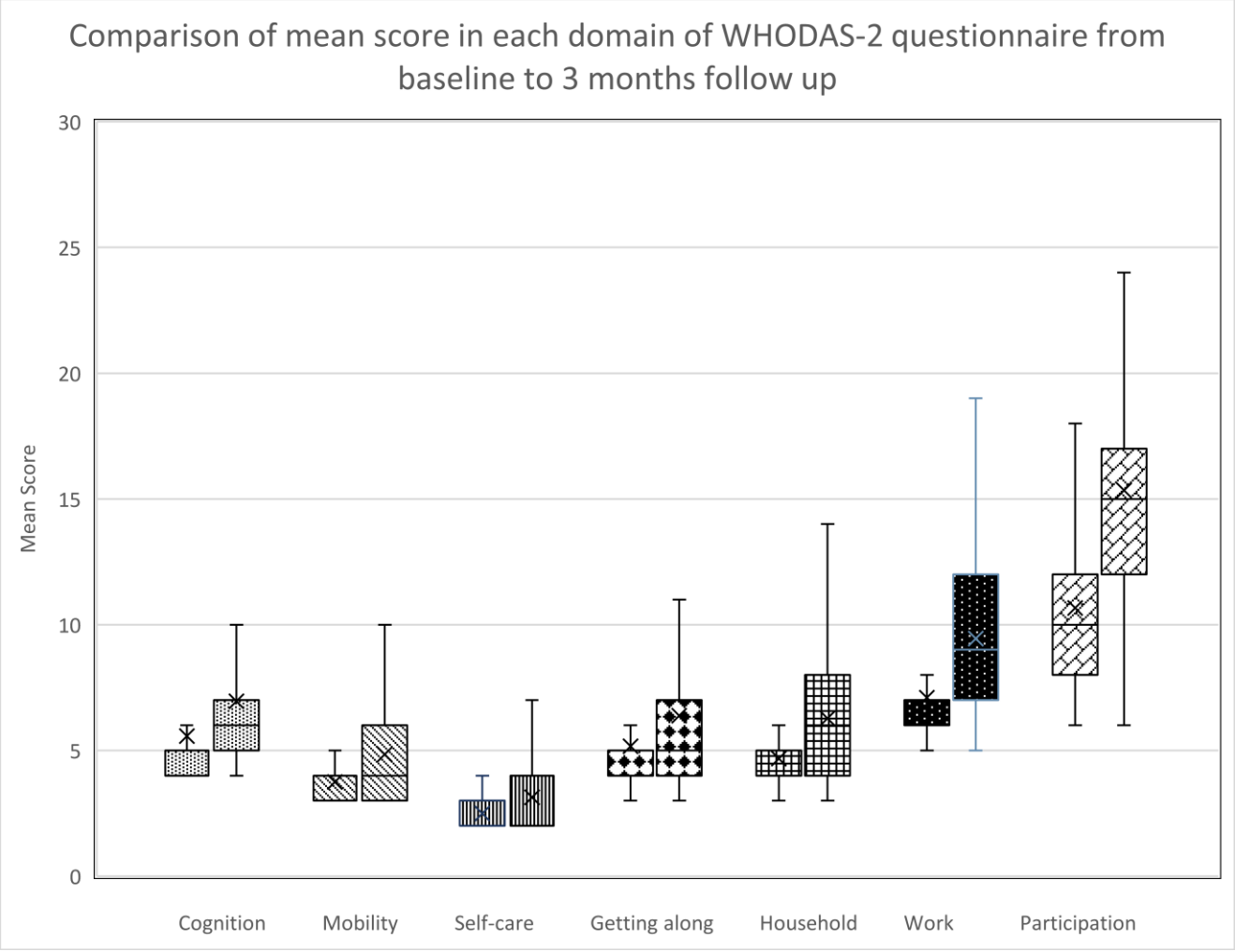

Figure 43: Box and whisker plot comparing mean, median, IQR and range of all domains in WHODAS-2 score at baseline and at 3-month follow up

Table below shows the mean score of WHODAS-2 and each component at baseline and at 3-month follow up with absolute and percentage change from baseline.

Table 6: Mean with standard deviation of WHODAS-2 score and domains at baseline and 3-month follow with absolute change and percentage change from baseline

SCORE	BASELINE	3-MONTH FOLLOW UP	ABSOLUTE CHANGE	PERCENTAGE CHANGE
WHODAS-2 score	56.32 ± 19.89	74.29 ± 29.18	17.96 ± 12.33	31.8%
Cognition	5.52 ± 2.42	6.95 ± 3.54	1.43 ± 1.49	25.9%
Mobility	3.74 ± 1.46	4.84 ± 2.54	1.1 ± 1.50	29.4%
Self-care	2.49 ± 0.99	3.13 ± 1.85	0.64 ± 1.07	25.7%
Getting along	5.16 ± 1.77	6.38 ± 2.77	1.22 ± 1.50	23.6%
Household	4.67 ± 1.93	6.26 ± 2.82	1.59 ± 1.55	34.0%
Work	7.09 ± 2.21	9.44 ± 3.13	2.35 ± 1.71	33.1%
Participation	10.66 ± 3.77	15.33 ± 4.89	4.66 ± 2.08	43.7%

Analysis of above data with Paired t-test showed significant change in each domain and for WHODAS-2 score from baseline to 3-month follow up as shown in the following table.

Table 7: Table showing paired t-test for WHODAS-2 score and each individual domain from baseline to 3-month follow up

	Paired Differences					t	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper		
WHODAS-2 score	17.96923	12.33005	1.08142	15.82962	20.10884	16.616	0.000
Cognition	1.43077	1.49386	0.13102	1.17154	1.69000	10.920	0.000
Mobility	1.10000	1.50374	0.13189	0.83906	1.36094	8.340	0.000
Self-care	0.64615	1.07011	0.09386	0.46046	0.83185	6.885	0.000
Getting along	1.22308	1.50073	0.13162	0.96266	1.48349	9.292	0.000
Household	1.59231	1.55865	0.13670	1.32184	1.86278	11.648	0.000
Work	2.35385	1.71569	0.15048	2.05613	2.65157	15.643	0.000
Participation	4.66923	2.08869	0.18319	4.30678	5.03168	25.488	0.000

Severity of physical disability with WHODAS-2 score is classified as follows:

Grade of disability	**Score**
Mild	39 – 75
Moderate	76 – 111
Severe	≥ 112

Using the above criteria, patients were classified into None, mild, moderate and severe disability at baseline and at 3 months follow up and is depicted below.

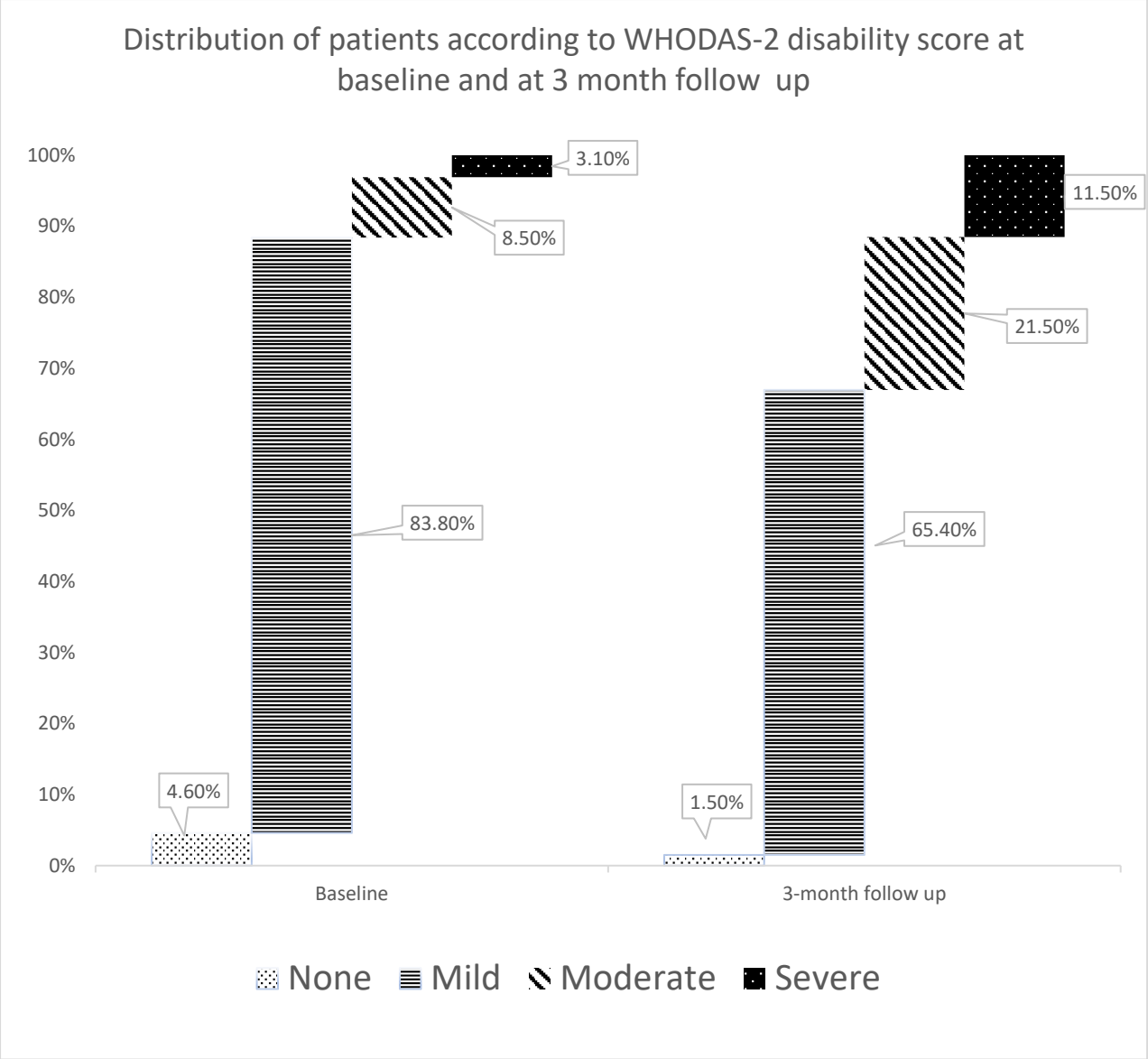

Figure 45: Distribution of patients based on severity of physical dysfunction at baseline and 3 months follow up

Proportion of patients with moderate and severe disability increased by 21% in 3 months following discharge as shown below.

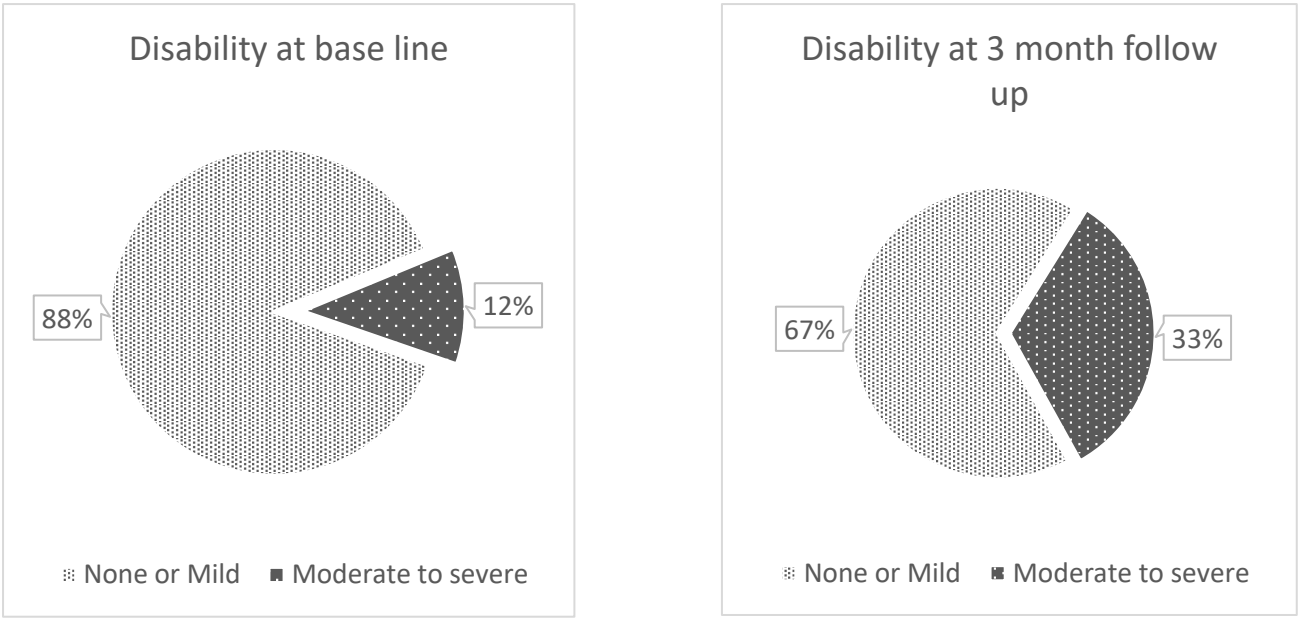

Figure 46: Comparison of distribution of patients with moderate/severe physical disability vs none/mild at baseline and at 3 months follow up

Cognitive functioning was assessed using RetroBCRS scale at admission and administration of BCRS at 3 months follow up. Mean RetroBCRS score at admission is 7.97 ± 3.90 and BCRS score at 3 months follow up is 10.14 ± 5.57 as depicted in box and whisker plot below. This corresponds to 27.2% increase in mean BCRS score from baseline to 3 months follow up. Mean score of each individual domains of the scoring is also compared from baseline to 3 months and depicted in plot below.

