

Why Medicine and Medical Ethics Must be Read Together?

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Medicine is a lot more than just figuring out what is wrong with someone and giving them some pills. It is a job that's all about doing what is right. Every time a doctor sees a patient they have to think about what's the best thing to do not just from a medical point of view but also from a moral point of view. What is the best thing for the patient? How do you make decisions when you are not really sure what to do when you do not have a lot of money to work with when there are risks involved and when people are hurting now? These are the kinds of questions that doctors and nurses think about every day in clinics, hospital rooms, emergency rooms, intensive care units, operating rooms, labs and in the systems that keep us healthy. That is why we need a journal that talks about medicine and medical ethics. Medicine and medical ethics are topics that need to be discussed. A journal, about medicine and medical ethics is really necessary.

Medicine is developing at an incredible pace in today's world. It is the age of precise medicine, artificial intelligence, digital health care, genomic testing, organ support systems, reproduction and more complicated treatments [1,2]. All this technology has made medicine more efficient and provided new possibilities for both diagnostics and therapy, thus changing the field significantly. On the other hand, the advancement of medicine creates ethical questions. The use of technology can make operations more convenient, but will it create any space for the protection of one's dignity? The therapy process may prolong an individual's life span, but what about maintaining their quality of life? When it comes to a data-based model, there is still a person making an assessment.

The split between medicine and ethics is artificial in many ways. Ethics is not an outside commentary on medical practice. It is woven into the fabric of good clinical care. The informed consent procedure is ethical. Confidentiality is an ethical responsibility. End-of-life decision-making poses an ethical challenge. The ethical responsibility of sharing scarce resources. Scientific practice is part of the same continuum as professional conduct, truth-telling, access to equity, respect for autonomy, research integrity and fair use of innovation. Medicine asks what can be done. Ethics asks what should be done. Responsible health care requires that both questions be asked in tandem.

The demand for such a framework is particularly relevant in modern health care. With the increasing emphasis placed on

the ethical dimensions of professional practice in health care institutions, clinicians are facing an ever-growing number of challenging moral scenarios that lack clear solutions [3]. Your intensive intervention will save the life of the critically ill patient, but at what price? The relatives insist on doing everything possible, yet the medical staff realize the pointlessness of such measures. You are a doctor with access to high-tech equipment, but not all your patients share such advantages. Artificial intelligence could be used for diagnostic purposes, but might trigger issues regarding potential bias, transparency, and privacy [4]. Although science makes research possible, it cannot ensure that ethical aspects are considered.

A journal like the *Annals of Medicine and Medical Ethics* is thus envisaged as a meeting point. It is where clinicians, researchers, educators, ethicists, lawyers, policy analysts, and public health practitioners can come together to have substantive discussions. It is a venue where a case report can reveal an ethical issue, where a research article can spark consideration of issues of justice or autonomy, where an editorial can address the ramifications of a new technology, where a personal reflection can remind us of the humanity in the system and numbers. Such a journal does not lessen scientific rigor, but deepens it by recognizing that medicine is practiced in a social and moral world.

There is also a pragmatic reason for uniting medicine and ethics on a single platform. Ethical questions appear to be discussed in the abstract, and clinical questions in technically specialized silos [5,6]. The effect is that crucial discussions continue to be split up. Clinicians don't always read ethics journals. Ethicists may not always be on the ground of the realities of frontline medicine. Policymakers may be presented with evidence that does not have sufficient ethical context. Procedures and protocols may be emphasized without equal emphasis on moral reasoning. Such a journal can bridge the gap between these two fields by producing research that is scientifically valid and ethically conscious at the same time.

In many parts of the world, including healthcare environments in developing countries, medicine and ethics become indistinguishable from one another. They are not theoretical questions of fairness, access, affordability, triage, public trust and professional accountability; they are lived realities. Healthcare Ethics cannot be discussed only in relation to advanced technologies and tertiary care environment. It has to address overburdened systems,

resource constraints, rural access, cultural diversity, public health priorities, vulnerable populations, and the responsibilities of institutions. A journal in this area must be open to grounded scholarship from the everyday practice, not only to philosophical analysis.

The current problems of academic medicine itself are also a strong argument for such a journal. Issues of research integrity, authorship disputes, conflicts of interest, abuse of artificial intelligence, predatory publishing, data manipulation and failures of transparency are increasingly becoming issues of concern. Medical ethics is more than bedside dilemmas. It also incorporates the way knowledge is produced, reviewed, published and applied. An ethically sensitive journal can raise the bar for integrity and promote thoughtful scholarship in the areas of medicine and ethics. In doing so, it can contribute not only to better publications, but to a healthier academic culture.

Medicine at its best is a science of conscience. The clinician needs to know the evidence but also to understand the person. The researcher must seek discovery, but must also remain responsible. The teacher has to teach knowledge but also has to teach character. "The institution must seek excellence, but must also protect justice. These are not different ambitions. They support each other. Ultimately, a medically competent system that is ethically neutral will lose credibility. An ethical system that is scientifically faulty would not provide good services to patients. Both of them are necessary for the development of healthcare in the future.

It is with this conviction that *Annals of Medicine and Medical Ethics* embarks on its mission. Our journal rests on the belief that academic scholarship needs to address both the capabilities of the profession as well as the way it should serve humanity. We look forward to receiving contributions that are scholarly, medically sound, ethically aware, and socially relevant. We welcome cross-disciplinary and cross-cultural discussions. We value scholarly courage, scholarly responsibility, and scholarly compassion in our contributors. In uniting medicine with ethics, we are not merely building an optional partnership. It is an essential restoration. Medicine cannot be humane, trustworthy, and responsive to community values without a central place for ethics.

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Building a Scholarly Home for Dialogue between Medicine, Ethics, and Society

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The practice of medicine has always been more than the management of disease. It is based on science, but it is exercised with judgment, formed in human relationships and challenged by ethical responsibility. In every age medicine has had to respond to changing patterns of illness as well as to changing expectations of society [1,2]. Today, with the technological sophistication and social complexity of healthcare systems increasing, it is more obvious than ever that a scholarly platform that efficiently links medicine and medical ethics is needed. It is in this vein that *Annals of Medicine and Medical Ethics* aims to provide a timely and much-needed academic forum.

A journal isn't just a place to archive manuscripts. It is a questioning philosophy. It sets the tone for conversations that are worth serious consideration. It allows disciplines to talk to one another instead of being stuck within their own borders. The vision of this journal is grounded in the understanding that clinical medicine and ethical reflection are not parallel enterprises. They are interconnected. Good medical care needs scientific competence but also fairness, accountability, sensitivity and moral clarity [3]. Likewise, the ethical dimensions of health care need to have their feet planted firmly in the concrete aspects of medical practice, suffering patients, organizational limitations, and the social environments within which medicine operates.

Worldwide, practitioners in health care are facing tougher questions each day. When challenges to decisions arise, how do health care providers negotiate between the patient's right of self-determination and the professional expertise of the practitioner? How can we allocate scarce resources during times of inequality and/or scarcity? How can we introduce artificial intelligence technology and other advanced digital technology to the healthcare sector without infringing on the right to privacy and trust for the individual? These are not trivial academic questions. These are in the everyday realities of hospitals, clinics, classrooms, ethics committees, research environments, and health systems. So a journal which embraces medicine and ethics is not only desirable, it is essential.

One of the main aims of *Annals of Medicine and Medical Ethics* is to encourage a cross-disciplinary forum which does not always get enough interaction in conventional publishing spaces. Even though clinicians can document the outcomes of their patients' treatment plans, they might find it difficult to explain the moral aspect associated with them. Though ethicists can provide conceptual analysis,

they might fail to deliver them to the relevant practitioners. Questions of great relevance to medicine are often addressed by experts in public health, educators, legal scholars, sociologists and policymakers but their perspectives are often scattered across separate journals and audiences. Such a journal aims to create a shared intellectual forum where these various perspectives can engage, challenge, and enhance each other.

A journal of this kind is all the more necessary when we consider the era of exploding scientific knowledge that surrounds us. There are amazing possibilities in terms of diagnosis, treatment, life support, reproduction, genetic science, and personalised medicine. But along with every breakthrough comes ethical questions of access, choice, affordability, quality of life, and justice. It often makes them keener. In this space, the role of an academic journal is not just to celebrate novelty, but to examine its implications with seriousness and balance [4].

The journal also acknowledges that medical ethics are not confined to exceptional dilemmas. It is found in routine care, everyday decisions, ordinary systems. This is evident in delivering bad news, in gaining consent, in caring for vulnerable patients, in disclosure of errors, in protecting research participants and in mentoring trainees. It is encountered in the ethics of documentation, publication, authorship, peer review and professional conduct. It is reflected in the culture of institutions and the trust between society and the medical profession. The journal encompasses the full range of these concerns, and welcomes contributions from across the spectrum of clinical medicine, research ethics, medical humanities, public health ethics, professionalism, policy and emerging technologies.

Another important goal of this journal is to promote academic inclusiveness. Important ethical and clinical lessons are not only learned in large centers or in systems of high resources. They also arise from community practice, district hospitals, training institutions, public sector settings and resource-constrained environments where the most difficult choices are often most visible [5,6]. But the real-life situation faced by practitioners and scholars working in these contexts warrants academic scrutiny. It is in this context that some of the most difficult ethical dilemmas emerge, such as those related to equality, access, prioritization, costs, public accountability, and culture. We hope that this journal will highlight research that is locally

rooted, yet universally applicable. This journal could also be used for training purposes by students and young researchers.

Traditionally, medical education has emphasized the acquisition of knowledge and technical skill. But there is a growing recognition that the development of a good doctor or health care professional also depends on ethical literacy, reflective capacity, professionalism, and sensitivity to the broader meaning of care. Such a journal can be part of that formation by publishing work which helps readers to think more clearly, more responsibly, and more compassionately about the profession in which they live. As Co-Editor, I would like to emphasize the necessity for the journal to contribute to the protection of scholarly integrity. In the face of increasing academic pressures and changes in the environment of scholarly publishing, much thought should be invested into such issues as authorship, transparency, plagiarism, artificial intelligence, peer review integrity, and scientific misconduct. Ethical publication equals ethical medicine, period. Therefore, a journal dedicated to medicine and ethics requires high editorial standards and ethical publishing practices.

The fate of the *Annals of Medicine and Medical Ethics* is in no way dependent on its editorial board, but rather on the community that it creates around itself. It must carry forward scholarly articles, insightful commentaries, case studies, reflective writings, educational insights, and cross-disciplinary papers. We look forward to receiving papers which raise clinical questions and discuss their implications from an ethical, professional, and sociological point of view. We will appreciate academic rigor in our papers, but scholarship can only be enriched by engagement.

The basic premise on which we shall run the journal could hardly be simpler. It can be stated as follows: medicine will serve humanity well if it is based on science and ethics. In other words, there need be no dichotomy between excellence in practice and morality. Indeed, each reinforces the other. If science dominates a healthcare system, there could be a problem of its unjust and impersonal character. If ethics dominates it, then it would be non-evident.

We hope that *Annals of Medicine and Medical Ethics* will be a meaningful forum for that joint effort. Contributions to this endeavour from clinicians, researchers, educators, ethicists and scholars from a range of disciplines are welcomed. We aim to build a future of health care which is intellectually robust, morally coherent and deeply responsive to the needs of patients and society through discourse, contemplation and scholarship.

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End-of-Life Care: Beyond Survival, Toward Dignity

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Introduction

Modern medicine has transformed the boundaries of human survival. Advances in intensive care, mechanical ventilation, renal replacement therapy, vasopressor support, artificial nutrition, cardiac devices, antimicrobials, and organ support technologies have allowed clinicians to sustain life in situations that were once considered irreversible. These developments are among the greatest achievements of medical science. They have saved countless lives, restored health, and extended meaningful survival for many patients. Yet, these same advances have also created new ethical and clinical dilemmas. Medicine can now maintain biological function even when the possibility of meaningful recovery has disappeared. A heart may continue to beat, lungs may be ventilated, blood pressure may be supported, and nutrition may be delivered artificially, but the patient may no longer have awareness, interaction, comfort, or any realistic chance of recovery.

This reality compels medicine to ask a difficult but necessary question: when does sustaining life cease to be healing and begin to prolong dying? This question is not merely theoretical. It is faced daily in emergency departments, intensive care units, oncology wards, neurology units, and homes where families struggle to decide what is right for their loved ones. End-of-life care begins at this intersection. It asks clinicians, families, institutions, and society to recognize that the purpose of medicine is not merely to extend life at all costs. The purpose of medicine is also to relieve suffering, respect human values, and preserve dignity when cure is no longer possible [1-3].

The Meaning of Dignity at the End of Life

Dignity is often discussed as a philosophical or moral ideal, but in end-of-life care it is also a clinical responsibility. A dignified death does not mean abandoning treatment. It means ensuring that the patient is not reduced to a collection of failing organs, laboratory values, ventilator settings, and drug infusions. Dignity requires that the patient remains at the center of care. Their comfort, values, beliefs, previously expressed wishes, and emotional needs must guide decision-making. The clinical team must ask not only “Can we continue treatment?” but also “Should we continue this treatment?” and “Is this treatment still serving the patient?” Preserving dignity also means protecting the patient from unnecessary pain, invasive procedures, isolation, and loss of privacy [2,4,5]. It requires the treating team to recognize

the patient as a person with a life story, relationships, fears, hopes, and values. Even when consciousness is lost, the patient's dignity must remain fully respected.

When recovery becomes impossible, the goal of care must shift deliberately and responsibly. The focus moves from prolonging life to preserving dignity, from intervention to intention, from survival alone to comfort and meaning, from aggressive treatment to compassionate care, and from doing everything possible to doing everything appropriate. This transition is not a failure of medicine. It is a sign of mature, ethical, and patient-centred medical practice. It reflects the understanding that medical success cannot be measured only by survival statistics, but also by the quality of care delivered in the final phase of life. Such a shift requires courage from clinicians and trust from families. It may be emotionally difficult because it involves accepting the limits of treatment. However, when done with honesty and compassion, it allows the patient's remaining time to be protected from avoidable suffering.

Life-sustaining Treatments are Not a Moral Obligation

Life-sustaining treatments include mechanical ventilation, vasopressor support, dialysis, cardiopulmonary resuscitation, invasive monitoring, antibiotics, blood products, clinically assisted nutrition, and hydration. These interventions can be lifesaving when used in reversible illness. However, they are still medical treatments. Like all treatments, they must be evaluated in relation to benefit, burden, prognosis, and alignment with the patient's goals.

No treatment is automatically obligatory simply because it is available. The mere ability to continue an intervention does not make its continuation ethically necessary [6,7]. Modern medicine must therefore distinguish between treatments that restore meaningful life and treatments that merely delay death. This distinction is especially important in intensive care settings, where machines and drugs may create the appearance of stability while the underlying disease remains irreversible. Families may interpret continued treatment as continued hope. It is the responsibility of clinicians to explain when treatment is no longer changing the outcome.

A treatment is appropriate when its expected benefit outweighs its burden. However, when treatment no longer offers meaningful recovery, symptom relief, or improvement in quality of life, it may become disproportionate [8-10]. Continuing such treatment can increase suffering rather than reduce it. For example,

mechanical ventilation may be appropriate in a patient with reversible respiratory failure. But in a patient with irreversible neurological injury, progressive multi-organ failure, or terminal illness with no possibility of recovery, ventilation may only prolong the dying process. Similarly, vasopressors, dialysis, and artificial feeding may be beneficial in selected situations, but they may become medically inappropriate when they only sustain organ function without improving the patient's overall condition or comfort. Proportionality requires a balanced view of what the treatment is achieving and what it is costing the patient physically, emotionally, and spiritually.

The burden of treatment may include pain, repeated procedures, loss of communication, prolonged ICU stay, distress to families, and loss of a peaceful dying process [11]. Therefore, benefit must not be assessed in purely physiological terms. It must be assessed in terms of the patient's overall welfare. Clinically assisted nutrition and hydration are often emotionally perceived as basic care [12-15]. Families may feel that stopping artificial feeding is equivalent to starving the patient. However, in medical and ethical terms, artificial nutrition and hydration are medical interventions. They require tubes, devices, monitoring, and clinical judgment.

When they no longer serve the patient's interests, or when they contribute to discomfort, complications, aspiration, fluid overload, or prolongation of dying, they may be ethically withheld or withdrawn. This is particularly relevant in irreversible conditions such as persistent vegetative state, advanced dementia, terminal illness, or severe irreversible brain injury. It is important to explain this distinction gently to families. Food and water have deep emotional and cultural meaning, and decisions about artificial nutrition can be painful. Clinicians must reassure families that comfort measures, mouth care, symptom relief, and compassionate presence will continue even if medically assisted feeding is not pursued.

Futility in End-of-Life Care

Futility refers to treatment that is unlikely to achieve its intended physiological or meaningful clinical goal [16-19]. It does not mean that the patient's life is futile. It means that a particular medical intervention is no longer useful for achieving recovery, comfort, or meaningful survival. This distinction is extremely important. The dignity of the patient must never be questioned. What may be questioned is the usefulness of continued intervention. The term futility should therefore be used carefully and respectfully. Families may misunderstand it as a judgment on the value of their loved one's life. Clinicians should instead explain that the disease has reached a stage where further intervention cannot reverse the condition or restore meaningful recovery.

The decision that treatment is futile must be based on careful medical assessment. It should not arise from emotional exhaustion, moral distress, bed shortages, financial constraints, or institutional pressure [9,10, 19-23]. Clinical futility must be judged through reversibility of the underlying illness, prognosis, response to ongoing treatment, expected quality of life, patient's known values and preferences, consensus among treating clinicians, and multidisciplinary discussion when needed. Such decisions should be transparent, documented, and communicated compassionately to the family. The process should allow time for questions, second opinions when appropriate, and repeated discussions if the family is struggling to understand the situation. Objective judgment also protects clinicians from making decisions based on impulse or fatigue. End-of-life decisions are too serious to be made casually. They require clinical clarity, ethical reflection, and institutional support.

The concept of futility must be used with great caution. It should not become a convenient label for difficult cases. It should not be used to deny care to patients who are elderly, disabled, economically disadvantaged, or socially vulnerable. Futility must remain anchored in medical reasoning, ethical reflection, and respect for the patient. The patient's age, disability, social status, or economic background must never become the basis for limiting care. Every patient deserves individualized assessment. A treatment that is inappropriate for one patient may be appropriate for another depending on prognosis, reversibility, and the patient's own goals. Ethical decision-making must therefore remain patient-specific and free from prejudice.

Withholding and Withdrawing Treatment

Withholding treatment means deciding not to start a medical intervention because it is unlikely to benefit the patient [9,10,24,25]. Withdrawing treatment means stopping an intervention that has already been started because it is no longer beneficial [24-27]. Emotionally, withdrawing treatment often feels more difficult than withholding it. Families and clinicians may feel that stopping a ventilator, dialysis, or vasopressor support is an active step. However, ethically, withholding and withdrawing inappropriate treatment are similar when the treatment no longer serves the patient's goals. This understanding is essential because many treatments are started during uncertainty or emergency. Once more information becomes available and prognosis becomes clearer, it is ethically acceptable to reassess and discontinue treatments that are no longer useful. Starting treatment should not mean that it must continue indefinitely.

A critical ethical distinction must be preserved: withholding or withdrawing life-sustaining treatment is not the same as

causing death. In such situations, the underlying illness causes death. The physician does not kill the patient. The physician recognizes the limits of medicine and allows the natural course of disease to proceed while ensuring that the patient is comfortable and cared for.

"Care does not stop when treatment stops.

We may withdraw machines, but we never withdraw care.

When cure is no longer possible, comfort becomes the priority."

This message must be clearly communicated to families. Many relatives fear that limiting treatment means the patient will be neglected [28]. The healthcare team must reassure them that attention, monitoring, symptom relief, nursing care, and emotional support will continue with even greater focus.

When life-sustaining treatment is withheld or withdrawn, the responsibility of the healthcare team increases rather than decreases. The patient must receive meticulous care focused on comfort, relief of suffering, privacy, communication, and emotional support. This includes control of pain and breathlessness, relief of agitation, management of secretions, skin care, nursing comfort, family presence, spiritual support, and clear explanation of what to expect during the dying process.

This is not passive care. It is active, compassionate, and deeply humane care. The aim is to ensure that the patient does not experience avoidable distress and that the family does not feel abandoned. Good end-of-life care also prepares the family for visible changes during dying, such as altered breathing, reduced consciousness, cold extremities, or decreased urine output. Explaining these changes reduces fear and prevents unnecessary panic-driven interventions.

The Indian Legal and Ethical Context

In India, end-of-life care has gradually gained ethical and legal recognition. Landmark judicial decisions have acknowledged that the right to life includes the right to live and die with dignity. These developments have helped clarify the permissibility of withholding and withdrawing life-sustaining treatment under appropriate safeguards. This legal evolution is important because many clinicians in India have historically feared legal consequences when limiting futile treatment (**Figure 1**). As a result, aggressive interventions have often continued even when they no longer benefit the patient.

The legal progress also reflects a broader moral recognition that dignity at the end of life is not a luxury. It is a fundamental component of humane care. However, awareness of these developments remains uneven across institutions and among healthcare workers.

Legal frameworks should not intimidate doctors. They should enable ethical care. Clear legal protection is essential for clinicians who act in good faith, follow due process, involve families, document decisions, and prioritize the patient's best interests. However, legal recognition alone is not enough. Hospitals must develop practical systems so that these principles can be implemented at the bedside. The law should provide confidence, not confusion. If procedures are too complex, clinicians may avoid appropriate end-of-life decisions despite legal permission. Therefore, legal clarity must be translated into simple institutional pathways. The aim should be to make ethical end-of-life care a routine part of good clinical practice, not an exceptional act [29].

Role of all Stakeholders

Role of Physicians

Doctors must not remain passive observers in end-of-life decision-making. They must lead with clinical clarity, ethical sensitivity, and compassionate communication. Physicians should initiate discussions when treatment is no longer beneficial. They should explain prognosis honestly and guide families through difficult decisions. Avoiding these conversations does not protect families. It burdens them with uncertainty and guilt.

The physician's duty does not end when cure is no longer possible. In many ways, the physician's role becomes even more important. Patients and families need guidance, reassurance, and presence. Being present at the end of life is a powerful form of care. Even when no curative treatment remains, the physician can still relieve symptoms, reduce fear, support the family, and ensure that the patient's final phase is peaceful and dignified.

Role of Hospitals and Institutions

Every hospital should have a clear end-of-life care policy. Such policies should define processes for identifying medically inappropriate treatment, conducting family meetings, documenting decisions, obtaining second opinions, involving ethics committees, and ensuring comfort care.

Without institutional support, clinicians may feel isolated and vulnerable. Institutional policies also create consistency. They prevent end-of-life decisions from varying widely depending on the individual doctor on duty. A clear policy reassures patients, families, and healthcare workers that decisions are being made through a fair and transparent process.

