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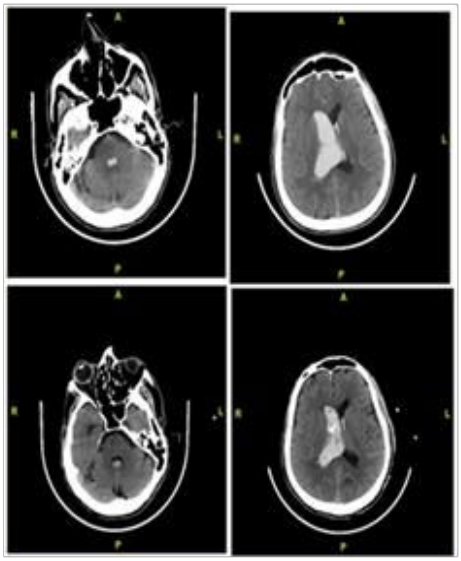
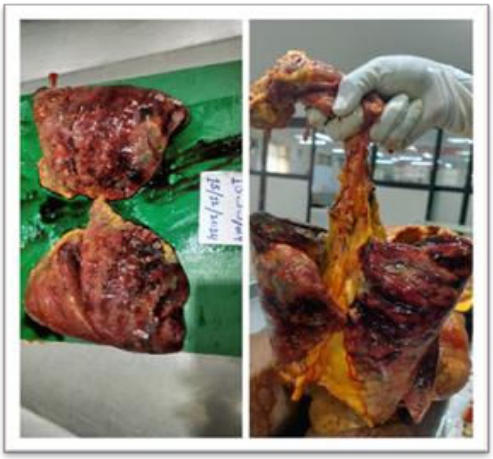
Non contrast CT of Primary IVH



Wound closed using Simple Interrupted Technique

Upper GI endoscopy with Guedel airway

Haemorrhagic, heavily congested lungs



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EDITORIAL

The Significance of Regulatory Provisions in Achieving Universal Health Coverage (UHC)

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Universal Health Coverage (UHC) means ensuring that all individuals and communities receive the health services they need without suffering financial hardship. Delivery of healthcare services—virtual care, telehealth or telemedicine, and digital health—is enabled through electronic and digital communication technologies.

Achieving this ambitious goal UHC requires more than just funding and infrastructure—it demands strong, transparent, and enforceable regulatory provisions. These play a critical role in shaping quality, equity, efficiency, and accountability in health systems.

On August 11, 2023, India passed the Digital Personal Data Protection Act, 2023 (DPDP Act). This new law governs how personal data is handled in India.

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Regulations aim to protect people's privacy while also establishing a framework for data accountability and governance.

The following objectives are central to safeguarding people's privacy

i) Safeguarding Equity and Access,
ii) Ensuring Quality and Patient Safety,
iii) Financial Protection and Pricing Controls,
iv) Regulation of Health Insurance Schemes,
v) Controlling Commercialization and Overmedicalization,
vi) Protecting Public Health and Pandemic Preparedness,
vii) Enabling Health Workforce Regulation &
viii) Building Trust and Accountability

Regulations for Secure Digital Healthcare

- ***Ayushman Bharat Digital Mission (ABDM)***
  - Aims to establish nationwide digital health infrastructure (such as digital IDs, health records) to enhance accessibility and efficiency across the country. Extension of the ABDM aims to create a seamless online platform for all stakeholders in the healthcare industry, including hospitals, insurance companies and citizens, to interact.
- ***Data Security Council of India (DSCI) Privacy Guide for Healthcare, 2021***
  - Identifies Personal Health Data or Information ("PHI") via multiple channels of data collection and distribution. Aids in visualizing potential scenarios of data breaches and liability under the applicable laws.
- ***Telemedicine Guidelines, 2024***
  - Released by the Ministry of Health and Family Welfare in collaboration with NITI Aayog, it provides a legal framework for remote healthcare services, especially helpful for rural areas. Cues increased the adoption of telemedicine services, thereby broadening the healthcare delivery landscape.
- ***Digital Personal Data Protection Act, 2023***
  - The India Digital Personal Data Protection Act 2023 (DPDPA) is landmark legislation that aims to safeguard the privacy of individuals in the digital age. The Act came into effect on September 1, 2023, and it applies to all organizations that process personal data about individuals in India.
- ***Clinical Establishments Act of 2010***
  - This mandates all State Governments to create and maintain a digital State Register of Clinical Establishments. This register, following the format and including the details specified by the Central Government, will document all clinical establishments within each state.
- ***Health Data Management Policy, 2020***
  - Introduces a consent framework for the collection, storage, processing and sharing of health data, ensuring users maintain control over their data.
- ***Consumer Protection Act, 2019 and Consumer Protection (E-commerce) Rules, 2020***
  - To regulate the marketing, sale and purchase of goods and services online. It also incorporates requirements and other applicable laws for the sale of goods online. It also distinguishes between the responsibilities of the marketplace, inventory entities and sellers.
- ***Information Technology Act, 2000***
  - Mandates implementation of reasonable security practices for Sensitive Personal Data or Information ("SPDI") considered under the Information Technology Act or similar standards approved by the Central government.
- ***The National Medical Commission Act, 2019 & The Indian Medical Council***
  - Regulations, 2002 Applicable to digital health applications involving

the delivery of healthcare by a physician to Indian patients.

