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OUTCOME OF WOMEN SUSPECTED OF HAVING SEPSIS BY USING FAST-M COMPLEX INTERVENTION AT TERTIARY CARE HOSPITAL

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Abstract

Objective: *To determine the outcome of women with suspected sepsis managed using the FAST-M complex intervention bundle at a tertiary care hospital.*

Study Design: *Descriptive, cross-sectional study.*

Place & Duration of Study: *Department of Obstetrics and Gynaecology, Civil Hospital, Liaquat University of Medical and Health Sciences (LUMHS), Hyderabad, over a period of three months (February 22, 2025 till May 21, 2025).*

Methodology: *Using non-probability, consecutive sampling, 180 pregnant or postpartum women aged 20-45 years with suspected sepsis were enrolled Feb 22, 2025 to May 21, 2025 after informed consent. Receipt of each component of the FAST-M bundle (Fluids, Antibiotics, Source identification and control, Transfer, and Monitoring) within one hour of recognition of sepsis was recorded, and factors associated with receipt of the full bundle were identified using univariate and multivariable logistic regression.*

Results: *The full FAST-M bundle was delivered within one hour in 28/180 (15.6%) women. Individual components were completed as follows: fluids 96 (53.3%), antibiotics 125 (69.4%), source identification 121 (67.2%), transfer 29 (16.1%), and monitoring 128 (71.1%). On multivariable analysis, no variable was independently associated with receipt of the full FAST-M bundle. Complete vital signs recording showed a non-significant trend toward lower odds of bundle completion (aOR 0.492, 95% CI 0.210–1.151, p=0.102). Mortality was 14/180 (7.8%).*

Conclusion: *Despite fair completion of individual FAST-M components, concurrent delivery of the complete bundle within one hour was achieved in only a small minority of women with suspected sepsis at this tertiary care hospital.*

Introduction

Maternal sepsis, or organ dysfunction due to infection during pregnancy, childbirth, post-abortion or the postpartum period, is one of the major but under-identified causes of maternal mortality globally (1). It is the third leading direct cause of maternal mortality worldwide, causing around 11% of maternal deaths, especially in low and middle income countries (2). Sepsis often has a vague early presentation and can rapidly worsen within hours of the onset of organ dysfunction after the initial infection, resulting in a critical

time window between recognition and treatment initiation that is important for survival, which is different to most other direct obstetric causes of death. Given the magnitude of the challenge, in 2012, Sepsis became a global health priority by being formally on the WHO agenda through a dedicated resolution of the World Health Assembly (WHA) Resolution 67.39 and then, the WHO Global Maternal and Neonatal Sepsis Initiative was established to accelerate the recognition and management of maternal sepsis in low-resource settings, with the purpose of reducing preventable maternal and neonatal deaths from sepsis by 2030 (3,4).

Given the rapid onset of multi-organ failure and mortality, the early detection and prompt, protocolised care is the key to making a difference in the prognosis of sepsis. Sepsis screening tools and treatment bundles, embedded within routine clinical workflow, have been shown to decrease the time to antibiotic and fluid use and the mortality associated with sepsis in the emergency care environment (5). Similarly, a sepsis bundle that includes a series of time-limited steps to be completed over a specific period after the onset of the sepsis pathway has been linked to lower in-hospital mortality (6). These observations, most largely made in high income emergency departments, have led to a more recent worldwide change in the way that sepsis is cared for, transitioning from a process of clinical judgement, towards a process which is checklist-driven and can be consistently implemented by staff of varying seniority and experience, even in the face of high clinical workload.

Complications of pregnancy and childbirth are still the major cause of mortality of women of reproductive age in Pakistan with approximately one-fifth of all deaths attributable to pregnancy and childbirth (7). Sepsis is the third leading cause of maternal death in the nation, accounting for about 15% of deaths (8). This is exacerbated by factors common to low-resource public-sector obstetric care facilities, such as provision of inadequate supplies and basic infrastructure, irregular supply of antibiotics, low maternal literacy and socioeconomic status, and poor antenatal care utilization and awareness of danger signs (9). In such environments, even when clinical expertise is available regarding sepsis management, the systems required to implement this expertise consistently on the bedside, including reliable monitoring of vital signs, timely access to antibiotics, timely detection and referral of deteriorating patients, etc., are often not in place or not consistently followed, and thus, guideline-concordant care on paper is not always being translated into guideline-concordant care in practice.