Role of Nurses and Allied Healthcare Workers

Nurses are often closest to patients and families. They observe suffering, provide comfort, explain bedside changes, and support families during the dying process. Their role in end-of-life care is central. They should be

EOL Journey of India



MILESTONES IN THE EVOLUTION OF END-OF-LIFE CARE

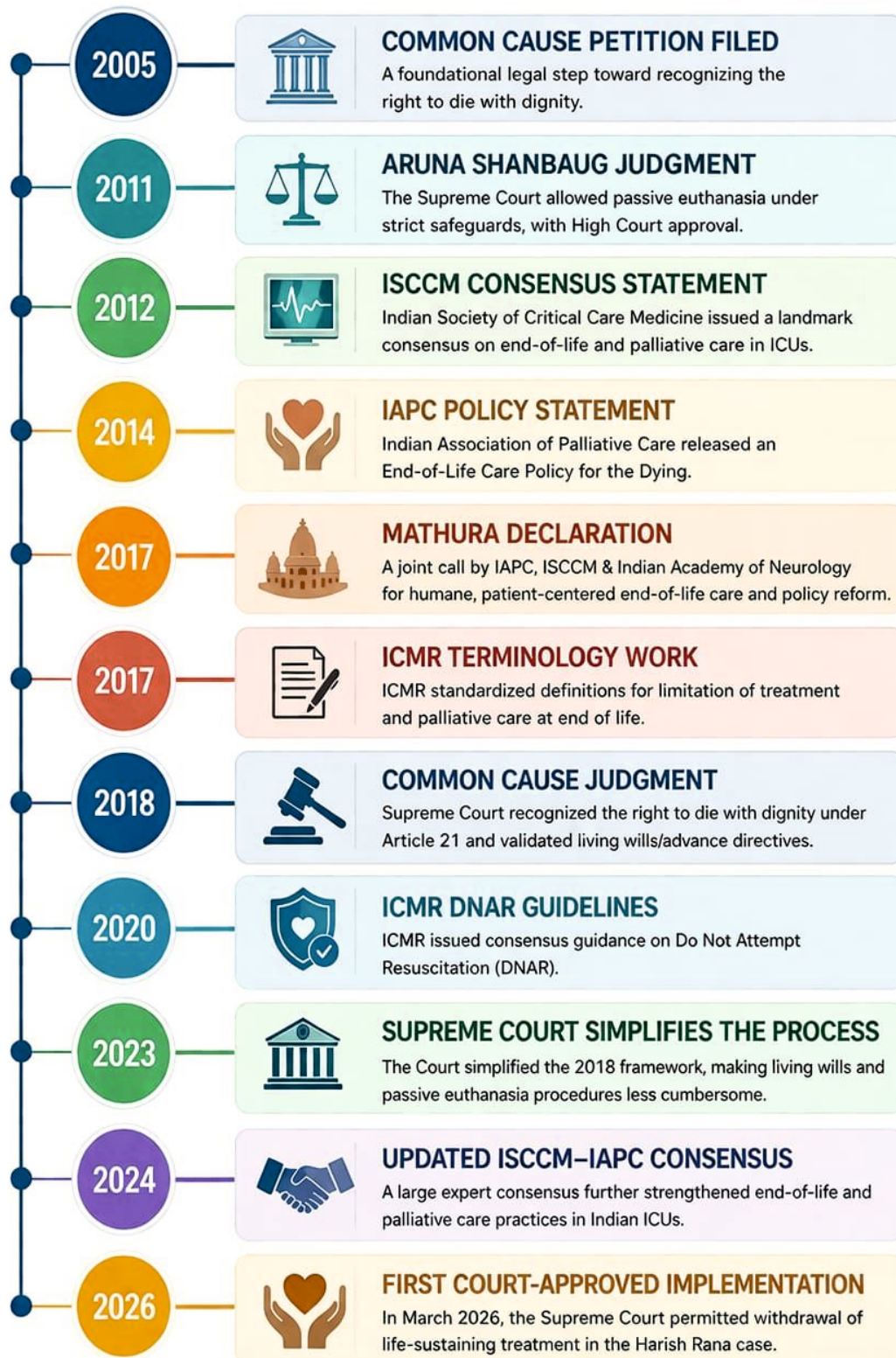


Figure-1: End-of-life Care journey of India

Abbreviations: EOL: End-of-life; ISCCM: Indian Society of Critical Care Medicine; IAPC: Indian Association of Palliative Care; ICMR: Indian Council of Medical Research; DNAR: Do Not Attempt Resuscitation; ICU: Intensive Care Unit; ICUs: Intensive Care Units.

included in decision-making conversations and trained in symptom recognition, comfort care, communication, and family support. Families often trust nurses because of their continuous presence at the bedside. Nurses can recognize subtle signs of discomfort and alert physicians early. Their involvement makes end-of-life care more responsive, compassionate, and practical.

Role of Primary Care Doctors

Primary care doctors and family physicians are often the first point of contact. They know the patient's family, social background, and long-term illness trajectory. They are well placed to initiate advance care planning and guide families before crisis occurs. Training in basic palliative care and end-of-life communication should be integrated into undergraduate and postgraduate medical education [30-32]. Primary care doctors can also help identify patients who need early palliative support. They can prevent unnecessary hospital visits by managing symptoms locally when appropriate. Their role is especially important for elderly patients, chronically ill patients, and those with limited access to tertiary care.

Role of Community Health Workers

Community health workers, including ASHA workers, can play an important role in bridging hospitals and homes. They often understand local culture, family dynamics, and community beliefs. With appropriate training, they can help identify patients needing palliative support, guide families, assist with symptom reporting, and encourage timely medical consultation.

They can also help families understand basic comfort measures and when to seek medical help. Their presence can reduce isolation for families caring for dying patients at home. In resource-limited settings, they may become the most accessible link between the healthcare system and the patient.

Role of Society and Culture

Death remains a taboo subject in many families. It is often discussed only when crisis has already occurred. This silence prevents planning and increases suffering. Society must become more comfortable discussing serious illness, dying, and medical limits [33]. Such conversations do not invite death. They prepare families to face it with clarity and dignity. Schools, communities, religious groups, media, and healthcare institutions can all help normalize these conversations. A society that can speak openly about dying is better able to care for the dying. Silence often leads to fear; conversation can create preparedness.

Role of Lawmakers and Policymakers

Lawmakers have a crucial role in bridging the gap between ethical principle and clinical practice. Legal procedures for withholding and withdrawing life-sustaining treatment

must be clear, accessible, and practical. Complicated processes may discourage implementation and leave patients exposed to prolonged suffering.

Legal pathways must be understandable for clinicians working in busy hospitals. They should not require excessive paperwork, repeated approvals, or unclear authority. Simplicity is not the enemy of safety; it is essential for implementation. India needs standard documentation formats, institutional pathways, and legal protections for clinicians acting in good faith. These frameworks should be usable not only in large hospitals but also in district and community settings.

Uniformity will reduce confusion and variation between institutions.

Standard forms can help clinicians document prognosis, family discussions, patient preferences, and care plans clearly. Such tools also reassure families that decisions are being made according to accepted norms rather than personal opinion. A national framework can bring confidence to both doctors and the public.

Building an End-of-Life Care Pathway

Patients with irreversible illness, advanced organ failure, severe neurological injury, terminal malignancy, advanced dementia, or progressive multi-organ dysfunction should be identified early for goals-of-care discussions. Early identification allows time for planning rather than crisis-driven decision-making. Clinicians should recognize warning signs such as repeated ICU admissions, poor functional status, treatment failure, progressive decline, and absence of realistic curative options. Once such patients are identified, communication should begin gradually and sensitively. Waiting until the last hours often deprives families of meaningful participation.

Hospitals should develop structured family meeting processes. These meetings should include explanation of diagnosis, prognosis, treatment options, likely outcomes, and comfort-focused alternatives. A structured meeting helps ensure that important information is not missed. Such meetings should be conducted in a private and calm environment. The family should be allowed to ask questions and express emotions. A single meeting may not be enough; difficult decisions often require repeated conversations and time for acceptance [34].

Difficult cases should have access to ethics consultation and palliative care teams. This provides support to both clinicians and families. Ethics support is especially useful when there is disagreement, uncertainty, or concern about the appropriateness of continued treatment. Palliative care teams can help manage symptoms and guide communication. Ethics teams can help clarify values, responsibilities, and processes. Together, they reduce conflict and improve confidence in decision-making.

Reassessment also shows families that decisions are not rushed or predetermined [34-39]. It demonstrates that the medical team remains attentive and thoughtful. This ongoing review builds trust and ensures that care remains appropriate to the patient's condition.

Conclusion

Medicine is not solely about defeating death. It is about honouring life in its entirety, including its final phase. To care well for the dying is not to surrender. It is to uphold the highest ideals of the profession. When cure is no longer possible, dignity must remain non-negotiable.

End-of-life care asks medicine to combine science with wisdom, law with compassion, and technology with humanity. It reminds us that the true measure of healthcare is not only how many lives we save, but also how gently, honestly, and respectfully we care for those who cannot be saved. A dignified death is not a failure of medicine. It is one of its most profound responsibilities. End-of-life care must therefore become a visible, taught, practiced, and protected part of modern healthcare.

The final goal is not only to help people live well, but also to ensure that when life reaches its natural end, patients are not left to suffer unnecessarily. They must be cared for with comfort, honesty, presence, and respect. In that commitment lies the deepest humanity of medicine.

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A Rare Case of Sjögren's Syndrome Associated with Autoimmune Hemolytic Anemia, Palindromic Rheumatism, and Hepatitis B

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Abstract

Background: Sjögren syndrome (SS) is a chronic systemic autoimmune disease that mostly causes dryness in moist areas such as the mouth or eyes, although it may include other parts of the body. Hematological abnormalities such as autoimmune hemolytic anemia are infrequent but can be confusing if they are dominant at the onset of the disease. We encountered a case of SS presenting with profound autoimmune hemolytic anemia (AIHA) and hepatitis B virus (HBV) infection. Immunosuppression therapy could theoretically increase the risks for reactivation of the chronic HBV infection. **Case Description:** A 32-year-old woman came with severe general malaise for 15 days, yellow staining of the eye and the body and migratory joint pain. At presentation, pallor, icterus, heart rate 110 beats/min and hepatosplenomegaly were documented. Laboratory tests revealed Hb 2.7 g/dL with remarkable reticulocytosis, bilirubin levels elevated at 18 mg/dL with indirect bilirubin 14 mg/dL, transaminases elevated with aspartate transaminase AST 228 U/L and alanine transaminase ALT 235 U/L and a direct Coombs test was positive for IgG and C3d. Laboratory testing revealed a positive ANA and strong positive results for SS-A, SS-B and Ro52 antibodies. Screening for hepatitis viruses showed HBsAg positive, but the HBV DNA load was only moderate (2261 IU/mL). She was diagnosed with SS associated with AIHA, palindromic rheumatism and chronic hepatitis B infection. She was given pulse methylprednisolone for 3 consecutive days, followed by oral prednisolone at a taper dosage. She was also started on tenofovir and hydroxychloroquine. Hb and liver enzymes slowly improved. **Conclusion:** SS can cause significant AIHA as the first prominent symptom, especially in young women without classical dryness, leading to the delayed diagnosis of the autoimmune disorder. Autoimmune screening in parallel with screening for chronic viral infection is recommended to identify potential risk factors before any initiation of immunotherapy, among hepatitis B carriers.

Keywords: Sjögren's Syndrome; Anemia, Hemolytic, Autoimmune; Hepatitis B, Chronic; Palindromic Rheumatism; Autoantibodies; Coombs Test; Hyperbilirubinemia; Glucocorticoids

Introduction

Sjögren's syndrome is a chronic, systemic, autoimmune disease predominantly characterized by xerostomia and xerophthalmia, though it can affect various organs and systems, including the musculoskeletal, pulmonary, renal, nervous, hepatobiliary and hematopoietic organs, making it difficult to diagnose when the presentation differs greatly from these two classical features [1].

The American College of Rheumatology/European League Against Rheumatism classification criteria were updated in 2016 to reflect the relative diagnostic importance of positive antibodies for anti-SSA/Ro, focal lymphocytic sialadenitis (an average of ≥ 1 lymphoid focus/4 mm²), objective ocular staining with rose bengal or fluorescein, Schirmer testing and salivary flow rate measurement. Anti-Ro/SSA and anti-La/SSB antibodies continue to be of major clinical importance in Sjögren's syndrome and these antibodies are typically related to the systemic manifestation of disease than the isolation of gland manifestations. Hematologic features are also important extraglandular manifestations that can arise in patients with primary Sjögren's. These are most often represented by anemia, leukopenia, thrombocytopenia, lymphopenia, monoclonal gammopathy,

and, less commonly, autoimmune cytopenias such as Coombs' positivity and/or autoimmune neutropenia or thrombocytopenia [2].

Primary Sjögren's patients may have anemia, cytopenias, monoclonal gammopathies and lymphoproliferative disorders, emphasizing the need to test patients with an abnormal or unexplained cytopenia for Sjögren's [3]. In earlier clinicopathological studies, hematologic abnormalities were described in as many as 11-47% of patients with Sjögren's syndrome, with 20-34% testing positive by direct antiglobulin test (DAT), some of whom did not show clinical evidence of hemolysis [4].

Autoimmune hemolytic anemia is an uncommon but clinically significant hematological manifestation of Sjögren's syndrome. It may precede, accompany, or follow the diagnosis of Sjögren's syndrome and can sometimes be the first major clue to an underlying systemic autoimmune disease [5,6]. Wen et al., in a large-scale cross-sectional study of hospitalized patients with primary Sjögren's syndrome, reported autoimmune hemolytic anemia as an uncommon manifestation, with a prevalence of 2.8% among 565 patients [5]. Earlier reports also described autoimmune hemolytic anemia preceding the clinical

recognition of Sjögren's syndrome, suggesting that patients initially labelled as having "idiopathic" autoimmune hemolytic anemia may later demonstrate systemic autoimmune features [6]. Therefore, when severe anemia is accompanied by jaundice, reticulocytosis, hepatosplenomegaly, or a positive direct antiglobulin test, evaluation for an autoimmune connective tissue disease becomes clinically relevant. In case reports of Sjögren's syndrome presenting with autoimmune cytopenia, patients often require close integration of hematological and rheumatological evaluation because the initial clinical presentation may be dominated by hematological abnormalities rather than sicca symptoms [7].

The diagnosis of autoimmune hemolytic anemia depends on the demonstration of hemolysis and immune-mediated red cell destruction. The direct antiglobulin test remains central to diagnosis, and warm autoimmune hemolytic anemia is typically associated with IgG-mediated red cell sensitization, with or without complement deposition [8]. International consensus recommendations state that corticosteroids remain the first-line treatment for warm autoimmune hemolytic anemia, although the addition of rituximab may be considered early in severe cases or when response is inadequate [8].

Another complication for these patients is palindromic rheumatism, a self-limiting inflammatory arthritis or peri-arthritis with periods of remission in between [9]. While palindromic rheumatism usually is related to Rheumatoid Arthritis (RA), it might occur in association with, precede or occur alongside various autoimmune connective tissue diseases. Because joints are only intermittently involved in this condition, its development in these patients may delay its diagnosis, especially if more acute manifestations like anemia or jaundice dominate their clinical presentation. Recurrent migratory arthralgia should thus be considered a manifestation of connective tissue disease in patients positive for RF or any of the various systemic autoantibodies than a sole issue involving the joints. A further problem is concomitant hepatitis B infection. Several immunosuppressive therapies that may be employed for autoimmune hemolysis (e.g., systemic corticosteroids and B-cell depleting therapy) can lead to reactivation of hepatitis B. American Association for studies in Liver Diseases (AASLD) suggests that patients positive for HBsAg should be given prophylactic antiviral therapy prior to initiation of immunosuppression or cytotoxic therapy [10]. We consider tenofovir and entecavir the optimal choices due to their effectiveness and the high bar to the development of resistance to these antivirals. Thus, for patients who must be treated with corticosteroids for autoimmune hemolytic anemia, HBsAg screening followed by timely prophylaxis are essential management components. We present this case of a patient

who had severe anemia, jaundice, hepatosplenomegaly, repeated joint pains, a positive direct Coombs test, strongly positive SS-A and SS-B antibodies and also had an infection with hepatitis B. This is clinically interesting as it created an overlap of autoimmune disease with viral issues. This case brings attention to the necessity of a comprehensive autoimmune workup in the setting of an unexplained severe anemia with systemic symptoms in patients not presenting with the classic clinical spectrum of Sjögren syndrome. Additionally, it highlights the challenge of finding a therapeutic regimen to adequately treat immune-mediated hemolysis while protecting against reactivation of hepatitis B virus during immunosuppressive treatment.

Case Presentation

The patient was a 32-year-old female admitted to the Department of Medicine with complaints of generalized weakness lasting 15 days, jaundice of the sclera and skin for about 15 days, and intermittent joint pain in the same period (**Figure 1**). Her blood pressure was 98/56 mm Hg, pulse rate was 125 beats/min, respiratory rate was 24 cycles/min, and temperature was 100.1°F. General examination revealed marked pallor and icterus. Abdominal examination showed hepatosplenomegaly.



Figure 1: Here we can see bilateral scleral icterus which is consistent with marked hyperbilirubinemia.

Initial laboratory evaluation revealed severe anemia with hemoglobin of 2.7 g/dL. The total leukocyte count was 5,400/mm³ and platelet count was 1.40 lakh/mm³. Peripheral smear showed markedly reduced red blood cells with anisopoikilocytosis, macrocytes, microcytes, and pencil cells, while white blood cells were normal and platelets were adequate. Reticulocyte count was markedly elevated at approximately 35%. Liver function tests were deranged, with total bilirubin 23.4 mg/dL, direct bilirubin 14.6 mg/dL, SGOT 1117 U/L, SGPT 953 U/L, and alkaline phosphatase 466 U/L. Renal function was preserved, with urea 72 mg/dL and serum creatinine 0.68 mg/dL. Ultrasonography of the abdomen confirmed hepatosplenomegaly. Screening for HIV, HCV, dengue, typhoid, and malaria was negative, while HBsAg was reactive with detectable viral load. A summary of the patients laboratory reports is shown in **Table 1**.

During admission, further evaluation was performed. Direct Coombs test was positive (**Figure 2**), with IgG 3+

Table 1: A summary of patients laboratory reports

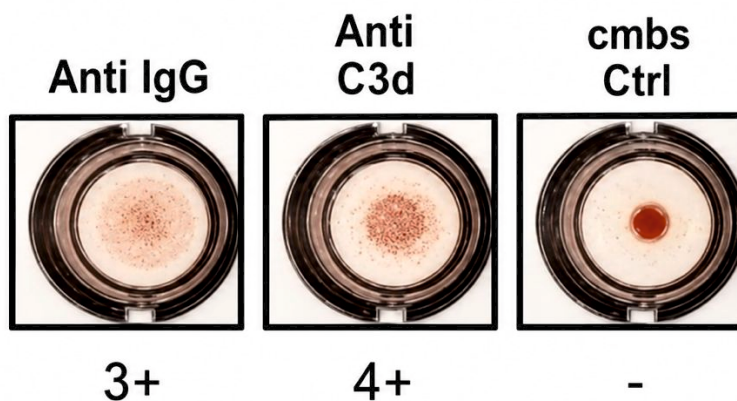
Test	Result	Test	Result
RA Factor	~29.8 IU/mL	HIV	Non -reactive
CRP	~7 mg/L	HBsAg	Reactive (Viral Load detected)
Procalcitonin	24.4 ng/mL	HCV	Non -reactive
Ferritin	1622 ng/mL	Dengue	Negative
LDH	557 U/L	Typhi IgM	Negative
Vitamin B12	~673 pg/mL	Malaria	Negative
TSH	~0.99	USG Abdomen	Hepato -splenomegaly
RBC	Moderately reduced	Special cells	Pencil cells seen
Morphology	Macrocytes + microcytes	WBC	Normal
Anisopoikilocytosis	Present	Platelets	Adequate
		Reticulocyte count	~35% ↑

and C3d 4+. ANA by immunofluorescence was positive. ENA profile showed strong positivity for SS-A, SS-B, and Ro-52, along with positive histone antibodies (**Figure3**). Rheumatoid factor was approximately 29.8 IU/mL, CRP was approximately 7 mg/L, procalcitonin was 24.4 ng/mL, ferritin was 1622 ng/mL, LDH was 557 U/L, vitamin B12 was approximately 673 pg/mL, and TSH was 0.99. Based on the clinical presentation and investigations, she was

diagnosed as a case of Sjögren's syndrome with autoimmune hemolytic anemia, palindromic rheumatism, and chronic hepatitis B infection. She was managed with pulse methylprednisolone for 3 days, followed by oral prednisolone at discharge with a planned taper. Tenofovir was started in view of hepatitis B infection, and hydroxychloroquine was added for joint symptoms. Supportive care and close monitoring of hematological and

Test Report

Test Name	Results	Units	Bio. Ref. Interval
COOMBS TEST, DIRECT (Erythrocytes Magnetized Technology)	Positive		

**Figure 2: Positive direct Coombs test supporting autoimmune hemolytic anemia**

SEROLOGY AND IMMUNOLOGY REPORT**Anti Nuclear Antibody (ANA) By IFA (HEP-2)**

Anti Nuclear Antibody by IFA	Positive	Negative
Pattern	Nucleus	
Grade	++	
Estimated Titre	1:100	

Interpretation:**Guidelines (Sample screening Dilution - 1:100):**

Negative : No Immunofluorescence

+ : Weak Positive

++ : Moderate Positive

+++ : Strong Positive

++++ : Very strong Positive

Test Report

Test Name	Results	Units	Bio. Ref. Interval
EXTRACTABLE NUCLEAR ANTIGENS (ENA)/ANTI NUCLEAR ANTIBODIES (ANA), QUALITATIVE PROFILE (LIA)			
U1-nRNP/Sm	Negative		
Sm	Negative		
SS-A	Strong Positive +++		
Ro- 52	Strong Positive +++		
SS-B/La	Strong Positive +++		
Scl - 70	Negative		
PM-Scl	Negative		
Jo - 1	Negative		
CENP-B	Negative		
PCNA	Negative		
ds-DNA	Negative		
Nucleosomes	Negative		
Histones	Positive ++		
Rib- P Protein	Negative		
AMA- M2	Negative		

Figure 3: Autoimmune serological profile supporting Sjögren's syndrome.

biochemical parameters were continued during hospitalization.

The patient showed gradual clinical and laboratory improvement. By discharge, hemoglobin had improved to 7.2 g/dL, total leukocyte count was 5,300/mm³, and platelet count was 1.44 lakh/mm³. A comparison of initial and later laboratory parameters is shown in **Table 2**. Total bilirubin decreased to 6.0 mg/dL, direct bilirubin to 4.7 mg/dL, SGOT to 74 U/L, SGPT to 257 U/L, and alkaline phosphatase to 230 U/L. Renal function remained stable, with urea 50 mg/dL and serum creatinine 0.61 mg/dL. She was discharged in stable condition on oral medications with advice for regular follow-up, serial complete blood counts,

reticulocyte counts, liver function monitoring, and specialist follow-up.

At 1-month follow-up, she reported clinical improvement. Her hemoglobin had increased to 11.2 g/dL, total leukocyte count was 7200/mm³, platelet count was 2.26 lakh/mm³, and MCV was 93.1 fL. Liver function tests also improved, with total bilirubin 2.1 mg/dL, direct bilirubin 0.8 mg/dL, indirect bilirubin 1.3 mg/dL, SGOT 92 U/L, SGPT 117 U/L, and alkaline phosphatase 208 U/L. Renal function and electrolytes remained within acceptable limits, with urea 40 mg/dL, creatinine 0.81 mg/dL, sodium 137 mmol/L, and potassium 4.3 mmol/L. The post treatment evaluation of the patient is shown in **Table 3**.

Table 2: A comparison of laboratory parameters on presentation and discharge

Parameter	Initial Value	Final Value
Hemoglobin (Hb)	2.7 g/dL	7.2 g/dL
TLC	5,400	5,300
Platelets	1.40 lakh	1.44 lakh
MCV	117	138
MCH	69	43
RDW	10.8	14.8
DLC	P70 L21 M04 E05	P81 L16 M1 E1
Urea	72	50
Creatinine	0.68	0.61
Sodium	132	137
Potassium	3.9	4.2
Total Bilirubin	23.4 mg/dL	6.0 mg/dL
Direct Bilirubin	14.6 mg/dL	4.7 mg/dL
SGOT (AST)	1117 U/L	74 U/L
SGPT (ALT)	953 U/L	257 U/L
ALP	466 U/L	230 U/L
Total Protein	5.8 g/dL	—
Albumin	3.2 g/dL	—

Table 3: 1 month Post Treatment evaluation of the patient

INVESTIGATION	FINDING
Hb	11.2 g/dL
TLC	7200
PC	2.26 lakh
MCV	93.1
T. Bilirubin	2.1mg/dL
Direct Bilirubin	0.8
Indirect Bilirubin	1.3
SGOT	92
SGPT	117
ALP	208
Urea	40
Creatinine	0.81mg/dL
Sodium	137
Potassium	4.3

Discussion

This case demonstrates the difficulty in diagnosis that can be expected when there are severe blood abnormalities seen alongside systemic autoimmunity and chronic virus infections. Sjögren's syndrome is traditionally diagnosed through the presence of sicca symptoms, but it is currently accepted as a systemic autoimmunity condition which can affect several organs and organ systems. According to the American college of Rheumatology/European League Against Rheumatism classification criteria for Sjögren's syndrome in 2016, there is considerable emphasis placed on the presence of anti-SSA/Ro antibodies and an objective evaluation of glands, but in actual clinical settings, patients can manifest extra-glandular symptoms first before eye and mouth dryness [1]. In the present case, the patient's

dominant clinical problems at admission were profound generalized weakness, jaundice, hepatosplenomegaly, and joint pain, with laboratory evaluation showing life-threatening anemia, marked hyperbilirubinemia, transaminitis, positive direct Coombs test, and strong positivity for SS-A, SS-B, and Ro-52 antibodies. These findings made the case diagnostically challenging, as the initial presentation was led by hematological and hepatobiliary abnormalities rather than classical sicca complaints.