Key Drivers of Digital Healthcare Growth in India

- **Evolving customer preferences:** Digital health is driving a revolution, making care convenient, accessible, and tailored. It's a tech-powered shift fueled mostly by a younger, tech-savvy generation, and it's here to stay
- **Building strategic partnerships & collaborations:** To become dominant players in the healthcare landscape, Indian digital healthcare companies are forging strategic partnerships. These alliances enable them to offer a more comprehensive suite of services, enhancing their competitiveness and market penetration.
- **Supportive government policy framework:** Supportive policies like ABDM, telemedicine, etc. are paving the way for a booming digital healthcare industry, making efficient, accessible care a reality for all.
- **Data privacy and security – a paramount need:** Healthcare providers who invest in robust data management and systems might see initial bumps in cost, but they'll win big in the long run. Strong security builds trust, and trust fuels adoption. So, get ready for a healthcare revolution built on patient privacy.
- **Compliance consistency for digital healthcare:** India's digital healthcare landscape is characterized by a dynamic and rapidly evolving regulatory environment.

Driving Sustainable Growth by Anticipating Evolving Customer Expectations

- Today's healthcare consumer is digitally savvy, increasingly relying on online platforms to make informed decisions. Growing awareness of digital tools and wearables, a surge in demand for mental health support and personalized wellness solutions, and an emphasis on inclusivity are reshaping the healthcare landscape. The outlook is promising—within India's digital health market, the Digital Fitness & Wellbeing segment is poised to take center stage.

Teleconsultation, Telemedicine Evolution

- India's telemedicine market is on a rapid growth trajectory, projected to expand from USD 830 million in 2022 to USD 5.5 billion by 2025—an impressive annual growth rate of 31%. Telemedicine is not just gaining ground; it's becoming a cornerstone of India's digital healthcare revolution. This surge is fuelled by increased internet penetration, smartphone usage, expanding rural connectivity, and a regulatory push for digital healthcare delivery. Thus, telemedicine has become a scalable and cost-effective solution to bridge healthcare access gaps across the country.

Delivering Hybrid Customer Experiences that Blend Physical and Digital Touchpoints

- Prioritising a high-quality "phygital" healthcare experience for users. This means seamless care, online and offline,

for a truly integrated healthcare journey. Online consumer feedback, particularly patient reviews and ratings, has become a critical factor influencing healthcare decisions. Numerous studies have highlighted the significance of patient reviews in healthcare decision-making.

International provisions in healthcare & medical data handling

Patient data has become one of the most valuable assets—and one of the most vulnerable. With the increasing digitization of health records, cloud-based platforms, telemedicine, and health apps, the safeguarding of sensitive health information has never been more critical.

Two of the most well-known data privacy frameworks—the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR) in the European Union—have set foundational standards for data protection in healthcare.

The Importance of Medical Data Privacy

In an interconnected global system, data privacy compliance extends beyond these regulations.

Medical data, also referred to as protected health information (PHI) or personal health data, includes a wide range of sensitive information such as:

- Medical histories
- Test results and diagnoses
- Prescriptions and treatment plans
- Genetic and biometric data
- Mental health records
- Insurance and billing details

- Unlike general personal data, health data is particularly sensitive because its exposure can lead to serious consequences, including discrimination, identity theft, emotional distress, and financial fraud.
- Moreover, patient trust is central to effective healthcare. A single data breach can damage a healthcare provider's reputation and compromise the patient-provider relationship.

HIPAA & GDPR status in India

- India does not have a direct equivalent of HIPAA, but it is moving towards a comprehensive data protection law with the Digital Personal Data Protection Act, 2023 (DPDP Act). While the DPDP Act is not yet fully operational, it will regulate the processing of digital personal data within India and in some cases, outside India if it involves offering services in India. GDPR, on the other hand, applies to organizations processing data of EU residents, regardless of where the organization is located.