In this context, the FAST-M complex intervention was designed specifically for low-resource maternity settings, and focuses on five time-critical aspects of maternal sepsis care: Fluids, Antibiotics, Source identification and control, Transfer to a higher level of care when required, and Monitoring of both mother and neonate (10). The intervention was purposefully developed to be implemented with the staffing and resources that are commonly found in low-resource public hospitals, rather than using highly sophisticated diagnostics, which was to make it easy to deliver and reliable. Multi-site evaluation of FAST-M in sub-Saharan African hospitals has shown significant gains in the completion of these components of care after implementation, and a recent multicomentre cluster randomized trial has added to the evidence base by showing a FAST-M-based multicomponent intervention has greater impact on maternal infection outcomes at scale (11,12).

However, quantitative data regarding the actual proportion of women who present with a suspected sepsis who receive each component of the FAST-M bundle and the speed at which each of these bundles is received compared to recommended timeframes in routine clinical practice is limited. To meaningfully scale FAST-M within the local health system, it is essential to generate such context-specific evidence, as the barriers to the reliable delivery of the FAST-M will likely be different in sub-Saharan Africa and South Asian tertiary care environments where the resource challenges seem at first glance to be similar. This study was thus planned to investigate the outcome of women suspected with sepsis at a

tertiary care hospital, Hyderabad after administering the complex intervention FAST-M.

Methodology

After approval from the institutional ethical review committee this descriptive, cross sectional study was carried out in the department of Obstetrics and Gynaecology Civil Hospital Liaquat University of Medical and Health Sciences (LUMHS) Hyderabad for six months starting from February 22, 2025 to May 21, 2025. The department serves as a tertiary referral unit for obstetric emergencies from a large catchment and was chosen as it has staffing levels, access to resources and patient numbers representative of public sector maternity units throughout the region. The sample size required was determined as 180 patients based on the WHO sample size calculation software, a previously reported rate of transfer to higher level care of 35.7% (11) and a 95% confidence interval with a margin of error of 7%. The non-probability sampling method used in this study was consecutive sampling, which excluded the possibility of selection bias due to purposive sampling or convenience sampling.

Those women of reproductive age who were pregnant or postsurgical aged 20-45 years with a clinical suspicion of sepsis were included. Sepsis is a clinical entity that was operationally defined as the presence of ≥2 of the following at admission: temperature ≥38 ° C or <36 ° C, heart rate >90 beats per minute, white blood cell count $<4 \times 10^9$/L (<4,000/mm³) confirmed by blood culture, and respiratory rate >20 breaths per minute. The operational definition was chosen over more complicated organ-dysfunction scoring systems because it could be implemented easily at the bedside with parameters readily available in most settings, even in resource-limited areas, and because it matched the criteria from the original synopsis and in similar FAST-M evaluations. Women who refused consent, women with pre-existing medical illnesses including cardiac disease, chronic respiratory disease, epilepsy or renal disease were excluded to minimise confounding due to pre-existing medical illnesses other than the septic process under study affecting maternal physiological parameters and/or clinical outcomes.

After informed written consent, patients were recruited sequentially who fulfilled the inclusion and exclusion criteria. Demographic and obstetric information was obtained at the time of enrolment, such as maternal age and gestational age. The researcher noted if the complete set of vital signs (respiratory rate, temperature, heart rate, blood pressure, urine output, and neurological assessment) was taken on admission, and if each of the four elements of the FAST-M package (Fluids, Antibiotics, Source identification and control, and Monitoring of mother and neonate) was provided for every enrolled woman. Full FAST-M bundle delivery within 1 hour of recognition of sepsis was documented as the primary outcome measure of interest, as the intervention is designed to treat sepsis in a time-critical manner. We a priori defined sepsis and each of the components of individual FAST as binary variables (Yes/No) and recorded them for each patient to ensure that data could be captured in a standardized and reproducible manner for all patients, irrespective of which member of the clinical team was directly involved in the patient's care. All data were recorded on a structured proforma created for the purpose of this study (Annexure), proformas were checked for completeness prior to data entry to minimise missing data.