Hematological manifestations of Sjögren's syndrome are well described but remain under-recognized in routine clinical practice. Manganelli et al. reported that anemia, leukopenia, thrombocytopenia, monoclonal gammopathy, and lymphoproliferative disorders may occur in primary Sjögren's syndrome [3]. Similarly, Ramakrishna et al. highlighted that hematological abnormalities may form an important part of the disease spectrum and may occasionally dominate the clinical presentation [4]. In this patient, the degree of anemia was severe, with an initial hemoglobin of 2.7 g/dL, and the presence of jaundice, hepatosplenomegaly, markedly elevated reticulocyte count, raised LDH, and direct antiglobulin test positivity supported immune-mediated hemolysis. The case therefore reinforces the importance of considering an autoimmune etiology in young patients presenting with unexplained severe anemia, especially when anemia is accompanied by systemic symptoms such as fever, arthralgia, jaundice, or organomegaly.

It is rare but significant when autoimmune hemolytic anemia occurs alongside Sjögren's syndrome. A minority of patients with primary Sjögren's syndrome in the study by Wen et al. Experienced autoimmune hemolytic anemia, although the authors stated the disorder occurred in only a few patients. Early studies report on Sjögren's syndrome cases occurring years after a diagnosis of autoimmune hemolytic anemia, indicating that hematological disorder can serve as the first evidence of an underlying connective tissue disorder [6]. This is evident in the current case study where anemia and jaundice were presenting symptoms. Likewise, primary Sjögren's syndrome presented with autoimmune cytopenia in Meena and Bohra's description [7], showing that the signs of autoimmune hematologic disease may precede or overshadow classic symptoms in some individuals with Sjögren's syndrome. Because of these potential correlations, patients who present with autoimmune hemolytic anemia should be investigated for underlying autoimmune disorders if they have any features such as joint pain, a positive ANA, positive rheumatoid factor or a positive ENA profile.

Positive results on the direct Coombs test, including the reactivity for both IgG and C3d, helped establish immune-mediated hemolysis. As recommended in guidelines based

on international consensus, the diagnosis of autoimmune hemolytic anemia includes correlation of clinical, biochemical and laboratory evidence for hemolysis and autoimmune hematologic evidence. Corticosteroids are recommended as the first line of treatment in cases of warm autoimmune hemolytic anemia [8]. The patient in this case responded to pulse methylprednisolone followed by oral prednisolone treatment with an improvement in her hemoglobin and liver parameters from 2.7 g/dL on admission to 7.2 g/dL at discharge and 11.2 g/dL at the 1-month follow-up visit.

The patient had joint pain recurrently, which opened the clinical perspective of the case. Palindromic rheumatism consists of attacks of joint pain or arthritis that appear and disappear and that can be a distinct clinical entity or the manifestation of an overlap in systemic autoimmune disease [9]. In this patient, joint manifestations, rheumatoid factor and strong autoimmune serologic results pointed to the need for evaluation by a rheumatologist. Hydroxychloroquine was prescribed to manage her palindromic rheumatism. The autoimmune nature of the arthralgia and other components of her presentation was evidenced by the serologic findings and the positive rheumatoid factor. Thus, musculoskeletal manifestations in this patient were part of a wider autoimmune spectrum.

Coexistence with chronic hepatitis B infection represented a major management difficulty because immunosuppression could trigger hepatitis B virus reactivation. According to the AASLD 2018 recommendations, antiviral therapy should be administered for HBsAg-positive patients before immunosuppression [10]. In this case, tenofovir was initiated together with corticosteroids. The immediate need to treat autoimmune hemolytic anemia needs to be weighed against the risks associated with hepatitis B virus reactivation and worsened hepatitis. This approach mitigated the risks while providing effective therapy for her autoimmune condition. Liver function test results improved with follow-up.

Anti-Ro/SSA and anti-La/SSB antibodies are the most useful autoantibodies for Sjögren's syndrome, especially concerning those with systemic disease expression [2]. The strong positive staining of SS-A, SS-B and Ro-52 was a plausible autoimmune reason for the symptoms experienced in this patient. The positive histone antibodies further reflected broad autoimmune reactivity, though the interpretation and significance need to be considered carefully with her medications and other features of autoimmunity. These findings suggest that ENA testing can be helpful for an unexplained cytopenia with a broader presentation.

This case report is strong because of the uncommon presentation and complete evaluation, as well as clear

clinical improvements at admission to the follow-up stage. It provides an example of a rare association of Sjögren's syndrome with autoimmune hemolytic anemia, palindromic rheumatism and hepatitis B and underscores the need for hepatitis B screening in patients before initiating therapy with immunomodulators. There are limitations because this is an anecdotal experience, the objective sicca assessment with the Schirmer test, ocular staining score, salivary flow rate testing or minor salivary gland biopsy findings are not reported in the study and the long-term outcome of the patient is not yet established. Additionally, it is not possible to find out the distinct effects of autoimmune hemolytic anemia, chronic hepatitis B virus infection and inflammation in the liver about the jaundiced presentation and deranged liver functions from the clinical data available.

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. Unexplained severe anemia with jaundice and positive Coombs test should prompt autoimmune evaluations.
2. Viral screening should be mandatory before starting immunosuppressive therapy.
3. Treatment should balance benefit and harm.
4. Young women with nonspecific symptoms such as fatigue, jaundice and joint pains often face diagnostic delay.
5. Access to advanced diagnostic tests matters in resource limited settings where autoimmune presentations are frequently missed.

Conclusion

This report documents a case of Sjögren's Syndrome characterized by severe autoimmune hemolytic anemia, as well as the presence of palindromic rheumatism and chronic infection with hepatitis B. The patient's primary complaints were significant anemia, jaundice, enlargement of the spleen and liver and joint pain, which overshadowed any typical dryness-related complaints, tests revealed a positive Coombs test and significant presence of SS-A, SS-B and Ro-52 antibodies. Management was complicated by the coexistence of chronic hepatitis B and was further enhanced by antiviral treatment initiated to prevent viral reactivation during treatment. Prompt assessment led to thorough testing, diligent observation and marked improvements both clinically and from laboratory markers.

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Esophageal Corrosion after Drinking a Dangerous Cocktail

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Abstract

Background: Unintentional ingestion of a corrosive acid or alkali is rampant in India due to inadequate legislature that regulate the sale of such substances. While all esophageal corrosives are due to acid and alkali chemicals used in materials, very few cases have been attributed to drinks and none to a cocktail. **Case description:** This report describes one 34-year-old male who presented to the emergency medicine department with a history of burning sensation in the chest for 2 days. The patient was a known alcoholic and had consumed a mixture of country liquor, energy drink and “Shirka” (a form of Indian Vinegar). Six hours following the ingestion, the patient started developing dyspepsia and abdominal discomfort. He experienced dysphagia and occasional bouts of severe chest pain. Upon endoscopy of the upper GI tract, a diffuse esophageal ulceration along the entire length of the esophagus along with the hypopharynx was observed. **Conclusion:** This case highlights the importance of understanding the risks associated with consuming alcohol and other substances in combination.

Keywords:

Esophageal corrosion, Endoscopy, Esophageal ulcer, Country Liquor

Introduction

Corrosive injuries to the esophagus are a devastating injury which carries significant morbidity. Liquids with extremes of pH of acid or alkali are corrosive and severely injure the Upper Gastro-intestinal Tract (UGIT). The severity of injury depends on the following aspects ie: the concentration of agent, the amount consumed, the duration of tissue contact, and the pH of the agent [1]. Unintentional ingestion of a corrosive acid or alkali is rampant in India due to inadequate legislature that regulate the sale of such substances. In the acute stage of corrosive injury, the endoscopy may reveal linear ulcers and necrosis in the esophagus closely followed by bleeding from the ulcers [2]. In the chronic stage, endoscopy images show esophageal stricture after 3 months of corrosive injury.

According to a review article on corrosive substances ingestion, corrosive chemical substance ingestions are a public health problem not just in developing but also developed countries [3]. Intake of the liquid may be intentional as seen in suicide attempts (mostly observed in adolescents and adults) or unintentional/accidental (mostly observed in children). The term “corrosive” rather than “caustic” is used in this report as it is more inclusive of the totality of chemical ingestions that can cause acute injury to the GIT.

Complications include but not limited to GIT (esophagus, stomach, pylorus, and duodenum) stricture formation, GI tract perforation, and hemorrhage. Systemic complications occur often late, such as disseminated intravascular coagulation (DIC), multi-organ system failure, and sepsis [3]. Esophageal reconstruction is to be performed in those

patients having had emergent esophageal resection and for those who developed esophageal strictures not responsive to dilation.

Case Description

A 34-year-old male presented to the emergency medicine department with the history of burning sensation in the chest since 2 days. Vitals on examination were within the normal limit. Airway was clear, breathing tachypneic and circulation normotensive. The patient was a known alcoholic since many years. ECG of the patient was normal. Upon detailed history it was revealed that the patient had consumed a mixture of country liquor, energy drink and “Shirka” (a form of Indian Vinegar) (**Figure 1**). 6 hours following the ingestion patient started developing dyspepsia and abdominal discomfort. He has experienced dysphagia and occasional bouts of severe chest pain. It was understood that he had never consumed this cocktail previously and was done only as a part of a bet. Troponin levels of the patient were reported normal and the patient was sent for an endoscopy of the upper GI Tract. Endoscopy suggested a diffuse Esophageal ulceration along the entire length of the esophagus along with the hypopharynx (**Figure 2**).

Fundus, cardia, body and the antrum of the stomach appeared normal. The patient was managed conservatively with sucralfate 1 g QID and was called for a follow-up after 3 months to look for strictures.

Discussion

The treatment of the patient early can always reduce the tissue damage. However, improper management of acute



Figure 1: Endoscopy of the patient showing diffuse esophageal ulcerations.



Figure2: The mixture from right to left used by the patient Shirka, Energy drink and Country Liquor.

corrosive injury is widely prevalent due to limited experience in managing this condition [4-5]. Gastrointestinal tissue is injured in 3 phases after injuries after ingestion of a corrosive agent. Cell necrosis and thrombosis occurs in phase 1, approximately 48–72 hours after the event. In the next phase there is mucosal sloughing with ulceration of the esophageal wall along with colonization of fibroblast and ultimately granulation. Liquefaction necrosis occurs when the is the esophagus comes in contact with alkaline agents. Thromboarthritis occurs also [1-6]. To the best of our knowledge there are very few cases reported of esophagitis following consumption of country liquor [7-8]. This is the first case reported that has been caused by a mixture of country liquor, energy drink and a variant of vinegar.

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. This case emphasizes the need for community education by social outreach which can be done by physicians and social workers.
2. Reducing the dependence on country made liquor especially amongst poor.
3. A need for referral to deaddiction and behavioral counseling should become a norm.
4. Even when acute phase is managed conservatively ED physicians should recognize the importance of follow up to monitor for esophageal stricture formation.

Conclusion

This case highlights the importance of understanding the risks associated with consuming alcohol and other substances in combination. We hope the medical fraternity takes note and educates patients to the harmful effects of consuming country liquor.

Declarations

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Cannabis Smoking Induced Diffuse Alveolar Hemorrhage in a Young Adult

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Abstract

Background: Diffuse alveolar hemorrhage (DAH) is a rare but potentially life threatening pulmonary syndrome caused by bleeding into the alveolar spaces, leading to acute respiratory compromise. It commonly presents with hemoptysis, hypoxemia, infiltrates and rapidly progressive respiratory failure. **Case description:** A 25 year old male presented with fever, cough, mild hemoptysis and altered sensorium. On arrival, he was breathless, hypoxic and requiring airway protection with a tube in the Emergency department (ED). He had no known comorbidities, was not on anticoagulant therapy, and had a history of cannabis smoking. High-resolution computed tomography (HRCT) of the chest revealed diffuse ground-glass opacities with a crazy-paving. A pattern suggestive of diffuse alveolar hemorrhage. The patient was managed with corticosteroids, lung-protective mechanical ventilation, and supportive care. Despite aggressive treatment, his clinical condition worsened and he succumbed to the illness. **Conclusion:** This case highlights cannabis smoking as a rare but significant possible cause of diffuse alveolar hemorrhage in young adults.

Keywords: Diffuse alveolar hemorrhage; Cannabis smoking; Hemoptysis; Bronchoalveolar lavage; Ground -glass opacities; Crazy-paving pattern; Acute respiratory failure

Introduction

Diffuse alveolar hemorrhage (DAH) is a life-threatening clinicopathological syndrome caused by disruption of the alveolar microcirculation, leading to bleeding into the alveolar spaces and rapid impairment of gas exchange [1-2]. Clinically patients may present with dyspnea, cough, hemoptysis, anemia, and diffuse pulmonary infiltrates, although hemoptysis may be absent in a substantial proportion of cases.

Due to its characteristic radiological findings that lack specificity, DAH remains a diagnostic challenge and warrants an early bronchoscopic evaluation with BAL fluid sampling. Haemorrhaging BAL fluid samples collected sequentially, along with hemosiderin-laden macrophages, provide strong evidence for DAH diagnosis [3].

The causes of DAH are extensive. In classic cases, autoimmune diseases of the pulmonary capillaries are common including ANCA-associated vasculitis, anti-glomerular basement membrane disease and connective tissue diseases [4].

In addition, infections coagulopathies medications toxins and inhalation exposures have been associated with the disease. Computed tomography is commonly used to identify bilateral ground-glass opacities and consolidation. A 'crazy paving' pattern can also be observed but there is an overlap between pulmonary oedema infections and other diffuse airspace diseases [5].

Cannabis-related pulmonary injury is increasingly being recognized, especially in younger patients [6-8]. While chronic cannabis smoking has long been associated with airway irritation and inflammation, DAH remains an

uncommon but important complication. Several case reports now describe acute hemoptysis, respiratory failure, diffuse infiltrates, and hemorrhagic BAL after marijuana inhalation, including use through improvised smoking devices or heavy inhalational exposure [9-11]. These reports suggest that cannabis smoking should be considered in the differential diagnosis of DAH in young adults when autoimmune, cardiac, infectious, and coagulations-related causes are not apparent. Against this background, the present case illustrates a fulminant and ultimately fatal presentation of suspected cannabis smoking-induced DAH in a previously healthy young male.

Case Presentation

A 25-year-old male presented to the emergency department (ED) with fever, cough, mild hemoptysis, and altered sensorium. On examination, he was tachypneic and had severe hypoxia and hypotension, prompting endotracheal intubation in the emergency room. He had no known comorbidities, was not receiving anticoagulants, and had a history of smoking cannabis. Chest X-Ray and High-resolution computed tomography (HRCT) of the chest showed diffuse ground-glass opacities with a crazy-paving pattern (**Figure 1 and 2**), which was considered suggestive of diffuse alveolar hemorrhage.

Bronchoalveolar lavage was subsequently performed. The serial lavage samples were hemorrhagic, supporting the diagnosis of alveolar hemorrhage. The washings sent for analysis were reportedly negative for cultures. Further evaluation for collagen vascular disease and vasculitis was normal. A 2-dimensional echocardiogram was normal, and there were no other features to suggest heart failure.

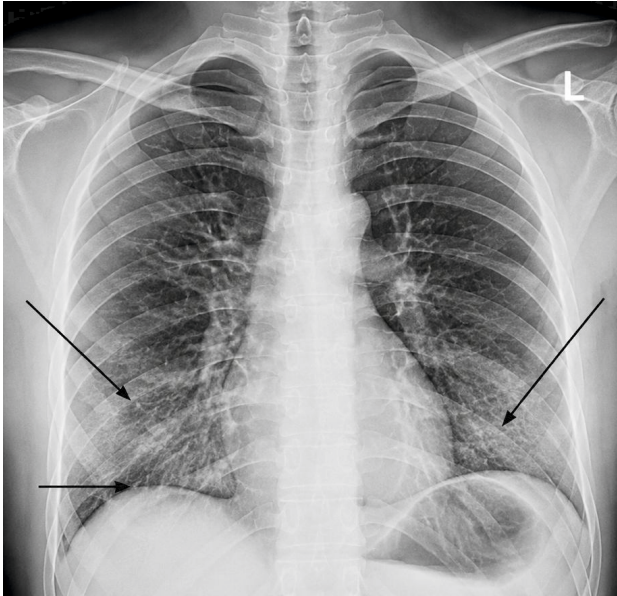


Figure 1: Chest radiograph showing bilateral diffuse patchy air-space opacities, predominantly in the mid and lower lung zones, consistent with alveolar hemorrhage.

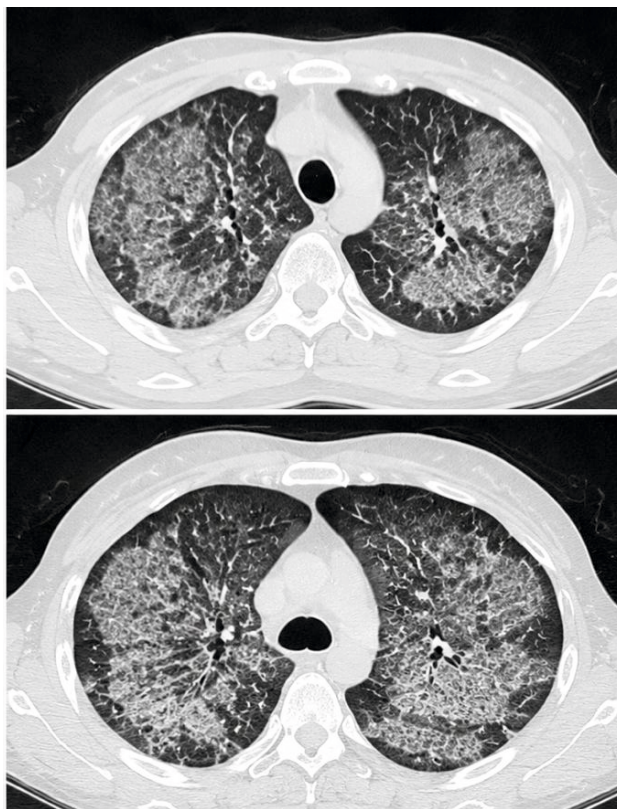


Figure 2: High-resolution CT chest showing diffuse bilateral ground-glass opacities with interlobular septal thickening (crazy-paving pattern), suggestive of diffuse alveolar hemorrhage.

The PT-INR was also within normal limits. Taken together, these findings argued against common autoimmune, infectious, cardiac, and coagulation-related causes of DAH. In the context of the patient's addiction history, cannabis smoking was considered the most likely precipitating factor.

Supportive care, steroids, and lung-protective ventilation were used for this patient, but he failed to respond positively to these efforts. Sadly, his condition became worse until he eventually succumbed to death. As we can see from the case above, DAH can be a very severe disease that presents itself especially in cases where the damage to the alveolar-capillary barrier is extensive.

Discussion

This case is clinically important because it demonstrates a classic syndromic presentation of DAH in a young adult with a relevant inhalational exposure and without an obvious traditional systemic cause. The combination of hemoptysis, acute hypoxemic respiratory failure, diffuse bilateral ground-glass opacities with crazy-paving, and hemorrhagic BAL is highly compatible with DAH. Although imaging findings in DAH are not pathognomonic, the radiologic pattern in the appropriate clinical setting should promptly trigger bronchoscopy and an urgent etiologic work-up. The present case also reinforces the value of BAL, since progressively hemorrhagic lavage remains one of the most practical tools for confirming alveolar bleeding [12].

A major strength of this case is the exclusion of several important differential diagnoses.

Autoimmune pulmonary capillaritis, especially ANCA-associated vasculitis, is among the best-recognized causes of DAH, and connective tissue disease, antiphospholipid syndrome, infection, coagulopathy, and cardiac causes must also be considered. In this patient, the reported normal vasculitis and collagen vascular work-up, normal coagulation profile, absence of anticoagulant exposure, negative cultures, and normal echocardiography reduced the likelihood of these alternative explanations. The clinical reasoning therefore rests on a diagnosis of exclusion supported by a consistent exposure history and compatible radiologic and bronchoscopy findings.

The association between cannabis smoking and DAH, though rare, is increasingly represented in the literature. Cases reported have included haemoptysis, dyspnoea, diffuse infiltrates and bronchoalveolar lavage-identified bleeding immediately following cannabis smoke inhalation [13]. Possible mechanisms include toxic effects on cells and organs from combustion products, airway and alveolar inflammation, increased alveolar permeability and barotrauma-related effects from deep inhalation and/or breath-holding during cannabis inhalation which can damage the alveolar-capillary membranes.

The management of DAH depends on the severity of the condition and the cause, although it mainly revolves around providing respiratory support, dealing with the trigger, and immunomodulation if there is evidence of inflammation or immune system involvement in the disease. Steroids are

commonly prescribed in severe cases, even though the prognosis largely relies on the etiology and how early the condition is diagnosed. Intubated patients are usually among the more seriously ill cases and may not have a favorable outcome despite receiving maximum medical intervention. The current case is another example of the aggressive form of DAH that requires the early consideration of substance-induced lung damage among younger patients presenting with diffuse infiltrates and hemoptysis.

A limitation of current report was that team unable to elaborate on other factors, including toxicology analysis, percentage of hemosiderin-laden macrophages on BAL, sequential hemoglobin values, and histopathology. As such, the association of DAH with cannabis use should be considered to be strongly suspected but not definitively proven. Nevertheless, the presentation described herein supports cannabis-induced DAH as the most likely diagnosis.

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. Cannabis smoking and vaping are considered non-harmful activities by teenagers but both these practices lead to lung disorders.
2. Stigma attached to cannabis consumption might lead to delayed diagnosis of the disease.
3. Non-judgemental approach is essential while dealing with cases pertaining to any substance abuse.
4. History of cannabis consumption must not restrict doctors from clinical decision-making.
5. Timely empathy and counseling would help in saving time required for excluding other causes of bleeding such as trauma or hemorrhage

Conclusion

Diffuse alveolar hemorrhage is a rare but potentially fatal pulmonary emergency that requires early recognition and prompt supportive management. This case highlights cannabis smoking as an uncommon yet important possible trigger of DAH in young adults, particularly after other autoimmune, infectious, cardiac, and coagulation-related causes have been excluded. The presence of hemoptysis, diffuse ground-glass opacities with crazy-paving on imaging, and hemorrhagic bronchoalveolar lavage should raise strong suspicion for this diagnosis. Clinicians should maintain a high index of suspicion for substance-related lung injury in similar presentation, as timely diagnosis may help guide appropriate management and improve outcomes.

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Evaluating the Rates of Caesarean Section Rates Using the Robson Classification in a Tertiary Care Center

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Abstract

Background: Across the world, caesarean section (CS) rates have been increasing steadily, leading to concern about avoidable procedures and the resulting maternal and neonatal morbidity. The Robson Ten-Group Classification System (TGCS) is a standardized and widely accepted method for assessing, monitoring, and comparing CS rates across institutions. **Methods:** The current retrospective observational study was carried out for a period of three years in a tertiary care facility. The information was collected through computer-based obstetric data. All the admitted women were categorized into ten Robson groups based on factors such as parity, previous CS, gestational age, onset of labour, foetal presentation, foetal lie, and number of foetuses. Thereafter, the analysis was performed regarding group size, CS rate per group, and contribution to overall CS rate. The objective of the study was to classify women delivering at a tertiary referral hospital according to the Robson TGCS and identify the major contributors to the overall CS rate. **Results:** A total of 5,493 deliveries occurred during the study period, of which 2,649 were CS, yielding an overall CS rate of 48.22%. Group 1 represented the largest proportion of the obstetric population, followed by Groups 2 and 5. Group 5 was the largest contributor to the overall CS rate, followed by Groups 2 and 1. Very high group-specific CS rates were observed in Groups 5, 6, 7, 9, and 10. Together, Groups 1, 2, and 5 accounted for the majority of all CS. **Conclusion:** The Robson TGCS is a practical and effective tool for auditing CS practices. Strategies targeting primary CS reduction, improved induction practices, and appropriate promotion of vaginal birth after caesarean may help optimize CS rates.

Keywords: Caesarean section; Robson classification; Ten-Group Classification System; obstetric audit; tertiary care hospital; Lower Segment Caesarean Section

Introduction

Lower Segment Caesarean Section (LSCS) or Caesarean Section (CS) is the most performed obstetric operation worldwide. CS can be very beneficial for the mother and the baby if used judiciously. In 1985, the World Health Organization set 10%–15% as a rate limit or any region to have a CS. However, in 2015, the World Health Organization issued a revised statement emphasizing that every effort should be made to ensure access to CS for women who need it, rather than focusing on achieving a specific target rate [1,2]. Medical fraternity universally agrees that a CS should not be performed unless an indicated, but its execution ultimately depends on obstetrician's discretion. Unfortunately rising CS rates have started causing worries globally. There is no standard and widely accepted classification to compare CS rates. Robson proposed a system that classified women into 10 groups based on their obstetric characteristics (parity, previous CS, gestational age, onset of labour, foetal lie, presentation and number of foetuses) without any mention regarding indication for CS [3]. The classification has been shown in **Table 1**.