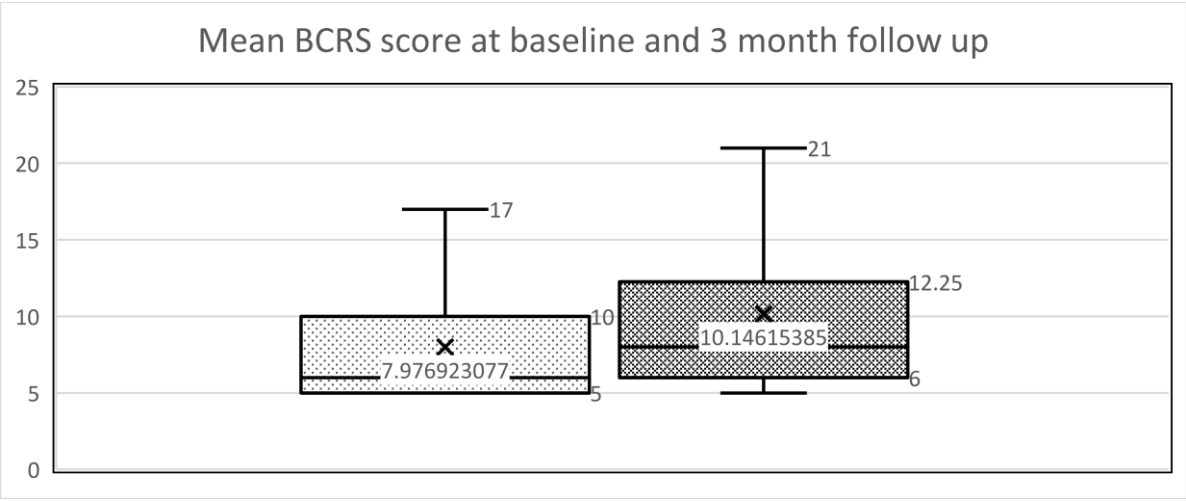

Figure 47: Box and whisker plot showing mean, median, IQR and range of BCSR score at baseline and at 3-month follow up

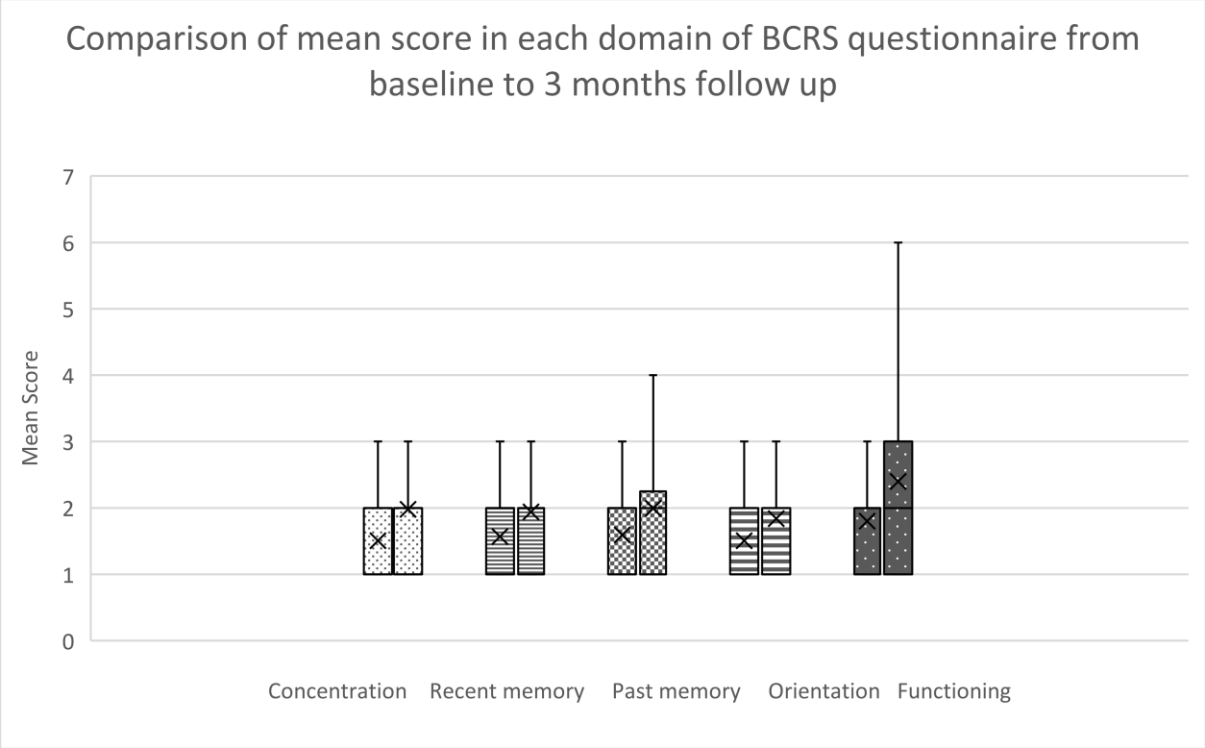

Figure 48: Box and whisker plot comparing mean, median, IQR and range of all domains in BCRS score at baseline and at 3-month follow up

Table below shows the mean score of BCRS and each component at baseline and at 3-month follow up with absolute and percentage change from baseline.

Table 8: Mean with standard deviation of BCRS score and domains at baseline and 3-month follow with absolute change and percentage change from baseline

SCORE	BASELINE	3-MONTH FOLLOW UP	ABSOLUTE CHANGE	PERCENTAGE CHANGE
BCRS	7.98 ± 3.90	10.14 ± 1.46	2.16 ± 2.36	27.2%
Concentration	1.51 ± 0.75	1.98 ± 1.07	0.46 ± 0.63	31.1%
Recent memory	1.57 ± 0.81	1.94 ± 1.11	0.36 ± 0.67	23.5%

Past memory	1.59 ± 0.86	1.99 ± 1.12	0.40 ± 0.61	25.1%
Orientation	1.51 ± 0.71	1.84 ± 1.13	0.33 ± 0.68	21.8%
Functioning	1.8 ± 1.07	2.4 ± 1.46	0.60 ± 0.77	33.3%

Analysis of above data with Paired t-test showed significant change in each domain and for BCRS score from baseline to 3-month follow up as shown in the following table.

Table 9 : Table showing paired t-test for BCRS score and each individual domain from baseline to 3-month follow up

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Concentration	0.469	0.637	0.056	0.359	0.580	8.396	129	0.000
Recent Memory	0.369	0.672	0.059	0.253	0.486	6.263	129	0.000
Past memory	0.400	0.618	0.054	0.293	0.507	7.385	129	0.000
Orientation	0.331	0.686	0.060	0.212	0.450	5.494	129	0.000
Functioning	0.600	0.774	0.068	0.466	0.734	8.843	129	0.000
BCRS	2.169	2.366	0.208	1.759	2.580	10.453	129	0.000

Cognitive dysfunction according to BCRS score has been classified into mild, moderate and severe as shown below.

Grade of cognitive disability	Score
Mild	6 – 10
Moderate	11 – 19
Severe	≥ 20

Using the above criteria, patients were classified into None, mild, moderate and severe disability at baseline and at 3 months follow up and is depicted below.

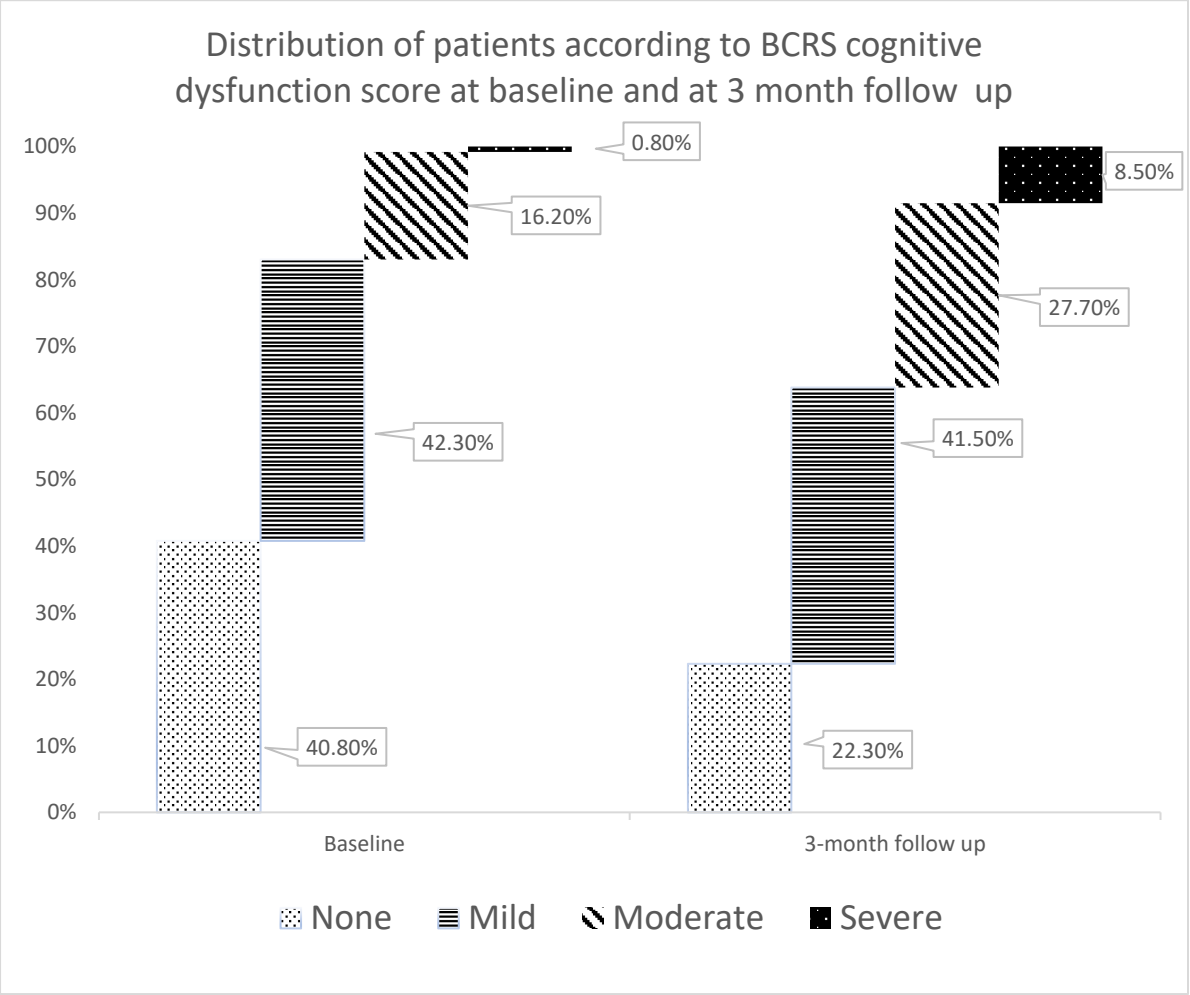

Figure 49: Distribution of patients based on severity of cognitive dysfunction at baseline and 3 months follow up

Proportion of patients with moderate and severe cognitive dysfunction increased by 19% in 3 month following discharge as shown below.

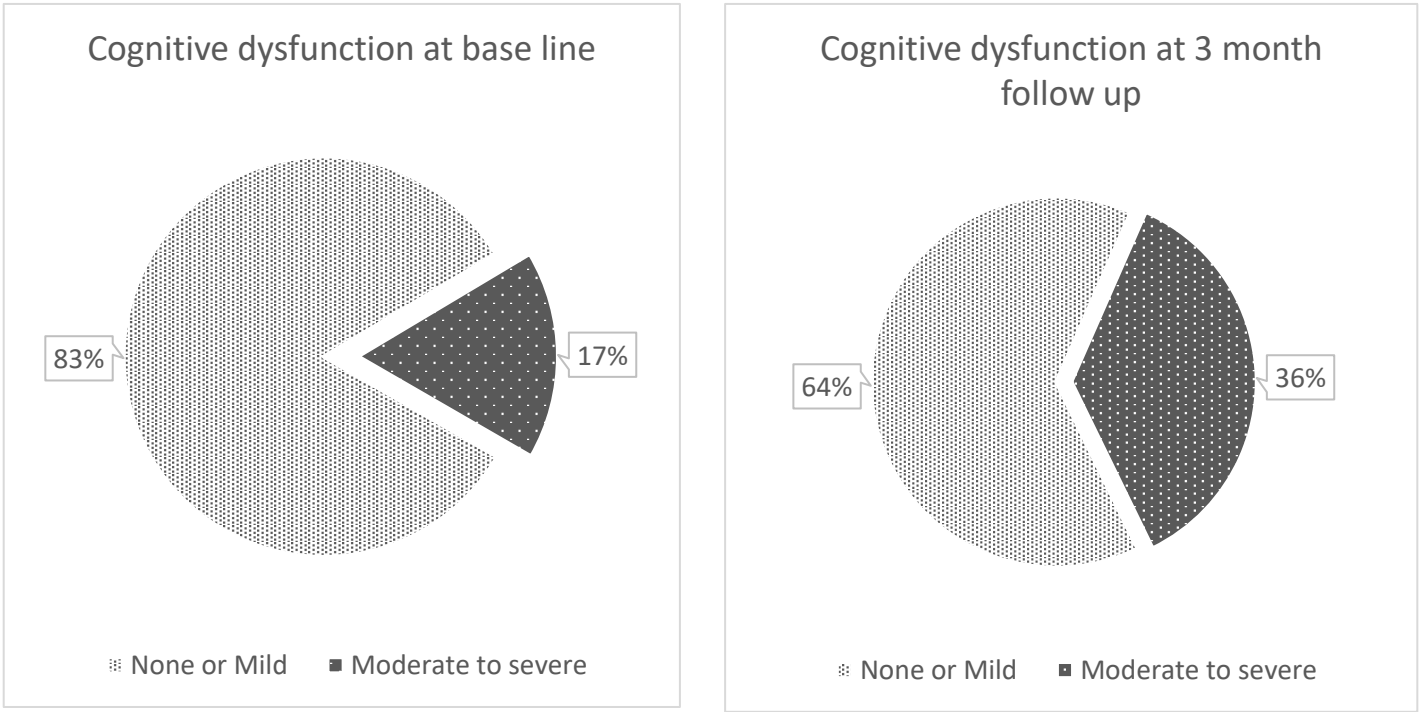

Figure 50: Comparison of distribution of patients with moderate/severe cognitive disability vs none/mild at baseline and at 3 months follow up

Analyzing the data using bivariate and multivariate logistic regression, multiple variables were evaluated for their influence on WHODAS-2 score following discharge. Overview of the results with P value is depicted in the table below.

Variable	**Odds ratio (95% confidence interval)**	**P value**
Age (> 60 years)	**9.29 (3.78,22.45)**	**0.0001**
Hospital stay (>10 days)	1.48 (0.71, 3.10)	0.289
Socioeconomic score (<15)	**3.02 (1.04, 8.78)**	**0.035**
Diabetes Mellitus	1.13 (0.53, 2.41)	0.74
HbA1c > 8mg%	0.76 (0.25, 2.27)	0.63
Hypertension	**2.89 (1.31, 6.37)**	**0.007**
Chronic Kidney disease (eGFR < 60ml/min/1.73m2)	1.50 (0.44, 5.04)	0.507
Significant alcohol consumption	1.65 (0.63, 4.29)	0.29
Smoking (>20 pack years)	1.82 (0.80, 4.12)	0.149
Resistant organism (ESBL, CRO, MRSA)	0.67 (0.26, 1.72)	0.411
Chronic obstructive airway disease	**3.29 (1.34, 8.08)**	**0.007**
PF ratio (<200)	2.05 (0.91, 4.63)	0.08
Ventilatory assistance	1.48 (0.63, 3.45)	0.358
Acute kidney injury (AKIN class > II)	1.71 (0.58, 5.03)	0.324
Hypotension	1.47 (0.67, 3.18)	0.328
SOFA score (>2)	**2.54 (1.08, 5.95)**	**0.029**

Hospital acquired infection	1.55 (0.33, 7.28)	0.572
Critical illness polyneuropathy	**3.17 (2.45, 4.10)**	**0.013**
Bed sore	**16.72 (1.98, 140.87)**	**0.001**
In hospital invasive procedure	2.18 (0.66, 7.24)	0.191

Table 10 : Table showing bivariate analysis of various variables with severe physical dysfunction

Similarly, analyzing the data using bivariate and multivariate logistic regression, multiple variables were evaluated for their influence on BCRS cognitive score following discharge. Overview of the results with P value is depicted in the table below.