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ORIGINAL ARTICLE

Efficacy of Video -based Teaching Versus Lecture cum Demonstration Regarding Compression Only Life Support: A Multi-Arm Randomized Control Study

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Abstract

Introduction: In sudden cardiac arrests, early initiation of chest compression by bystanders increases the survival rate by two to three times. Hence training lay population in COLS is imperative. However, due to limited resources, alternate training modes for COLS must be explored. Aim: To evaluate efficacy of video-based teaching compared to traditional lecture-cum-demonstration (LCD) for teaching COLS. **Material & Methods**: A multi-arm parallel-group non-inferiority randomized control study was conducted among 85 first year physiotherapy students. The participants were randomly allocated to three arms. Traditional LCD was control while video song (VS) and video-based LCD (VLCD) were test arms. Post intervention, psychomotor skill gain as well as cognitive assessment was done using objective methods. **Results:** The mean age of the 85 participants was 19.04 years (S.D.= 0.932; Range: 17 to 22). Of these, 63 (74.11%) were females and 22 (25.88%) were males. One way ANOVA for psychomotor assessment showed no statistically significant difference between the 3 groups (F value: 1.918, p = 0.153). One way ANOVA showed that there is no statistically significant difference in knowledge gained among the three groups (F value: 0.056, p = 0.946). **Conclusion:** Skill and knowledge acquisition using VS and VLCD is not as good as LCD.

Keywords: cardiopulmonary resuscitation, COLS, audio-video demonstration, randomized controlled trial, non-inferiority trial, simulation training

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Graphical Abstract

Efficacy of Video -based Teaching Versus Lecture cum Demonstration Regarding Compression Only Life Support: A Multi-Arm Randomized Control Study

Introduction: In sudden cardiac arrests, early initiation of chest compression by bystanders increases the survival rate by two to three times. Hence training lay population in COLS is imperative. However, due to limited resources, alternate training modes for COLS must be explored. Aim: To evaluate efficacy of video-based teaching compared to traditional lecture-cum-demonstration (LCD) for teaching COLS.

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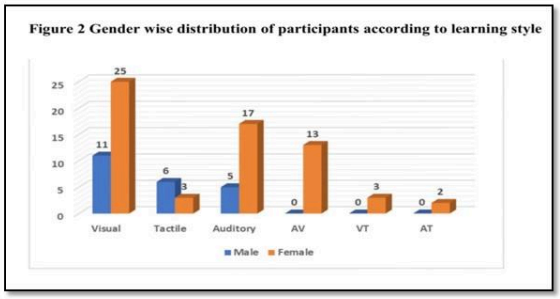

Results: The mean age was 19.04 years. Of these, 63 (74.11%) were females and 22 (25.88%) were males. One way ANOVA showed that there is no statistically significant difference in knowledge gained among the three groups.

Conclusion: Skill and knowledge acquisition using VS and VLCD is worse than LCD.

Introduction

Globally, 15 – 20% of all deaths are caused by sudden cardiac arrest, amounting to nearly half of all cardiovascular deaths [1]. Over the past five years, a steep rise in sudden cardiac deaths has been witnessed in India; experts believe due to COVID-19 pandemic. The salient features of these deaths include accelerated build up, early age of disease onset and high case fatality rate [2]. However, the case fatality rate can be brought down through basic cardio-pulmonary resuscitation (CPR). CPR is a simple yet critical method through which life can be sustained until medical help arrives. After cardiac arrest, there is short window of time before irreversible damage occurs to vital organs. Hence, role of bystanders in providing CPR becomes crucial. Compression only life support (COLS) is the simplest method to administer CPR. Early initiation of chest compressions increases chances of survival by two to three times [3].

Training of laypersons will enable them to administer COLS timely. The COLS training is usually imparted using didactic lectures, lecture cum demonstration (LCD) or simulation-based training [4,5]. However, scarcity of health professionals and manikins; which leads to exorbitant course fees; pose many challenges. In India less than 1-5% of citizens are aware of COLS [4].

Taking into consideration the hurdles with traditional method, it is mandatory to find other suitable alternate method of training which can be easily implemented, available at low cost even in remote areas and is user friendly. Such method should also be helpful to refresh the skill as it decays within months [6].

Solution to this problem can be found in video-based teaching. It is one of the modern and dramatic means for learning

[7,8]. It can reach large audience with minimal cost. Video can be saved on personal devices for self-paced learning and as ready reckoner. Previous studies provide evidence that video-based teaching can improve learning outcomes [9,10]. However, there is dearth of research on whether such method can be utilized for COLS.

Hence, this study was undertaken to find whether video-based training in COLS is as effective as the usually practiced method. Aim of this study is to evaluate efficacy of video-based teaching compared to instructor-based LCD for teaching COLS to lay people. The objectives are 1. To develop video-based training material for teaching COLS. 2. To teach COLS to study participants using video and instructor-based LCD training methods. 3. To evaluate the efficacy of each teaching method. 4. To compare efficacy of video-based teaching with efficacy of instructor-based LCD method. 5. To report feedback of participants and faculty about teaching methods.

Null hypothesis

The gain of psychomotor skill for COLS in test arms is not as good as that in instructor-based LCD arm

Alternate hypothesis

The gain of psychomotor skill for COLS in test arms is as good as in instructor-based LCD arm.