The simplicity of this system allows minimal requirements of resources and variables for its implementation. So, this system can be easily used in the low resource settings. A good example of how a monitoring system can work is

Iceland. Iceland began using the Robson classification as the basis of its CS monitoring program in 2000. Between 2000 and 2011, its total CS rate decreased from the highest to the lowest among the nations of the Nordic region. This suggests that implementation of a structured monitoring system may help improve CS surveillance and may be associated with favorable reductions in CS rates [4-5].

Material and Methods

This study which was retrospective and observational in nature was conducted at a tertiary care referral hospital over a 3-year period. The study included all antenatal women who underwent CS, whether primary or repeat, during the study period. Data were obtained from the computerized medical records of the Hospital, and relevant obstetric details were retrieved and analyzed systematically. The primary objective of the study was to evaluate the relative contribution of each group in the Robson Ten-Group Classification System (TGCS) to the overall CS rate. As the institution functions as both a teaching hospital and a referral center, the TGCS was applied to all women who were either registered or referred for delivery during the study period in order to assess the distribution and pattern of caesarean deliveries across the obstetric population.

Classification was done using Robson classification which included categories such as pregnancy, obstetric history, gestational age at birth, and mode of labour and birth.

Table 1: Robson classification groups

Number	Group
1	Nulliparous, single cephalic, >37 weeks in spontaneous labour
2	Nulliparous, single cephalic, >37 weeks (2a: induced labour 2b: CS before labour)
3	Multiparous (excluding previous CS), single cephalic, >37 weeks in spontaneous labour
4	Multiparous (excluding previous CS), single cephalic, >37 weeks, induced or CS before labour
5	Previous CS, single cephalic, >37 weeks
6	All nulliparous breeches
7	All multiparous breeches (including previous CS)
8	All multiple pregnancies (including previous CS)
9	All abnormal lies (including previous CS)
10	All single cephalic, <37 weeks (including previous CS)

Pregnancy was described as either single cephalic, single breech, single transverse/oblique presentation, and multiple pregnancies. Obstetric history was grouped as either nulliparous, multiparous without history of CS, and multiparous women with a history of caesarean sections. Gestation was determined based on the gestational age at the time of delivery. Labour and delivery factors were described as spontaneous labour, induced labour, and caesarean delivery without induction of labour. All caesarean sections performed were then assigned to one of the 10 Robson groups.

The study outcomes included calculation of the relative contribution of each Robson group to the overall CS rate, the CS rate within each Robson group, and the relative size of each group in the total obstetric population. In addition, the CS rate among women undergoing induction of labour and among those entering spontaneous labour was determined. CS rates in primigravida and multigravida women were also calculated separately, and the distribution of foetal lie in the study population was assessed.

Quantitative data were represented by mean $\pm$ standard deviation, while qualitative data were reported in frequencies and percentages. A p -value < 0.05 was taken as statistically significant. Quantitative differences among two groups were assessed with the unpaired Student's t -test. Quantitative differences among proportions in two independent groups were assessed with the Z test for proportions. Relationships among categorical data were assessed through chi-square test if the number of observations in each cell was equal or greater than five; if not, the relationship was assessed through Fisher's exact test. All statistical analysis was done using SPSS v.20.

Results

During a study period of three years, 5493 deliveries were recorded which included both vaginal and caesarean births. When classified in the TGCS, Group 1 constituted the largest segment of the obstetric population, accounting for 1,760 deliveries (32.0%). This was followed by Group 2 with 1,145 deliveries (20.8%), Group 5 with 840 deliveries

(15.3%), Group 3 with 660 deliveries (12.0%), Group 10 with 552 deliveries (10.0%), Group 4 with 210 deliveries (3.8%), Group 8 with 149 deliveries (2.7%), Group 6 with 114 deliveries (2.1%), and Groups 7 and 9 with 32 (0.6%) and 31 (0.6%) deliveries, respectively. Thus, the largest contributors to the total obstetric population were Groups 1, 2, and 5. This distribution in the study group has been shown in **Figure 1**.

Among the 2,649 women who underwent CS, the majority were between 23 and 32 years of age. The mean age of participants who underwent CS was 28.24 ± 4.59 years, with an overall age range of 18–52 years. Specifically, 315 women (11.9%) were aged 18–22 years, 863 (32.6%) were aged 23–27 years, 1,016 (38.4%) were aged 28–32 years, 383 (14.5%) were aged 33–37 years, and 72 (2.7%) were older than 37 years. The age distribution of patients who underwent CS is shown in **Figure 2**.

Marked variation in CS rates was observed across the Robson groups (**Table 2**). Group 1 had a CS rate of 29.4%, whereas Group 2 showed a substantially higher rate of 57.1%. In multiparous women without a previous CS, the rate was 8.6% in Group 3 and 16.2% in Group 4. Group 5 demonstrated a notably high CS rate of 91.9%, highlighting the major influence of previous caesarean delivery on repeat operative birth. Caesarean delivery was universal in Groups 6 and 9, both of which had a rate of 100%, while Group 7 showed a similarly high rate of 93.8%. Group 8 had a CS rate of 72.5%, and Group 10 had a rate of 60.0%.

The analysis of parity demonstrated CS rate more among multiparous women than among primiparous women, being 58.8% and 39.8%, respectively (**Table 3**). Of all women who underwent CS, 1,220 (46.1%) were primiparous and 1,429 (53.9%) were multiparous, indicating a slightly greater contribution from multiparous women to the total CS burden (**Table 4**).

Labour characteristics also showed important differences. Of the total 5,493 deliveries, 2,991 women (54.45%) underwent spontaneous labour, whereas 2,502 (45.55%) did not. However, the CS rates was considerably lower

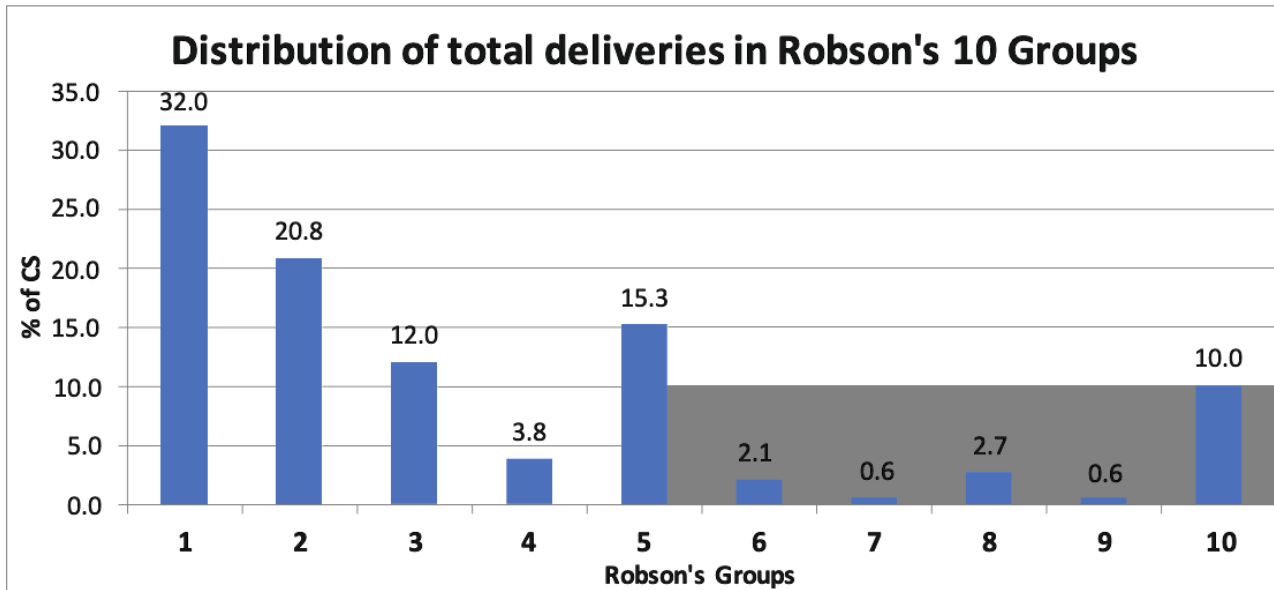


Figure 1: The distribution of total deliveries studied according to Robson's 10 group classification in the study group.

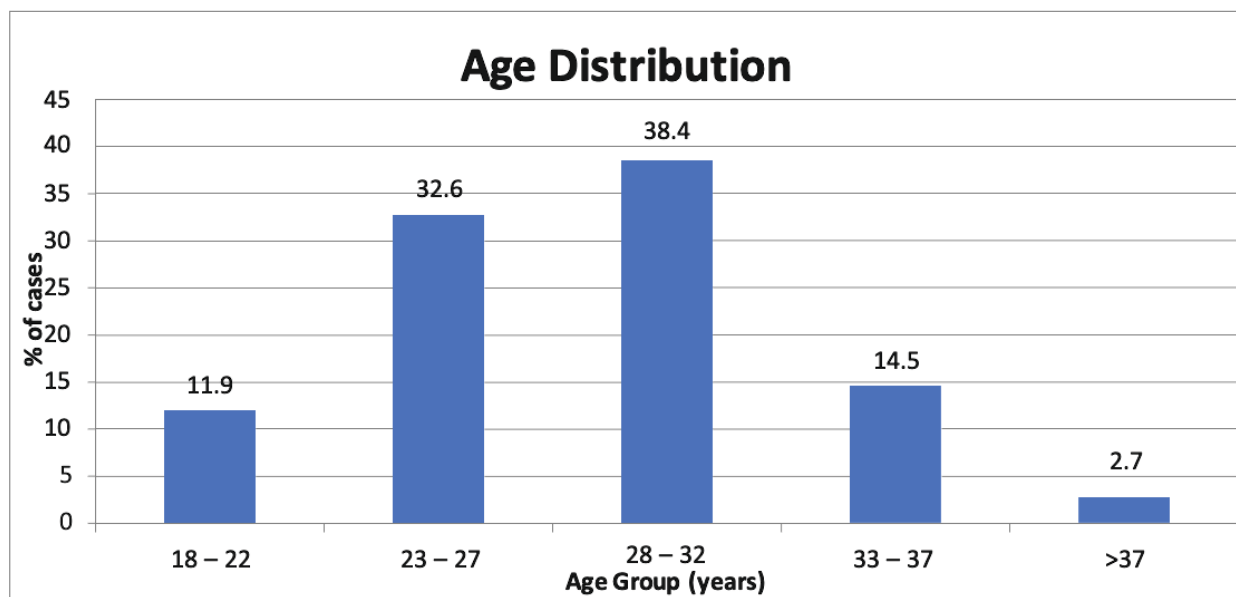


Figure 2 The age distribution of cases studied in the study group.

among patients who entered spontaneous labour than among those who did not, at 34.13% and 65.07%, respectively. Consistent with this, among the 2,649 women who underwent CS, 1,628 (61.5%) had not gone into spontaneous labour, whereas 1,021 (38.5%) had undergone spontaneous labour. These findings suggest that absence of spontaneous labour was associated with a substantially greater likelihood of caesarean delivery in the study population.

A similar trend was observed with induction of labour. Among the women who underwent CS, 515 (19.44%) had labour induced, whereas 2,134 (80.55%) had no induction. Of the 1,189 women in whom labour was induced,

515 underwent CS, yielding a CS rate of 43.31% in the induced labour group.

With regard to foetal lie, most women who underwent CS had a longitudinal lie, seen in 2,614 cases (98.7%), while oblique and transverse lie were observed in 17 (0.6%) and 18 (0.7%) cases, respectively. Similarly, cephalic presentation predominated among caesarean deliveries, being present in 2,468 cases (93.2%), whereas breech and shoulder presentations were noted in 165 (6.2%) and 16 (0.6%) cases, respectively.

Taken together, these findings show that although Groups 1 and 2 constituted the largest proportions of patients, the greatest section rates were seen in Groups 5, 6, 7, 8, 9, and 10.

Table 2: The distribution of CS cases studied according to Robson's 10 group classification in the study group

Robson's Group	No. of CS(a)	No. of vaginal deliveries (b)	Total deliveries (a+b)	% of CS (a divided by a+b) x 100
1 (Nulliparous, single cephalic, >37 weeks in spontaneous labor)	518	1242	1760	29.4
2 (Nulliparous, single cephalic, >37 weeks 2a: induced labour ii. 2b: CS before labour)	654	491	1145	57.1
3 (Multiparous, excluding previous CS, single cephalic, >37 weeks in spontaneous labour)	57	603	660	8.6
4 (Multiparous, excluding previous CS, single cephalic, > 37 weeks, induced or CS before labour)	34	176	210	16.2
5 (Previous CS, single cephalic, >37 weeks)	772	68	840	91.9
6 (All nulliparous breeches)	114	0	114	100.0
7 (All multiparous breeches (including previous CS))	30	2	32	93.8
8 (All multiple pregnancies including previous CS)	108	41	149	72.5
9 (All abnormal lies including previous CS)	31	0	31	100.0
10 (All single cephalic, <37 weeks, including previous CS)	331	221	552	60.0

Table 3 - The distribution of CS in each parity

Parity	No. of CS(a)	Total deliveries (CS + vaginal deliveries) (x)	% of CS (a/x) multiplied by 100
Primiparous	1220	3063	39.8
Multiparous	1429	2430	58.8

Table 4 - The distribution of parity of cases studied in the study group

Parity	No. of CS(a)	Total deliveries (CS + vaginal deliveries) (x)	% of CS (a/x) multiplied by 100	% of cases (a/z) multiplied by 100
Primiparous	1220	3063	55.8	46.1
Multiparous	1429	2430	44.2	53.9
Total	2649(z)	5493(y)	100.0	100.0

Previous CS, lack of spontaneous labour, and induction-related labour characteristics appeared to be important contributors to the overall CS burden in this tertiary referral hospital.

Discussion

WHO has in 2015 proposed the use of the Robson Classification at the facility level as a global standard for assessing, monitoring, and comparing CS rates within healthcare facilities over time and between facilities [2].

This retrospective study classifies all the antenatal patients delivering in the facility in the study period into ten groups of Robson's Classification. During the study period a total of 5493 deliveries, both caesarean and vaginal deliveries, took place at the facility. The study group comprises of all the CS in the study period, i.e., 2649. So, the total number of vaginal deliveries comes out to be 2844. The study observes the CS cases according to the Robson's Classification to identify groups contributing most to the CS so that close monitoring and analysis of those groups can be done to reduce the CS rate.

The CS rate at facility comes out to be 48.22%. This CS rate is very high than the once recommended CS rate of WHO (10-15%). Although WHO retracted their statement in 2015 and emphasized that every woman requiring CS should

receive it irrespective of CS rate. The caesarean rates at population level in India seem to be 17.2 %. In India as per District level household survey 3 (DLHS) CS rate is 28.1% in private sector and 12% in public sector health facilities [6]. According to NFHS-4, Telangana ranks highest in terms of CS rate with 57.7% and Nagaland ranks lowest with CS rate of 5.8%. Maharashtra has CS rate of 20.1%, although this rate significantly varies between urban and rural areas. According to NFHS-5 (2019–21), the population-level CS rate in India was 21.5%. CS rates were 47.4% in private health facilities and 14.3% in public health facilities [7].

The CS rate in TGCS group 1 was 29.4% and relative contribution to overall CS is 19.6% in this study. Although Group 1 represented maximum 32% (1760) deliveries of total deliveries. Another study found the relative contribution to CS from nulliparous group 1 was 18.6% and CS rate was of 16.4% [8]. In the present study, the CS rate in Group 1 was relatively high. Women in this group are generally considered to be at low risk for caesarean delivery because they are less likely to have pre-existing medical indications warranting operative intervention. When CS is performed in this group, it is most often attributable to intrapartum complications such as labour dystocia or foetal

distress. Consequently, the CS rate in Group 1 is expected to remain relatively low and is regarded as an important indicator, as primary caesarean delivery in these women may substantially influence the likelihood of repeat CS in subsequent pregnancies.

Previous studies have described strategies aimed at reducing caesarean delivery rates in this group. In one such study published in 2009, several targeted measures were implemented to lower the overall CS rate [9]. Within Group 1, particular emphasis was placed on improving the assessment and management of foetal distress and dystocia, which constituted the major indications for caesarean delivery in that cohort. The investigators reported replacing routine cardiotocography-based monitoring with alternative foetal heart rate surveillance methods and mandated the use of the partogram for all labouring women, although clinician compliance was initially variable. In addition, promotion of vacuum-assisted vaginal delivery, in appropriately selected cases, in preference to forceps also contributed to a reduction in caesarean deliveries [10].

Groups 2 and 4 of the TGCS constituted 20.8% and 3.8% of total deliveries, respectively, making them the next largest groups after Group 1. These categories include nulliparous women and multiparous women without a prior CS, respectively, with term singleton cephalic pregnancies who underwent induction of labour or pre-labour CS. Out of 1189 patients in whom labour was induced, 515 underwent CS (43.31%).

The CS rate for Group 2 is 57.1%, and the relative contribution of Group 2 to the overall CS rate is 24.7%. The second-highest relative contribution to the overall CS rate comes from Group 2. Another study has found that the relative contribution of Group 2 to the overall CS rate is 15.3% [11]. The CS rate for Group 4 is 16.2%, and the relative contribution of Group 4 to the overall CS rate is 1.3%. The CS rate of women belonging to Group 1 experiencing spontaneous labour was 29.4%, while the CS rate of women experiencing labour induced by physicians, included in Groups 2 and 4, was 41.71%. The elevated rates in these groups may reflect a substantial prevalence of clinical conditions warranting intervention, such as term pre-eclampsia, although the possibility of elective induction of labour or pre-labour CS for non-medical or less clearly defined indications cannot be excluded.

The rising number of women undergoing labour induction further underscores the need for closer evaluation of these groups. Detailed assessment of the indications for terminating pregnancy before the onset of spontaneous labour, either by induction or CS before labour, as well as review of labour induction protocols and their implementation, may help identify deficiencies in adherence to evidence-based obstetric practice. Such an

approach could assist in recognizing potentially avoidable CS and in developing targeted measures to safely reduce caesarean delivery rates in these groups. The group of women undergoing CS for non-progress of labour require detailed evaluation.

According to the Robson's Classification, there were certain groups whose contribution towards the CS rate was high. This made it possible for them to be targeted effectively. The present research project also considered the CS rates among various groups. The health administration and the local researchers must use the information gathered regarding the CS rates and devise ways that will make it possible to use this information effectively. If this system is applied in our hospital, a tertiary care teaching hospital, it can make a big difference in terms of reduction of CS rate. The Robson TGCS demonstrates the need to focus on the case of women in group 1, 2 and 5 particularly if the section rate needs to be reduced. These 3 groups together contribute 73.4% of total CS occurring in the hospital. Efforts should be made to reduce primary CS (Groups 1 and 2) and promote the practice of Vaginal Birth after Caesarean (VBAC) - Group 5. If used uniformly, this system can also allow comparison between different institutions, regions and even countries to help in identifying the priority areas for the changes in clinical practice and help in reducing the caesarean rate.

Study Strengths and Limitations

The strengths of this study include the use of the internationally accepted Robson Ten-Group Classification System, a large sample size covering all deliveries over a three-year period, and the use of real-world institutional data from a tertiary care referral hospital. The study not only quantified the overall caesarean section rate but also identified the Robson groups contributing most substantially to the caesarean burden, thereby providing practical direction for targeted clinical audit and quality-improvement strategies. This research has many limitations. The study's retrospective, single-centre methodology restricts its validity and renders it susceptible to potential biases related to incomplete or erroneous information based on records. Since the study was carried out in a tertiary referral hospital, there is a possibility that the CS rate might be skewed by the presence of more complicated pregnancies. Furthermore, while the Robson classification clearly states the important factors, no investigation was made into why CS was chosen and the other factors involved in the process of making the decision. The analysis was largely descriptive, without multivariable assessment of predictors of CS, and no year-wise trend analysis was performed over the study period.

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. The high overall caesarean section rate indicates the need for regular institutional review of indications for caesarean delivery, particularly in high-contributing groups such as Groups 5, 2 and 1.
2. The findings suggest that reducing primary caesarean sections in nulliparous women may help lower repeat caesarean rates in future pregnancies.
3. The high contribution of women with previous caesarean sections emphasizes the need for careful counseling and appropriate selection of patients for vaginal birth after caesarean section.
4. Caesarean section should be performed when clinically justified, and not merely because of convenience, institutional practice patterns, fear of litigation, or non-medical preferences.
5. Women should receive balanced counseling regarding the benefits and risks of caesarean delivery, induction of labour, and trial of labour after caesarean, allowing informed and shared decision-making.
6. Ethical obstetric care requires avoiding both extremes: Unnecessary caesarean sections and delayed caesarean sections when the mother or foetus truly needs operative delivery.

Conclusion

In conclusion, the classification into 10 groups according to Robson was found to be a useful way to determine the most important factors contributing to the CS rate in this hospital. Group 5, group 2, and group 1 were found to be the main contributors to the caesarean rate. Efforts to decrease primary CS and increase VBAC may help decrease CS delivery among these women. The classification of Robson could therefore be used routinely to conduct audits within obstetrics.

Declarations

Acknowledgment: None.

Artificial intelligence uses declaration statement: No artificial intelligence tools were used in the preparation of this manuscript.

Author Contribution: LM, AK and MB conceptualized the study. AK and MB made the initial draft, and contributed to literature review, interpretation of findings and critical revision of manuscript for intellectual content. LM was involved in data acquisition, statistical analysis and manuscript editing. All authors approved the final version of manuscript with LM being the guarantor.

Ethical approval: The study was conducted in accordance with the ethical standards of the responsible Ethics Committee and in compliance with the Declaration of Helsinki. Ethical approval was obtained from the Scientific

Research Committee, Deenanath Mangeshkar Hospital and Research Centre, Pune (DMHRC Code: DNB_2019_OBGY_023). Written informed consent was obtained from all participants prior to their inclusion in the study.

Conflict of interest: None to declare

Data availability statement: Data supporting the findings of the study are available from the corresponding author upon reasonable request.

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A Specimen-level Analysis of Polymicrobial Bacterial and Viral Detections in Hospital-acquired Pneumonia Using Multiplex PCR

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Abstract

Background: Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), remains a major cause of morbidity and mortality in critically ill adults. Conventional culture-based microbiology is time-consuming and may underestimate the true microbial burden, especially after prior antibiotic exposure. Multiplex molecular platforms such as the BioFire® FilmArray Pneumonia Panel (BFPP) provide rapid pathogen detection, but the specimen-level microbial complexity revealed by these assays in HAP has been less well described. This study was done with the objective to characterize specimen-level microbial complexity in ICU patients with suspected HAP using BFPP, with special emphasis on polymicrobial bacterial detections, viral co-detection, and resistance-gene profiles. **Methods:** This secondary, exploratory, specimen-level analysis was performed on the intervention arm of a previously conducted single-center randomized controlled trial in an adult anesthesia ICU of a tertiary government teaching hospital in Kanpur, India, from January 2020 to October 2021. Thirty respiratory specimens from patients with suspected HAP were analyzed using BFPP. Bacterial targets were considered clinically significant at a semi-quantitative threshold of $\geq 10^6$ copies/mL. The specimen was used as the unit of analysis. Main outcomes included bacterial detection, number of bacterial targets per specimen, polymicrobial detection, viral detection, bacteria-virus co-detection, virus-only detection, and resistance-gene detection. **Results:** Among 30 specimens, 21 (70.0%) showed at least one clinically significant bacterial target, while 9 (30.0%) showed none. Polymicrobial bacterial detection was present in 13/30 specimens (43.3%) and in 13/21 bacteria-positive specimens (61.9%). A total of 43 bacterial detections were recorded, most commonly *Acinetobacter calcoaceticus* - *baumannii* complex, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* group, *Escherichia coli*, and *Staphylococcus aureus*. Viral targets were detected in 7/30 specimens (23.3%), including 4/30 (13.3%) with bacteria-virus co-detection and 3/30 (10.0%) with virus-only detection. Six resistance-gene detections were identified. BFPP showed 100% positive percent agreement and 92.9% negative percent agreement compared with conventional culture. **Conclusion:** BFPP frequently identified complex microbial patterns in ICU patients with suspected HAP, including substantial polymicrobial bacterial detections and clinically relevant bacteria-virus co-detection. Rapid multiplex testing may help clinicians interpret lower respiratory tract infections more precisely and support earlier, stewardship-guided antimicrobial decisions.