Table 11: Table showing bivariate analysis of various variables with severe cognitive dysfunction

Variable	**Odds ratio (95% confidence interval)**	**P value**
Age (> 60 years)	**9.79 (4.12, 23.25)**	**0.0001**
Hospital stay (>10 days)	1.33 (0.64, 2.74)	0.434
Socioeconomic score (<15)	2.57 (0.88, 7.43)	0.074
Diabetes Mellitus	1.41 (0.67, 2.97)	0.36
HbA1c > 8mg%	1.01 (0.34, 2.99)	0.97
Hypertension	**3.09 (1.43, 6.69)**	**0.003**
Chronic Kidney disease (eGFR < 60ml/min/1.73m2)	1.87 (0.56, 6.19)	0.295
Significant alcohol consumption	1.76 (0.68, 4.54)	0.232
Smoking (>20 pack years)	2.12 (0.94, 4.80)	0.066
Resistant organism (ESBL, CRO, MRSA)	0.66 (0.26, 1.66)	0.385
Chronic obstructive airway disease	**3.37 (1.36, 8.31)**	**0.006**
PF ratio (<200)	**2.81 (1.25, 6.33)**	**0.011**
Ventilatory assistance	1.23 (0.53, 2.86)	0.617
Acute kidney injury (AKIN class > II)	1.50 (0.54, 4.19)	0.43
Hypotension	1.61 (0.75, 3.46)	0.212

SOFA score (>2)	**3.73 (1.55, 8.96)**	**0.002**
Hospital acquired infection	1.34 (0.28, 6.29)	0.704
Critical illness polyneuropathy	**2.88 (2.27, 3.66)**	**0.02**
Bed sore	**14.35 (1.70, 120.64)**	**0.002**
In hospital invasive procedure	1.29 (0.38, 4.32)	0.67

7. Discussion:

This prospective cohort included 130 patients admitted and discharged with a diagnosis of sepsis and were followed up after a period of 3 months, to ascertain the physical and cognitive disability conferred during this period. Nearly half the patients included were elderly, with age more than 60 years of age. This was similar to demographic characteristics of similar studies wherein patients admitted with sepsis had mean age ranging from 61 (6) to 75 years (11). The elderly is more prone for acquiring infections in view of underlying comorbidities and declining immunity. They also tend to be more dependent for activities of daily living on immediate family, resulting in caregiver burden (51), nursing home admissions (52) and increased incidence of depression (82). At baseline 14.6% of the study population was dependent for activities of daily living and at 3 months follow up this proportion increased to 24.6% which gives insight to the physical and cognitive decline suffered by the study population. One fifths of the patients in this study required intensive care unit admissions and the mean length of ICU stay was 4 days and of entire hospital stay was 8 days. Comparable figures from the INDICAP study (83) is 5 days in ICU and 12 days hospital stay in survivors and in the ANZICS (84) study is 6 days ICU, though ANZICS study population was of comparatively higher mean age on admission 60.7 years as opposed to our study. Critical care admissions and longer duration of hospital stay are associated with poorer quality of life in survivors (76) and high economic drain (56,61). This coupled with the fact that majority of the patients hail from middle class families (92.3%) paints the picture of financial burden which heralds our societal development.

Baseline characteristics of the study population revealed high burden of underlying comorbidities. 60% of the patients are diabetics and this was 3 times higher as compared to 20% of patients admitted with sepsis in western nations who were diabetic (85). This proportion was also larger as compared studies done in North India were diabetics only constituted 40% of the patients with sepsis (86). Glycemic control of most of the diabetics were poor with 60% of the having HbA1c more than 8gm% at admission. Studies have shown that patients with diabetes had a greater risk of developing lower respiratory tract infection (Adjusted odds ratio AOR 1.32 [95% CI, 1.13-1.53]), urinary tract infection (AOR, 1.24 [95% CI, 1.10-1.39]), bacterial skin and mucous membrane infection (AOR, 1.33 [95% CI, 1.15-1.54) (87), but at the same time did not affect mortality following admission with sepsis as compared to non-diabetics (88). This data was comparable to our study as 90% of the etiology of sepsis comprised of genitourinary, pulmonary and skin as source of infection. Half the patients admitted had underlying hypertension and quarter of them had underlying chronic obstructive airway disease. Reported prevalence of hypertension in south India ranges from 21% to 31% (89) and the higher proportion could be attributed to study being conducted in a tertiary referral care center hospital. The prevalence of obstructive airway disease was comparable to similar study done in sepsis in North India (86). Diagnosed coronary artery disease was only seen in 10% of the study population which was lower as compared to studies conducted in the west were it is 31% (6) but was similar to epidemiological studies conducted in India were prevalence has been estimated to be 9-10% (90).

Among the sepsis patients, etiology for half of them from genitourinary source followed by pulmonary origin. This was contradictory to findings from North (86) and East India (91) were most common source of infection was pulmonary and contributed 48% - 53% respectively. Higher proportion of long-standing diabetic population with uncontrolled HbA1c and diabetic complications such as cystopathy could probably explain greater prevalence of genitourinary source of infections. This coupled with high prevalence of community acquired extended spectrum beta lactamase inhibitory organisms, 64% in this study, could explain the greater incidence of sepsis and multiple organ dysfunction syndrome arising from urinary tract infections. 63% of the admission with sepsis diagnosed on SOFA score calculation had isolated organisms in relevant cultures, which was higher than 57.8% (84) and 53% (3) positive blood cultures in similar studies of sepsis conducted in Australian and French studies respectively, suggesting that our criteria may have resulted in overdiagnosis rather than underdiagnosis of sepsis. Escherichia coli was most isolated organism and resistance pattern as mentioned above was similar to microbiological guidelines from hospital infection control committee which estimated the prevalence of ESBL to 75%.

Mean SOFA score of the sepsis patients in this study was 3.9 and this hinted high proportion of patients with underlying multiple organ dysfunction syndrome. This data is skewed as only patients who survived sepsis for available for 3 months follow up is included. This finding was similar to study done in Pune, India were mean SOFA score

in survivors of sepsis was 4.5 (92). SOFA score of more than or equal to two was used as criteria for enrolment into this study and this channeled patients with high incidence of underlying organ dysfunction. On comparison to studies conducted on sepsis in intensive care settings, the presence of multiple organ dysfunction ranged from 40% (93) to 55.8% (86). However most common organs affected in sepsis survivors were renal, pulmonary and cardiovascular (11) which was similar findings in our study. However even with high incidence of renal dysfunction and acute respiratory dysfunction, only 2.3% of the patients required dialysis in hospital and 5.4% required invasive ventilation in our study. Comparable results showed 19.7% requiring ventilatory assistance and 4.3% requiring dialysis among sepsis survivors in their hospital stay as reported by Iwashyna et al (11). Being a subset of survivors of sepsis included in this study, exploration of requirement for dialysis and ventilatory requirements in all admissions with sepsis was reported to be 6.1% (94) and 21.3% (95) respectively. Even though need for dialysis was comparable among similar studies, lower requirement of ventilation could be explained by respiratory distress syndrome in our study was secondary to non-pulmonary source of infection as compared to most common etiology of sepsis elsewhere, which is of pulmonary source.

5.3% of the patients had hospital acquired infection during their stay and this was comparable to prevalence survey involving 11,282 patients from 183 US hospitals published by Centre for Disease Control in 2014 which reported that 4% of inpatients suffer from at least one healthcare-associated infection (96). Most common documented infection was central line related blood stream infection followed by catheter associated

urinary tract infection and ventilator associated pneumonia. High incidence of Acinetobacter baumanii among organisms isolated is of concern in view of its multiple drug resistant traits and is of common occurrence un tertiary care centers and intensive care units, including our center (97). Next most common complications of prolonged hospital stay were developing bed sores and critical illness neuropathy. Polyneuropathy is of serious concern in view of high incidence in patients with underlying sepsis and increasing risk with presence of multiple organ dysfunction (98,99) and administration of steroids (98), both of which are part and parcel in a diagnosis of sepsis. Implications of these complications in affecting the domain of physical mobility cannot be overlooked, but in view of low incidence of the same, our study was not powered to discriminate the same.

Primary objective of this study was to identify the functional and cognitive status in survivors of sepsis after 3 months. Conceptualization of this study was derived from previous studies conducted by Iwashyna et al (11) and Eddleston et al (37) wherein they showed cognitive and physical dysfunction respectively in sepsis and intensive care survivors. Realization and demonstration were attempted by incorporating WHODAS-2 score for assessing physical and BCRS for cognitive disability, which have been validated in previous studies. Survival is, by far, still the most commonly used outcome determinant in studies involving sepsis. In contrast to the relative abundance of facts documenting survival, there is a dearth of information evaluating morbidity, both in terms of physical and cognitive, which this study aimed at exploring.

7.1 Functional status of sepsis survivors

WHODAS-2 score calculated at baseline showed that 88% of the patients had mild or no disability. At baseline 12% of the population had moderate to severe physical disability which could be explained by evolved age of the study population with high prevalence of underlying comorbidities. This sect of the population would also contribute to approximately 14% of study patients being dependent on immediate family for activities of daily living. The most affected domain was participation in society and impact of health on self and family as a whole followed by limitation at work which either restricted hard labor or compromised the ability or time to get work done. The least affected domain was self-care and most patients were able to manage their own needs at baseline. At follow up period 3 month later there was significant change in the abilities, or rather disabilities of the study population, with maximal limitation in the front of participation in societal activities and impact of health on family. The mean score in WHODAS-2 increased by 32%, with increase in the proportion of patients with moderate to severe disability to 33% and dependency rate for activities of daily living increasing to 24.6%. Statistical analysis showed that increase in disability was consistent across all domains. As mentioned earlier, the most affected domain was the participation of the sepsis survivors in activities which was now restricted by change in their attitude, newly elated barriers, financial constraints or time spent in tending to health care. The next domains affected were their role in household activities as they were not able to perform tasks as well or as quickly as earlier. Their ability to be employed in purposeful work was also restricted due to lower

health standard and this prevented nearly one fifth of study population from returning to work in a time span of 3 months following discharge. Fatigue, change in sleep pattern and reduced ability to concentrate have been previously described (37) in patients post critical care and these factors could also explain relatively slow return to work of patients who were previously employed.

Other studies performing quality of life assessments have also shown worse outcome in patients after severe sepsis compared with either controls or to an age- and sex-adjusted general population (7,100). Assessing of quality of life using validated instruments in large unselected cohorts without major exclusions, with reasonably long follow-up, provided comparison with baseline is available, is reasonable (34). However, there is no consensus regarding which is the ideal tool for the same (60). Similar study done by Cuthbertson et al (101) in critically ill patients wherein he evaluated changes in quality of life from premorbid status to 3, 6, and 12 months after discharge, but using different questionnaire (Short Form-36 and EQ-5D) showed that physical component of quality of life was lowest at 3 months and had subsequently returned to premorbid level at 12 months. Hence our study can be seen as validating similar results in drop in physical ability in sepsis survivors similar to other critically care patients in 3 months follow up and further studies having longer follow up arm may help to validate improvements in physical abilities to baseline over time.

7.2 Cognitive function in sepsis survivors

Cognitive functioning was evaluated via BCRS score at baseline and showed that 17% of the study population had moderate to severe cognitive dysfunction. The world is aging via "demographic transition". The elderly population, > 60 years of age, constituted 11% of global and 8% of Indian population in 2011, and this is expected to reach 19% by 2050 (102). Aging is associated with cognitive Impairment which has been accepted as a risk factor for dementia (103) and elderly with memory impairment have rapid rate of conversion to Alzheimer's dementia, with annual conversion rates of 5%–15% (104). Community based studies has shown the prevalence of moderate to severe cognitive dysfunction in India ranged from 11% (105) to 25% (106) and our study showed similar results. Education (107), employment (108) and social support (109) have been found to have strong negative and independent association with cognitive dysfunction. At follow up period of 3 months, mean BCRS score of the population increased to 10.4, which is a 27.2% increase from baseline. This led to considerable increase in proportion of population with moderate to severe cognitive dysfunction, from 17% to 36%, a two-fold increase. Statistical analysis showed significant worsening in all the domains of cognitive dysfunction with the most affected domain being functioning and self-care followed by concentration. Patients were most troubled by performing complex tasks requiring handling multiple tasks and remembering, organizational capacity and subjective decrease in functional ability. Patients and relatives also noticed deficits in concentration while performing tasks and easy distractibility. Relatively well preserved was orientation to surroundings and

recent and remote memory. This picture emphasizes the gap in assessing cognitive ability beyond memory abilities as it seems to be involved only later.

Study conducted by Iwashyna et al (11) looked into the cognitive impairment and disability after severe sepsis and compared them with non-sepsis general hospital admissions and they concluded that severe sepsis was independently associated with a tripling in the odds of moderate to severe cognitive impairment and was independently associated with the acquisition of 1.5 new functional limitations in patients with nil to moderate pre-existing functional limitations. Our study did not have comparison arm, but was powered to detect the increase in cognitive disability in sepsis survivors. Findings of our study are similar to these and an episode of severe sepsis may represent a sentinel event in the lives of patients and their families, resulting in new and often persistent disability. These cognitive decline lead to great caregiver burden as the dependence of the affected population increases and this represents an underrecognized public health problem with major implications for patients, families, and the health care system and one that has received almost no attention, even in the face of the dramatically increasing incidence of severe sepsis (4). Compared to natural Alzheimer's disease or other vascular etiology for cognitive decline, the onset and progression of physical and mental abilities of sepsis survivors seems largely preventable and modifiable. With greater input into physiotherapy and cognitive challenging exercises prior to discharge and regular follow up with adequate addressal of these issues might improve the standard of living and reduce the dependency burden of the population on care givers.

7.3 Factors influencing poor functional and cognitive outcomes in sepsis survivors

Secondary objective of the study was to find variables which resulted in poorer outcomes and using statistical analysis it was shown that age more than 60 years was a significant contributor to the acceleration of physical and cognitive decline. Other factors which were found to enhance decline was higher SOFA score which indicated greater organ dysfunction and the presence of greater than moderate respiratory distress, critical illness polyneuropathy and bed sores which all would raise barriers in carrying out expected physical roles of the patient.

8. Limitation:

Our study had several limitations. Our study period was aimed at 3 months follow up of the patients and only provides a cross sectional image of the disabilities of the patients and longer follow up studies are needed to demonstrate improvement in physical sphere of functioning as has shown by similar studies

During the study period time we were able to recruit 150 patients and accounting for 20 patients who were lost to follow up, only 130 were included in the analysis. This was short of the required sample size needed to demonstrate statistical significance for the primary objective.

Cognitive categories and cut offs showing good clinical correlation have been employed in the study and better neuropsychological battery of testing would have been appropriate to demonstrate diagnosis of dementia.

As only the survivors were followed up after 3 months the data showing actual physical and cognitive decline might have been skewed.

Even though association was demonstrated, causality could have been better appreciated with an additional arm of study comprising of non-sepsis hospital admissions and evaluating the physical and cognitive change following discharge.

9. Conclusion:

1. Our study showed significant decline in physical and cognitive function at 3 months follow up in patients following discharge, with 31.8% and 27.2% increase in scores of assessments as compared to baseline values.

2. Age above 60 years, underlying chronic obstructive airway disease, SOFA score of more than 2, moderate or higher grade of Acute respiratory distress syndrome and developing in hospital critical illness polyneuropathy and bed sores were variables which were associated with greater decline in physical and cognitive functioning of patients at 3 months follow up.

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11. Annexures

11.1 Abstract

TITLE OF THE ABSTRACT : Evaluation of cognitive and functional status among survivors of sepsis in a tertiary care hospital in South India (CAFDASS)

DEPARTMENT : General Medicine

NAME OF THE CANDIDATE : George Abraham Ninan

DEGREE AND SUBJECT : MD General Medicine

NAME OF THE GUIDE : Dr. Alice Mathuram

OBJECTIVES:

Primary objective of this study is to measure the change in cognitive function and functional ability in survivors of Sepsis up to 3 months after discharge. Secondary objective of this study is to compare outcomes in both groups and identify factors which may have contributed to poorer outcome.

METHODS:

This was a prospective observational cohort study of patients admitted and discharged with a diagnosis of sepsis and survivors were followed up 3 months after discharge. Baseline physical and cognitive evaluation was assessed prior to discharge using WHODAS 2 and the RetroBCRS questionnaires and was reassessed withWHODAS-2 and BCRS questionnaire at 3 months follow up. 130 patients were included in the study

and statistical analysis was done using paired t-test to evaluate cognitive and physical decline in sepsis survivors and bivariate analyses was done to assess variables that resulted in poorer outcome.