The data were analysed using SPSS version 20. Quantitative variables (maternal age, gestational age, parity, and vital sign measurements at admission, respiratory rate, temperature, heart rate, systolic and diastolic blood pressure) were summarized as mean ± standard deviation if normally distributed or as median and interquartile range (IQR) if the distribution was not normally distributed, with normality assessed using the Shapiro-Wilk test. Pregnancy status, comorbidities (hypertension, diabetes mellitus, previous caesarean section), completeness of urine output and neurological assessment recording, completeness of overall vital signs, and each FAST-M component (fluids, antibiotics, source identification and control, transfer, and monitoring) were reported as frequencies and

percentages for qualitative variables. Univariate logistic regression analyses were conducted for each of the independent variables to determine factors associated with receiving the entire FAST-M package. All clinically relevant variables were included in a multivariate logistic regression model to determine independent predictors and to control for potential confounding among the variables. Following the model selection, crude and adjusted odds ratios (OR) with 95% confidence intervals (CI) for the final model were provided for each variable included in the final model. Throughout, a p-value of ≤ 0.05 was deemed statistically significant. This manuscript is attached with SPSS output sheet for reference.**Results**

There were 180 women enrolled and all were analyzed, the distribution of pregnancy status is shown in Table 1. Most of the above were postpartum at the time of presentation, and the rest were pregnant.

Baseline characteristics of the cohort: The mean age of participants was in the third decade of life. The women of the pregnant group at the time of enrolment were in the late second to early third trimester of pregnancy. Table 1 lists the parity, comorbid status and vital sign measurements at admission.

Table 1: Baseline Characteristics of Study Participants (n=180)

*Gestational age was analyzed only for pregnant women in weeks (n=87)

Characteristic	Value
Demographics	
Age (years), Median (IQR)	32.0 (26.3 - 38.8)
Gestational Age (weeks)*, Mean±SD	28.89 ± 5.39
Pregnancy Status, n (%)	
Pregnant	87 (48.3)
Postpartum	93 (51.7)
Parity Status, n (%)	
≤ 2	80 (44.4)
≥3	100 (55.6)
Comorbidities, n (%)	
Hypertension	20 (11.1)
Diabetes Mellitus	25 (13.9)
Previous C-Section	49 (27.2)
Vital Signs at Admission, Median (IQR)	
Respiratory Rate (bpm)	25.0 (18.0 - 33.0)
Temperature (°C)	37.5 (36.1 - 38.9)
Heart Rate (bpm)	98.0 (81.0 - 123.0)
Systolic BP (mmHg)	118.0 (94.0 - 138.0)
Diastolic BP (mmHg)	68.0 (53.0 - 84.0)

From the clinical evaluation, a considerable number of the group had previously been delivered via a caesarean section and hypertension and diabetes mellitus were found in a smaller minority. The completeness of vital sign recording (including urine output and neurological assessment) is described in Table 2.

Table 2: Process and Clinical Outcomes (n=180)

Outcome	n (%)
Vital Signs Recording	
Urine Output Recorded	102 (56.7)
Neurological Assessment Recorded	151 (83.9)
Complete Vital Signs	90 (50.0)
FAST-M Bundle Components (within 1 hour)	
Fluids	96 (53.3)
Antibiotics	125 (69.4)
Source Identification	121 (67.2)
Transfer Considered	29 (16.1)
Monitoring	128 (71.1)
Full FAST-M Bundle	28 (15.6)
Secondary Outcomes	
Escalated to Senior Practitioner	175 (97.2)
Clinical Review by Senior Decision-Maker	175 (97.2)
Clinical Outcomes	
Survived	166 (92.2)
Died	14 (7.8)

Documentation and interventions for the components of the FAST-M bundle ranged. Overall, there was only a small proportion of the population who received the whole FAST-M package within 1 hour of the recognition of sepsis. The frequencies for each bundle component and other secondary clinical outcomes are presented in Table 2 and shown as a graph in Figure 1.