Material and Methods

Study design

Multi-arm parallel-group randomized control study (2 test and 1 control arm). **Research setting:** A tertiary care teaching hospital. **Study area:** Skill Development Unit **Study period**: March to June 2024 **Study population**: Undergraduate students enrolled in first year of bachelor of physiotherapy course. These students were chosen as COLS was not yet taught to them. Hence, these students nearly match untrained lay people. **Inclusion criteria**: 1. Students willing to provide written informed consent to participate in the study 2. Students well versed in English as well as Hindi and Marathi, the languages used as medium of instruction for training. **Exclusion criteria:** Students who have had previous (in school, etc) information/training in COLS or resuscitation. **Sample size:** Calculated using online sample size calculator by Department of quantitative health sciences, Cleveland Clinic. For this, significance level was considered to be 0.05 and power to be 0.8 for non-inferiority trial, dichotomous outcome. Expected proportion in each arm was taken to be 0.5. Sample size came to be 78 (26 in each arm). The investigators included 90 students taking into consideration non response. **Randomization:** All the students meeting inclusion criteria were listed and were assigned a number. Allocation into the 3 arms was done in 1:1:1 ratio using computer generated random sequence.

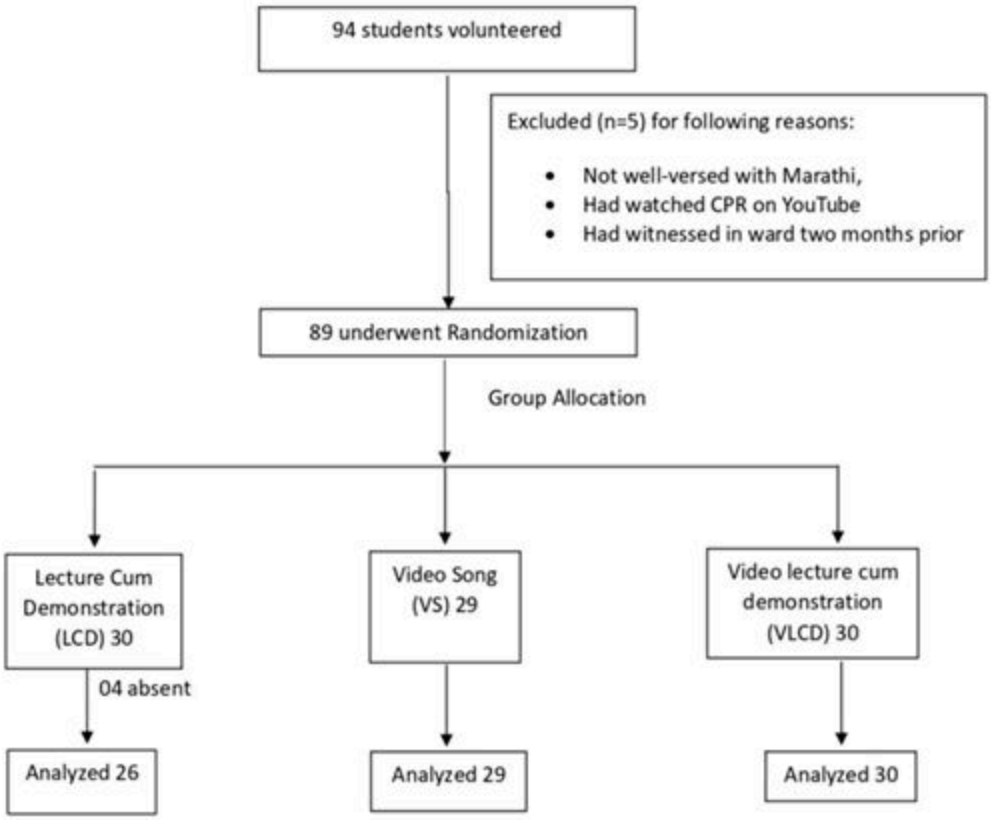

Figure 1. Flow chart depicting randomization process.

After randomization, the learning styles of all participants was evaluated using scale which was developed based on quiz by Pennsylvania Higher Education Assistance Agency (PHEAA) [11]. It was found that all learning styles were equally distributed among the three arms. The three teaching modality interventions were as follows- 1. Video explaining the procedure of COLS with help of visuals and song with music [video song (VS)] [test arm]. The song used is Jeevan Sanjeevani CPR song as per Indian Society of Anaesthesiologists (ISA) and Indian Resuscitation Council (IRC) guidelines and directed by Dr Rajan Joshi. 2. Video explaining the procedure of COLS with help of instructions by qualified COLS trainer followed by enactment and simulation [video lecture cum demonstration (VLCD) [test arm] In case of VLCD, content and enactment were approved by 10 subject experts (IRC/AHA accredited instructors from Skill lab of institute). 3. Instructor based live lecture cum demonstration using simulation manikins (LCD), [control arm]. For live LCD, instructor for training was an accredited faculty of IRC and American Heart Association. Laerdal half body manikin with CPR feedback was used.