Keywords: Antimicrobial stewardship; BioFire FilmArray; Critical care; Hospital-acquired pneumonia; Multiplex polymerase chain reaction; Randomized controlled trial; Ventilator-associated pneumonia

Introduction

Hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP), is one of the leading healthcare-associated infections in adults managed in the ICU. It increases mechanical ventilation, the length of stay in the ICU, the duration of antibiotic use and the outcomes of critically ill adults. Contemporary American Thoracic Society/Infectious Diseases Society of America (ATS/IDSA) and European Society of Clinical Microbiology and Infectious Diseases (ESCMID) guidelines recommend distinguishing HAP/VAP from other forms of pneumonia but recognize that HAP/VAP is not a single entity and has different prognosis due to host factors, the day of presentation, the local bacterial ecology and the microbiological species of bacteria involved in the

infection [1-4]. In a large group of ICU patients, patients with ventilator-acquired pneumonia as well as non-ventilator-related ICU-acquired pneumonia were observed to have an increased risk for death at 30 days, indicating the clinical importance to promptly identify the causes of VAP and diagnose pneumonia in such patients early on [4].

In HAP/VAP, physicians are forced to make treatment decisions without definitive results in microbiology. Cultures are standard in most of the hospitals. However, bacterial identification requires incubation until colony formation and determination of its susceptibility, except some microorganisms, such as fungi. Studies about diagnostics for VAP confirm that cultures with bacterial identification and antibiotic resistance patterns take on average 48-72 hours and require an empiric use of

broad-spectrum antibiotics during the time required [3]. This time delay is of great importance in the ICU environment because adequate empirical therapy can help critically ill patients, whereas excessive antibiotic treatment drives antibiotic pressure on pathogens and causes damage to healthy microbiota. Moreover, the bacterial recovery rate in the respiratory samples can be modified by the antibiotic coverage before obtaining such cultures. In one well-protocolized study of the quality of sputum culture obtained from patients with suspected VAP, antibiotics can have a strong positive effect on the detection of pathogens with reduced recovery of most pathogens, starting after hours of therapy (including antibiotics with similar mechanisms of action or resistance profiles as expected for VAP) [5]. This study showed a drastic negative impact of antibiotics on the rate of positive cultures (especially with gram-negative organisms). Routine microscopy and bacterial culture may underrepresent the true bacterial pathogens present in patients who have already received antibiotics [3,5].

Another relevant characteristic of HAP/VAP in the ICU is their complexity. Infections of the ICU with multidrug-resistant gram-negative bacilli and *Staphylococcus aureus* are reported with a significant frequency. Nonetheless, more than half of the cases with nosocomial pneumonia do not solely involve single microorganisms. Mixed polymicrobial bacterial infections have historically been described in mechanically ventilated patients. In one classical cohort using bronchoscopy, Combes and colleagues documented 48% of their patients with polymicrobial VAP. Many bronchoalveolar lavages included three or even four bacterial species [6]. In 2017, Natarajan and coworkers found a polymicrobial VAP rate of 62.9% in a medical ICU and demonstrated that polymicrobial episodes were associated with more duration of mechanical ventilation and hospital length of stay [7]. These data have critical clinical importance, since mixed infections can impact decisions about empiric antibiotic therapy, hide relationships between clinical symptoms and microorganisms and complicate the interpretation of diagnostic tests. There is also a major practical question for rapid molecular tests, including those performed on direct respiratory specimens: When should multiple species of bacteria be detected in the same sample? Which findings are from the infection and which from the colonization of the lung and the airway [6,7]? How to consider the entire bacterial load at the patient's side?

With the wider use of multiplex molecular diagnostic assays for pathogens that causes pneumonia, increasing attention has been placed on the involvement of respiratory viruses in VAP. In the ICU, viral testing was historically done inconsistently and in only selected cases, which certainly underestimated the number of patients affected by

viral pneumonia and of co-infection of bacterial and viral pathogens. The review of Cawcutt and Kalil emphasizes that bacterial and viral co-infections have become increasingly evident in the community setting as well as in healthcare settings and contribute to more severe pneumonia, to increased hospitalizations in ICUs and higher rates of mortality [8]. Respiratory viruses were found in 32% of cases with HAP at ICUs by Loubet et al [9]. Using multiplex PCR arrays, these were divided into two relevant scenarios: newly acquired respiratory viral infections and prolonged viral carriers, in immunocompromised patients and the latter cases with high rates of concomitant bacterial infections. In this group, mixed infections have been shown to be linked to longer stays and a trend towards more frequent mortality [9]. In the study by Shen et al., 42.1%, 24.3% and 22.4% of patients were shown to have bacterial pneumonia only, viral pneumonia only or concurrent bacterial-viral pneumonia, respectively [10]. These results indicate that viral detection in VAP is not merely noise but may accurately determine relevant subgroups when tested simultaneously with contemporary findings for bacterial infections [8-10].

Rapid syndromic molecular testing has emerged in response to these diagnostic gaps. The BioFire® FilmArray Pneumonia Panel/Panel Plus is a multiplex real-time PCR platform that can identify common bacterial pathogens, atypical bacteria, respiratory viruses, and selected antimicrobial-resistance markers directly from lower respiratory tract specimens within approximately one hour [11,12]. Several evaluation studies have shown that these panels detect pathogens in more samples than routine microbiology and frequently identify more than one target in the same specimen. In ICU patients with suspected HAP, Crémet et al. evaluated the FilmArray Pneumonia Plus Panel in mechanically ventilated patients and demonstrated rapid broad-pathogen detection in bronchoalveolar lavage and endotracheal aspirate samples [11]. Webber et al. found that the BioFire® panel identified a viral or bacterial target in 58.5% of lower respiratory samples and detected 92 additional bacteria beyond standard methods, while also identifying bacterial-viral co-detection in a subset of specimens [13]. Lee et al. reported coinfections in 42.3% of specimens from adult ICU patients and showed that the panel markedly outperformed conventional viral isolation for viral detection [14]. In the multicenter INHALE study, FilmArray identified pathogens in 74.2% of nosocomial pneumonia samples compared with 44.2% by routine microbiology and detected more pathogens per sample than conventional testing [15].

These advantages have obvious stewardship implications. If pathogens and selected resistance genes are available within hours rather than days, clinicians may be able to

optimize empirical therapy earlier, avoid unnecessary broad-spectrum escalation, or de-escalate treatment when a more precise microbiological explanation is available. In critically ill patients with HAP, Erich et al. estimated that availability of the FilmArray pneumonia panel results could have prompted a change in therapy in nearly two-thirds of patients, with an anticipated reduction of about 51 hours to optimized treatment [16]. Recent reviews confirm that rapid multiplex molecular panels can shorten turnaround times and increase diagnostic accuracy among critically ill patients [17], but increased sensitivity raises diagnostic issues. Molecular panels detect nucleic acids, not organisms and detection of resistance genes is not a direct replacement for phenotypic antimicrobial susceptibility testing. Lee et al. Emphasize the need to clinically correlate detection of multiple organisms and antibiotic-resistance genes, while Jitmuang et al. point out that multiple bacteria may exist in the same sample and antibiotic-resistance genes may be poorly attributed to a particular organism [12, 14]. Few published studies of the BioFire panel versus culture have examined the specimen-level ecology identified by the test itself, which is an important omission. The positive status of a test, the presence of no bacterial target, a single presumed pathogen, multiple bacterial targets, the presence of virus alone or with bacteria or the presence of resistance genes within these specimens, all may be clinically relevant for bedside decision making. These findings are especially important in ICU hospital-acquired pneumonia, where colonization, prior antimicrobial therapy, resistance to multiple drugs and overlap in the syndromic diagnoses coexist [3,8,14,16]. Further evaluation of polymicrobial bacterial results and viral coinfection could thus have value for patient care in this complex setting, beyond the concordance of the results of the test with results of culture or simple test positivity. In view of the issues raised above, this study was intended to examine results from specimens from ICU patients with hospital-acquired pneumonia suspected by means of BioFire® FilmArray Pneumonia Panel. This analysis is secondary to the primary objective of assessing overall clinical superiority of test over culture and is aimed at exploring microbial complexity identified by the panel by defining the proportions of patients with single compared with multiple bacterial identifications, the relative frequency of viral-only or viral-bacterial coinfections and the pattern of associated antibiotic-resistance genes. Such an approach may help refine interpretation of multiplex respiratory diagnostics in critically ill adults and provide a more practical microbiological framework for clinicians confronted with complex panel results in HAP/VAP.

Materials and Methods

Study design and setting: This study was a secondary, exploratory, specimen-level analysis of the intervention

arm of a previously conducted single-center, parallel-group randomized controlled trial performed in the adult anesthesia intensive care unit of a tertiary-level government teaching hospital in Kanpur, India, between January 2020 and October 2021. The parent trial evaluated rapid molecular diagnosis using the BioFire® FilmArray Pneumonia Panel (BFPP) against conventional semi-quantitative streak culture in patients with suspected hospital-acquired pneumonia (HAP). The present analysis was restricted to the respiratory specimens tested by BFPP in the intervention arm and was undertaken to characterize specimen-level microbial complexity, including polymicrobial bacterial detections, viral co-detection, and resistance-gene detection.

Study Population: Adult patients aged 18-65 years were eligible in the parent trial if they developed clinical suspicion of HAP, defined as a new or worsening pulmonary infiltrate on chest imaging along with at least two of the following occurring more than 48 hours after hospital admission: fever >100.4°F, leukocytosis or leukopenia, and purulent respiratory secretions. Patients with respiratory infection at admission, ICU stay <48 hours, uncontrolled diabetes mellitus, severe immunocompromised state, positivity for HBsAg or HCV, chronic kidney disease, or chronic liver disease were excluded. For the present study, only patients randomized to the BFPP arm were included, yielding a dataset of 30 respiratory specimens from 30 patients.

Specimen collection and BioFire® FilmArray Pneumonia Panel testing: Respiratory samples were obtained at the time of clinical suspicion of HAP and included sputum, endotracheal aspirate, or bronchoalveolar lavage, depending on patient status and airway access. Samples were analyzed using the BioFire® FilmArray Pneumonia Panel on the BioFire® FilmArray 2.0 system according to the manufacturer's protocol. For this analysis, bacterial targets were considered clinically significant only when reported at a semi-quantitative bin value of $\geq 10^6$ copies/mL. Viral targets and resistance-gene markers were recorded qualitatively.

A specimen was the basic unit of analysis in this study, including any bacterial detection, number of bacterial targets per specimen, polymicrobial bacterial detection, viral detection, virus-only detection, bacteria-virus co-detection and resistance-gene detection. To achieve an analysis more focused on active infection than on colonization, two thresholds for bacterial detection were incorporated: bacterial targets at a semi-quantitative bin value of $\geq 10^6$ copies/mL were considered significant and Polymicrobial was the presence of two or more bacterial targets, each $\geq 10^6$ copies/mL, detected within a single specimen. Virus-Only detection was the presence of one or more viral targets in the absence of significant bacterial

detection, while bacteria-virus co-detection required the presence of at least one significant bacterial target alongside at least one viral target. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated against semi-quantitative streak culture results as the reference standard.

Data handling and statistical analysis: Data were retrieved from the microbiological records of the intervention group from the parent study. This paper includes secondary exploratory analysis based on the specimen level data obtained from the parent study. In the parent study, there was a randomized controlled patient-based experimental design; however, this secondary exploratory analysis is based on the specimen level data obtained. The dataset comprises 30 distinct respiratory specimens (sputum, endotracheal aspirate, or bronchoalveolar lavage) collected from 30 patients within the molecular intervention arm of the parent study. Only bacterial detections meeting the predefined threshold were entered into the final bacterial dataset. Statistical analysis was primarily descriptive. Categorical variables were summarized as frequency and percentage. The proportions of specimens with 0, 1, 2, 3, 4, and 5 bacterial targets were calculated, along with the proportion of specimens showing polymicrobial bacterial detection. Frequencies of individual bacterial targets, viral targets, and resistance-

gene detections were also tabulated. No separate sample size calculation was performed for this secondary analysis because the complete intervention-arm dataset of the parent trial was used. The parent trial had prior approval from the Institutional Ethics Committee, and written informed consent had been obtained from all participants or their legally authorized representatives.

Results

A total of 30 respiratory specimens tested by the BioFire® FilmArray Pneumonia Panel (BFPP) were included in this secondary specimen-level analysis. Using the predefined threshold of $\geq 10^6$ copies/mL for clinically significant bacterial detection, 21/30 specimens (70.0%) showed at least one bacterial target, while 9/30 specimens (30.0%) had no detectable bacterial target.

Analysis of within-specimen bacterial burden showed that 8/30 specimens (26.6%) had one bacterial target, 6/30 (20.0%) had two, 4/30 (13.3%) had three, 2/30 (6.6%) had four, and 1/30 (3.3%) had five bacterial targets (**Table 1**). Thus, polymicrobial bacterial detection, defined as detection of two or more bacterial targets in the same specimen, was present in 13/30 specimens (43.3%). Among bacteria-positive specimens alone, 13/21 (61.9%) were polymicrobial (**Figure-1**). The maximum bacterial burden observed in a single specimen was five bacterial targets.

Table 1: Number of bacteria in each Biofire FilmArray Pneumonia panel specimen

TOTAL NUMBER OF BACTERIA POSITIVE	NUMBER OF PATIENTS	PERCENTAGE
0	9	30%
1	8	26.6%
2	6	20%
3	4	13.33%
4	2	6.6%
5	1	3.3%
Total	30	100%

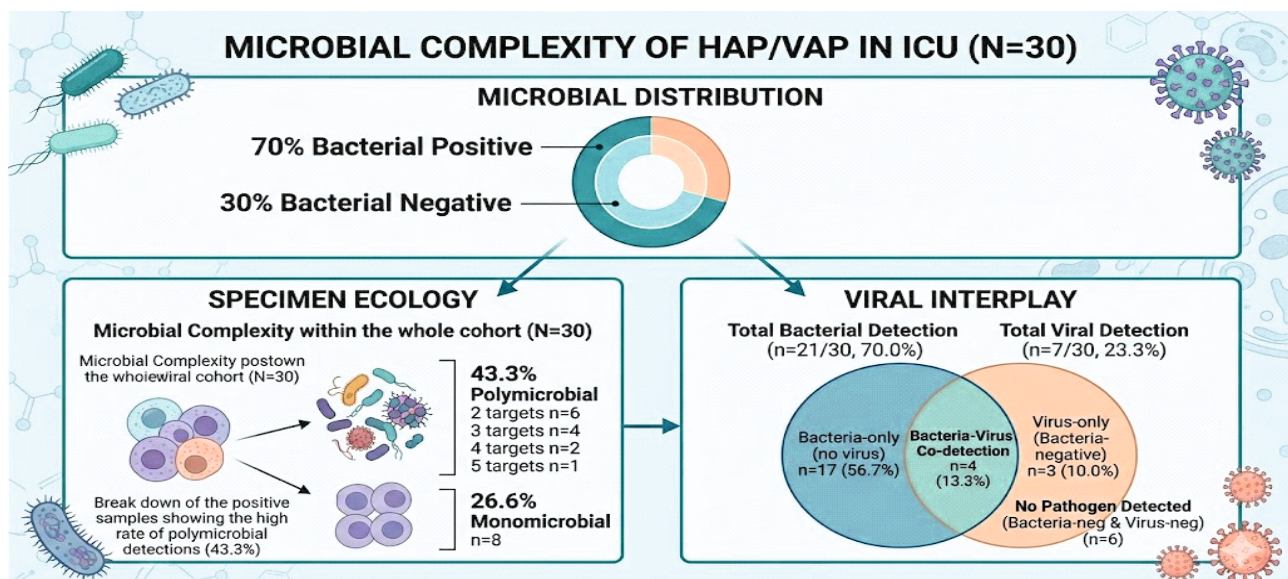


Figure 1. Microbial complexity of HAP/VAP in ICU specimens assessed by multiplex PCR.

Abbreviations: HAP, hospital-acquired pneumonia; VAP, ventilator-associated pneumonia; ICU, intensive care unit; N, total number of specimens; n, number of specimens in each subgroup; PCR, polymerase chain reaction.

A total of 43 bacterial detections were recorded across the 30 BFPP-tested specimens (**Table 2**). The most frequently detected bacterial target was *Acinetobacter calcoaceticus-baumannii* complex (11 detections), followed by *Pseudomonas aeruginosa* (9 detections), *Klebsiella pneumoniae* group (8 detections), *Escherichia coli* (6 detections), and *Staphylococcus aureus* (6 detections). Less frequent bacterial detections included *Enterobacter*

species., *Serratia marcescens*, *Streptococcus pneumoniae*, or *Streptococcus pyogenes*. No atypical bacterial targets, including *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*, were identified.

Viral targets were detected in 7/30 specimens (23.3%). Influenza A was the most common virus, detected in 4 specimens, while adenovirus, human metapneumovirus, and parainfluenza virus were each detected in 1 specimen.

Table 2: Summary of Organism in Group B (Biofire filmarray Pneumonia panel) n = 30

PATHOGENS (TOTAL DETECTION IS 57)	TOTAL NUMBER (%)
ANY BACTERIA	43 (75)
<i>Acinetobacter calcoaceticus-baumannii</i> complex	11 (19.2)
<i>Enterobacter cloacae</i> complex	1 (1.7)
<i>Escherichia coli</i>	6 (10.5)
<i>Haemophilus influenza</i>	0
<i>Klebsiella aerogenes</i>	0
<i>Klebsiella oxytoca</i>	1 (1.7)
<i>Klebsiella pneumoniae</i> group	8 (14)
<i>Moraxella catarrhalis</i>	0
<i>Proteus</i> species	0
<i>Pseudomonas aeruginosa</i>	9 (15.8)
<i>Serratia marcescens</i>	0
<i>Staphylococcus aureus</i>	6 (10.5)
<i>Streptococcus agalactiae</i>	1 (1.7)
<i>Streptococcus pneumoniae</i>	0
<i>Streptococcus pyogenes</i>	0
Atypical Bacteria <i>Chlamydia pneumoniae</i> <i>Legionella pneumophila</i> <i>Mycoplasma pneumoniae</i>	0
ANY VIRUS	7 (12.3)
Adenovirus	1 (1.7)
Coronavirus	0
Human Metapneumovirus	1 (1.7)
Human Rhinovirus/Enterovirus	0
Influenza A	4 (7)
Influenza B	0
Parainfluenza Virus	1 (1.7)
Respiratory Syncytial Virus	0
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	0
Antimicrobial Resistance Genes	6 (10.5)
CTX-M	4 (7)
IMP	1 (1.7)
KPC	0
NDM	0
OXA-48-like	0
VIM	1 (1.7)
mecA/C and MREJ	0

cloacae complex (1 detection), *Klebsiella oxytoca* (1 detection), and *Streptococcus agalactiae* (1 detection). No detections were noted for *Haemophilus influenzae*, *Klebsiella aerogenes*, *Moraxella catarrhalis*, *Proteus*

Bacteria-virus co-detection was observed in 4/30 specimens (13.3%), whereas 3/30 specimens (10.0%) showed virus-only detection. Multiple viral detections were not observed in any specimen. No detections were recorded

for coronavirus, human rhinovirus/enterovirus, influenza B, respiratory syncytial virus, or Middle East respiratory syndrome coronavirus (MERS-CoV).

With respect to resistance markers, the BFPP identified

pneumoniae group, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*. However, the positive predictive value was relatively low overall (27.9%), with particularly low values for *Pseudomonas aeruginosa* (11.1%),

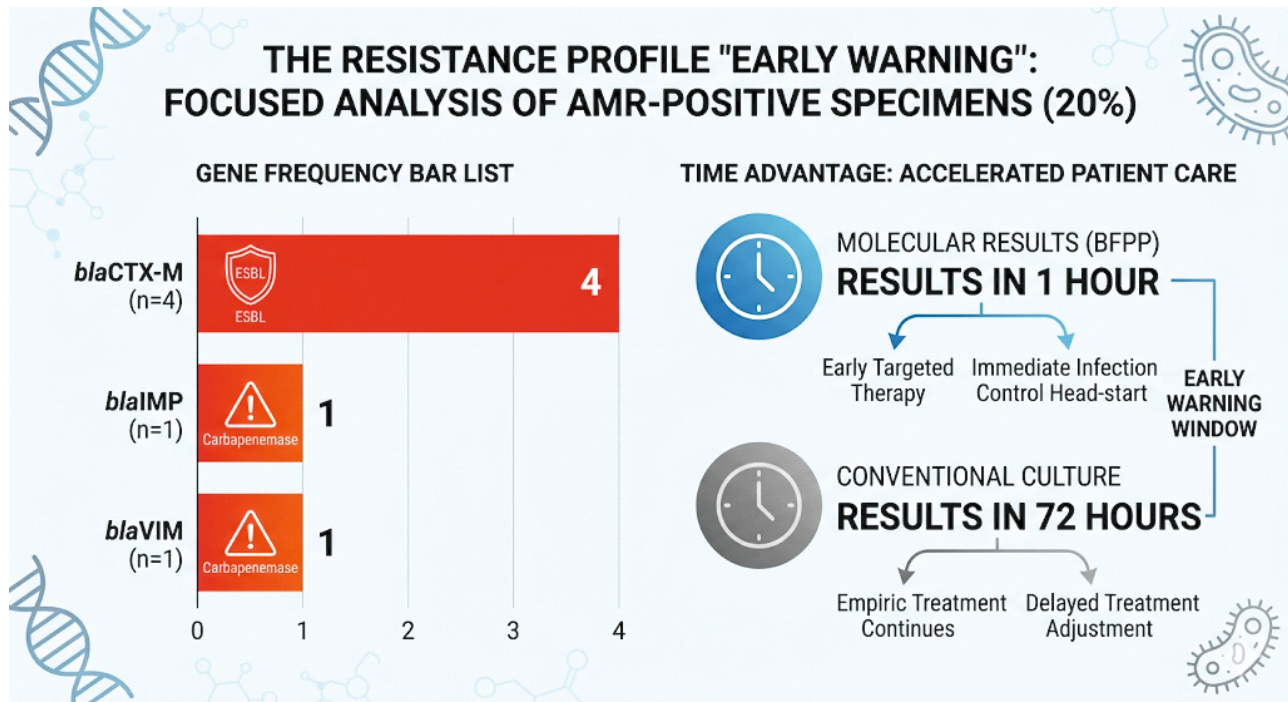


Figure 2. Resistance-gene profile and early-warning value of BFPP in AMR-positive HAP/VAP specimens. Abbreviations: AMR, antimicrobial resistance; BFPP, BioFire® FilmArray Pneumonia Panel; HAP, hospital-acquired pneumonia; VAP, ventilator-associated pneumonia; bla, beta-lactamase gene; CTX-M, cefotaximase-M; IMP, imipenemase; VIM, Verona integron-encoded metallo-β-lactamase; ESBL, extended-spectrum beta-lactamase; n, number of specimens.

6 resistance-gene detections. These included CTX-M in 4 specimens, IMP in 1 specimen, and VIM in 1 specimen. No detections were recorded for KPC, NDM, OXA-48-like, or mecA/C with MREJ (Figure-2).

Overall, this specimen-level analysis demonstrated that BFPP frequently identified complex microbial patterns in suspected hospital-acquired pneumonia, including a substantial proportion of polymicrobial bacterial detections, occasional bacteria-virus co-detection, and a limited but clinically relevant number of resistance-gene signals.

When compared against conventional streak culture, the BioFire® FilmArray Pneumonia Panel (BFPP) demonstrated excellent overall diagnostic performance, with an overall positive percent agreement (sensitivity) of 100% and negative percent agreement (specificity) of 92.9% (Table 3). Notably, there were no false-negative results for any culture-positive bacterial target, resulting in an overall negative predictive value of 100%, which suggests that a negative BFPP result was highly reliable in ruling out bacterial pathogens detected by culture. Organism-wise, sensitivity was 100% for all culture-positive detections including *Acinetobacter calcoaceticus-baumannii* complex, *Escherichia coli*, *Klebsiella*

Staphylococcus aureus (16.7%), and *Klebsiella pneumoniae* group (25%), indicating that BFPP detected additional organisms not recovered by culture. Overall, these findings suggest that BFPP is highly sensitive and has excellent rule-out ability, while also identifying a broader range of bacterial targets than conventional culture.