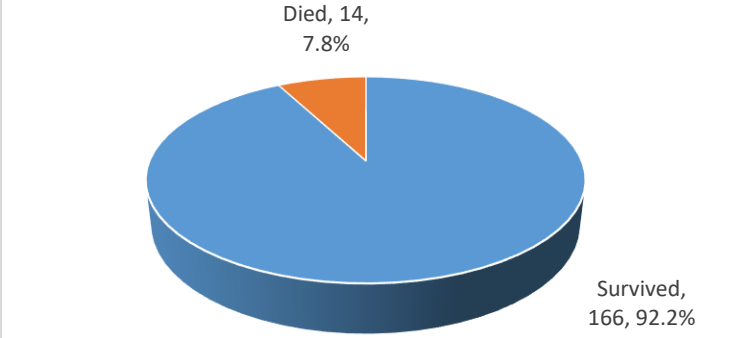

Figure 1: Maternal Outcomes (n=180)

The factors associated with receiving the full FAST-M bundle were determined using univariate analyses (Table 3). In univariate analysis, complete vital signs recording showed a trend toward association with receipt of the full FAST-M bundle (OR 0.500, 95% CI 0.216–1.155, p=0.104). On multivariable analysis, no variable was independently associated with bundle completion. Complete vital signs recording remained non-significant (aOR 0.492, 95% CI 0.210–1.151, p=0.102). (Table 3)

Table 3: Logistic Regression Analysis of Factors Associated with Receipt of Full FAST-M Bundle

Variable	Unadjusted OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Age (years)	0.999 (0.943 – 1.058)	0.961	0.998 (0.941 – 1.058)	0.956
Gestational Age (weeks)	1.002 (0.996 – 1.009)	0.480	1.002 (0.996 – 1.008)	0.637
Parity Group (≥3)	0.926 (0.411 – 2.091)	0.854	0.998 (0.425 – 2.340)	0.996
Hypertension	1.049 (0.286 – 3.848)	0.942	0.852 (0.214 – 3.394)	0.821
Diabetes	1.410 (0.392 – 5.072)	0.599	0.698 (0.181 – 2.691)	0.601
Complete Vital Signs	0.500 (0.216 – 1.155)	0.104	0.492 (0.210 – 1.151)	0.102

Discussion

In the present study of 180 women all the components of FAST-M were completed within 1 hour of recognition, only 15.6% women with suspected sepsis got the entire bundle and 71.1% received monitoring while 53.3% received fluids. This lack of the component to bundle level performance is a common observation in maternal sepsis quality-improvement studies and is due to the fact that each component of the bundle must be provided at the same time and not one after another. In the original multi-site evaluation of FAST-M in Malawi, Zambia and Ghana, Cheshire J et al. found similar that although individual components of FAST-M improved significantly following the intervention, completion of the bundle within the recommended window was the most challenging goal to achieve (11). This observation, that a more complex bundle of services has not previously resulted in stable implementation at the bed-side in low-resource settings, was the basis of the modified Delphi process used to develop the FAST-M framework, which is limited to five elements (10). More recently, Lissauer D et al. reported a multicomentre cluster randomized trial where a multicomponent intervention based on the FAST-M framework was found to be effective at scale when structured training and audit was provided, suggesting that low bundle completion rates seen in the current study might be due to local infrastructure that is less suited to the implementation of FAST-M rather than a limitation of the framework itself (12).

The pattern of individual component performance seen here is similar to what is seen internationally, as reflected in WHO Global Maternal Sepsis Study (GLOSS). In the GLOSS study protocol, Bonet M et al., outlined a global one-week inception cohort to specifically describe the frequency and quality of infection management for mothers in health facilities with different resource levels (13). For source control and antibiotic administration, the subsequent GLOSS Research Group report identified a high degree of variation in timeliness of antibiotic administration and source control across facilities, with lower-resourced being significantly behind higher-resourced facilities with respect to time-critical steps (14). Another study of the same GLOSS dataset by Brizuela V et al. demonstrated that having adequate facility resources (e.g. enough antibiotics, functioning lab services, blood transfusion capacity) was independently associated with maternal outcomes related to infection, which lends further support to the fact that a lack of knowledge is not the only issue in settings like ours; it is also a systems problem (15). Overall, the proportion of women who received antibiotic was 69.4%, which was intermediate between that reported in high income quality improvement studies in emergency departments and that generally reported in low resource settings. Gatewood MO et al. showed that the incorporation of an algorithmic sepsis screening tool and antibiotic-ordering pathway in the ED workflow resulted in a significant decrease in time to first antibiotic dose (5); and Seymour CW et al. found that the time to initiation of antibiotic therapy was associated with lower in-hospital mortality in the mandated sepsis protocols of New York State (6). A similar improvement was observed in a paediatric ED following the implementation of a triage sepsis alert with a

standardised order set, which resulted in a reduction in the median time for antibiotic and fluid administration, by over 50%, (16). Overall, these data are consistent with the recommendations of the Surviving Sepsis Campaign guidelines (17), which advise giving broad-spectrum antibiotics according to the guidelines within one hour of recognition and thus emphasize the need to have antibiotics readily available at the point of care, and suggest that the moderate rate of antibiotic completion in our cohort may be related to the intermittent availability of antibiotics rather than to systemic unavailability, and that improvements could be achieved by triage-level alerts and pre-packaged order sets, as described in these studies of emergency medicine.