The 3 groups of participants were shown the allotted video or demonstration separately in sound proof hall. Duration of all interventions was similar (4 min 15 sec to

4 min 35 sec). The participants who reported that they understood the content in first attempt were asked to wait outside the hall in separate designated areas. Remaining participants were again shown the content. Two such extra chances were given. The number of times content was shown to the participant was recorded. After this, assessment (cognitive and psychomotor) of participants was done by the principal investigator, one by one.

Primary outcome assessed was psychomotor skill gained by the participant. This was done by asking them to perform COLS on a manikin (Laerdal Simpad Plus Q-CPR). A pre-validated binary checklist for assessment of psychomotor skill was used (Annexure A). A score between 0 and 6 was assigned based on their performance. *Secondary outcome* was cognitive assessment of students done with help of pre-validated multiple-choice questionnaire (Annexure B).

Feedback from the participants & investigators was collected regarding quality of training. (Annexure C).

The ethical approval for the study was obtained from the institutional ethics committee (letter no MGM/ECRHS/2024/133; dated 30 March 2024). Formal administrative permission to conduct the study was obtained from the Principal of concerned institute. Written informed consent of students was obtained after explaining purpose of study. Confidentiality was maintained. *Data analysis:* Data was cleaned and entered into Microsoft excel. SPSS version 25 was used for analysis. Quantitative data was presented in form of frequency and percentage. A p value of less than equal to 0.05 was deemed significant. Chi square test was applied to analyze categorical variables. One way ANOVA was applied to test for difference in means of continuous variables across groups. Post hoc test was applied as per requirement.

Observation and Results

There were total 85 participants. The mean age was 19.04 years with standard deviation of 0.932 and range between 17 to 22 years. Of 85 participants, 63 (74.11%) were females and 22 (25.88%) were males.

Table 1. Distribution of Participants According to Baseline Characteristics

Characteristic	Categories	VS (N= 29)	VLCD (N= 30)	LCD (N= 26)	Total (N= 85)	Chi square value, degree of freedom, p value
Age (in years)	17 – 19	19	22	20	61	χ^2= 0.9365, d.f. = 2, p = 0.626
	19 – 22	10	08	06	24	
Gender	Male	05	05	12	22	χ^2= 8.026,

	Female	24	25	14	63	d.f.= 2, p= 0.018
Learning style	Auditory + Tactile	01	01	00	02	χ^2= 4.752, d.f. = 10, p= 0.907
	Auditory + Visual	06	03	04	13	
	Auditory	07	08	07	22	
	Tactile	02	03	04	09	
	Visual + Tactile	01	02	00	03	
	Visual	12	13	11	36	