RESULTS:

Study showed significant decline in physical and cognitive function at 3 months follow up in patients following discharge, with 31.8% and 27.2% increase in scores of assessments as compared to baseline values respectively. Age above 60 years, underlying chronic obstructive airway disease, SOFA score of more than 2, moderate or higher grade of acute respiratory distress syndrome and developing in hospital critical illness polyneuropathy and bed sores were variables which were associated with greater decline in physical and cognitive functioning of patients at 3 months follow up.

KEYWORDS:

Sepsis, physical and cognitive dysfunction, long term outcome in sepsis survivors

11.2 Institutional review board approval

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

August 29, 2018

Dr George Abraham Ninan,
PG Registrar,
Department of Medicine - 1,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
Evaluation of cognitive and functional status among survivors of sepsis.
Dr George Abraham Ninan ,PG Registrar, Emp No.29639, Medicine, – Dr. Alice Joan Mathuram Emp. No. 28529, Dept. of Medicine - 1, Dr Vignesh Kumar C, Emp. No.33782, Med – 2, Dr Aditya John Binu, Emp No.29070, Med – 3, Dr Nirmal, Emp No.29106, Med – 4. Dr Sohini Das, Emp. No. 29139, Med – 5. Mrs. Thenmozhi, Lecturer, Biostatistics.

Ref: IRB Min. No. 11284 [OBSERVE] dated 04.04.2018

Dear Dr George Abraham Ninan,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Alice Joan Mathuram. Chacko, Dept. of Medicine - 1, CMC, Vellore

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

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Ref: IRB Min. No. 11284 [OBSERVE] dated 04.04.2018

Dear Dr George Abraham Ninan,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Evaluation of cognitive and functional status among survivors of sepsis" on April 04th 2018.

The Committee reviewed the following documents:

1. IRB application format
2. Patient information sheet and Consent form (English, Tamil, Hindi)
3. Proforma
4. Cvs of Aditya Binu, Vignesh, Alice, George, Nirmal, Sohini, Ms. Thenmozhi,
5. No. of documents 1- 4.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on April 04th 2018 in the New IRB Room, Bagayam, Christian Medical College, Vellore 632 004.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor,Endocrinology, CMC, Vellore	Internal, Clinician
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

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Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Barney Isaac	M.B.,B.S. D.N.B (Respiratory Diseases)	Associate Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Mrs. Sophia Vijayananthan	MSc Nursing	Addl. Deputy Dean CMC, Vellore	Internal, Nurse
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical SurgicalNursing, CMC, Vellore	Internal, Nurse

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Evaluation of cognitive and functional status among survivors of sepsis" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 67,300/- INR (Rupees sixty Seven Thousand Three hundred Only) will be granted for 12 Months.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

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IRB Min. No. 11284 [OBSERVE] dated 04.04.2018

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11.3 Clinical research form

Demography and Baseline Data

Name:

Hospital Number: ☐☐☐☐☐☐

Age ☐☐ in years

Sex Male ☐ Female☐

Address

Occupation

Contact numbers:

1.

2.

State: Tamil Nadu☐ Kerala☐ Andhra Pradesh☐ Karnataka ☐

Where was patient admitted from? ☐Casualty ☐OPD

Where was the patient admitted to? Ward ☐ MHDU ☐ ICU ☐

Height (in cms)

Weight (in kgs)

BMI

Independent living:

Independent ☐ Dependent on relatives ☐ Professional care ☐ Hospital care ☐

Date of hospital admission ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

Date of hospital discharge ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

Date of ICU admission ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

Date of ICU discharge ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

Duration of hospital stay ☐☐ days

Duration of stay in ICU (if applicable) ☐☐ days

If dead, Date of death ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

Marital status ☐Married ☐Unmarried ☐Divorced ☐Widowed

Socioeconomic Details:

Modified Kuppuswamy Scale	(Total Score to be filled after calculating components below)	
a.Education of Head	☐Profession or honors	7 ☐
	☐Graduate or post graduate	6 ☐
	☐Intermediate or post high school diploma	5 ☐
	☐High school certificate	4 ☐
	☐Middle school certificate	3 ☐
	☐Primary school certificate	2 ☐
	☐Illiterate	1 ☐
b.Occupation of head	☐Profession	10☐
	☐Semi-profession	6 ☐
	☐Clerical, Shop-owner, farmer	5 ☐
	☐Skilled worker	4 ☐
	☐Semi-skilled worker	3 ☐
	☐Unskilled worker	2 ☐
	☐Unemployed	1 ☐
c.Family income per month	Rs 43184 and above	12☐
	Rs 21592 - Rs 43184	10☐
	Rs 16194 - Rs 21591	6 ☐
	Rs 10796 - Rs 16193	4 ☐
	Rs 6478 - Rs 10795	3 ☐
	Rs 2181 - Rs 6477	2 ☐
	Rs 2180 and below	1 ☐
Total Score	Total Score :☐☐ (to be filled after calculating components)	
Kuppuswamy Class	**Total score**	**SES class**
	26-29	☐Upper code-1
	16-25	☐Upper Middle code-2
	11-15	☐Lower Middle code-3
	5-10	☐Upper Lower code-4
	<5	☐Lower code-5

Comorbidities

Diabetes Mellitus Yes ☐ No ☐ Duration☐☐. ☐☐yrs Last HbA1c value: ☐☐. ☐☐g%

On OHA Yes ☐ No ☐ On insulin Yes ☐ No ☐

Hypertension Yes ☐ No ☐ Duration☐☐. ☐☐yrs on antihypertensives Yes ☐ No ☐

Dyslipidemia Yes ☐ No ☐ Duration☐☐. ☐☐yrs on statins Yes ☐ No ☐

Coronary Artery Disease Yes ☐ No ☐ Duration☐☐. ☐☐yrs

Previous ACS Yes ☐ No ☐

Known Case of Heart Failure Yes ☐ No ☐ Duration☐☐. ☐☐yrs Last Known EF: ☐☐. ☐☐%

Chronic kidney disease Yes ☐ No ☐ Duration☐☐. ☐☐yrs

Dialysis: Yes ☐ No ☐ Duration☐☐. ☐☐yrs Frequency: ☐ per week

Chronic Liver DiseaseYes ☐ No ☐ Duration☐☐. ☐☐yrs

Cirrhosis Yes ☐ No ☐ Portal hypertension Yes ☐ No ☐ Etiology:

Stroke in past Yes ☐ No ☐ MRS score: ☐

Hypothyroidism Yes ☐ No ☐ Duration☐☐. ☐☐yrs Dose of Thyroxine ☐☐☐mcg

Long term steroid use Yes ☐ No ☐ Duration☐☐. ☐☐yrs on maintenance steroids Yes ☐ No ☐

Dose of steroids in Prednisolone equivalents ☐☐ mg per day

Valvular heart disease? Yes ☐ No ☐ Is RHD the etiology? Yes ☐ No ☐

List Valves involved and lesion and severity (based on previous records)

☐MS ☐MR ☐TS ☐TR ☐AS ☐AR ☐PS ☐PR

Alcohol consumption Yes ☐ No ☐ Duration☐☐. ☐☐yrs

Duration since last Frequency of drinking ☐daily ☐3-6 days per week ☐1-2 days per week ☐2-3 days per month ☐<once a month

Number of Units per day (☐☐☐☐ drink☐☐. ☐☐yrs

Smoking Yes ☐ No ☐ Pack years ☐☐☐. ☐☐years

Tobacco chewing Yes ☐ No ☐ Duration☐☐☐. ☐☐yrs

Any other substance uses? Yes ☐ No ☐ Duration☐☐☐. ☐☐yrs

IV drugs Yes ☐ No ☐

Tuberculosis in Past Yes ☐ No ☐

Site: ☐pulmonary ☐extrapulmonary ☐not known

Treatment: ☐ Cat 1 ☐Cat II

Resistance: Sensitive ☐Sensitive ☐MDR code ☐XDR code

Atrial Fibrillation Yes ☐ No ☐ Duration☐☐. ☐☐yrs Anticoagulation Yes ☐ No ☐

HIV infection Yes ☐ No ☐ Duration☐☐☐. ☐☐yrs Last CD4+ count ☐ ☐☐☐/dl

On HAART Yes ☐ No ☐

Bronchial Asthma Yes ☐ No ☐ Duration☐☐. ☐☐yrs

COPD Yes ☐ No ☐ Duration☐☐. ☐☐yrs

Past history of cancer Yes ☐ No ☐

Treatment: Chemotherapy: Yes☐ No☐ Radiotherapy: Yes ☐ No ☐ Surgery: Yes ☐ No ☐

ECOG status: ☐

Sepsis Related

Duration of fever at presentation ☐☐ days

Source of infection:

Pulmonary ☐ Cardiac ☐ Gastrointestinal ☐ Genitourinary ☐ CNS☐ Musculoskeletal ☐ Acute febrile illness ☐ Skin and soft tissue ☐ Unknown ☐

PF ratio at presentation 200-300 ☐ 100-200 ☐ <100 ☐

RR at presentation: ☐☐

Mechanical ventilation Non-invasive ☐ Invasive ☐

Duration of ventilation: Non-invasive ☐☐ Invasive ☐☐

Use of paralytics Yes ☐ No ☐ Duration ☐☐ days

Tracheostomy Yes ☐ No ☐

Acute kidney Injury Yes ☐ No ☐ AKIN class ☐ Oliguric: Yes ☐ No ☐

Dialysis required Yes ☐ No ☐

Type of dialysis: ☐HD ☐SLED ☐UF ☐SCUF ☐CRRT

Hypotension Yes ☐ No ☐

If yes: - Duration of inotropes ☐☐ days Maximal number of inotropes: ☐☐

Duration of Noradrenaline ☐☐ days Dose ☐☐

Duration of Dopamine☐☐ days Dose ☐☐

Duration of Vasopressin ☐☐ days Dose ☐☐

Duration of adrenaline ☐☐ days Dose ☐☐

Hepatic dysfunction: Yes ☐ No ☐

Coagulopathy Yes ☐ No ☐ Lowest Platelet count: ☐☐☐☐☐☐

Bleeding manifestations: Yes ☐ No ☐

Transfusions: Yes ☐ No ☐

PC Yes ☐ No ☐ Number of products: ☐☐

PRC Yes ☐ No ☐ Number of products: ☐☐

FFP Yes ☐ No ☐ Number of products: ☐☐

Cryo Yes ☐ No ☐ Number of products: ☐☐

GCS at admission: ☐☐

SOFA score: ☐☐

Use of steroids Yes ☐ No ☐

Cumulative dose of steroids (In mg of hydrocortisone) ☐☐☐☐

Hospital acquired infections:

I. Ventilator associated pneumonia Yes ☐ No ☐

Date

Organism

Sensitivity

ii. Urinary tract infections Yes ☐ No ☐

Date

Organism

Sensitivity

iii. Central line related blood stream related infections Yes ☐ No ☐

Date

Organism

Sensitivity

Complications during hospital stay:

Critical illness polyneuropathy Yes ☐ No ☐

Bed sores Yes ☐ No ☐ Grade☐

DVT Yes ☐ No ☐

PE Yes ☐ No ☐

Stroke Yes ☐ No ☐ MRS score☐

Acute coronary syndrome Yes ☐ No ☐ ☐Anticoagulated
☐Thrombolysed

New onset Arrhythmia: Yes ☐ No ☐

Procedure undergone if any:

Discharge outcomes

Mortality: Yes ☐ No ☐

Date of death: ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

If alive, GCS at discharge: ☐☐ Ambulant Yes ☐ No ☐

First Follow up

MoCA score:

WHODAS-2 score:

Status of complication:

Tracheostomy present Yes ☐ No ☐

Bed sore healing Yes ☐ No ☐

Power of limbs Grade 5 ☐ Grade 4 ☐ Grade 3 ☐ Grade 2 ☐ Grade 1 ☐ Grade 0 ☐

Dyspnea on exertion MMRC grade ☐

New problems: Yes ☐ No ☐ Details:

3 months follow up

Mortality: Yes ☐ No ☐ Date of death: ☐☐/☐☐/☐☐☐☐ in dd/mm/yyyy

MoCA score:

WHODAS-2 score:

Return to work Yes ☐ No ☐ Duration ☐☐☐ days

Effort tolerance: ☐MMRC/NYHA

Weight (in kgs)

BMI

Independent living:

Independent ☐ Dependent on relatives ☐ Professional care ☐ Hospital care ☐

Status of complications:

Tracheostomy present Yes ☐ No ☐

Bed sore healing /healed Yes ☐ No ☐

Power of limbs Grade 5 ☐ Grade 4 ☐ Grade 3 ☐ Grade 2 ☐ Grade 1 ☐ Grade 0 ☐

New problems: Yes ☐ No ☐ Details:

11.4 Patient information sheet

11.4.1 English

Christian Medical College, Vellore

Department of Medicine

EVALUATION OF COGNITIVE AND FUNTIONAL STATUS AMONG SURVIVORS OF SEPSIS – CAFDASS study

Information sheet

What is the study about?

This study is about the long-term effects on people who have been admitted in hospital following sepsis. We want to know what functional and cognitive effects people have suffered after 3 months of admission.

If you take part what will you have to do?

If you agree to participate in this study, your base line data will be collected. You will also be administered a questionnaire at admission regarding your quality of life, habits, work and financial status before the illness.

For the study, details regarding your treatment in ICU and ward, blood tests needed for the study will be recorded. This is to help us identify if any factor will change the way your illness affects your health.

All treatments that you are already on will be continued and your regular treatment will not be changed during this study. This is only an observational study and there will be no change to your standard treatment plan for disease.

After discharge from the hospital, you will be given a phone number to contact us and asked to come back to the hospital at 2-4 weeks and then later at 3 months to see how your condition has changed since your discharge. No other additional procedures or blood tests will be conducted routinely for this study.

If at any time you experience any problems, you can report this to the doctor.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you because of taking part in this study.

Will you have to pay anything extra to take part in the study?

You will not incur any extra charges for taking part in this study

Any other treatment that you usually take will continue and the usual arrangements that you have with the hospital will decide how much you pay for this.

What happens after the study is over?

You may or may not benefit from the study that you are a part of. However, the conclusions drawn from this study will be useful to manage similar patients in future.

Will your personal details be kept confidential?

The results of this study may be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please ask

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11.4.2Tamil

தகவல் தாள்

செப்சிஸில் அறிவாற்றல் நிலை மற்றும் செயல்பாட்டு நிலை

1. இந்த ஆய்வின் நோக்கம் என்ன?

இந்த ஆய்வில், செப்சிஸ்ஸை தொடர்ந்து மருத்துவமனையில் அனுமதிக்கப்பட்டிருந்தவர்களுக்கு ஏற்படும் நீண்ட கால விளைவுகளைப் பற்றியதாகும்.
3 மாதங்களுக்குப் பிறகு மக்கள் என்ன அனுபவமற்ற மற்றும் அறிவாற்றல் விளைவுகளை அனுபவித்திருக்கிறார்கள் என்பதை நாம் அறிய விரும்புகிறோம்.

2. நீங்கள் இதில் கலந்துகொள்ள என்ன செய்ய வேண்டும் ?

இந்த ஆய்வில் பங்கேற்க நீங்கள் ஒப்புக்கொண்டால், உங்கள் அடிப்படை தகவல்கள் சேகரிக்கப்படும்.
உங்கள் வாழ்க்கைத் தரம், பழக்கம், வேலை மற்றும் நிதி நிலை குறித்த நோய்க்கு முன்னுரிமை உள்ளிட்ட வினாத்தாள்களை நீங்கள் வழங்கலாம்.