The component least likely to be completed was transfer to a higher level of care; only 16.1% of women completed this component, significantly less than fluids, antibiotics, source identification, and monitoring. This result aligns with the overall body of evidence on availability of critical care resources in low to middle income countries. In a survey of resource availability to manage maternal sepsis in Malawi and similar low resource countries, Abdu M et al (18) reported that referral pathways and the capacity to provide more advanced care were often the stumbling blocks along the care continuum for maternal sepsis. In a continent-wide survey of anaesthesia providers throughout Africa, Baelani I et al. also reported the significant scarcity of critical care beds and monitors, and lack of referral systems, and noted that the physical ability to move up the care ladder—rather than clinical decision making at the bedside was the most significant constraint on sepsis outcomes (19). Previous studies by Tsu VD and Coffey PS revealed similar structural challenges to maternal mortality reduction in low-resource public-sector facilities, such as transportation issues, staffing problems and poor communication between facilities, which aligns closely with the present cohort's low rates of transfers completed (9). The low transfer rate is likely more indicative of the fact that very few women needed onward escalation than a lack of referral of those who did, as our tertiary centre is a referral centre as opposed to a lower level facility; however, this finding does highlight the importance of having locally agreed criteria for identifying those women who truly need higher level critical care.

Moderate completeness of recording of vital signs e.g. 69.4% of women had full records of vital signs, and urine output and neurological assessment were recorded less fully. Closing this gap is crucial and is largely driven by objective, structured criteria for recognising and initiating monitoring for sepsis. Rudd KE et al. found that the qSOFA score, which we were able to capture as part of our proforma and which included only minimal data from vital signs and mental status, had a significant prognostic value in consistent measurement and was validated as a simple bedside tool in multiple low/middle income country settings, including excess hospital mortality among patients with suspected infection (20). The National Institute for Health and Care Excellence guidance on suspected sepsis in pregnant and recently pregnant people also highlights the importance of systematic and regular assessment of vital signs including urine output and neurological status, as the basis for early recognition, and not just clinical gestalt (21). The Royal College of Obstetricians and Gynaecologists Green-top Guideline on maternal sepsis, written by Lissauer D et al., supports this same point and states that assessing all vital signs should be routinely recorded in observation charts for all women with suspected infection on the maternity service (22). The higher proportion of neurological assessment recording than urine output may be because opportune assessment of neurological status is easy during the usual ward round whereas deliberate checking of urine output can be more easily missed in the hectic nature of clinical work.

In this cohort, no variable was independently associated with receipt of the full FAST-M bundle within one hour. Although complete vital signs recording showed a trend toward inverse association with bundle completion (aOR 0.492, 95% CI 0.210–1.151, p=0.102), this did not reach statistical significance. The absence of significant predictors suggests that the barriers to

full bundle delivery in this setting are likely systemic and multifactorial — relating to workflow constraints, staff availability, and resource limitations — rather than attributable to specific patient characteristics or documentation practices. The trend toward lower odds of bundle completion among women with complete vital signs recording may reflect the competing time demands of comprehensive documentation versus time-critical treatment delivery, though this hypothesis requires confirmation in larger studies with adequate statistical power.