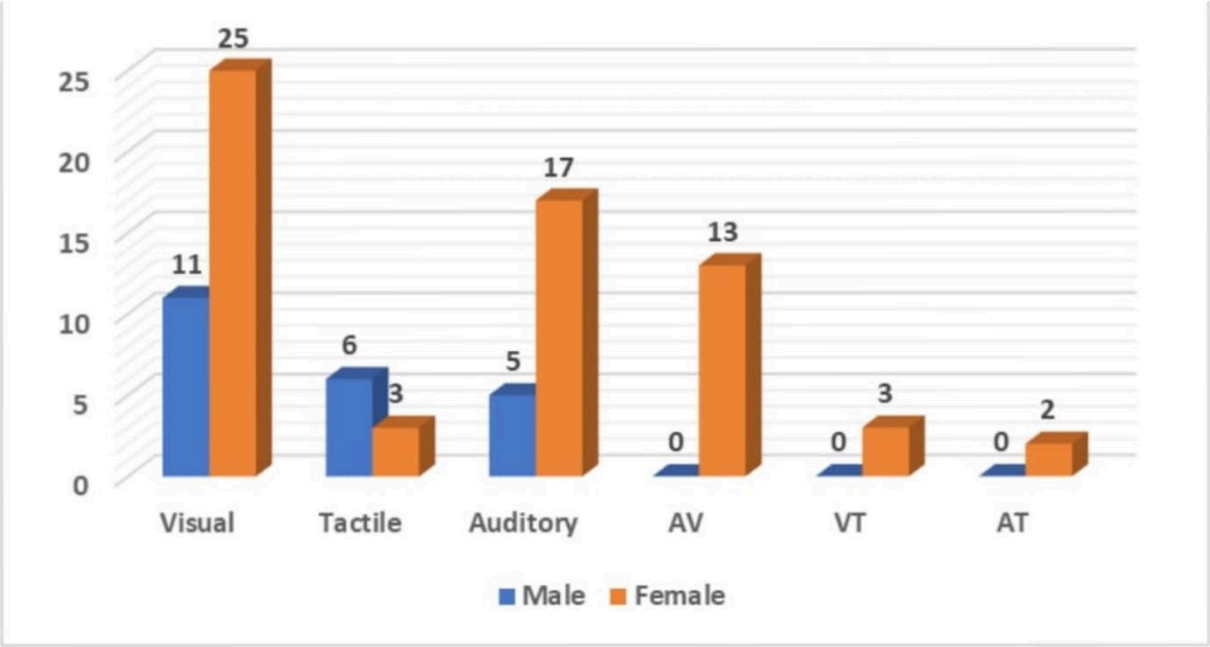

Figure 2. Gender wise distribution of participants according to learning style

Majority of the students reported that they understood the content in first attempt [53 (62.35%)] while remaining reported the same after two attempts [32 (37.64%)]. None of the students required third attempt. For instructor-based group, most of the participants i.e. 16 (61.53%) required two attempts. For video lecture group, 23 (76.66%) students felt confident in the first attempt itself. Similarly, 19 (65.51%) students from video song group felt confident in first attempt.

In the LCD group, one participant scored 0 in psychomotor skill checklist, while 7 (26.92%) students scored 4 or above. Majority [9 (34.61%)] of this group scored 2 points. When tested for knowledge gained, majority i.e. 9 (34.61%) scored 8 points. 2 (7.69%) students scored a perfect score of 10. 25 (96.15%) students scored 7 and above points.

In the VLCD group, only 01 (03.33%) student scored perfect 6 points in psychomotor skill assessment. 11 (36.66%) students scored 4 or above. Majority of this group i.e. 07 (23.33%) students scored 9 points in test for knowledge gained. 3 (10.00%) students scored perfect 10 points. 26 (86.66%) students scored 7 and above points.

For the VS group, none scored perfect 6 while one student scored 0 in psychomotor skill assessment. Only 6 (20.68%) students scored 4 or above. In the test for knowledge gained, majority i.e. 19 (65.51%) scored 8 points. 28 (96.55%) scored 7 or above. 01 (3.44%) student scored perfect 10.

Table 2. Number of participants performing each step in COLS

Name of group	Assessed safety	Assessed response	Called for help	Initiated chest compression	Rate 120/min	Adequate depth
LCD	06	14	12	13	25	12
VLCD	10	25	09	13	08	08
VS	08	16	08	17	21	24

One way ANOVA test was applied to compare means of psychomotor skill gained based on checklist scores among the three groups. The results are shown in table 3.

Table 3. Comparison of psychomotor skill gained in control and test arms

Group	N	Mean	Standard deviation	Standard error	95% Confidence interval for mean		Minimum	Maximum
					Lower bound	Upper bound		
LCD	26	2.69	1.436	0.282	2.11	3.27	0	6
VS	30	3.30	1.088	0.199	2.89	3.71	1	6

VLCD	29	2.79	1.264	0.235	2.31	3.27	0	5
Total	85	2.94	1.276	0.138	2.67	3.22	0	6

	Sum of squares	Df	Mean square	F	P value
Between groups	06.109	2	03.054	1.918	0.153
Within groups	130.597	82	1.593		
Total	136.706	84			

As F value is 1.918 and difference between the 3 groups is not significant (p = 0.153), the post hoc test was not applied.

The one way ANOVA test shows that there is no statistically significant difference between the groups. Hence, null hypothesis i.e. the gain of psychomotor skill for COLS in test arms is worse than in instructor-based simulation arm, is accepted.

The secondary outcome of this study was knowledge gained by the participants. Table 4 shows frequency distribution of right answers in cognitive assessment.

Table 4 shows the comparison of means of knowledge gained scores between the three groups.

Table 4. Comparison of knowledge gained among the control and test arms

Group	N	Mean	Standard deviation	Standard error	95% Confidence interval for mean		Minimum	Maximum
					Lower bound	Upper bound		
IBD	26	7.96	1.113	0.218	7.51	8.41	5	10
VS	30	7.87	1.332	0.243	7.37	8.36	5	10
VL	29	7.93	0.753	0.140	7.64	8.22	6	10
Total	85	7.92	1.082	0.117	7.68	8.15	5	10

	Sum of squares	Df	Mean square	F	P value
Between groups	0.133	2	0.067	0.056	0.946
Within groups	98.290	82	1.199		
Total	98.424	84			

The one way ANOVA shows that there is no statistically significant difference in knowledge gained among the three groups ($p = 0.946$).

Feedback was collected from participants after completion of assessment. All participants in all three groups agreed that content was adequately helpful in understanding COLS as well as that time of training was adequate. Highest number of participants from LCD group reported that they liked the method of training. Participants from VS group remarked that training required very little time. One participant from VLCD felt that site of compression should be communicated more clearly.