Discussion

In this analysis of a secondary data set that includes samples from ICU patients with suspicion for HAP, the highest rate of intra specimen polymicrobial bacterial detection observed by the BFPP was 43.3% for all BFPP-tested specimens and 61.9% for bacteria-positive specimens, with a maximum of five bacterial targets detected within one specimen. Therefore, based on this analysis, HAP in at least a substantial proportion of these critically ill patients appears to be a microbiologically complex illness with several common bacterial species, not an exclusive monomicrobial event. Similar findings of polymicrobial infection have been reported in earlier VAP studies, including with three and four bacterial species reported by Combes et al. And by Natarajan et al. (62.9%) in a cohort of an Indian ICU [6,7]. These findings collectively suggest that polymicrobial infection is a common finding in severe

Table 3: Diagnostic accuracy of Biofire FilmArray Pneumonia panel

BACTERIA	PP2+ Culture+	PP2+ Culture-	PP2- Culture+	PP2- Culture-	PPA/ Sensitivity %	NPA/ Specificity %	PPV%	NPV%
<i>Acinetobacter calcoaceticus-baumannii</i> complex	5	6	0	19	100	76	45.4	100
<i>Enterobacter cloacae</i> complex	0	1	0	29	-	96.7	-	100
<i>Escherichia coli</i>	3	3	0	24	100	88.9	50	100
<i>Haemophilus influenza</i>	0	0	0	30	-	100	-	100
<i>Klebsiella aerogenes</i>	0	0	0	30	-	100	-	100
<i>Klebsiella oxytoca</i>	0	1	0	29	-	96.7	-	100
<i>Klebsiella pneumoniae</i> group	2	6	0	22	100	78.6	25	100
<i>Moraxella catarrhalis</i>	0	0	0	30	-	100	-	100
<i>Proteus</i> species	0	0	0	30	-	100	-	100
<i>Pseudomonas aeruginosa</i>	1	8	0	21	100	72.4	11.1	100
<i>Serratia marcescens</i>	0	0	0	30	-	100	-	100
<i>Staphylococcus aureus</i>	1	5	0	24	100	82.8	16.7	100
<i>Streptococcus agalactiae</i>	0	1	0	29	-	96.7	-	100
<i>Streptococcus pneumoniae</i>	0	0	0	30	-	100	-	100
<i>Streptococcus pyogenes</i>	0	0	0	30	-	100	-	100
ALL	12	31	0	407	100	92.7	27.9	100

nosocomial pneumonia and may be more readily visualized with molecular-based testing than with the use of only standard culture.

Our findings are also consistent with the clinical utility of the Multiplex molecular testing as an indicator of bacteria at the specimen level, instead of a simple yes/no result for positivity. Multiplex molecular testing offer detection of a broad spectrum of pathogens rapidly and can categorize bacteria semiquantitatively, in contrast to routine culture methods that often underestimate the extent of diversity, when used in conjunction with antibiotics. Lee et al. state that the FilmArray provides rapid, sensitive detection of pathogens in lower respiratory tract samples but stress that interpretation of the presence of multiple pathogens requires correlation with the clinical circumstances [14]. Gong et al. described higher semiquantitative bacteria as predictive of a closer relationship with conventional cultures and suggest a basis for thresholds in interpreting bacterial results [18]. Cojuc-Konigsberg et al. also reported improved specificity when assessing higher genetic loads among panel-positive samples [19]. These data continue to support the interpretation of a semiquantitative signal value as a tool to assist in differentiating greater clinical significance from minor bacterial findings or background signal.

Because a threshold for clinically relevant bacterial

detection was implemented in our current analyses, it further reduces concerns that the polymicrobial bacterial burdens observed represent primarily assay limitations and instead further supports our interpretation as evidence of true clinical infectious complexity, although it cannot wholly exclude that the increased burden detected represents a result of bacterial colonization. Detection of viral organisms in an ICU HAP cohort was an additional noteworthy finding: 10.0% of samples had only a viral detection and another 13.3% had evidence of bacteria and virus together. The occurrence of respiratory viruses is rarely emphasized in nosocomial pneumonia, as testing is frequently reserved for patients with influenza in settings that involve the use of ventilators in adult ICUs. Cawcutt and Kalil mention the significance of bacterial-viral co-infection in altering the disease severity and increasing the ambiguity surrounding the differential diagnosis of pneumonia [20]. Loubet et al. found that the viruses were present in 32.0% of cases of HAP in patients admitted to an ICU and showed that those who had combined viral bacterial pneumonia spent longer durations in the hospital and had higher mortality [9]. Shen et al. also found separate categories of only bacterial pneumonia, only viral pneumonia or bacterial viral mixed infection in patients admitted to an ICU who were mechanically ventilated [10]. This information confirms that the diagnosis and care of

patients can be changed by the finding of viral disease in addition to bacterial disease in severe pneumonia. Our observation that some patients have only a viral illness, as others have evidence of bacterial-viral infections, strongly suggests that the rapid, broad pathogen detection capabilities of Multiplex molecular testing may identify subgroups of patients who differ from one another in ways that standard bacterial testing would otherwise leave unnoticed and unaddressed from a therapeutic viewpoint.

The frequency of viral detections observed in our cohort was comparatively lower than that reported in certain published ICU series, however, this variation is clinically plausible. Viral prevalence in HAP/VAP depends on case-mix, seasonality, local epidemiology, immune status, and the intensity of viral testing. Our study was relatively small and limited to a single ICU population, which may partly explain the lower proportion of viral findings. Even so, the presence of virus-only samples is clinically meaningful. In real-world decision-making, a virus-only BFPP result does not by itself rule out bacterial infection, but in the right clinical context it may increase confidence in withholding, narrowing, or discontinuing unnecessary antibacterial therapy, especially when serial clinical assessment does not support ongoing bacterial sepsis. That implication is particularly relevant for stewardship-focused use of syndromic panels in HAP. [9-10, 20-21].

The present analysis also helps explain why rapid molecular diagnosis may have clinical value beyond simple acceleration of microbiology reporting. In the parent randomized report from the same cohort, BFPP-guided diagnosis was associated with lower mortality, shorter ICU stay, shorter antibiotic exposure, and lower total cost [22]. The current specimen-level analysis offers a plausible microbiological rationale for those findings. When clinicians are confronted early with evidence of multiple bacterial targets, virus-only detection, or bacteria-virus co-detection, they may be better positioned to tailor empirical therapy more precisely than when relying on delayed culture alone. This analysis finds substantial empirical evidence in the existing literature on BFPPs. In one study by Van der Westhuyzen et al., the FilmArray panel detected significantly more pathogens compared to culture, as well as demonstrated bacterial and viral coinfections in 27% of cases [21]. Moreover, Ferrer et al. argued that the use of FilmArray findings would help facilitate changes in empiric antimicrobial treatment and possibly even save money [23]. Likewise, Matsuura et al. suggested that timely identification of antibiotic resistance through the pneumonia panel, along with Gram stain and clinical judgment, might affect antimicrobial step-up decisions [24].

On the other hand, the findings in this study should not be

considered as an indication that all multiple detections would always result in actionable pathogens. One of the most difficult aspects of multiplex respiratory testing is being able to tell infection from colonization, particularly among patients under intubation in ICUs. This problem can become even more complex when there is a presence of multiple bacteria in the same sample. As a matter of fact, Lee et al. emphasized that multiple pathogens and resistant genes should not always be taken at face value [14]. Berteau et al. showed that in culture-positive VAP, non-targeted bacteria not included in the FilmArray panel were present in 23% of cases, and that polymicrobial VAP carried a higher risk of such non-targeted organisms [25]. Thus, a molecular panel may reveal more than culture, but it does not reveal everything. The implication is not that BFPP should replace conventional microbiology, but that it should be used as an adjunctive rapid test interpreted alongside clinical findings, conventional culture, and local epidemiology.

A similar principle applies to resistance-gene interpretation. Although the current manuscript is not centered on detailed resistance analysis, the presence of resistance markers in this cohort adds to the clinical significance of rapid syndromic testing. Gong et al. found good positive agreement between molecularly detected antimicrobial resistance determinants and phenotypic resistance, especially for CTX-M and *mecA/C-MREJ* [18]. According to Matsuura and colleagues, a rapid identification of pathogens that are resistant to common antibiotics could lead to a more targeted antimicrobial treatment at an earlier stage of therapy [24]. Nevertheless, this does not imply that the resistance genes identified in the samples definitively come from a specific organism in the mixed sample and the results do not replace conventional phenotypic susceptibility tests. Therefore, data on resistance genes would be most beneficial as an early indicator and to help guide the early phase of antibiotic selection, pending a full susceptible test on the organisms isolated. The overall impact of pneumonia diagnostic panels on clinical care, though, hinges on the level of adoption into the process by which a physician makes decisions about antibiotics. While our study concluded there was a clinical benefit, not all outside researchers have been so convinced about the potential role of panels as part of the diagnosis in solely improving mortality. Riaño-Sánchez and coworkers observed no improved mortality, shorter ICU stay or fewer days of antibiotics associated with using an multiplex pneumonia panel in intensive care units in Spain, and, conversely, found an increased use of Infectious Disease consults to be associated with superior outcomes [26]. This underscores the fact that rapid molecular tests are not self-implementing tools, their value is likely enhanced when accompanied by stewardship oversight, thoughtful analysis by a clinician at the bedside and defined pathways for

interpreting conflicting and mixed results.

Strengths and Limitations

The case-by-case analysis revealed the complexity of the microbes encountered in ICU-acquired pneumonia specimens, but several limitations must be mentioned to properly interpret the findings. We conducted the study within one adult medical anesthesia ICU in a tertiary teaching medical center, with 30 samples in the molecular analysis portion. Thus, the results presented in this study should be considered exploratory. Although the study showed excellent sensitivity (100% PPA) with a reasonable N of 12, this overestimates the accuracy and findings must be confirmed with larger multi-center studies to ensure external generalizability to different ICUs with different microbial ecosystems. Being a tertiary care referral hospital, we tend to treat more critically ill patients who might have undergone previous health care exposure, thereby having a higher possibility of exposure to Multi drug resistant organisms and polymicrobial pneumonia. However, conventional streak culture is not the best gold standard. Because molecular panels detect DNA from both dead/viable and nonculturable/viable bacteria, the many false positives we found (27.9% PPV) are often real pathogens that had been exposed to antibiotics and were unable to culture. We recommend the next logical steps: use another type of secondary molecular investigation to confirm Discordant cases such as rRNA (16S sequencing) analysis. Differentiating true infection from colonization remains problematic for all molecular tests. Although we used the high threshold of 106 copies/mL with high confidence in increasing the specificity of tests about the presence of DNA from only the viable organism

(pathogen), it still remains critical that the test results should only be evaluated with clinical evolution, radiographic features, inflammatory marker values and procalcitonin. The BioFire® panel only tests for the following 15 bacteria and 9 viruses, most of which are commonly encountered pathogens in the ICU. Other pathogens like *Stenotrophomonas maltophilia* or various fungi cannot be tested on the panel, which leads to an incompletely identified microbial agent in polymicrobial samples. Finally, because some microbiological components of the parent trial have already been reported in the page-proof manuscript, the present discussion deliberately focuses on microbial complexity and co-detection patterns rather than repeating the main between-group diagnostic-yield narrative.

Overall, the present secondary analysis suggests that the major added value of BFPP in suspected ICU-acquired pneumonia may lie not only in faster positivity, but in its ability to reveal how microbiologically complex a given specimen is. The high rate of polymicrobial bacterial detection, the presence of virus-only samples, and the identification of bacteria-virus co-detection together support the concept that HAP/VAP in critically ill adults often represents a mixed and layered infectious syndrome. In this setting, rapid multiplex testing may help clinicians move beyond a binary culture-positive/culture-negative framework toward a more nuanced interpretation of lower respiratory tract infection (**Figure-3**). Future studies should validate whether explicit specimen-level interpretation algorithms based on bacterial burden, co-detection patterns, and stewardship review can further improve antibiotic precision and patient outcomes.

THE SPECIMEN ECOLOGY ALGORITHM: OPTIMIZING ICU PNEUMONIA MANAGEMENT

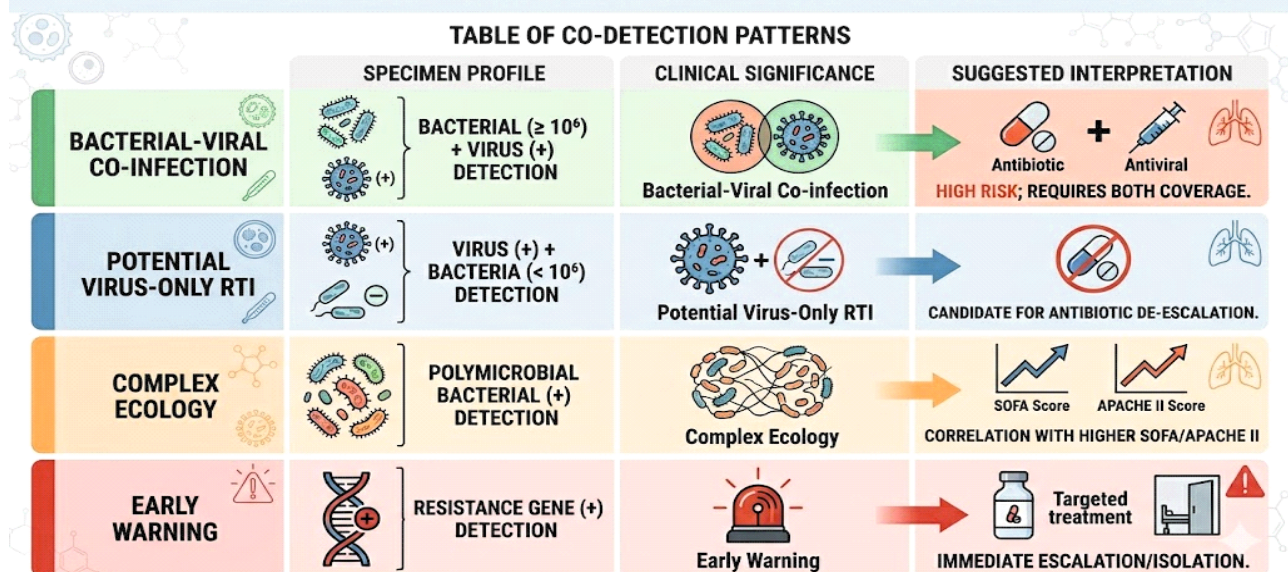


Figure 3: Specimen ecology algorithm for optimizing ICU pneumonia management based on co-detection patterns. **Abbreviations:** ICU, intensive care unit; RTI, respiratory tract infection; SOFA, Sequential Organ Failure Assessment; APACHE II, Acute Physiology and Chronic Health Evaluation II; n, number; $>10^6$, bacterial load greater than 10^6 copies/mL

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. The study supports earlier and more precise antimicrobial decision making in critically ill ICU patients with suspected HAP/VAP by using multiplex PCR to rapidly detect their bacterial burden, whether they are polymicrobially infected, have viral coinfections or carry resistance genes, all information that may not fully be included with conventional culture.
2. The authors' findings suggest that HAP is often polymicrobially and not monomicrobially suspected in critically ill patients and that physicians should interpret findings on their pneumonia panel by combining quantitative information about bacterial and viral loads with resistance markers, clinical condition, radiology and culture results.
3. Because this test results in faster molecular diagnosis, it encourages more prudent use of antibiotics by allowing clinicians to avoid unnecessary broad-spectrum agents, reinforcing antimicrobial stewardship.
4. The study findings create an ethical responsibility for physicians to carefully interpret molecular test results, given that detection of bacterial and/or viral nucleic acids does not equate with active bacterial or viral infection and that over-treatment with the panel could cause patients harm.
5. Given that molecular testing quickly delivers test results, there arises a duty to be timely, as prompt administration of appropriate antibiotic treatment in critically ill patients often improves outcomes.
6. Better antimicrobial stewardship has the potential to mitigate the societal burden of antimicrobial resistance in ICU patients as well as throughout hospitals and communities.
7. In this manner, use of the multiplex panel may contribute to decreasing length of ICU stay, duration of antibiotic therapy and healthcare costs, thereby relieving patients' families of financial burdens and patients of emotional distress.

Conclusion

This secondary, specimen-level analysis has shown that the BioFire FilmArray Pneumonia Panel often finds complicated microbiological profiles among patients with ICU-acquired pneumonia, involving many instances of polymicrobial bacterial infection as well as significant cases of bacteria-viruses co-detection. These findings suggest that suspected HAP in critically ill adults is often microbiologically more complex than conventional binary pathogen reporting may indicate. By identifying polymicrobial bacterial loads and viral co-detections within the first hour of suspicion, clinicians can move away from

"one-size-fits-all" empiricism toward a targeted, stewardship-guided treatment algorithm. This approach not only reduces mortality and antibiotic duration but also addresses the significant economic burden of ICU care. Larger prospective studies are needed to validate how polymicrobial burden and co-detection patterns can be integrated into stewardship-guided treatment algorithms and whether such specimen-level interpretation improves clinical outcomes.

Declarations

Acknowledgment: We acknowledge the nursing and laboratory staff of the LLR, Hospital Intensive Care Unit.

Artificial intelligence uses declaration statement: The graphical illustrations and visual schematics used in this manuscript were created with the assistance of Google Gemini, a generative artificial intelligence tool. The tool was used only for designing and refining visual representations of the study concepts, including microbial complexity, resistance-gene profiling, and specimen-level interpretation algorithms. All scientific content, numerical data, labels, interpretations, and final figure legends were reviewed, verified, and approved by the authors. No patient-identifiable information or raw clinical data were entered into the AI tool. The authors take full responsibility for the accuracy, integrity, and scientific interpretation of all figures included in the manuscript.

Author Contribution: SS and AA designed the study, SS and PS collected the data, and AKM performed the analysis. SS, SP, AA, and PS wrote the first draft of the manuscript. All authors reviewed and approved the final manuscript with PS being the guarantor.

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Ethical Approval: The study was conducted in accordance with the ethical standards of the responsible Ethics Committee and in compliance with the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee for Biomedical Health & Research, GSVM Medical College, Kanpur for the study titled "Comparison of the BioFire FilmArray Pneumonia Panel versus Traditional Streak Culture Method for Detection of Hospital-acquired Respiratory Infection in Anaesthesia Intensive Care Unit of a Tertiary Care Center: A Randomized Control Trial" (Ref. No.: EC/205/Oct./2021, dated 16-10-2021). The Ethics Committee approval stated

that the study should be conducted as per the submitted protocol and in accordance with applicable regulatory and ethical guidelines. Written informed consent was obtained from all participants or their legally authorized representatives prior to inclusion in the study.

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Comparative valuation of Wound Healing and Wound Contraction Time in Diabetic Foot Ulcers Treated with Vacuum-assisted Closure and Conventional Dressing

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Abstract

Background: The rising incidence of diabetes mellitus (DM) has led to an increase in severe DM complications, such as diabetic foot ulcers (DFUs). DFUs cause prolonged morbidity, prolonged hospitalization, deep and soft tissue infections, amputations and are associated with high mortality rates. DFUs require meticulous wound care for their effective management and despite the advances made, healing time of the ulcers and recurrence rate continue to be high. Various conventional dressings are used in modern medicine for managing DFU, which include moist dressing (using silver-backed, hydroactive polyurethanes) in addition to advanced dressing. It is often seen that a combination of techniques or therapies is used for better clinical outcome. The novel technique of vacuum-assisted closure (VAC) therapy is another technique that promotes wound healing by removal of air from the wound bed and by reducing wound complications by drawing serum and particulate matter from the surface. VAC therapy enhances angiogenesis and controls infection, leading to a faster rate of healing of DFUs compared to conventional dressing. **Methods:** This study aimed to evaluate and compare VAC dressing with conventional dressing in the management of diabetic wounds about healing time of ulcers, reduction of ulcer area, controlling infection and outcome. This was a hospital-based, prospective observational study conducted in the Department of General Surgery, Muzaffarnagar Medical College, Uttar Pradesh, among 60 patients of diabetic wounds from October 2022 to September 2023. The 60 patients of diabetic wounds were categorized into 2 groups. Thirty patients were treated with vacuum-assisted closure (VAC) and 30 patients with conventional dressings. Patients were randomly assigned to either the VAC dressing group or the conventional dressing group. Wound healing parameters were documented at weekly intervals for 3 months. Statistical analysis was done by applying unpaired Student's t test for continuous variables and chi-square test for categorical variables, with $p < 0.05$ being considered statistically significant. **Results:** In the VAC dressing group, 36.7% of patients were in the age group of 40-49 years, whereas in the conventional dressing group, 33.3% of patients belonged to the same age group. Both groups had similar baseline characteristics. The average initial wound area of diabetic ulcers in both groups was 53.66 ± 7.24 mm² and 48.92 ± 7.98 mm². There was a statistically significant reduction in the final wound area of diabetic ulcers in the VAC group (35.2 ± 6.78 mm²) compared to the conventional group (48.92 ± 7.98 mm²). The mean reduction in wound area was greater in the VAC group (18.44 ± 3.68 mm²) than in the conventional group (7.08 ± 0.85 mm²), emphasizing the efficacy of VAC dressing. The percentage of wound area reduction was greater in the VAC group ($33.8 \pm 3.89\%$) than in the conventional group ($12.89 \pm 1.89\%$). The average duration of wound contracture in the VAC group was 4.47 ± 0.39 weeks compared to the conventional dressing group, where it was 6.14 ± 0.45 weeks. **Conclusion:** The results indicate that the VAC dressing has been more beneficial over conventional dressing for diabetic wounds in terms of wound healing, wound area reduction and control over infection. Given these findings, VAC therapy is strongly recommended as a preferred mode of treatment for diabetic wounds.

Keywords: Diabetic wound, VAC dressing, Vacuum-assisted closure, Wound healing, Diabetic foot Ulcer, Negative-pressure wound therapy

Introduction

Diabetes prevalence is expected to rise by 156% in Africa, 16% in Europe, 35% in North America and the Caribbean, and 84% in Southeast Asia by 2045, according to the International Diabetes Federation (IDF) [1]. As the prevalence of the disease increases, so do the complications, which affect almost all the body's systems. Along with other serious aftereffects, diabetic wounds are a major cause of morbidity and mortality among the overall effects of diabetes [2]. Diabetic wounds are the leading cause of hospitalization and a serious side effect of diabetes

mellitus [3]. Diabetic wounds cause 50% to 70% of lower limb amputations and hospitalization for about 50% of diabetic patients. Relative mortality after diabetic wounds is estimated to be 48% after five years [4].

Diabetic foot ulcers (DFU) are one of the consequences of diabetes mellitus (DM), a rapidly expanding global health concern that greatly increases patient morbidity and death. About 19% to 34% of diabetes individuals worldwide suffer from DFU, a serious and common condition that is especially common in India [5]. Effective and creative treatment solutions are required to prevent amputations and

enhance patient outcomes since, despite improvements in wound management procedures, the recurrence and healing time of diabetic wounds have remained virtually unchanged over the past few decades.

Usually, debridement, antibiotic treatment, and traditional dressings are used to treat diabetic wounds. However, new research indicates that by encouraging angiogenesis, improving granulation tissue production, boosting blood circulation, and lowering infection, vacuum-assisted closure (VAC) therapy—which makes use of negative pressure wound therapy—can hasten wound healing [6]. Originally presented by Argenta and Morykwas in 1997, vacuum-assisted closure is a non-pharmacological, non-surgical technique for improving wound healing [7]. With its several operating modes and ability to provide constant and continuous negative pressures, vacuum-assisted closure (VAC) therapy is a cutting-edge type of negative pressure drainage technology. It is necessary to maintain the appropriate negative pressure range of 125 - 200 mm Hg [8]. In spite of the promising results yielded by VAC therapy, conventional dressings remain widely used due to their convenience and popularity; thus, there is a lack of information about their effectiveness when used in comparison with other methods of wound treatment.

The comparative effectiveness of VAC dressing and conventional dressing in diabetic wounds treatment should be investigated deeply because of high costs related to such conditions. In terms of their impact on wound healing, infection control, and overall health state, the aim of this study is to compare the clinical efficacy of both techniques. A comprehensive analysis will provide physicians with valuable information to use the most efficient method of wound treatment among diabetic patients.

Material and Methods

This prospective comparative intervention study was done in the Department of General Surgery at Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh. The study duration was of 18 months in which data was collected for 12 months followed by data analysis for 6 months, i.e., [Nov 2022 to June 2025]. A total of 60 patients with diabetic wounds were enrolled consecutively during the study period.

Patients with chronic diabetic wounds measuring more than 1 cm in diameter and willing to provide written informed consent were included in the study. Patients with evident local infection or gangrene, osteomyelitis on X-ray, positive probe-to-bone test, elevated C-reactive protein, end-stage organ failure, hepatic or renal failure, thrombocytopenia, steroid use, anticoagulant or antiplatelet therapy, ulcers measuring less than 1 cm or more than 8 cm in diameter, ulcers deeper than 2 cm, and lower limb ischemia were excluded. Lower limb ischemia was ruled

out clinically by the presence of distal limb pulsations and an ankle-brachial index greater than 0.9.