ஆய்வில், ICU மற்றும் வார்டுகளில் உங்கள் சிகிச்சையைப் பற்றிய விவரங்கள், ஆய்வுக்கு தேவையான இரத்த பரிசோதனைகள் பதிவு செய்யப்படும்.
இது உங்கள் நோய் உங்கள் உடல்நலத்தை பாதிக்கும் விதத்தை எந்த காரணி மாற்றும் என்பதை அறிய உதவும்.

நீங்கள் ஏற்கனவே உள்ள அனைத்து சிகிச்சையும் தொடரும் மற்றும் உங்கள் வழக்கமான சிகிச்சை இந்த ஆய்வின் போது மாற்ற முடியாது.
இது ஒரு ஆராய்ச்சிக் கருவி மட்டுமே, நோய்க்கான உங்கள் வழக்கமான சிகிச்சையளிக்கும் திட்டம் மாறாது.
மருத்துவமனையில் இருந்து வெளியேற்றப்பட்ட பிறகு, எங்களை தொடர்பு கொள்ள நீங்கள் ஒரு தொலைபேசி எண்ணை வழங்குவீர்கள், 2-4 வாரங்களில் மருத்துவமனைக்கு மீண்டும் வரவும், பிறகு மூன்று மாதங்கள் கழித்து உங்கள் நிலைப்பாட்டிலிருந்து உங்கள் நிலை மாறிவிட்டது என்பதைப் பார்க்கவும் வேண்டும்.

வேறு எந்த கூடுதல் நடைமுறைகள் அல்லது இரத்த பரிசோதனைகள் இந்த ஆய்வுக்காக செய்யப்படாது. எந்த நேரத்திலும் நீங்கள் எந்த பிரச்சனையும் அனுபவித்தால், இதை டாக்டரிடம் தெரிவிக்கலாம்.

3. தொடங்கியதிலிருந்து இந்த ஆய்வில் இருந்து மீளப்பெற முடியுமா?
   இந்த ஆய்வில் உங்கள் பங்களிப்பு முற்றிலும் தன்னார்வற்றது.
   இதிலிருந்து எப்போதும் விலகிக்கொள்ள முழு அனுமதி உள்ளது.
   அதனால் உங்கள் வழக்கமான சிகிச்சை பாதிக்காது..

4. இந்த ஆய்வில் பங்ககேற்பதன் மூலம் ஏதேனும் பாதிப்பு ஏற்படுமா? இந்த ஆய்வில் பங்ககேற்பதனால் எந்த பாதிப்பும் எற்படாது.

5. நீங்கள் இந்த ஆய்வினில் பங்கேற்க ஏதேனும் கூடுதலாக செலுத்த வேண்டுமா ? நீங்கள் இந்த ஆய்வினில் பங்கேற்க கூடுதலாக பணம் எதுவும் செலுத்த வேண்டியதில்லை. உங்களின் வழக்கமான மருத்துவ சிகிச்சை தொடரப்படும். இதற்காக வேறேதும் கட்டணங்கள் விதிக்கப்படுமாயின் அம்முடிவுகள் மருத்துவமனையையே சேரும்.

6. ஆய்வு முடிந்த பின்னர் என்ன நடக்கும்? நீங்கள் ஆய்வினில் பங்கேற்பது உங்களுக்கு பயனளிக்காமல் போகலாம். எனினும் இந்த ஆய்வில் இருந்து வரையப்பட்ட முடிவுகள் எதிர்காலத்தில் இதேபோன்ற நோயாளிகளை நிர்வகிக்க பயனுள்ளதாக இருக்கும்.

7. உங்கள் தனிப்பட்ட விவரங்கள் இரகசியமாக வைக்கப்படுமா? ஆய்வின் முடிவு ஒரு பத்திரிக்கையில் அல்லது ஒரு வழங்கல் மூலமாக வெளியிடப்படலாம். உங்கள் தனிப்பட்ட விவரங்கள் மற்றும் அடையாளங்கள் வெளியிடப்படாது. எனினும், உங்கள் மருத்துவ குறிப்புகளை ஆய்வு தொடர்புடைய மக்களால், உங்கள் கூடுதல் அனுமதி இல்லாமல், மதிப்பாய்வு செய்யப்படும் 300 பேர் இந்த ஆய்வில் கலந்து கொள்கின்றனர். உங்கள் முழு மற்றும் சரியான விவரங்களை தருமாறு கேட்டுக்கொள்கிறோம்

எந்த கேள்விகள் இருந்தாலும் நீங்கள் தொடர்பு கொள்ள,
டாக்டர் ஜார்ஜ் ஆபிரகாம் நினான்

செனைல் சைடிசின் - I
கிறிஸ்தவ ைருத்துவ கல்லூரி,
நவலூர் , திழ் ாடு
Tel: 96566776199
Email: georgeabraham90@gmail.com

11.4.3Hindi

ईसाई मेडिकल कॉलेज, वेल्लोर

चिकित्सा विभाग

सेप्सीस के जीवों के बीच ठोस और भविष्यकालीन निर्णय का मूल्यांकन - CAFDASS का अध्ययन

सूचना पत्र

के बारे में क्या अध्ययन है?

यह अध्ययन उन लोगों पर दीर्घकालिक प्रभावों के बारे में है जिनके सेप्सीस के बाद अस्पताल में भर्ती कराया गया है। हम यह जानना चाहते हैं कि 3 महीने के प्रवेश के बाद लोगों को कौन-कौन सी कार्यात्मक और संज्ञानात्मक प्रभाव पड़ा है।

यदि आप भाग लेते हैं तो आपको क्या करना होगा?

यदि आप इस अध्ययन में भाग लेने के लिए सहमत हैं, तो आपका बेस लाइन डेटा एकत्र किया जाएगा। बीमारी से पहले अपनी गुणवत्ता, आदतों, कार्य और वित्तीय स्थिति के बारे में प्रवेश पर आपको एक प्रश्नावली भी दी जाएगी।

अध्ययन के लिए, आईसीयू (ICU) और वार्ड में आपके उपचार के बारे में जानकारी, अध्ययन के लिए आवश्यक रक्त परीक्षणों को दर्ज किया जाएगा। यह हमें यह पहचानने में मदद करने के लिए है कि क्या आपकी बीमारी आपके स्वास्थ्य को प्रभावित करने के तरीके को बदल सकती है।

आपके द्वारा पहले से मौजूद सभी उपचार जारी रहेंगे और इस अध्ययन के दौरान आपका नियमित उपचार नहीं बदला जाएगा। यह केवल एक अवलोकन अध्ययन है और रोग के लिए आपकी मानक उपचार योजना में कोई परिवर्तन नहीं होगा।

अस्पताल से छुट्टी मिलने के बाद, हमसे संपर्क करने के लिए आपको एक फोन नंबर दिया जाएगा और आपको 3 महीने में अस्पताल वापस आने के लिए कहा जाएगा ताकि आपके डिस्चार्ज से आपकी स्थिति में बदलाव आया हो। इस अध्ययन के लिए कोई अन्य अतिरिक्त प्रक्रिया या रक्त परीक्षण नियमित रूप से नहीं किया जाएगा।

अगर किसी भी समय आप किसी भी समस्या का अनुभव करते हैं, तो आप डॉक्टर को इसकी रिपोर्ट कर सकते हैं।

क्या यह शुरू होने के बाद आप इस अध्ययन से वापस ले सकते हैं?

इस अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है और आप इस अध्ययन में भाग लेने की अनुमति वापस लेने का निर्णय लेने के लिए भी स्वतंत्र हैं। यदि आप ऐसा करते हैं, तो यह इस अस्पताल में किसी भी तरह से आपके सामान्य उपचार को प्रभावित नहीं करेगा।

यदि आप किसी भी अध्ययन से संबंधित चोट का विकास करते हैं तो क्या होगा?

इस अध्ययन में भाग लेने के कारण हमें आपकी कोई चोट होने की उम्मीद नहीं है।

क्या आपको अध्ययन में भाग लेने के लिए अतिरिक्त कुछ देना होगा?

इस अध्ययन में भाग लेने के लिए आपको कोई अतिरिक्त शुल्क नहीं लिया जाएगा

कोई भी अन्य उपचार जिसे आप आमतौर पर लेते हैं, जारी रहेगा और अस्पताल से आपके पास सामान्य व्यवस्था तय होगी कि आप इसके लिए कितना भुगतान करते हैं

अध्ययन खत्म होने के बाद क्या होता है?

आप इस अध्ययन से लाभान्वित नहीं हो सकते हैं या नहीं कि आप इसका हिस्सा हैं। हालांकि, इस अध्ययन से तैयार किए गए निष्कर्ष भविष्य में समान रोगियों को प्रबंधित करने के लिए उपयोगी होंगे।

क्या आपकी व्यक्तिगत जानकारी गोपनीय रखी जाएगी?

इस अध्ययन के परिणामों को एक चिकित्सा पत्रिका में प्रकाशित किया जा सकता है लेकिन आपको किसी भी प्रकाशन या परिणामों की प्रस्तुति में नाम से पहचाना नहीं जाएगा। हालांकि, आपकी मेडिकल नोट्स की आपकी अतिरिक्त अनुमति के बिना, अध्ययन से जुड़े लोगों द्वारा समीक्षा की जा सकती है, आपको इस अध्ययन में भाग लेने का फैसला करना चाहिए।

अगर आपके पास कोई और सवाल है, तो कृपया पूछें

डॉ। जॉर्ज अब्राहम नैनन

चिकित्सा यूनिट 1 विभाग

ईसाई मेडिकल कॉलेज अस्पताल

वेल्लोर, तमिलनाडु

632,004

मोबाइल नंबर 9566776199

ईमेल: georgeabraham90@gmail.com

11.5 Patient consent form

11.5.1 English

Informed Consent Form for Subjects

Informed Consent form to participate in a research study

Study Title: Evaluation of Cognitive and Functional status among sepsis survivors

Study Number: _____

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that ***the Sponsor of the clinical trial, others working on the Sponsor's behalf (delete as appropriate)***, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

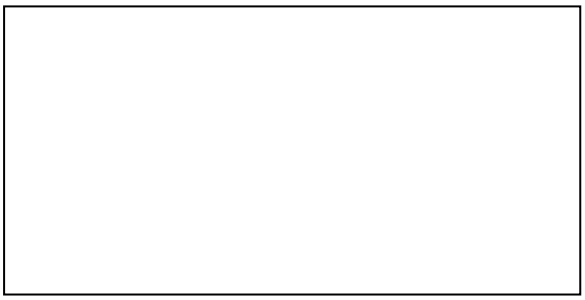
(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or



Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____

11.5.2Tamil

ஒப்புதல் படிவம்

ஆராய்ச்சி ஆய்வில் பங்கு பெற ஒப்புதல் ஒப்புதல் படிவம்

ஆய்வு: தறைப்பு: செப்சிஸில் அறிவாற்றல் நிலை மற்றும் செயல்பாட்டு நிலை

ஆராய்ச்சி எண்: _____

பபாருளின் பபயர்: _____

பிைப்பு / வயது கததி: _____

(*தறைப்பு*)

1. ***நான் போடுத்திருக்கும் தேவல் தாறை படித்து புரிந்துபோண்டதுடன். எனக்கு எற்பட்ட சந்கதேங்ேறையும் இன்று _____ கேட்டு பதரிந்துபோண்கடன்.***
2. ***இந்த ஆய்வில் நான் பங்குபேடுக்ே முழு மனகதாடு சம்மதிக்கிகைன். கமலும் எனக்கு இந்த ஆய்வில் ஒருகவறை விருப்பமின்றம ஏற்பட்டால், எவ்வித ே◌ாரணம் பசால்◌◌ாமல் விைக்போள்கவன். எனது மருத்துவ பராமரிப்புக்கும், சட்ட உரிறமக்கும் எவ்வித பாதிப்பும் எற்படாது என்பறத அறிகவன்.***
3. ***இந்த ஆய்வின் சார்பாே கவறை பசய்பவர்ேஞுக்கும், பநறிமுறை குழு மற்றும் ஒழுங்குமுறை குழுவிற்கும், நான் இந்த ஆய்விலிருந்து விைகிக்போண்டாள் கூட எனது மருத்துவ விவரங்ேறை ே◌ாணவும் அதறன இந்த ஆய்வினில் மட்டுமல்◌◌ாது இதறன கசர்ந்த பின்வரும் ஆய்விற்கும் பயன்படுத்த முழு உரிறம உள்◌பதன அறிகவன். எனினும் என்றன பற்றிய தேவல்ேறை இந்த ஆய்வில் சார்ந்கதார் அல்◌◌ாது கவறு எவரிடமும் கசராது என அறிகவன்.***
4. ***இதில் கிறடக்கும் தரவுேறையும், முடிவுேறையும் இந்த ஆய்வுக்கு மட்டுமின்றி. ஒருகவறை அறிவியல் சார்ந்து கவறு ஆய்வுக்கும் கதறவப்பட்டால் பயன்படுத்த உரிறம உள்◌து என்பறத அறிகவன்.***
5. ***நான் கமகை குறிப்பிட்டிருக்கும் இந்த ஆய்வில் பங்குபோள்◌ சம்மதிக்கிகைன்.***

றேபயாப்பம் (அல்◌து பபருவிரல் கரறே)

கததி: __ / __ / __

றேபயாப்பமி டு ம் பபயர்: _____ ***றேபயாப்பம்:***

அல்◌த

பிரதிநிதி: _____

கததி: __ / __ / __

றேபயாப்பமி டு ம் பபயர்: _____

ஆராய்ச்சியாைராே றேபயாப்பம்: _____

கததி: __ / __ / __

ஆய்வு ஆராய்ச்சியாைராே பபயர்: _____

சாட்சி றேபயாப்பம் அல்ைது பபருவிரல் கரறே: _____

கததி: __ / __ / ____

பபயர் & சாட்சி முேவரி:

11.5.3Hindi

<u>सहमति पत्र</u> अध्ययन

सेप्सिस में संज्ञानात्मक गिरावट और कार्यात्मक स्थिति

अध्ययन संख्या: _____

मरीज का नाम: _____

जन्म की तिथि / आयु: _____

1. मैं पुष्टि करता हूं कि मैंने सूचना पत्र पढ़ लिया है और समझ लिया है दिनांक _____ और सवाल पूछने का अवसर मिला है
2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं बिना किसी कारण के बिना, किसी भी समय बिना किसी चिकित्सा कारण या कानूनी अधिकारों को प्रभावित किए बिना वापस लेने के लिए स्वतंत्र हूं
3. मैं समझता हूं कि नैदानिक परीक्षण के प्रायोजक, एथिक्स कमेटी और नियामक प्राधिकारियों को मौजूदा अध्ययन के संबंध में अपने स्वास्थ्य के रिकॉर्ड दोनों को देखने की मेरी अनुमति की आवश्यकता नहीं है और इसके संबंध में किसी और शोध का आयोजन किया जा सकता है, भले ही मैं परीक्षण से वापस ले जाता हूं. मैं इस पहुंच से सहमत हूं. हालांकि, मैं समझता हूं कि मेरी पहचान तीसरी पार्टी के लिए जारी किसी भी जानकारी या प्रकाशित में प्रकट नहीं होगी।
4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित करने के लिए सहमत नहीं हूं, लेकिन ऐसे प्रयोग केवल वैज्ञानिक उद्देश्य के लिए हैं
5. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं।

विषय के हस्ताक्षर (या अंगूठे की छाप) (कानूनी रूप से स्वीकार्य)

दिन : _____/_____/_____

हस्ताक्षरकर्ता का नाम : _____ हस्ताक्षर:

य

प्रतितनथि: _____

दिन : _____/_____/_____

हस्ताक्षरकर्ता का नाम: _____

अन्वेषक के हस्ताक्षर: _____

दिन : _____/_____/_____

अध्ययन अन्वेषक का नाम: _____

साक्षी के हस्ताक्षर या अंगूठे का छाप: _____

दिन : _____/_____/_____

साक्षी का नाम और पता

11.6 WHODAS-2 Questionnaire

WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

12+24-item version, interviewer-administered

Introduction

This instrument was developed by the WHO *Classification, Terminology and Standards* team, within the framework of the WHO/National Institutes of Health (NIH) Joint Project on Assessment and Classification of Disability.