Similarly, feedback from investigators was also collected. The following were the main points highlighted by them: 1. Time was less to reinforce important points in LCD. 2. Most of students enjoyed video song when it was played. 3. Skill acquisition practice on manikin and feedback is essential. 4. VLCD and VS can be used after LCD to reinforce and for further practice. 5. Power point should be used in LCD to clarify the technical details.

Discussion

This study was conducted in order to test efficacy of video-based training as against standard instructor-based LCD training for COLS. No statistically significant difference was found among the three groups with respect to both gain in psychomotor skill as well as knowledge. Hence, null hypothesis is accepted.

Many researchers have observed that digital technologies can enhance learning by offering flexibility, self-paced learning as well as luxury of environment of choice [12]. Moreover, videos offer a medium where learner can observe instructor up close, which is difficult in large group setting. Another advantage is that they can view them repeatedly until satisfactory understanding is achieved [12]. All observations recorded in the feedback of present study are comparable.

In this study, it was observed that gain of psychomotor skill was poor irrespective of learning styles across all three groups. However, gain in knowledge

was found to be satisfactory among all participants having different learning styles. Several other studies show that the relationship between learning outcome and medium of instruction for persons with various learning styles is complex [13-16].

Martisorov et al. compared preference and performance among first year pharmacy students using traditional and non-traditional presentation methods. The authors found that students preferred the traditional lecture method over other methods like podcast, escape room and video. Also, students taught with lecture method performed better in examination. The present study also supports the indispensable role of traditional teaching methods [17].

A randomized controlled trial comparing video-based learning and traditional lecture methods for teaching disaster medicine core competencies among resident doctors was conducted by Curtis et al. The authors found that knowledge and comfort score did not show statistically significant difference between the two groups. In practical skills assessment, the difference between groups was found to have statistically significant difference. This is in contrast with the finding of present study [18].

A 2024 study from Korea, reports result of quasi experimental pre and post test study employing video assisted training for advanced cardiac life support (ACLS) among 110 nursing students. The researchers found that supplementary training using simulation videos was an effective method for maintaining and enhancing nurses' ACLS competency, offering a sustainable approach to repetitive CPR training. On the contrary, the present study attempted to test whether video based training can replace instructor based training. If findings of both study are compared, it can be concluded that although video based training cannot replace traditional training methods, it can be used as supplementary training material to refresh knowledge and skill [19].

Similarly, another cluster randomized trial from Uganda reported that adding a video-debriefing to standard training was effective in skill attainment and retention of neonatal resuscitation among birth attendants. This study also supports the view that videos can act as supplementary training material [20]. An important finding of present study is that majority of the students in video-based training groups felt confident about providing COLS in the first attempt itself. It might be due to greater audio-visual appeal of videos. Ronny Lehmann et al also found similar results for pediatric basic life support training [21].

Kerketta et al. conducted COLS training for 300 non-medical staff and found that lecture along with audio-visual display, demonstration and hands on training were effective [22]. Present study findings also suggest that multiple methods need to be employed in training lay persons regarding COLS.

Waffa (2017) conducted a study among nursing students to investigate the effect of using simulation-based blood pressure measurement on practice competency. Simulation by video, demonstration method, simulation by video & demonstration were the three methods

used. It was concluded that demonstration is the best method for teaching the skill of blood pressure measurement and that simulation by video is not enough alone [23]. This is similar to the conclusion of present study.

There are some advantages of LCD method like it utilizes several senses where learners experience an actual event, better stimulation of learner's interest, teacher can adjust the pace along with voice modulations based on real time observation of learner engagement and understanding. Personal presence of teacher makes the session more engaging through eye contact. On the other hand, engagement with videos may wane as learner passively consumes the content, offering limited depth.

Conclusion

The study found that psychomotor skill gain ($F = 1.918$, $p = 0.153$) as well as knowledge gain ($F = 0.056$, $p = 0.946$) did not show statistically significant difference across the three groups. Thus, non-inferiority is not demonstrated. Hence, it is concluded that skill and knowledge acquisition using video song with music and video explaining the procedure of COLS with help of enactment, simulation and instructions is not as good as than that using instructor based simulation.

Strength of study

It is a randomized controlled trial conducted among physiotherapy students who had never been exposed to COLS before, thus chances of bias are reduced significantly. It is unique in testing video song featuring COLS as well as video with simulation and instructions. The assessment of outcome is objective based on score.

Limitations

The study population does not accurately represent general population. Hence, the results cannot be generalised.

Implications

The study implies that video assisted training cannot replace the traditional instructor-based training. There is need to focus on capacity building of institutes imparting COLS training. Further research needs to be conducted among general lay population to see whether technology based training modes are useful for teaching COLS. Another aspect that needs exploration is whether such modes can act as refresher after COLS training by traditional method.

Recommendations

Future studies exploring role of videos as supplementary material along with traditional method in training of COLS need to be conducted. A follow up after 3 and 6 months can be done to study the usefulness of videos in retention of skill and knowledge.