Following careful history taking and clinical evaluation along with laboratory investigations, surgery for debridement was conducted in all the patients. Two groups were formed with patients randomly allocated to each group: Group A patients were dressed conventionally while Group B patients had vacuum-assisted closure (VAC) dressings. Suitable antimicrobial agents were prescribed to all the patients. A sensitivity test was conducted in both the groups, and antibiotics were changed as per sensitivity reports.

For patients in the VAC group, wound bed preparation included removal of the old dressing, wound irrigation with normal saline, microbiological culture sampling where indicated, minimal surgical debridement of slough or necrotic tissue, achievement of hemostasis, and cleaning of the surrounding skin with alcohol. A sterile polyurethane ether foam dressing was placed within the wound cavity and connected to a regulated vacuum pump through a suction tube as shown in **figure 1**. The wound was then sealed with an iodine-impregnated adhesive drape extending onto the surrounding healthy skin to ensure an airtight seal. Negative pressure of 120-130 mm Hg was applied through the system.



Figure 1: VAC dressing in a patient.

Patients were followed up at regular intervals, and wound size and depth were assessed every 3 weeks for a period of 3 months. The two groups were compared with respect to healing time, wound size reduction, depth reduction, and wound regression in order to evaluate the effectiveness of the two dressing methods in the management of diabetic wounds.

Ethical clearance for the study was obtained from the Institutional Clinical Trial Screening Committee and the Institutional Ethics Committee Ref. No. MMC/IEC/2023/234 dated 20th March 2023. Written informed consent was obtained from all participants, and patient confidentiality was maintained by assigning anonymous identification numbers.

The collected data were entered into Microsoft Excel. Continuous variables were summarized as mean $\pm$ standard deviation, while categorical variables were presented as proportions and percentages. The significance of differences between means was assessed using Student's *t* test, and differences between proportions were analyzed using the chi-square test. A *p* value of less than 0.05 was considered statistically significant.

Results

The average age of the participants in our study was 48.97 ± 11.39 years for the VAC dressing group and 49.77 ± 9.68 years for the traditional dressing group. The mean age of the two groups did not differ statistically

In our study, the distribution of male and female participants was identical in both groups, with 70% males and 30% females in each. The distribution of genders in the two groups did not differ statistically significantly ($p > 0.05$).

Although the VAC dressing group's mean hemoglobin level was marginally lower (11.11 ± 0.86 g/dL) than that of the traditional dressing group (11.62 ± 1.3 g/dL) in our investigation, the difference was not statistically significant ($p = 0.079$). The VAC group's mean fasting blood sugar levels were 110.73 ± 11.07 mg/dL, whereas the traditional group's were 115.73 ± 10.5 mg/dL. There was no significant difference between the two groups ($p = 0.078$). There was no significant difference ($p = 0.298$) in the mean HbA1C values between the two groups (7.86 ± 0.83 vs. 7.65 ± 0.69). The statistical comparison of hemoglobin, fasting blood sugars and HbA1c levels are shown in **Table 1**.

In our study, the initial wound area was comparable in both groups (53.97 ± 8.8 mm² in the VAC group vs. 56.02 ± 8.32 mm² in the conventional group, $p = 0.359$). The final wound area was significantly smaller in the VAC dressing group (35.2 ± 6.78 mm²) compared to the conventional group (48.92 ± 7.98 mm²), with a significant *p*-value (< 0.001). The mean reduction in wound area was significantly higher in the VAC dressing group (18.44 ± 3.68 mm²) compared to the conventional dressing group (7.08 ± 0.85 mm²), showing a highly significant difference ($p < 0.001$).

These findings indicate that VAC dressing was more

Table 1- Comparison of Haemoglobin, Fasting Blood Sugar, and HbA1C Levels Between VAC Dressing and Conventional Dressing Groups

Variable	VAC dressing		Conventional Dressing		Test of significance	
	Mean	SD	Mean	SD	t value	p value
Haemoglobin	11.11	0.86	11.62	1.3	1.79	0.079
Fasting Blood Sugar	110.73	11.07	115.73	10.5	1.795	0.078
HbA1C	7.86	0.83	7.65	0.69	1.051	0.298

significantly ($p > 0.05$).

With 36.7% of participants in the VAC dressing group and 33.3% in the conventional dressing group, the majority of participants in our study were between the ages of 40 and 49. With minor variations in the 50–59 age group (20.0% in VAC vs. 36.7% in conventional dressing), the age group distribution was comparatively similar in both groups. The age distributions of the two treatment groups did not differ statistically significantly, indicating that the age profiles were similar ($p > 0.05$).

effective in promoting wound size reduction compared to conventional dressing (**Table 2 and figure 2**). In our study, the percentage of wound area reduction was significantly greater in the VAC dressing group ($33.8 \pm 3.89\%$) compared to the conventional dressing group ($12.89 \pm 1.89\%$). There was statistically significant difference ($p < 0.001$) between both the study groups (**Table 3**).

In our study, the VAC dressing group experienced wound contracture for an average of 4.47 ± 0.39 weeks, which was

Table 2- Comparison of Wound Area (Initial, Final, and Change in Area) Between VAC Dressing and Conventional Dressing Groups

Variable	VAC dressing		Conventional Dressing		Test of significance	
	Mean	SD	Mean	SD	t value	p value
Initial area (mm ²)	53.97	8.8	56.02	8.32	0.925	0.359
Final area (mm ²)	35.2	6.78	48.92	7.98	7.177	<0.001
Change in Area (mm ²)	18.44	3.68	7.08	0.85	16.469	<0.001

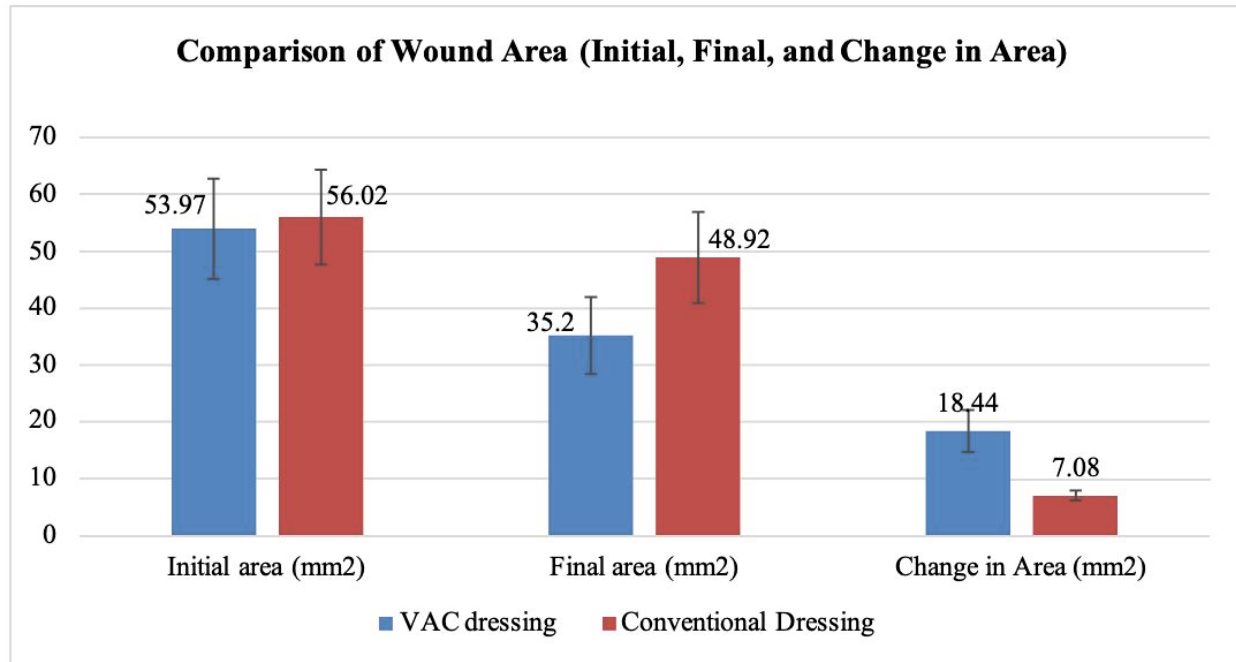


Figure 2: Comparison of Wound Area (Initial, Final, and Change in Area)

Table 3- Comparison of Percentage of Wound Area Reduction Between VAC Dressing and Conventional Dressing Groups

Variable	VAC dressing		Conventional Dressing		Test of significance	
	Mean	SD	Mean	SD	t value	p value
% of Area Reduction	33.8	3.89	12.89	1.89	26.452	<0.001

considerably shorter than the traditional dressing group's 6.14 ± 0.45 weeks.

The two study groups differed statistically significantly, showing that VAC dressings caused wounds to heal more quickly than conventional dressings ($p < 0.05$) (Table 4).

concluding that VAC dressing was better to conventional dressing in this regard [10]. VAC also is associated with lower length of hospital stays and the incidence of complications [11].

VAC causes increased tissue pressure, which subsequently reduces intravascular hydrostatic pressure (Bernoulli's

Table 4- Comparison of Duration of Wound Contracture (in Weeks) Between VAC Dressing and Conventional Dressing Groups

Variable	VAC dressing		Conventional Dressing		Test of significance	
	Mean	SD	Mean	SD	t value	p value
Duration of Wound Contracture (weeks)	4.47	0.39	6.14	0.45	15.515	<0.001

Discussion

The two groups' initial wound areas were similar in the current investigation. Nonetheless, there was a statistically significant difference in the end wound area between the VAC dressing group and the conventional group. VAC therapy was more successful than traditional dressings at promoting wound healing, as seen by the VAC group's much larger mean reduction in wound area.

Similar findings were reported in a study done in Pakistan, where it was showed that after VAC therapy, the original average wound area of 50.6 ± 27.6 cm² decreased to an average size of 11.4 ± 4.55 cm² [9]. Additionally, another study observed a noteworthy distinction in the reduction of wound size between diabetic patients treated with VAC dressing and those treated with conventional dressing,

principle) by compressing vessels and increasing intravascular fluid velocity (principle of continuity). Both processes lead to less edema and less intravascular fluid outflow. Furthermore, according to the Venturi principle, higher blood velocity attracts extracellular fluid into the channel. Furthermore, edema is successfully removed from the injured tissues by the compressive forces of negative pressure wound therapy. These routes result in improved cellular oxygenation and decreased interstitial hydrostatic pressure. By immobilizing the wound, VAC therapy speeds up the healing process [12, 13]. These speeds up the healing process by creating the ideal moist environment.

Furthermore, the enhanced diffusion of oxygen and critical nutrients essential for tissue repair due to increased blood flow in the wound bed with Negative Pressure Wound

Therapy (NPWT) offers a dynamic healing process that is continuously involved in wound remodelling with a less total wound load than traditional passive absorption and frequently changing wound dressing. The negative pressure induces mechanical stress at the wound-foam interface, causing cellular deformation with subsequent signalling pathways that promotes angiogenesis and cellular proliferation. In this context, release of growth factors such as, FGF, TGF-beta, VEGF, fibroblast proliferation, a-smooth muscle actin and IL-8, were promoted [14-16]. NPWT play a major role in promoting angiogenesis, increasing blood flow, preventing infection, enhancing the speed of wound closure and increasing growth of granulation tissue in wound [17]. These all imply that VAC treatment improved the decrease in wound size when comparing to standard dressing. VAC provides its superiority due to the peculiar characteristics that it actively leads to wound contraction and granulation tissue by creating a controlled negative pressure environment. With the aid of negative pressure, wound contraction improved and additional fluid and exudate can be removed, therefore decreasing infection and wound maceration. This results from the continuous providing of negative pressure [18, 19]. VAC creates a favorable environment by reducing tissue oedema and bacterial load, thus reducing impediment of the wound bed from granulation tissue formation and wound closure. This combined result leads to an improved decrease in wound size in the VAC group and shows superiority to conventional dressings in the treatment of chronic diabetic wound. Wound area percentage of the VAC dressing group, when comparing to the traditional dressing group, was greater. The difference observed between the two groups was statistically different. Contracture was noted among VAC dressing group on an average of 4.47 ± 0.39 weeks whereas 6.14 ± 0.45 weeks was noted among the traditional dressing group and this difference is statistically significant that shows the fast pace of healing caused by VAC dressings, similar to a trial mentioned previously in which VAC group had an average time for recovery of 21.75 ± 10.55 days [9]. In a comparable study including 60 patients suffering from diabetic foot ulcers showed that VAC therapy group healed in 17.2 days compared to 34.9 days in the traditional dressing group [20]. The result is consistent with findings from other single and multi-center trials [21, 22]. VAC bandages can lead to decreased rates of amputation and autoamputation [23-25]. Application of negative pressure on the wound bed through VAC therapy brings about mechanical micro deformation of the cells. The mechanical stress promotes tissue healing by inducing various biological reactions like growth of fibroblasts and stimulating angiogenesis. The increased

blood flow in the wound bed from negative pressure induces growth of granulation tissue. Tissue regeneration and repair necessitate high levels of fibroblast growth factors, i.e., fibroblast growth factor (FGF), transforming growth factor-beta (TGF- β), vascular endothelial growth factor (VEGF), as well as other significant growth factors. VAC Therapy helps to remove fluid collected in interstitial tissues, which lessens tissue swelling and restores the circulation of blood. By so doing, it helps the supply of oxygen and other necessary nutrients in the body required for healing. By removing continuous exudate outflow, bacterial colonization in the wound is reduced, therefore reducing the chances of infection and speeding up the healing process, by maintaining a wound that is clean and moist. It protects the wound from external contaminants and maintains the stable environment of the wound beneficial for quick epithelialization and wound contraction by closing the wound to form a closed environment. Other cytokines released such as IL-8, which can attract cells of the immune system and can promote inflammation, help regenerate tissue and lead to a decreased period of healing.

Strengths and Limitations of the Study

The study has some limitations. A small sample size may hinder the generalisability of the results. The investigation was conducted in a single location which could affect external validity as outcomes may differ in other hospital settings. Additionally, the minimal follow-up period precludes the evaluation of long-term outcomes such as wound recurrence chronic complications or overall limb salvage. Patient adherence and other factors related to patient health such as underlying comorbidities beyond the control of the study design may also have influenced the outcome. Since our study was carried out at a tertiary referral center that specializes in complex diabetic foot ulcers, one of its limitations is the possibility of bias. As a result, the results could not apply entirely to primary care settings or smaller hospitals. Larger, multi-center trials with longer follow-up times should be the main focus of future research to confirm these results and investigate long-term effects including cost-effectiveness and recurrence rates.

According to the study's findings, VAC dressing may be used as a first-line treatment for diabetic wounds, especially when a quicker healing time is crucial. The effectiveness of VAC therapy in improving the wound healing process and lowering the incidence of complications associated with chronic diabetic wounds necessitates the establishment of a standardized set of procedures and recommendations. This standardization is essential to maximize positive patient outcomes and reduce the economic and personal burden posed by these chronic diabetic wounds.

CLINICAL, ETHICAL AND SOCIAL IMPLICATIONS

1. VAC dressing can be considered to have effective clinical benefits in the treatment of diabetic foot ulcers, in those patients needing to achieve quicker healing, a greater percentage reduction in wound area and earlier contraction of the wound when compared with conventional dressings.
2. A shorter healing period for diabetic foot ulcers can result in shorter hospital visits, fewer days lost from work, reduced reliance on and burden of care from caregivers and financial relief to patients and families.
3. Improvements in methods for the management of diabetic foot ulcers might be able to contribute to a reduction in the feelings of social shame, the loss of function and limitations in mobility experienced by many patients with chronic diabetic foot ulcers.
4. This study leads one to conclude that it is important to raise public awareness, increase the number of diabetic patients screened early and promptly referred for further management and increase the availability of wound care in peripheral as well as tertiary care areas.
5. Clinicians should offer evidence-based wound care options while ensuring that patients are informed about the benefits, limitations, cost, availability, and expected outcomes of VAC therapy before treatment selection.

Conclusion

An obvious benefit in accelerating wound healing was shown by the analysis of VAC dressing. In comparison to the traditional dressing group, the VAC dressing group experienced a considerably higher mean and percentage reduction in wound area. In the VAC group, the final wound area was considerably smaller. The VAC dressing promotes quicker wound healing, as seen by the considerably shorter mean time of wound contracture in the VAC group. This demonstrates the shortcomings of traditional dressings in the treatment of complicated diabetic wounds, especially when a smaller wound and quicker healing are essential. Diabetic foot ulcers were successfully treated with the VAC dressing. It accomplishes microbiological clearance and encourages wound bed granulation and wound area reduction.

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Can a Doctor's Family be Held Liable after the Doctor's Death? Legal and Ethical Reflections on the Kumud Lall Judgment

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Abstract

Medical negligence claims may continue for several years, and difficulties arise when the treating doctor dies before final adjudication. Here we examine the Supreme Court's judgment in Kumud Lall v Suresh Chandra Roy, which considered whether legal heirs of a deceased doctor can be brought on record in a pending consumer complaint. The judgment clarifies that such claims do not automatically end with the doctor's death, but any liability is civil in nature and limited to the estate inherited by the legal heirs. It does not impose personal blame or professional guilt on the doctor's family. The commentary discusses the distinction between civil and criminal liability, compares medical negligence with other professional negligence claims, and highlights ethical concerns related to patient compensation, evidentiary fairness, documentation, and prolonged litigation. The judgment reinforces the need for evidence-based adjudication, careful record keeping, informed consent, and professional indemnity in medical practice.

Keywords: Medical Malpractice; Professional Liability; Jurisprudence; Ethics, Medical; Physicians; Informed Consent; Medical Records; Documentation; Compensation and Redress

Introduction

Medical negligence cases often continue for many years before reaching final judgment. During this period, patients may die, families may change, and occasionally even the treating doctor may no longer be alive. This raises an important legal and ethical question: can a negligence claim continue against the legal heirs of a deceased doctor?

The Supreme Court recently examined this issue in Kumud Lall v Suresh Chandra Roy [1]. The case involved allegations of negligent ophthalmic surgery resulting in loss of vision. During the pendency of proceedings, the treating doctor died, following which the complainant sought substitution of the doctor's legal heirs in the ongoing case.

Questions of this nature are not limited to medicine alone. Similar situations may arise in cases involving architects, engineers, lawyers, or drivers, where civil claims continue after the death of the individual against whom negligence was alleged. In medicine, the issue carries additional sensitivity because medical outcomes are uncertain even when treatment is appropriate and complications may occur despite reasonable care. The Supreme Court itself noted in paragraph 24 of the judgment that the principles discussed in this case may have implications for other tortious claims, including motor vehicle accident compensation and industrial injury litigation [1].

For doctors, the judgment has practical importance. Medical negligence litigation in India frequently extends over years before final adjudication. If proceedings automatically end upon the death of the doctor, patients and families may lose the opportunity for compensation solely because of delay in adjudication. At the same time, continuation of proceedings against the family members of

a deceased doctor raises concerns regarding fairness, professional liability, and the extent to which civil claims can survive after death.

The Court was required to examine whether a medical negligence claim survives against the estate of a deceased doctor and whether legal heirs can be brought on record in pending consumer proceedings. In doing so, it revisited the common law principle *actio personalis moritur cum persona*, meaning a personal action dies with the person. In deciding whether the claim could continue against the legal heirs of the deceased doctor, the Supreme Court considered Section 306 of the Indian Succession Act, 1925, Order XXII of the Code of Civil Procedure, 1908, and Section 13(7) of the Consumer Protection Act, 1986 [1–4].

What happened in the case?

The dispute began in 1990, when the complainant took his wife to Dr. PB Lall, an ophthalmologist in Munger, Bihar, for severe pain in her right eye. According to the complainant, Dr Lall examined her on 10 February 1990 and advised immediate surgery, which was performed the next day. The patient later developed recurrent pain and continued to remain symptomatic despite further treatment. The complainant subsequently consulted doctors in Bhagalpur, Aligarh and Chennai, and alleged that his wife had lost vision in the right eye due to wrong treatment and surgery.

In 1997, the complainant filed a consumer complaint against Dr Lall before the District Forum, Munger, alleging deficiency in service and claiming compensation of ₹4,50,000. The claim included treatment expenses, travel expenses, compensation for loss of vision, and mental agony.

The District Forum partly allowed the complaint in 2003. It held Dr Lall negligent and directed him to pay a total compensation of ₹2,60,000, including ₹2,00,000 for loss of vision, ₹35,000 towards treatment-related expenditure, and ₹25,000 for mental agony.

Both sides appealed. In 2005, the State Consumer Disputes Redressal Commission, Patna, reversed the District Forum's order. It held that the patient's loss of vision was due to glaucoma and that there was no expert evidence to prove medical negligence by Dr Lall. The State Commission also observed that the surgery had been performed with the intention of relieving pain and was acceptable under medical ethics.

The complainant then approached the National Consumer Disputes Redressal Commission through a revision petition. During the pendency of this revision, Dr Lall died on 4 August 2009. The complainant applied to bring Dr Lall's legal heirs, his wife and son, on record. The NCDRC allowed this application in 2010. The legal heirs objected, arguing that Dr Lall had already succeeded before the State Commission and that there was no existing decree against him on the date of his death. They contended that the case should abate and that they could not be made parties for the alleged personal negligence of the deceased doctor.

The NCDRC rejected their objection in 2018 and held that, if liability was eventually established, the legal heirs would be liable only to the extent of the estate inherited from Dr Lall. The legal heirs then approached the Supreme Court. The central question before the Court was whether, after the death of a doctor during pending appellate or revisional proceedings, the legal heirs could be impleaded and held liable for alleged medical negligence, and if so, to what extent.

Why did the Court Face a Dilemma?

The difficulty before the Court arose because two competing principles were pulling in opposite directions. On one side was the older legal principle that a personal action dies with the person. In simple terms, if a claim is purely personal to an individual, it may not continue after that person's death. The legal heirs of Dr Lall relied on this principle and argued that an allegation of medical negligence was personal to the doctor. Since Dr Lall had died during the pendency of the revision, they submitted that the case should come to an end. They also pointed out that, on the date of his death, there was no existing decree against him because the State Commission had already set aside the District Forum's order.

On the other side was the argument that the complainant's claim was a civil claim for compensation. If the doctor had left behind an estate, and if negligence was eventually proved, the compensation could be recovered only from that estate. The respondents argued that the heirs were not

being blamed personally for the doctor's conduct. They were being brought on record because they represented the estate of the deceased doctor.

The Consumer Protection Act also added to the difficulty. Section 13(7) of the Consumer Protection Act, 1986 provides that when a complainant or opposite party dies during proceedings, Order XXII of the Code of Civil Procedure applies. Order XXII allows legal representatives to be brought on record when the right to sue survives. The problem was that the procedure allowed substitution, but the Court still had to decide whether the substantive right to continue the case survived after the doctor's death.

The Court also had to consider Section 306 of the Indian Succession Act, 1925. This provision deals with which legal claims survive against the estate of a deceased person. The older rule protects heirs from being personally answerable for certain personal wrongs of the deceased. At the same time, civil claims connected with loss to estate may still survive. This created the central difficulty: *Should medical negligence be treated as a purely personal claim that ends with the doctor's death, or as a compensatory claim that may continue against the estate?*

The case also raised a practical concern. Medical negligence litigation often takes many years. If a claim automatically ends because the doctor dies before final judgment, delay itself may defeat the complainant's right to compensation. But if every claim continues fully against the doctor's family, the heirs may be dragged into litigation for professional acts they did not perform and could not defend from personal knowledge.

The Court therefore had to balance three concerns: *The patient's right to seek compensation, the doctor's right to defend his professional conduct, and the heirs' right not to be made personally liable for an act they did not commit.* This is why the question was not simply whether the doctor's wife and son could be added as parties. The real issue was the extent to which a negligence claim could survive against the estate of a deceased doctor.

How is this Different from Criminal Liability?

Doctors often worry that continuation of a negligence case against legal heirs means that the family is being punished for the doctor's conduct. That is not correct. There is an important difference between criminal liability and civil liability.

Criminal liability is personal. If a doctor is accused of a criminal offence, the case is against that doctor as an individual. Criminal responsibility cannot be inherited by the doctor's spouse, children, or other legal heirs [5]. A deceased doctor cannot be tried or punished after death, and the family cannot be sent to jail or criminally punished for the doctor's alleged act.

Civil liability is different. Civil cases usually deal with compensation. The question is not punishment, but whether a person who suffered harm should receive monetary relief [1,6]. If a civil claim survives after the death of a defendant, the legal heirs are brought on record because they represent the estate of the deceased person. They are not treated as wrongdoers. Their liability, if any, is limited to the property or assets inherited from the deceased. This was also the position recorded in the NCDRC order under challenge, where the legal heirs were stated to be liable only to the extent of the estate left behind by Dr Lall, if the claim was ultimately decided against him.