Before using this instrument, interviewers must be trained using the manual *Measuring Health and Disability: Manual for WHO Disability Assessment Schedule – WHODAS 2.0* (WHO, 2010), which includes an interview guide and other training material.

The versions of the interview available are as follows:

- 36-item – Interviewer-administered[a]
- 36-item – Self-administered
- 36-item – Proxy-administered[b]
- 12-item – Interviewer-administered[c]
- 12-item – Self-administered
- 12-item – Proxy-administered
- 12+24-item – Interviewer-administered

[a] A computerized version of the interview (*iShell*) is available for computer-assisted interviews or for data entry

[b] Relatives, friends or caretakers

[c] The 12-item version explains 81% of the variance of the more detailed 36-item version

For more details of the versions please refer to the WHODAS 2.0 manual *Measuring Health and Disability: Manual for WHO Disability Assessment Schedule – WHODAS 2.0* (WHO, 2010).

Permission to translate this instrument into any language should be obtained from WHO, and all translations should be prepared according to the WHO translation guidelines, as detailed in the accompanying manual.

For additional information, please visit www.who.int/whodas or contact:

Dr T Bedirhan Üstün
Classification, Terminology and Standards
Health Statistics and Informatics
World Health Organization (WHO)
1211 Geneva 27
Switzerland

Tel: + 41 22 791 3609
E-mail:ustunb@who.int

WHODAS 2.0

WORLD HEALTH ORGANIZATION
DISABILITY ASSESSMENT SCHEDULE 2.0

12+24
Interview

This questionnaire contains the interviewer-administered 12-item version of WHODAS 2.0.

Instructions to the interviewer are written in bold and italics – do not read these aloud
Text for the respondent to hear is written in
standard print in blue.

Read this text aloud

Section 1 Face sheet

Complete items F1–F5 before starting each interview				
F1	Respondent identity number			
F2	Interviewer identity number			
F3	Assessment time point (1, 2, etc)			
F4	Interview date	_____ day	_____ month	_____ year
F5	Living situation at time of interview (circle only one)	Independent in community		1
		Assisted living		2
		Hospitalized		3

Please continue to next page...

Section 2 Demographic and background information

This interview has been developed by the World Health Organization (WHO) to better understand the difficulties people may have due to their health conditions. The information that you provide in this interview is confidential and will be used only for research. The interview will take 10–20 minutes to complete.

For respondents from the general population (not the clinical population) say:

Even if you are healthy and have no difficulties, I need to ask all of the questions so that the survey is complete.

I will start with some background questions.

A1	***Record sex as observed***	Female Male	1 2
A2	How old are you now?	_____ years	
A3	How many years in all did you spend studying in school, college or university?	_____ years	
A4	What is your current marital status? ***(Select the single best option)***	Never married Currently married Separated Divorced Widowed Cohabiting	1 2 3 4 5 6
A5	Which describes your main work status best? ***(Select the single best option)***	Paid work Self employed, such as own your business or farming Non-paid work, such as volunteer or charity Student Keeping house/ homemaker Retired Unemployed (health reasons) Un employed (other reasons) Other (specify)_____ _____	1 2 3 4 5 6 7 8 9

Please continue to next page...

Section 3 Preamble

Say to respondent:

The interview is about difficulties people have because of health conditions.

Hand flashcard #1 to respondent

By health condition, I mean diseases or illnesses, or other health problems that may be short or long lasting; injuries; mental or emotional problems; and problems with alcohol or drugs.

Remember to keep all of your health problems in mind as you answer the questions. When I ask you about difficulties in doing an activity think about:

Point to flashcard #1 and explain that "difficulty with an activity" means:

- Increased effort
- Discomfort or pain
- Slowness
- Changes in the way you do the activity.

Say to respondent:

When answering, I'd like you to think back over the past 30 days. I would also like you to answer these questions thinking about how much difficulty you have had, on average, over the past 30 days, while doing the activity as you usually do it.

Hand flashcard #2 to respondent and say:

Use this scale when responding.

Read the scale aloud:

None, mild, moderate, severe, extreme or cannot do.

Ensure that the respondent can easily see flashcards #1 and #2 throughout the interview

Please continue to next page...

Section 4 Core questions

Show flashcard #2

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
S1	Standing for long periods such as 30 minutes?	1	2	3	4	5
S2	Taking care of your household responsibilities?	1	2	3	4	5
S3	Learning a new task, for example, learning how to get to a new place?	1	2	3	4	5
S4	Joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	1	2	3	4	5
S5	How much have you been emotionally affected by your health problems?	1	2	3	4	5

If any of S1–S5 are endorsed (rated greater than none), continue with S6–S12. Otherwise, this is the end of the interview, in which case say:

This concludes our interview. Thank you for participating.

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
S6	Concentrating on doing something for ten minutes?	1	2	3	4	5
S7	Walking a long distance such as a kilometre (or equivalent)?	1	2	3	4	5
S8	Washing your whole body?	1	2	3	4	5
S9	Getting dressed?	1	2	3	4	5
S10	Dealing with people you do not know?	1	2	3	4	5
S11	Maintaining a friendship?	1	2	3	4	5
S12	Your day-to-day work?	1	2	3	4	5

Please continue to next page...

Continue by administering the specified domains as follows:

If question is endorsed (coded 2–5)	Go to	Domain number
D3 or D6	⇒	1 on page 6
D1 or D7	⇒	2 on page 7
D8 or D9	⇒	3 on page 7
D10 or D11	⇒	4 on page 7
D2 or D12	⇒	5 on pages 8–9
D4 or D5	⇒	6 on page 10

Domain 1 Cognition

I am now going to ask some questions about understanding and communicating.

Show flashcards #1 and #2

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D1.2	Remembering to do important things?	1	2	3	4	5
D1.3	Analysing and finding solutions to problems in day-to-day life?	1	2	3	4	5
D1.5	Generally understanding what people say?	1	2	3	4	5
D1.6	Starting and maintaining a conversation?	1	2	3	4	5

Please continue to next page...

Domain 2 Mobility

I am now going to ask you about difficulties in getting around.

Show flashcards #1 and #2

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D2.2	Standing up from sitting down?	1	2	3	4	5
D2.3	Moving around inside your home?	1	2	3	4	5
D2.4	Getting out of your home?	1	2	3	4	5

Domain 3 Self-care

I am now going to ask you about difficulties in taking care of yourself.

Show flashcards #1 and #2

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D3.3	Eating?	1	2	3	4	5
D3.4	Staying by yourself for a few days?	1	2	3	4	5

Domain 4 Getting along

I am now going to ask you about difficulties in getting along with people. Please remember that I am asking only about difficulties that are due to health problems. By this I mean diseases or illnesses, injuries, mental or emotional problems and problems with alcohol or drugs.

Show flashcards #1 and #2

In the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D4.3	Getting along with people who are close to you?	1	2	3	4	5
D4.4	Making new friends?	1	2	3	4	5
D4.5	Sexual activities?	1	2	3	4	5

Please continue to next page...

Domain 5 Life activities

5(1) Household activities

I am now going to ask you about activities involved in maintaining your household, and in caring for the people who you live with or are close to. These activities include cooking, cleaning, shopping, caring for others and caring for your belongings.

Show flashcards #1 and #2.

	Because of your health condition, in the past 30 days, how much difficulty did you have in:	None	Mild	Moderate	Severe	Extreme or cannot do
D5.2	Doing your most important household tasks well?	1	2	3	4	5
D5.3	Getting all the household work done that you needed to do?	1	2	3	4	5
D5.4	Getting your household work done as quickly as needed?	1	2	3	4	5

If any of the responses to D5.2–D5.4 are rated greater than none (coded as "1"), ask:

D5.01	In the past 30 days, on how many days did you reduce or completely miss household work because of your health condition?	*Record number of days* ____

If respondent works (paid, non-paid, self-employed) or goes to school, complete questions D5.6–D5.10 on the next page. Otherwise, skip to D6.2 on page 10.

5(2) Work or school activities

Now I will ask some questions about your work or school activities.

Show flashcards #1 and #2

Because of your health condition, in the past 30 days how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D5.6	Doing your most important work/school tasks well?	1	2	3	4	5
D5.7	Getting all the work done that you need to do?	1	2	3	4	5
D5.8	Getting your work done as quickly as needed?	1	2	3	4	5
D5.9	Have you had to work at a lower level because of a health condition?				No	1
					Yes	2
D5.10	Did you earn less money as the result of a health condition?				No	1
					Yes	2

If any of D5.6–D5.10 are rated greater than none (coded as "1"), ask:

D5.02	In the past 30 days, on how many days did you miss work for half a day or more because of your health condition?	*Record number of days* ____

Please continue to next page...

Domain 6 Participation

Now, I am going to ask you about your participation in society and the impact of your health problems on you and your family. Some of these questions may involve problems that go beyond the past 30 days; however, in answering, please focus on the past 30 days. Again, remember to answer these questions while thinking about your health problems: physical, mental or emotional, alcohol or drug related.

Show flashcards #1 and #2

In the past 30 days:		None	Mild	Moderate	Severe	Extreme or cannot do
D6.2	How much of a problem did you have because of barriers or hindrances in the world around you?	1	2	3	4	5
D6.3	How much of a problem did you have living with dignity because of the attitudes and actions of others?	1	2	3	4	5
D6.4	How much time did you spend on your health condition, or its consequences?	1	2	3	4	5
D6.6	How much has your health been a strain on the financial resources of you or your family?	1	2	3	4	5
D6.7	How much of a problem did your family have because of your health problems?	1	2	3	4	5
D6.8	How much of a problem did you have in doing things by yourself for relaxation or pleasure?	1	2	3	4	5

H1	Overall, in the past 30 days, how many days were these difficulties present?	***Record number of days*** ____
H2	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	***Record number of days*** ____
H3	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	***Record number of days*** ____

This concludes our interview. Thank you for participating.

11.7 BCRS and RetroBCRS questionnaire

NAME: _____ ID#: _____ DATE: ___/___/___

BRIEF COGNITIVE RATING SCALE (BCRS)

INFORMANT: _____

RELATIONSHIP OF INFORMANT: _____

AXIS I: CONCENTRATION (circle only one, i.e., the most appropriate level)
1 No objective or subjective evidence of deficit in concentration.
2 Subjective decrement in concentration ability.
3 Minor signs of poor concentration (e.g., subtraction of serial 7s from 100).
4 Definite concentration deficit for persons of their background (e.g., marked deficit on serial 7s, frequent deficit in subtraction of serial 4s from 40).
5 Marked concentration deficit (e.g., giving months backwards or serial 2s from 20).
6 Forgets the concentration task. Frequently begins to count forward when asked o count backwards from 10 by 1s.
7 Marked difficulty counting forward to 10 by 1s.

AXIS II: RECENT MEMORY (circle only one, i.e., the most appropriate level)
1 No objective or subjective evidence of deficit in recent memory.
2 Subjective impairment only (e.g., forgetting names more than formerly).
3 Deficit in recall of specific events evident upon detailed questioning, (e.g. about recent meals, current reading, recent appointments, etc.). No deficit in the recall of major recent events.
4 Cannot recall major events of previous weekend or week. Scanty knowledge (not detailed) of current events, favorite TV shows, etc. May not know telephone number and/or telephone area code and/or postal (zip) code.
5 Unsure of weather, and/or may not know current president and/or current address.
6 Occasional knowledge of some recent events. Little or no idea of current address, weather, etc. Given the current president's first name, may recall their last name.
7 No knowledge of any recent events.

AXIS III: PAST MEMORY (circle only one, i.e., the most appropriate level)
1 No subjective or objective impairment in past memory.
2 Subjective impairment only. Can recall two or more primary school teachers.
3 Some gaps in past memory upon detailed questioning. Able to recall at least one childhood teacher and/or one childhood friend.
4 Clear-cut deficit. The spouse recalls more of the patient's past than the patient. Cannot recall childhood friends and/or teachers but knows the names of schools attended. Confuses chronology in reciting personal history.
5 Major past events sometimes not recalled (e.g., names of schools attended). Characteristically, at this stage patients recall some schools attended, but not others.
6 Some residual memory of past (e.g., may recall country of birth or former occupation, may or may not recall mother's name, may or may not recall father's name). Generally, patients do not recall any of the schools which they attended.
7 No memory of past (cannot recall country, state, or town of origin, cannot recall names of parents, etc.)

AXIS IV: ORIENTATION (circle only one, i.e., the most appropriate level)
1 No deficit in memory for time, place, identity of self or others.
2 Subjective impairment only. Knows time to the nearest hour. Knows location.
3 Any mistake in time of two hours or more, day of the week of 1 day or more, date of 3 days or more.
4 Mistakes day of the month by 10 days or more, and/or confuses month of the year by 1 month or more.

5 Unsure of month and/or year and/or season, unsure of locale.
6 No idea of date. Identifies spouse but may not recall name. Knows own name.
7 Cannot identify spouse. May be unsure of personal identity.

AXIS V: FUNCTIONING AND SELF-CARE a *(circle only one, i.e., the most appropriate level)*
1 *No difficulty*, either subjectively or objectively.
2 Complains of forgetting location of objects. *Subjective work difficulties*.
3 Decreased job functioning evident to co-workers. Difficulty in traveling to new locations. *Decreased organizational capacity*.*
4 *Decreased ability to perform complex tasks*, e.g., planning dinner for guests, handling personal finances (such as forgetting to pay bills), difficulty marketing, etc.*
5 *Requires assistance in choosing proper clothing* to wear for the day, season, or occasion, e.g. patient may wear the same clothing repeatedly, unless supervised.*
6 *Requires assistance in putting on clothing*, and/or bathing, and/or toileting, and/or feeding.*
7 *Requires constant assistance* in all activities of daily life.*
*Scored primarily on the basis of information obtained from a knowledgeable informant and/or caregiver.

NAME: _____ ID#: _____ DATE: ___/___/___

RETRO BRIEF COGNITIVE RATING SCALE (BCRS)

INFORMANT: _____

RELATIONSHIP OF INFORMANT: _____

AXIS I: CONCENTRATION (circle only one, i.e., the most appropriate level)
1 No objective or subjective evidence of deficit in concentration.
2 Subjective decrement in concentration ability.
3 Minor signs of poor concentration (e.g., subtraction of serial 7s from 100).
4 Definite concentration deficit for persons of their background (e.g., marked deficit on serial 7s, frequent
deficit in subtraction of serial 4s from 40).
5 Marked concentration deficit (e.g., giving months backwards or serial 2s from 20).
6 Forgets the concentration task. Frequently begins to count forward when asked o count backwards from 10 by 1s.
7 Marked difficulty counting forward to 10 by 1s.