The findings need to be interpreted in the light of the FAST-M implementation literature, specifically at the local level in Pakistan. In the published protocol for testing the feasibility of the FAST-M intervention in Pakistan, Ahmed SI et al. noted that resource constraints, staffing patterns, and documentation practices would vary in Pakistani tertiary hospitals, such as in sub-Saharan Africa where FAST-M was originally validated, and that these would require locally relevant feasibility data to inform broader implementation. (24) Qualitative follow on work by Ahmed SI et al. into the adaptation of FAST-M for the Pakistani context revealed that the antibiotic supply chain was inconsistent, senior clinicians were not always available out of hours and there was a lack of structured handover documentation, which were the main barriers to reliable bundle delivery (25), and a companion qualitative study by the same group, which found that frontline staff generally welcomed the simplicity of the FAST-M framework but reported high patient volumes and competing clinical demands as the primary challenges to completing all five components within the recommended time frame (26). These qualitative results are very similar to the quantitative results seen in our cohort, with each component being achieved by most of the women in our cohort, but only a minority of women achieving all the components at the same time. In this context, the high burden of maternal mortality due to sepsis in Pakistan (estimated as 15% of maternal deaths in multiple Demographic and Health Surveys (7,8)) highlights the clinical significance of closing this implementation gap not just in the quality of documentation.

This should be placed in the broader context of the global burden of sepsis. In a systematic review of barriers to sepsis care in LMICs, Rudd KE et al. listed deficiencies with diagnostics, essential medicines and referral capacity, which were similar to the gaps found in our cohort, with a special focus on source identification and transfer (27). The age-standardised mortality of sepsis was highest in sub-Saharan Africa and South Asia, where the majority of the evidence base was drawn from, with around 20% of global deaths in 2017 attributed to sepsis (28). In this global context, WHO's recognition of sepsis as a global health priority, through the World Health Assembly resolution (3) and through the operational Global Maternal and Neonatal Sepsis Initiative (4), sets a policy agenda that can support locally generated implementation data, like that reported here, to focus quality-improvement efforts where they are needed most. Although lower than a number of hospital-based series from similar settings, the 7.8% case fatality in our cohort reflects the low completion of the full-bundle despite low completion of the bundle, which highlights the need for cautious interpretation given the small number of deaths and the descriptive, non-comparative study design.

The findings in this study should be interpreted with caution due to several limitations. As it is designed as a single centre, cross sectional study, it may not be generalizable to other Pakistani tertiary care settings, which have different resource profiles or staffing arrangements, and the time period of 6 months may not account for the seasonality of patient numbers and availability of resources. The operational definition of suspected sepsis adopted in this study, which was selected for ease of use at the bedside and was not necessarily the diagnostic criteria, is not exactly the same as the organ dysfunction-based Sepsis-3 criteria (23) and may make direct comparison with studies using more stringent definitions of sepsis difficult. Documentation-based outcome ascertainment is important for obtaining standardized data, but does not differentiate between care provided and not documented, and

care provided but not documented, which is a limitation shared by most bundle adherence studies of this nature, including the original FAST-M studies (10–12). These caveats aside, the consistency of our results with the international GLOSS literature and with the Pakistan-specific qualitative FAST-M studies (24-26) gives us some confidence that the low full-bundle completion rate and the workflow-competition pattern that generated our urine-output results are more likely a reflection of actual practice in this setting than artifacts of measurement. Future studies should focus on prospective, multicentre assessment of specific interventions to tackle the concurrent-delivery challenge highlighted in this study as the main barrier to completing full FAST-M in Pakistani tertiary-care settings, including the creation of new FAST-M nursing roles or the development of electronic bundle-tracking systems.

Conclusion

Complete FAST-M bundle delivery within one hour was achieved in only a small minority of women with suspected maternal sepsis in this tertiary care cohort. No independent predictors of bundle completion were identified, suggesting that the barriers to timely, concurrent delivery of all bundle components are systemic and multifactorial. Future quality improvement efforts should focus on addressing workflow constraints and systems-level barriers rather than targeting specific clinical or documentation variables.

Patient Consent

Written informed consent was obtained from all participants prior to their enrolment in the study.

Competing Interest

Authors declared no conflict of interest.

Disclosures

This study was carried out as part of the corresponding author's postgraduate (FCPS) requirement at Liaquat University of Medical and Health Sciences (LUMHS).

Authors Contribution

Sindhu Devi: Conception and design of the study, data collection, data analysis, and drafting of the manuscript.
Sabreena Abbas: Supervision of the study, critical revision of the manuscript for important intellectual content, and final approval of the version to be published.
Dua Memon: Data collection and literature review.
Shahana Ramzan: Data analysis and manuscript drafting.
Anoshia Nabi: Data collection and manuscript proofreading.
Duray Shehwar Naqvi: Data collection and referencing.
Akash Kumar: Manuscript drafting
Arshad Hussain Abro: Literature review

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