This distinction is important for doctors. A finding of civil negligence may lead to compensation. A finding of criminal negligence requires a much higher threshold, involving gross negligence or recklessness, and may lead to penal consequences. The Supreme Court has previously emphasized this difference in medical negligence cases, particularly in *Jacob Mathew v State of Punjab* [7], where it held that criminal prosecution of doctors requires a degree of negligence much higher than negligence sufficient for civil liability.

In the present case, the question was limited to civil liability in a consumer complaint. The Court was not deciding whether the doctor's heirs could be criminally prosecuted. It was deciding whether a pending compensation claim could continue against the estate of the deceased doctor. This makes the issue less about punishment and more about the survival of financial responsibility after death.

How Other Professions Handle Negligence, and Why Doctors are Different?

The concern raised by this judgment should not be seen as a problem faced only by doctors. Civil negligence is a broader professional issue. Architects, engineers, lawyers, auditors, drivers, contractors and doctors may all face claims when their work causes harm. The common thread is the same: a professional or service provider owes a duty of care, fails to meet the expected standard, and another person suffers loss.

For example, if an engineer gives a defective structural design and the building later becomes unsafe, the claim is not only about the engineer's intention. It is about the loss caused by professional failure. If an architect certifies poor construction or overlooks serious design defects, a civil claim may arise. If a lawyer misses a limitation period and the client loses the right to pursue a valid case, the loss may be financial rather than physical, but it still arises from professional negligence. In motor accident cases, the same principle operates in a more familiar form: compensation is linked to injury, loss of income, medical expenses and other measurable consequences.

In professional negligence, the central question is usually whether the professional met the standard of care expected from a reasonably competent person in that field [6]. The traditional test for professional medical negligence was stated in *Bolam v Friern Hospital Management Committee*, where the court held that a doctor is not negligent if acting in accordance with a practice accepted as proper by a responsible body of medical opinion [6].

The Supreme Court in *Kumud Lall* recognised that the issue before it had implications beyond medical negligence. It specifically observed that the principle may affect many tortious claims, including personal injury claims, motor vehicle accidents and industrial accidents. This is important because doctors should not read the judgment as an isolated attack on the medical profession. The legal question is part of a larger civil liability framework.

The comparison with other professions is useful for another reason. In most professional negligence claims, the law is concerned with compensation rather than moral condemnation. The architect's family is not morally blamed for a defective design. The lawyer's heirs are not treated as professionally guilty. The engineer's children are not accused of having caused the structural defect. If a claim survives, it survives only as a claim against the estate, not as a personal accusation against the heirs. The same logic applies to doctors. In this case, one of the arguments before the Court was that if liability were eventually fixed, it would be recoverable only from the estate inherited by the legal heirs.

Doctors, however, are different from many other professionals in their work. An engineer usually works with materials that behave according to predictable physical principles. An auditor works with records. A lawyer works with documents, limitation periods and procedure. A doctor works with human biology, uncertainty, incomplete information, emergencies, co-morbidities, patient variation and rapidly changing clinical conditions. A bad outcome in medicine does not automatically mean negligence.

This difference is recognised in medical negligence law. In *Jacob Mathew v State of Punjab*, the Supreme Court drew a clear distinction between ordinary civil negligence and criminal negligence in medical practice. It observed that a doctor may be liable in tort for want of due care, but that such conduct may still fall short of the recklessness or gross negligence required for criminal liability [5]. This distinction matters because medical decision-making often involves risk even when the doctor acts with reasonable competence.

Medicine also differs because treatment decisions are often made under pressure. Emergency physicians may need to act before a full history is available. Surgeons may face unexpected intraoperative findings. Intensivists may make

decisions in unstable patients where every option carry risk. Obstetricians, anaesthetists and emergency doctors often work in situations where delay itself may be dangerous. In such settings, later review of the outcome must be careful not to confuse complication with negligence.

Another difference is the emotional nature of medical harm. When a building defect causes financial loss, the dispute may remain largely commercial. When a patient loses vision, suffers disability or dies, the injury affects dignity, trust and family life. This emotional context makes medical negligence litigation more intense for both sides. Patients and families may feel abandoned or deceived. Doctors may feel that years of training and service are being judged only by one adverse event.

The comparison with other professions therefore leads to a balanced position. Doctors should not be placed above the law. Patients harmed by negligent treatment deserve a remedy. At the same time, doctors should not be treated as insurers of cure. The standard should remain reasonable care, not perfect outcome. The law must preserve compensation for proven negligence while protecting doctors and their families from automatic blame based only on poor clinical outcome.

The estate-liability question must also be handled with care. If a deceased engineer's estate can answer for proven civil loss, there is no obvious reason why a deceased doctor's estate should receive complete immunity in every case. But medical claims require a stricter and more clinically informed assessment of negligence. The Court's discussion of "loss to estate" is useful here. Claims for measurable pecuniary loss, such as treatment expenses or financial loss, stand on a different footing from purely personal claims such as pain and suffering. The amicus in *Kumud Lall* specifically suggested that loss-to-estate claims may survive even if personal injury claims do not survive in full.

Ethical Concerns

The judgment raises a difficult ethical question for both patients and doctors: how should the law respond when alleged professional negligence is still undecided and the doctor dies during the case?

The First Concern is Justice for the Patient. A patient who has suffered harm should not lose the possibility of compensation only because litigation has taken too long. Medical negligence cases often move slowly through consumer forums and appellate bodies. If the death of the doctor automatically ends the case, delay may decide the outcome instead of evidence. The patient's suffering, expenditure and disability may remain real, but the legal remedy may disappear. In *Kumud Lall v Suresh Chandra Roy*, the Supreme Court noted that the issue before it had implications beyond medical negligence, including other tortious claims such as motor vehicle accidents and

industrial accidents. Patients should not be denied compensation for proven negligence merely because the professional died before the case ended.

The Second Concern is Fairness to the Doctor's Family.

The legal heirs did not treat the patient. They did not make the clinical decision. They may not have access to the doctor's memory, reasoning, or communication with the patient beyond what is available in the medical record. Making them personally answerable for the doctor's alleged negligence would be unfair. The distinction between personal liability and estate liability therefore becomes central. Legal heirs represent the estate of the deceased; they do not inherit professional guilt [1,3].

The Third Concern is Moral Blame. Negligence law must be careful not to convert a compensation claim into inherited guilt. A doctor's spouse, son or daughter cannot inherit professional misconduct. They can only represent the estate in a pending civil proceeding, if the law permits the claim to continue. This distinction protects the dignity of the deceased doctor's family while allowing the complainant's claim to be examined.

The Fourth Concern is the Uncertainty Of Medicine.

Medical practice is different from many commercial or technical services. A poor outcome may occur despite proper care. Complications may occur without negligence. Disease biology, co-morbidities, delayed presentation, incomplete information and emergency circumstances may all influence outcomes. The Supreme Court has repeatedly cautioned that negligence in medicine cannot be inferred merely from an adverse result. In *Jacob Mathew v State of Punjab*, the Court distinguished civil negligence from criminal negligence and held that criminal liability requires a much higher degree of negligence than that required for civil liability [5].

The Fifth Concern is Evidentiary Fairness. Once the doctor has died, the defence may become weaker. The doctor cannot explain why a particular decision was taken, what risks were discussed, what clinical findings were present, or how the patient's condition evolved. This makes contemporaneous documentation extremely important. Poor records harm both sides: patients struggle to prove what went wrong, and the doctor's family struggles to defend the care given.

The Sixth Concern is the Burden Of Prolonged Litigation.

A family already dealing with bereavement may be drawn into a dispute involving old medical records, expert opinions and allegations against a deceased doctor. At the same time, a patient's family may also have spent years seeking compensation for an injury they believe was preventable. Ethical adjudication should therefore avoid unnecessary delay, repeated procedural disputes and avoidable harassment of either side.

The Seventh Concern is Professional Trust. Patients must believe that the healthcare system offers a remedy when negligence is proved. Doctors must believe that the legal system will not punish them or their families merely for adverse outcomes. A fair approach should preserve both expectations. It should allow genuine claims to proceed where the law permits, while protecting heirs from personal liability and protecting doctors from outcome-based blame.

The Court's approach reflects this tension. It examined the older principle *actio personalis moritur cum persona*, meaning that a personal action dies with the person, and considered its statutory expression in Section 306 of the Indian Succession Act, 1925 [1,3]. The ethical importance of this distinction lies in separating blame from compensation. Grief and guilt cannot be inherited, but financial claims connected with the estate may require separate consideration.

The judgment in *Kumud Lall v Suresh Chandra Roy* should be read carefully by the medical profession. It does not make the doctor's family personally guilty. It does not convert medical negligence into hereditary blame. It deals with a narrower civil question: whether a pending compensation claim can continue against the estate of a deceased doctor. The Supreme Court held that the legal heirs of an alleged medically negligent doctor can be brought on record, and that the extent of liability must depend on the pleadings and evidence. [1]

Even while accepting this legal position, the concerns of doctors deserve serious attention. Medical practice cannot be judged in the same manner as a simple commercial transaction. A patient may suffer despite correct diagnosis, reasonable treatment and proper care. Biology is unpredictable, complications are sometimes unavoidable, and emergency decisions are often taken under pressure. The law must therefore remain cautious in separating negligence from poor outcome. The Supreme Court recognised this distinction in *Jacob Mathew v State of Punjab*, where it warned against criminalising ordinary errors of judgment and held that criminal negligence in medicine requires a much higher degree of fault than civil negligence. [7]

The liability of a deceased doctor's estate should therefore never become a shortcut to compensation. The complainant must still prove negligence. The standard of care must still be assessed with the help of proper medical evidence. The death of the doctor should not weaken the requirement of proof. If anything, adjudicating bodies must be more careful because the doctor is no longer available to explain the clinical reasoning, consent discussion, intraoperative findings or follow-up advice.

A doctor's legal heirs should not be forced to defend professional reputation from personal memory. Their role

should be limited to representing the estate. They should not be treated as wrongdoers, subjected to moral suspicion, or exposed beyond the assets inherited from the deceased doctor. Civil law may permit claims against an estate, but professional blame remains personal. This distinction must be preserved in every future medical negligence case.

The judgment also highlights the need for stronger protection systems for doctors. Professional indemnity insurance should become routine, not optional. Hospitals must maintain complete medical records for legally appropriate periods [1,8]. Consent forms, operative notes, discharge summaries and follow-up advice must be written in a way that can speak for the doctor even years later. Medical associations should work toward clearer guidance on estate exposure, indemnity coverage after death, and support for families of doctors drawn into prolonged litigation.

The ethical balance should be this: patients must have access to compensation when negligence is proved, but doctors and their families must be protected from outcome-based blame. A death, disability or complication is not proof of negligence [7,9,10]. A long legal battle should not become punishment by process. The medical profession should accept accountability, but accountability must remain evidence-based, clinically informed and fair.

For doctors, the message is practical. Good care must be accompanied by good documentation. Good intentions must be supported by recorded reasoning. Communication, consent and follow-up are not defensive rituals; they are part of ethical medical practice. For courts and consumer forums, the message is equally important: justice for patients cannot come by diluting fairness to doctors. The law must compensate proven negligence, not every medical misfortune.

Conclusion

This judgment clarifies that a medical negligence claim may survive the death of a doctor, but only as a civil claim against the estate inherited by the legal heirs. It does not make the doctor's family personally liable or morally responsible for the alleged negligence. The judgment reinforces the need for evidence-based adjudication, careful medical documentation, informed consent, and professional indemnity. Courts must protect the patient's right to compensation where negligence is proved, while ensuring that doctors and their families are not unfairly burdened for adverse outcomes alone.

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Excessive use of LLMs by postgraduate medical students: An academic disaster !

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Abstract

Postgraduate medical training occupies a unique position in medical education. Postgraduate (PG) trainees are simultaneously learners, clinicians, researchers, and teachers. During their training, they participate in seminars and academic activities while also providing patient care, performing procedures, making clinical decisions, and conducting research. This dual academic-clinical responsibility makes postgraduate training intellectually demanding.

The rapid availability of artificial intelligence (AI)-based large language models (LLMs) has substantially changed PG training landscape. PG trainees increasingly use these tools for seminar preparation, case discussions, clinical documentation, conference material preparation, academic communication, and even thesis-related work. While these systems provide rapid access to organised information and improve efficiency, their expanding role raises important educational concerns. The objective of postgraduate training is not merely task completion but the development of clinical reasoning, critical thinking, scientific inquiry, and independent decision-making. Excessive dependence on AI-generated outputs may shift learning from active knowledge construction to passive information acceptance.

Artificial intelligence should serve as an educational aid rather than a cognitive substitute. Medical educators and training bodies should therefore develop structured guidance and regulatory frameworks promoting responsible AI use while preserving the fundamental processes of clinical reasoning, comprehension, and scholarly development that define postgraduate medical education.

Keywords: Artificial intelligence; Large language models; Postgraduate medical education; Medical students; Clinical reasoning; Critical thinking; Academic integrity; AI dependency; Medical training; Generative AI

Postgraduate medical courses are interesting link in the career of a medical student. By then, they become qualified and registered medical practitioners. Still, they are students as they are pursuing postgraduate master's degree course like students. They have to read books, presents cases and seminars and take care of their patients as well. On many occasions, they have to make independent decisions to save lives in times of crisis for their patients. Hence, they have to fit in multiple shoes every day during their three-year training program.

Postgraduate medical(PG) students begin their day in seminar rooms like novices, by lunch, they perform a few procedures, and by night, they become super doctors. Again, as the morning follows the night, they become lamb back in the seminar rooms. These students are not just college students, they are Students for some time, researchers for other times, and doctors for much of the day.

Earlier, it used to be a difficult journey altogether. They had to do a lot of academic, clinical, and research work with their own intelligence and human intelligence, with minimal technological assistance. They used to discuss cases more with their seniors and teachers as they were the only source of information other than books. Human Intelligence had two great limitations: first, it is not available on demand, and second, it is mostly in bits and pieces. So, there was a great need for omnipresent, easily

accessible, complete, and comprehensive intelligence for PG medical students, and they got AI, one for all.

Currently, the situation has changed drastically. With the easy availability of AI-based LLM software and algorithms, they are utilising it for everything left and right for seminar preparation, clinical notes, and thesis writing. It has become difficult to understand whether these PG medical students are getting AI assistance to improve their learning or simply they are making the machines learn postgraduate students' problems and their resolutions in a better way.

AI helps them with everything from eliciting patient history to conducting clinical examinations, formulating differential diagnoses, initiating treatment plans, ordering appropriate investigations, and documenting detailed clinical notes. The increasing use of large language models by postgraduate medical students has extended far beyond occasional academic assistance. Many trainees now rely on these tools for a wide range of tasks, including drafting personal communication with faculty and senior residents, preparing seminar presentations, conference slides, mortality and morbidity discussions, and case presentations. More concerning is the growing tendency to use these systems to prepare postgraduate theses.

While artificial intelligence can assist in organizing information and improving language clarity, excessive dependence on such tools risks undermining the

educational purpose of postgraduate research training. The purpose of a postgraduate thesis is not merely to produce a document, but to cultivate the intellectual discipline required for scientific inquiry—an objective that cannot be achieved through algorithmic shortcuts.

Literature suggests that excessive reliance on artificial intelligence tools to answer academic queries may reduce medical students' engagement in active problem-solving and clinical reasoning, potentially impairing the development of critical thinking skills essential for medical practice [1]. AI-generated summaries and instant answers can promote superficial learning behaviors, where students rely on quick information retrieval rather than deep understanding and long-term knowledge retention [2]. Frequent use of generative AI tools for assignments may foster academic dependence, reducing students' motivation to independently search literature, analyze data, and synthesize knowledge [3]. If AI tools are used as a primary source of answers rather than as supportive learning aids, medical students may develop weaker diagnostic reasoning and clinical decision-making abilities [4]. Generative AI systems can enable students to complete essays, reports, and assignments without fully engaging in the learning process, raising concerns regarding academic integrity and genuine competency development [5].

This is a matter of serious concern for medical teachers. A great apprehension growing in their minds as PG students are losing critical thinking skills day by day. They are losing their attention span and memory retention. Moreover, use of free LLM software frequently produces erroneous contents. These students have firm believe in the output of these LLM software, as these output contents are very much organised. They look like perfect descriptions. Unfortunately, these organised contents have errors. PG students may learn wrong things, which may become difficult to unlearn later on. These tools make their job easier, being students, they may believe more in the completion of their academic/clinical assignments rather than factual status of the contents.

While artificial intelligence offers valuable support for information retrieval and educational assistance, excessive dependence on AI-generated outputs may promote superficial learning. Artificial intelligence may serve as an educational aid rather than a cognitive substitute; otherwise, the very process of learning medicine may be gradually undermined. Therefore, medical educators must carefully evaluate the role of AI in postgraduate medical education and develop structured strategies or regulatory frameworks that encourage responsible use of these tools while preserving the essential processes of clinical reasoning, comprehension, and analytical thinking that form the foundation of medical training.

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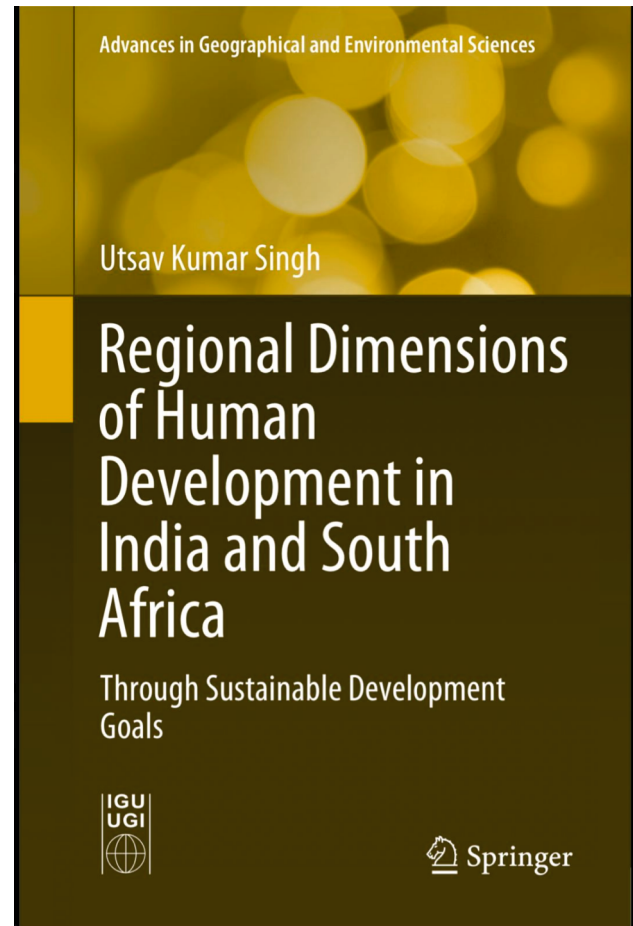
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Utsav Kumar Singh, Regional Dimensions of Human Development in India and South Africa Through Sustainable Development Goals, Springer Publication, 2024, 221 pg, ISBN 978-981-97-5845-6.

Human development in contemporary world has a multidimensional and comprehensive approach to it. It involves the well-being, dignity, and autonomy of each and every individual. It transcends economic growth and aims at increasing people's choices, capabilities, and opportunities. By investing in human development, individuals, communities, and societies can thrive and reach their full potential. For attainment of this potential, in the year 2015 there was a universal call from the United Nations to adopt and achieving Sustainable Development Goals by the year 2030. Human development and SDGs are intrinsically linked. These SDGs not only ensure the well being of each and every individual (its targets such as eradicating poverty, ensuring healthy lives, inclusive and equitable quality education, access to water and sanitation, and achieving gender equality and zero hunger, etc.) but also corroborates it through promoting sustainable practices for protecting the planet as well (promoting urgent action to combat climate change, conserving and sustainably using the oceans, seas, and marine resources, additionally protecting, restoring, and promoting sustainable use of terrestrial ecosystems, etc.)

As the world is in the last phase of achieving SDGs, the book "*Regional Dimensions of Human Development in India and South Africa through Sustainable Development Goals*" authored by Dr. Utsav Kumar Singh unveils the ongoing contradictions and deliberations upon how to achieve developmental goals efficiently and effectively? What should be the focus of policy formulation and implementation of state - economic growth as suggested by neoliberal scholars like Arvind Panagariya in India or human development as suggested by Amartya Sen? Why is there a presence of regional heterogeneities and how socio-economic, cultural contexts hinders or prospers the attainment of SDGs?

The book sets out to explore these questions by spatial comparison of India and South Africa through the analysis of their respective achievements in attaining Sustainable Development Goals through five chapters. Both India and South Africa belong to Global South and share the common lineage of colonial exploitation, hence starting from the very bottom in a world which was already way ahead. The two countries serve as perfect exemplar of the contradiction between economic or human development as India is marching aggressively towards becoming one of the fastest growing economies, but when it comes to human development indicators it still lags behind country like



South Africa, who is not doing so well on economic scale.

The first chapter aims to conceptualize what human development is, its evolution and how it has encapsulated different forms of growth from time to time. Starting from Buddha's all-inclusive idea of development to the modernized Sustainable Development Goals. It deals with multiple epistemic reckonings with respect to the idea of development. It further elucidates on how all endeavors are focused on achieving the goals of human development set forth by Mahbub Ul Haq and Amartya Sen. It further elaborates on the extension of the parameters for measuring poverty and deprivation refined by Foster and Sabina Alkire in concept of Multi-Dimensional Poverty Index from Human Development Index.

The second chapter deals with strides and contestations regarding the implementation of Sustainable Development Goals in Indian context and its learnings from Millenium Development Goals. Not only for the country itself, but achieving SDGs in India also has a global impact since 1/6th of the world's population lives in the country. This

chapter presents a statistical analysis on various targets of SDGs in India and how much has been achieved. While the author mentions about how country has done well in various indicators relating to health and literacy but what concerns him the most is the persistent challenge of spatial and social heterogeneities in achieving progress. Also, even though the country has done economically well, but is it reaching the lower strata of society is what Singh ponders upon. Singh also stresses upon the diversity across the nation, socio-political and economic context which effects the entire policy process, hence the variation in results. As Nussbaum suggests, one needs to be in consonance with the local particularities when it comes to enhancing capabilities of an individual.

The next chapter takes the same Sustainable development goal analysis to South Africa. The author mentions how South Africa embraced right-based strategies and with increased public expenditure and infrastructure, has become a nation with extensive reach of social safety net programs, as compared to the low-income nations that rely on international donor organizations. South African practice of "Ubuntu" forms the epistemic root of its Sustainable practices which helps them in harmony between humans and their biotic and abiotic surroundings. He further elaborates on how South Africa's National Development Program in convergence with SDGs assists them in achieving social security goals much efficiently and effectively. Even though South Africa does well in many social indicators however, author highlights the need to address the poverty, public health and gender pay gaps for wholistic development.

The second last chapter has a lot of empirical and quantitative data of the two countries which the author analyses. The analysis reveals the causality between GDP growth rate (proxy for well-being) and chosen indicators of SDGs, which are envisioned in long term development goals in India and South Africa. The findings also unmasked the pertinence of local preview and asymmetric strategies, dismantling the one size fits all model to achieving SDGs. For instance, Singh highlights how GDP effects health and hunger indicator in India but not in South Africa to substantiate the argument.

The last chapter concludes the entire findings and tries to suggest alternatives and recommendations for these two countries in the light of their asymmetric structures. Singh argues that the COVID Pandemic which pushed many people deep into the abyss and unveiled the catastrophic conditions of health and social sectors all across the world. Singh throughout his book and in conclusion ardently believes in following the Amartya Sen's idea of "Freedom as development". Following the capability approach, Singh pushes for moving beyond glittery economic development

and to tap into the existing reservoir of human's capabilities. A calibrated and composed approach towards human development with both economic and social security is fundamental to human development.

The book does provide some nuanced arguments; however, falls short on some aspects. Firstly, the author who highlights historical "Ubuntu" practice in South Africa should also have made reference to major ancient Indian practices which focuses on collective and community-based living, as emphasized by Gandhi. Secondly, the author though includes the gender analysis of the SDGs, but fails to recognize that these universalistic goals are themselves Eurocentric, patriarchal and doesn't question the unequal socio-economic power relations. Thirdly, the author uses Sen's "development as freedom" framework for enhancing the capabilities but he fails to recognize the limitations of the same model which universalizes the concept of freedom, keeping many perspectives from Global South at bay.

However, with all its limitations, the book offers a compelling read for researches, academicians and scholars who are working or choose to work in the development sector.

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