AXIS II: RECENT MEMORY (circle only one, i.e., the most appropriate level)
1 No objective or subjective evidence of deficit in recent memory.
2 Subjective impairment only (e.g., forgetting names more than formerly).
3 Deficit in recall of specific events evident upon detailed questioning, (e.g. about recent meals, current reading, recent appointments, etc.). No deficit in the recall of major recent events.
4 Cannot recall major events of previous weekend or week. Scanty knowledge (not detailed) of current events, favorite TV shows, etc. May not know telephone number and/or telephone area code and/or postal (zip) code.
5 Unsure of weather, and/or may not know current president and/or current address.
6 Occasional knowledge of some recent events. Little or no idea of current address, weather, etc. Given the current president's first name, may recall their last name.
7 No knowledge of any recent events.

AXIS III: PAST MEMORY (circle only one, i.e., the most appropriate level)
1 No subjective or objective impairment in past memory.
2 Subjective impairment only. Can recall two or more primary school teachers.
3 Some gaps in past memory upon detailed questioning. Able to recall at least one childhood teacher and/or one childhood friend.
4 Clear-cut deficit. The spouse recalls more of the patient's past than the patient. Cannot recall childhood friends and/or teachers but knows the names of schools attended. Confuses chronology in reciting personal history.
5 Major past events sometimes not recalled (e.g., names of schools attended). Characteristically, at this stage patients recall some schools attended, but not others.
6 Some residual memory of past (e.g., may recall country of birth or former occupation, may or may not recall mother's name, may or may not recall father's name). Generally, patients do not recall any of the schools which they attended.
7 No memory of past (cannot recall country, state, or town of origin, cannot recall names of parents, etc.)

AXIS IV: ORIENTATION (circle only one, i.e., the most appropriate level)
1 No deficit in memory for time, place, identity of self or others.
2 Subjective impairment only. Knows time to the nearest hour. Knows location.
3 Any mistake in time of two hours or more, day of the week of 1 day or more, date of 3 days or more.
4 Mistakes day of the month by 10 days or more, and/or confuses month of the year by 1 month or

more.
5 Unsure of month and/or year and/or season, unsure of locale.
6 No idea of date. Identifies spouse but may not recall name. Knows own name.
7 Cannot identify spouse. May be unsure of personal identity.

AXIS V: FUNCTIONING AND SELF-CARE a *(circle only one, i.e., the most appropriate level)-*

1. No difficulties, either subjectively or objectively

2. Complains of forgetting location of objects. Subjective word finding difficulties.

3. Decreased job function evident to co-workers; difficulty in traveling to new locations. Decreased organizational capacity.

4. Decreased ability to perform complex tasks (e.g., planning dinner for guests), handling personal finances (forgetting to pay bills), difficulty marketing, etc.

5. Requires assistance in choosing proper clothing to wear for day, season, occasion.

6a. Difficulty putting clothing on properly without assistance

b. Unable to bathe properly; e.g., difficulty adjusting bath water temperature) occasionally or more frequently over the past weeks.

c. Inability to handle mechanics of toileting (e.g., forgets to flush the toilet, more frequently over the past weeks.

d. Urinary incontinence, occasional or more frequent.

e. Fecal Incontinence, (occasional or more frequently over the past week).

7a. Ability to speak limited to approximately a half dozen different words or fewer, in the course of an average day or in the course of an intensive interview.

b. Speech ability limited to the use of a single intelligible word in an average day or in the course of an interview (the person may repeat the word over and over.

c. Ambulatory ability lost (cannot walk without personal assistance).

d. Ability to sit up without assistance lost (e.g., the individual will fall over if there are no lateral rests [arms] on the chair).

e. Loss of the ability to smile.

11.8 STROBE checklist

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

1

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

11.9 Thesis Data entry

slno	hospno	name	axis1	axis2	axis3	axis4	axis5	age	sex	state	admitfrom	admitto	bmi	independ	hospstay	icustay	marital	totalscor	dm	dmdura	hba1c
1	621025H	CHENGARE	2	2	2	2	2	82	1	1	1	1	20	2	5	0	4	8	2	0	0
2	047041F	CHINNARAJ	2	3	3	3	4	79	1	1	1	1	22	2	16	0	4	12	1	120	9.6
3	634989A	KRISHNAN	2	2	2	2	2	79	1	1	1	1	23	2	12	0	1	17	1	240	5.5
4	544637B	LOGANATH	1	1	1	1	2	69	1	1	1	1	22	2	5	0	1	20	1	120	6.6
5	629590H	MANJULA	1	1	1	1	1	54	2	1	1	1	29	1	14	0	1	17	1	84	10.2
6	569922H	NATARAJ	2	2	1	1	1	64	1	1	1	1	30	1	5	0	1	10	2	0	0
7	600910	RAJESWAR	1	1	1	1	1	64	2	1	1	1	30	1	10	0	1	15	1	240	10.6
8	623030H	KASTHURI	1	1	1	1	1	58	2	1	1	1	29	1	14	0	1	20	1	120	9.3
9	032838D	62	1	1	1	1	2	62	2	1	1	1	30	1	21	0	1	17	1	120	7
10	851320D	SWARAJ	4	3	3	3	6	87	1	1	1	1	2.2	2	5	0	4	20	1	240	6.2
11	064164b	BOOSHNAM	2	2	1	2	3	71	2	1	1	1	27	1	3	0	1	14	1	240	10.3
12	118094B	SHANTHI	5	5	6	4	96	68	2	1	1	1	21	2	5	0	1	13	1	240	9.6
13	458260H	MANOVER	1	1	1	1	1	49	1	1	1	1	28	1	5	0	1	18	2	0	0
14	458607H	VAJRAVELL	2	3	3	3	4	84	1	1	1	1	24	1	10	0	1	20	2	0	0
15	458650H	JAYATHAM	3	4	4	3	5	84	2	1	1	1	29	2	8	0	4	17	1	1	7
16	458667H	ROODHABA	3	3	3	2	4	77	2	1	1	1	24	2	6	0	4	12	2	0	0
17	458674H	SANTHAMA	1	1	1	1	2	60	1	1	1	1	24	1	5	0	1	20	1	120	10
18	458693	BABU	1	1	1	1	1	40	1	3	1	1	30	1	30	0	1	22	1	120	9.8
19	458829H	MANOKAR	1	1	1	1	1	64	1	1	1	1	28	1	6	0	1	22	2	0	0
20	513283A	SAROVAR	3	3	2	3	4	68	1	4	1	1	26	2	3	0	1	27	1	120	8
21	354412H	SRINIVASA	2	1	1	2	2	63	1	1	1	1	23	1	12	0	4	17	1	160	4.7
22	458563H	SUKUMAR	2	3	3	2	3	71	1	1	1	1	22	1	4	0	1	18	2	0	0
23	622555C	ABHIJITDUT	2	2	1	1	2	52	1	1	1	1	25	1	10	0	1	18	2	0	0
24	567920H	KALAVANI	1	1	1	1	1	22	2	1	1	1	19	1	5	0	1	19	2	0	0
25	618737F	MALA	2	1	1	1	2	47	2	1	1	1	28	1	5	0	1	18	1	120	9.4
26	565062H	ROSI	2	3	3	2	3	70	2	1	1	1	22	2	7	0	4	17	1	170	9
27	119599F	MANOHAR	1	1	1	1	1	30	1	1	1	1	20	1	5	0	1	20	2	0	0
28	608558H	VILVARATH	2	3	3	3	3	58	1	1	1	1	29	1	5	0	1	17	1	120	7
29	874063F	VISALAKSHI	3	3	2	3	3	75	2	1	1	1	26	2	5	0	4	19	2	0	0
30	652879H	ZUNOOTIYA	1	1	1	1	1	25	2	1	1	1	19	1	10	0	1	19	2	0	0
31	002176D	SULOCHAN	1	1	1	1	1	38	2	1	1	1	19	1	10	0	1	24	2	0	0
32	620386H	RESHAMMA	2	2	3	2	3	75	2	1	1	1	23	2	3	0	1	19	1	240	9
33	568272H	ASHRAFAHA	1	1	2	2	3	59	2	1	1	1	30	1	10	0	1	22	1	240	12.2
34	043609F	SUSEELA	1	1	2	1	2	59	2	1	1	1	28	1	6	0	1	16	1	84	12.4
35	162057C	ARUL	2	2	2	3	3	57	1	1	1	1	20	1	5	0	1	18	1	360	10
36	532428F	KASTHURI	1	2	2	1	1	46	2	1	1	1	27	1	5	0	1	19	1	120	6.2
37	565763H	SHANTHI	1	1	2	1	1	52	2	1	1	1	29	1	5	0	1	12	1	120	12
38	566380H	ERUSON	1	2	1	2	2	53	1	1	1	1	23	1	14	0	1	18	1	200	12.6
39	986209F	VASANTHA	2	2	2	2	2	70	2	1	1	1	22	1	14	0	1	20	2	0	0
40	411270F	BHARATH	1	1	1	1	1	44	1	3	1	1	24	1	10	0	1	18	2	0	0
41	475996F	BANUMATH	2	2	2	2	2	51	2	1	1	1	24	1	7	0	1	18	1	160	9
42	523866H	REGINA	1	1	1	1	1	62	2	1	2	1	30	1	5	0	1	27	1	180	10.8
43	106811H	CHANDRA	1	1	2	1	2	69	1	1	1	1	20	1	10	0	1	18	1	160	8
44	078295H	LAKSHANA	1	1	1	1	1	54	2	1	1	1	21	1	7	0	1	19	1	240	8.9
45	593008G	PADMAVAT	1	1	1	1	1	48	2	1	1	1	28	1	7	0	1	18	1	120	9
46	593021G	RAGHAV	1	1	1	1	1	22	1	3	2	1	19	1	12	0	1	26	2	0	0
47	593612G	RAJESWAR	2	2	1	2	2	68	1	1	1	1	26	1	10	0	1	20	2	0	0
48	594252G	PANCHANA	4	3	4	3	5	87	1	1	1	1	20	2	14	0	1	16	2	0	0
49	181965H	LAWRENCE	2	3	2	3	3	71	1	1	1	1	26	1	10	0	1	15	1	260	9
49	181965H	LAWRENCE	2	3	2	3	3	71	1	1	1	1	26	1	10	0	1	15	1	260	9
50	182495H	DEEPA	1	1	1	2	1	24	2	1	1	1	22	1	4	0	1	18	2	0	0
51	182505H	RATAN	2	2	2	2	2	63	1	3	1	1	29	2	10	0	1	20	2	0	0
52	188166H	SARADHA	1	1	1	1	1	45	2	1	1	1	22	1	10	0	1	18	2	0	0
53	188702H	VENNILA	1	1	2	2	2	65	2	1	1	1	20	1	4	0	1	16	1	160	8
54	188716H	SUBBAIAH	2	2	3	3	3	79	1	1	1	1	20	2	7	0	4	18	1	260	12
55	188734H	RAMASUBR	2	2	2	2	2	53	1	1	1	1	22	1	11	0	1	18	1	180	9
56	002176G	EBENEZER	1	1	2	2	2	69	1	1	1	1	24	1	7	0	1	17	1	160	6
57	012355H	VEDACHALA	2	2	2	2	2	72	1	1	1	1	27	1	10	0	1	15	2	0	0
58	251324H	PUSHPA	1	1	1	1	1	62	2	1	1	1	29	1	14	0	1	15	1	140	11
59	351395H	AKTHER	2	1	1	2	1	57	1	1	1	1	27	1	7	0	1	18	1	180	11.7
60	351782H	EMMACULA	3	4	3	3	4	80	2	1	1	1	27	1	4	0	1	20	2	0	0
61	309359C	THENMOZH	1	1	1	1	1	40	2	1	1	1	21	1	7	0	1	20	1	20	8
62	343879H	AZRA	1	1	1	1	1	41	2	1	1	1	25	1	7	0	1	19	1	60	7.3
63	353775H	PASANG	2	2	3	2	3	60	2	3	1	1	24	1	7	0	1	18	1	120	9
64	353793H	ANITHAKAN	1	2	1	1	1	59	2	1	2	1	29	1	6	0	1	21	1	60	6
65	354499H	MANIVANNA	2	2	2	1	2	48	1	1	1	1	25	1	10	0	1	20	1	120	14
66	354889H	ASOK	3	3	2	2	3	62	1	3	1	1	22	1	7	0	1	19	1	120	8
67	357046H	MANIMALAI	2	2	2	2	2	64	1	1	1	1	22	1	10	0	1	18	1	240	8
68	357049H	BABU	1	1	1	1	1	41	1	1	1	1	27	1	14	3	1	22	1	120	9
69	763584C	BISWAJITH	1	1	2	2	2	64	1	4	1	1	25	1	10	0	1	20	2	0	0
70	079684B	CHANDRA	2	2	2	1	1	70	2	1	1	1	20	1	12	0	1	22	1	180	9.1
71	106032F	ANNAKKILI	1	1	1	1	1	53	1	1	1	1	22	1	10	4	1	20	1	150	6.7
72	127364G	ROSE	1	1	1	1	1	55	2	1	1	1	29	1	10	0	1	20	1	160	7.3

73	187802G	UMESH	1	1	1	1	1	38	1	1	1	1	29	1	70		1	26	1	180	10.1
74	262108D	TANUSHRE	1	1	1	1	1	27	2	1	2	1	23	1	7	0	1	26	2	0	0
75	287413H	ZONTHANP	1	2	1	1	1	43	1	4	1	1	22	1	10	0	1	26	1	180	8
76	371344H	UMA	1	1	1	1	1	59	2	3	1	1	25	1	5	0	1	20	1	180	6.5
77	450337H	RAJESWAR	1	1	1	1	1	39	3	1	1	1	26	1	10	0	1	18	1	160	8
78	451725H	SAVITRIAMM	2	2	2	2	2	70	2	1	1	1	28	1	10	0	1	20	1	160	8.7
79	452083H	VASANTHA	2	2	2	2	2	65	2	1	1	1	23	1	10	0	1	20	1	240	9
80	452045H	KANTHA	1	1	1	1	1	35	2	1	1	1	24	1	7	0	1	20	1	180	10.6
81	455876H	ELLAMAL	1	1	1	1	1	55	2	1	1	1	22	1	5	0	1	20	1	180	9.4
82	455879H	THULASIYA	1	1	1	1	1	61	2	1	1	1	24	1	6	0	1	19	1	240	8
83	452688H	BASU	1	1	1	1	1	55	1	1	1	1	23	1	5	0	1	20	2	0	0
84	456022H	VODIRI	1	2	2	1	1	52	1	1	1	1	20	1	7	0	1	15	1	240	11
85	456066H	CHANDAPA	1	2	2	1	2	65	1	1	1	1	23	1	7	0	1	13	2	0	0
86	456599H	NAGAMMAL	1	1	2	2	2	60	2	1	1	1	23	1	5	0	1	18	2	0	0
87	457111H	GOMATHI	1	1	1	1	1	34	2	1	1	1	22	1	6	0	1	20	2	0	0
88	457147H	KUMAE	2	2	2	2	3	81	1	3	1	1	25	2	10	0	1	19	1	240	8
89	457153H	SURESH	1	1	1	1	1	21	1	1	1	1	22	1	10	0	1	19	2	0	0
90	457179H	ARUMUGAN	2	1	1	1	2	55	1	1	1	1	25	1	7	0	1	19	1	120	8
91	003580H	HEYAN	1	1	1	1	1	50	2	1	1	1	25	1	7	0	1	19	1	120	10
92	359471G	SALAUDEEN	1	1	1	1	1	50	1	1	1	1	30	1	7	0	1	20	1	180	9
93	547642G	VIJAY	1	1	1	2	2	46	1	3	1	1	26	1	7	0	1	19	1	220	12
94	581322G	MAHENDRA	1	1	1	1	1	20	1	1	1	1	19	1	7	0	2	19	2	0	0
95	581967G	VANDANAM	2	1	2	1	2	55	2	3	1	1	27	1	5	0	1	20	2	0	0
96	583450G	AATHIRA	1	2	1	1	2	60	2	1	1	1	23	1	7	0	1	14	1	120	8
97	585102G	GONDAMAL	3	2	4	3	4	83	2	1	1	1	24	2	10	0	4	17	1	180	11

97	585102G	GONDAMAL	3	2	4	3	4	83	2	1	1	1	24	2	10	0	4	17	1	180	11
98	585182G	NIKHILA	1	1	1	1	1	64	1	1	1	1	30	1	10	0	1	22	1	180	11.2
99	585242G	ADILI	1	1	1	1	1	39	2	3	1	1	20	1	10	0	1	20	2	0	0
100	586375G	DEEPAK	1	1	1	1	1	24	1	3	1	1	20	1	7	0	2	18	2	0	0
101	575131G	JAIN	1	1	1	1	1	56	2	1	1	1	23	1	7	0	1	25	1	120	12.6
102	575127G	JAYAVEL	1	1	1	1	2	55	1	1	1	1	20	1	5	0	1	19	2	0	0
103	582772B	VENKATESA	3	4	4	3	3	80	1	1	1	1	22	2	10	0	4	22	2	0	0
104	744336d	SUNDARES	2	2	2	2	2	79	1	1	1	1	22	1	7	0	4	27	1	240	8.7
105	92636HK	RISHNAMO	2	2	1	1	2	71	1	1	1	1	22	1	5	0	1	20	2	0	0
106	938468G	PADMA	1	1	1	1	1	57	1	1	1	1	27	1	5	0	1	20	2	0	0
107	938534G	RAMUDU	1	1	1	1	1	35	1	1	1	1	22	1	10	0	1	25	2	0	0
108	176376D	SUNDARAM	1	1	1	1	1	63	1	1	1	1	23	1	12	0	1	22	2	0	0
109	563485H	MARIYAMM	1	1	2	1	1	57	2	1	1	1	27	1	7	0	1	22	1	120	8
110	183267H	DHANALAKS	1	1	1	1	1	72	2	1	1	1	34	1	5	0	4	18	1	120	9
111	097749h	sasikala	1	1	1	1	1	52	2	1	1	1	27	1	14	0	1	20	1	240	7
112	176076h	karunakaran	2	2	2	2	2	73	1	1	1	1	24	1	7	0	1	19	1	180	7.1
113	012356h	hemalatha	2	2	2	2	2	72	2	1	1	1	22	1	5	0	4	17	2	0	0
114	186379h	fuaris	2	1	1	1	1	69	1	1	1	1	25	1	5	0	1	19	2	0	0
115	188166h	saradha	1	1	1	1	1	45	2	1	1	1	27	1	7	0	1	20	2	0	0
116	188702f	vennila	1	1	2	1	1	65	2	1	1	1	28	1	5	0	1	20	1	120	10
117	180369h	malar	1	1	1	1	1	36	2	1	1	1	29	1	5	0	1	20	2	0	0
118	030925h	jahora	1	1	1	1	1	51	2	4	1	1	25	1	14	0	1	23	1	240	14
119	186242h	james	1	1	1	1	1	51	1	1	1	1	26	1	7	0	1	22	2	0	0
120	306623f	managya	1	1	1	1	1	41	2	1	1	1	24	1	10	0	1	20	1	60	8

120	306623f	managya	1	1	1	1	1	41	2	1	1	1	24	1	10	0	1	20	1	60	8
121	317093D	GAJENDRA	2	2	2	2	2	70	1	1	1	1	21	1	14	0	4	14	2	0	0
122	318658G	ALPANA	1	1	2	1	1	39	2	1	1	1	24	1	6	0	1	20	2	0	0
123	350865h	sigamani	1	1	1	1	1	67	1	1	1	1	22	1	5	0	1	20	2	0	0
124	351336h	suguna	2	2	1	2	2	75	2	1	1	1	20	2	10	0	4	12	1	240	7
125	457851h	kesavan	1	1	1	1	2	64	1	1	1	1	24	1	15	0	1	19	1	120	8.9
126	488378d	mukesh	1	1	1	1	1	37	1	4	1	1	22	1	10	0	1	22	2	0	0
127	514235d	shaneem	1	1	1	1	1	39	2	1	1	1	25	1	10	0	1	20	1	60	7
128	124588h	chitteri	1	2	2	2	2	69	1	3	1	1	24	1	10	0	1	19	2	0	0
129	saroja	186247h	2	2	1	1	2	60	2	1	1	1	27	1	5	0	1	20	2	0	0
130	967233f	kumari	1	1	1	1	1	40	2	1	1	1	22	1	10	0	1	24	1	60	12

	insulin	htn	htndura	dyslipid	coronary	acs	heartfail	heartdura	knownef	ckd	dialysis	dialdura	dialfreq	cld	clddura	cirrhosis	portalhtn	stroke	mrsscore	hypothy	cushings	cushdura
2	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
3	2	1	150	1	1	1	2	0	0	2	2	0	0	2	0	2	2	2	0	1	2	0
4	0	1	240		2	2	2	0	0	1	2	12	0	2	0	2	2	2	0	2	2	0
5	1	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
6	2	1	120	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
7	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
8	1	1	210	1	1	1	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
9	1	2	0	1	1	2	1	60	0	2	2	0	0	2	0	2	2	2	0	2	2	0
10	1	1	120	2	2	2	2	0	0	1	2	0	0	2	0	2	2	2	0	2	2	0
11	2	2	0	2	2	2	2	0	2	2	2	0	0	2	0	2	2	2	0	2	2	0
12	2	1	240	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
13	1	1	240	2	2	2	2	0	0	2	2	0	0	2	0	2	2	1	3	2	2	0
14	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
15	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
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18	1	1	140	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
19	2	1	120	2	2	2	1	60	45	2	2	0	0	2	0	2	2	2	0	2	2	0
20	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
21	2	1	140	2	2	2	2	0	0	2	0	0	0	2	0	2	2	2	0	2	2	0
22	2	1	240	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
23	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
24	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0

25	2	2	0	2	2	2	2	0	0	2	0	0	0	2	0	2	2	2	0	2	2	0
26	1	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
27	1	1	240	2	2	2	1	120	50	1	2	120	0	2	0	2	2	2	0	2	2	0
28	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
29	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
30	2	1	120	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
31	2	2	0	2	2	2	2	0	0	2	0	0	0	2	0	2	2	2	0	2	2	0
32	2	1	120	2	1	2	1	120	50	1	2	60	0	2	0	2	2	2	0	2	2	0
33	2	1	240	2	2	2	1	120	40	2	2	0	0	2	0	2	2	2	0	2	2	0
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35	1	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
36	1	1	120	2	2	2	2	0	0	1	2	120	0	2	0	2	2	2	0	2	2	0
37	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	0	2	0
38	1	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
39	1	1	160	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
40	2	1	0	2	2	2	1	120	50	2	2	0	0	2	0	2	2	2	0	2	2	0
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48	2	1	120	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
49	2	2	0	2	2	2	1	120	50	2	2	0	0	2	0	2	2	2	0	2	2	0

50	1	1	240	1	2	2	2	0	0	2	2	0	0	2	0	2	2	1	3	2	2	0
51	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
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58	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
59	2	1	180	1	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
60	1	1	180	1	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
61	2	1	240	1	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
62	2	2	0	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
63	2	1	60	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
64	2	1	160	2	2	2	2	0	0	2	2	0	0	2	0	2	2	1	2	2	2	0
65	2	1	120	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
66	1	1	20	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
67	2	1	160	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
68	2	1	240	2	2	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
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72	2	1	240	1	1	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
73	2	1	180	1	1	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0
74	2	1	180	2	1	2	2	0	0	2	2	0	0	2	0	2	2	2	0	2	2	0

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117	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
118	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
119	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
120	0	2	2	2	2	2	2	2	2	2	2	1	1	3	2	1	10	2	0	2	2	2
121	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
122	0	2	2	2	2	2	2	2	2	2	2	1	1	3	2	1	12	2	0	2	2	2
123	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	3	0	3	0	3	3	3
124	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	1	18	2	0	2	2	2
125	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
126	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
127	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
128	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
129	0	2	2	2	2	2	2	2	2	2	2	1	1	3	3	1	12	2	0	2	2	2
130	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2
131	0	2	2	2	2	2	2	2	2	2	2	2	2	0	0	2	0	2	0	2	2	2

	tuberculos	ifyessite	resistance	atrial	atrialdura	anticoag	hivinfect	hivdura	lastcd4	nrti	nnrti	pi	bronchial	brondura	copd	copdura	hocancer	chemo	radio	surgery	ecogstatus	feverdura
2	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	1
3	2	0	0	0	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
4	1	1	1	2	0	2	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	7
5	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
6	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
7	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
8	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
9	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
10	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
11	2	0	0	2	0	2	2	0	0	2	2	2	1	120	2	0	2	2	2	2	0	5
12	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
13	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
14	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
15	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	40	2	2	2	2	0	2
16	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
17	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
18	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
19	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
20	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
21	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
22	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
23	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
24	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
25	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
26	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
27	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
28	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
29	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
30	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
31	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
32	2	0	0	2	0	2	2	0	0	2	2	2	1	240	2	0	2	2	2	2	0	4
33	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
34	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	8
35	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
36	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
37	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
38	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
39	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
40	2	0	2	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
41	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
42	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
43	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
44	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	6
45	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
46	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
47	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
48	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
49	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	10
50	2	0	2	2	0	2	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	8
51	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
52	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	1	2	2	2	2	7
53	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
54	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	8
55	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	5
56	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	10	2	2	2	2	0	4
57	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
58	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
59	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
60	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	6
61	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
62	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
63	2	0	2	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
64	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
65	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
66	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
67	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
68	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	10	2	2	2	2	0	3
69	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	10	2	2	2	2	0	5
70	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
71	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
72	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
73	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2		2	2	2	2	0	5
74	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
75	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
76	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
77	2	0	0	2	0	2	2	0	0	2	2	2	1	240	2	0	2	2	2	2	0	3
78	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
79	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	8
80	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
81	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
82	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
83	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
84	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	7
85	2	0	0	2	0	2	1	60	293	1	1	2	2	0	1	120	2	2	2	2	0	3
86	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	3
87	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
88	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
89	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	360	2	2	2	2	0	3
90	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
91	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
92	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
93	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
94	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4
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96	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
97	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	360	2	2	2	2	0	3
98	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5

99	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
100	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
101	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
102	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
103	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
104	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
105	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
106	2	0	0	1	60	1	2	0	0	2	2	2	2	0	1	240	2	2	2	2	0	4
107	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
108	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	10
109	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	7
110	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
111	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
112	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
113	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
114	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	2
115	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
116	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	6
117	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	3
118	2	0	0	2	0	2	2	0	0	2	2	2	1	120	2	0	2	2	2	2	0	10
119	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
120	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	7
121	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
122	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
123	3	0	0	3	0	3	3	0	0	3	3	3	3	0	3	0	3	3	3	3	0	10
124	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	1
125	2	0	0	2	0	2	2	0	0	2	2	2	1	360	2	0	2	2	2	2	0	9
126	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	7
127	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	10
128	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
129	2	0	0	2	0	2	2	0	0	2	2	2	2	0	1	120	2	2	2	2	0	5
130	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	5
131	2	0	0	2	0	2	2	0	0	2	2	2	2	0	2	0	2	2	2	2	0	4

1	sepsiseto	sepsisecol	sepsisabc	sepsisstap	sepsisstre	sepsiskleb	sepsispseu	sepsissens	sepsisesbl	sepsiscro	sepsismrsa	sepsisvr	pfratio	rrpresent	mechanical	noninvasiv	invasive	paralytic	paradura	tracheost	aki	akinclass
2	4	1	2	2	2	2	2	1	2	2	2	2	1	22	1	0	0	2	0	2	2	0
3	4	1	2	2	2	2	2	1	2	2	2	2	1	32	1	0	0	2	0	2	1	2
4	1	2	2	2	2	2	2	0	0	0	0	0	2	24	1	0	0	2	0	2	1	2
5	4	1	2	2	2	2	2	1	2	2	2	2	2	18	1	0	0	2	0	2	1	2
6	4	1	2	2	2	2	2	2	1	2	2	2	2	20	1	0	0	2	0	2	1	3
7	4	1	2	2	2	2	2	1	2	2	2	2	1	18	1	0	0	2	0	2	2	0
8	4	1	2	2	2	2	2	1	2	2	2	2	1	18	1	0	0	2	0	2	1	3
9	4	1	2	2	2	2	2	2	1	2	2	2	2	24	1	0	0	2	0	2	2	3
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11	8	2	2	2	1	2	2	1	2	2	2	2	2	30	1	0	0	2	0	2	2	0
12	4	2	2	2	2	1	2	1	2	2	2	2	1	18	1	0	0	2	0	2	2	0
13	1	2	2	2	2	2	2	0	0	0	0	0	2	22	1	0	0	2	0	2	1	2
14	4	2	2	2	2	2	2	0	0	0	0	0	2	20	1	0	0	2	0	2	1	2
15	1	2	2	2	2	2	2	0	0	0	0	0	3	32	2	3	0	2	0	2	1	2
16	1	2	2	2	2	2	2	0	0	0	0	0	3	30	2	3	0	2	0	2	1	2
17	1	2	2	2	2	2	2	0	0	0	0	0	3	24	1	0	0	2	0	2	1	2
18	4	2	2	2	2	2	2	0	0	0	0	0	2	18	1	0	0	2	0	2	1	3
19	8	2	2	2	2	2	2	0	0	0	0	0	2	20	1	0	0	2	0	2	1	2
20	4	1	2	2	2	2	2	2	1	2	2	2	2	18	1	0	0	2	0	2	1	3
21	1	2	2	2	2	2	2	0	0	0	0	0	3	30	2	3	0	2	0	2	1	2
22	4	2	2	2	2	1	2	2	2	1	2	2	2	26	3	3	3	1	3	2	1	3
23	3	2	2	2	2	1	2	2	2	1	2	2	2	20	1	0	0	2	0	2	1	3
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	oliguric	dialysis1	typedialy	hypotensi	hepatic	coagulo	lowplate	bleedmani	transfusi	pc	pcproduct	flp	flpproduc	gcsadmn	sofascore	steroids	cumulative	acqinfect	ventilator	ventiecoli	ventiabc	ventistaph
1																						
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1	ventistrep	ventiklebs	ventipseud	ventisensi	ventiesbl	venticro	ventimrsa	ventivr	uti	utiecoli	utiabc	utistaph	utistrep	utiklebsie	utipseudon	utisensiti	utiesbl	uticro	utimrsa	utivr	bloodstrea	bloodecoli
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	bloodabc	bloodstaph	bloodstrep	bloodklebs	bloodpseud	bloodsensi	bloodesbl	bloodcro	bloodmrsa	bloodvr	polyneuro	bedsores	grade	dvt	pe	stroke1	mrsscore1	acs1	newonset	procedure	gcsdisch	whodas2
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2	9	6	4	9	7	19	15	131	12	10	4	12	12	19	23	2	0	2	0	2	2	19
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128	1	1	20	1	1	1	1	1
129	2	1	19	2	2	2	2	3
130	1	1	22	2	2	1	1	2
131	1	1	24	1	1	1	1	1