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Ethical Approval

The ethical approval for the study was obtained from the institutional ethics committee (letter no MGM/ECRHS/2024/133; dated 30 March 2024).

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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Annexures

Annexure A

Checklist for Compression only life support psychomotor skill assessment

Sr. No.	Checklist	Did not perform 0 mark	Performs 1 mark
1	Assess safety		
2	Assess Response		
3	Calls 108		
4	Chest Compression- Centre of Chest		
5	Rate 100-120per min		
6	Position of Hands (Fingers interlaced, hands straight)		

Annexure B

List of multiple choice questions used for cognitive assessment

Sr no	Question	Yes	No	Not sure
1	I can recognize person who needs resuscitation			
2	I will confirm consciousness by sprinkling water on face			
3	Before starting resuscitation, I will confirm scene safety			
4	Site of chest compression is on left side of chest			
5	Compress chest for at least 5 cm			
6	Chest compression rate should be 1/sec			
7	I will stop compressions if I observe any movement of patient			
8	Single hand should be used for chest compressions for adult patient			
9	Training received today is useful to every one			
10	Emergency ambulance number is			

Annexure C

Feedback form for participants

Sr. No.	**Question**	**Adequate**	**Inadequate**	**Can't Tell**
1.	Content was			
2.	Time allotted for training was			
3.	Understanding of the contents			
4.	What did I like in today's training?			
5.	What was deficient in today's training?			

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ORIGINAL ARTICLE

A comparative study of Minimally Invasive Procedure for Hemorrhoids (MIPH) with Open Hemorrhoidectomy (Milligan-Morgan Hemorrhoidectomy)

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Abstract
Background: Hemorrhoidal disease, characterized by the enlargement and displacement of anal cushions, presents significant discomfort including pain, bleeding, and prolapse. The surgical treatment for advanced hemorrhoids (Grade III-IV) traditionally involved Open hemorrhoidectomy (Milligan-Morgan Hemorrhoidectomy), which is effective but associated with considerable postoperative pain and prolonged recovery. Minimally Invasive Procedure for Hemorrhoids (MIPH), introduced by Dr. Antonio Longo, offers a less painful alternative with faster recovery. This study compares the outcomes of MIPH and Open Hemorrhoidectomy by assessing duration of surgery, post operative pain, post operative bleeding, hospital stay, wound healing, return to work, and recurrence of hemorrhoids. **Methods:** This prospective study, conducted from August 2022 to July 2024, randomized 60 patients with Grade III and IV hemorrhoids into two groups: 30 undergoing MIPH and 30 undergoing Open Hemorrhoidectomy. Outcomes were evaluated using standardized tools and statistical analysis with a P-value <0.05 considered significant. **Results:** MIPH patients had significantly shorter operative times (23.83 ± 2.84 minutes vs 28.33 ± 2.73 minutes, $P<0.001$), less postoperative pain on Day 1 (VAS score 2.80 ± 1.34 vs 5.10 ± 1.15, $P<0.001$), and shorter hospital stays (1.40 ± 0.56 days vs 1.90 ± 0.76 days, $P<0.01$). Wound healing time was significantly faster in the MIPH group (6.40 ± 1.61 days vs 21.47 ± 4.48 days, $P<0.001$). Return to work was also quicker for MIPH patients (7.83 ± 2.48 days vs 17.70 ± 7.27 days, $P<0.001$). Both procedures had comparable rates of post-operative bleeding, recurrence, and residual prolapse, with no significant differences in anal stenosis or incontinence. **Conclusions:** MIPH is a superior alternative to Open Hemorrhoidectomy, offering reduced pain, shorter operative time, faster recovery, quicker return to work and similar safety outcomes. MIPH should be considered a preferred option for patients requiring surgical hemorrhoid treatment.
Keywords: Hemorrhoids, Minimally invasive procedure for Hemorrhoids (MIPH); Open hemorrhoidectomy (Milligan – Morgan hemorrhoidectomy), Longo's stapled hemorrhoidopexy

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Introduction

Hemorrhoids are a very common anorectal condition defined as the symptomatic enlargement and distal displacement of the normal anal cushions. Haemorrhoids are known as one of the most prevalent and oldest diseases [1]. Haemorrhoids mainly occur because of chronic constipation. Haemorrhoids can also happen secondarily because of pregnancy, carcinoma of rectum, tumours of uterine origin, problem during micturition because of presence of enlarged prostate or strictures, and portal hypertension [2].

Hemorrhoids are categorized into external, internal, and mixed types. Internal hemorrhoids occur above the dentate line and are covered by mucous membranes, while external hemorrhoids are located below the dentate line and are covered by skin. Internal hemorrhoids are further classified into four grades based on their degree of prolapse, following Goligher's classification. This classification system is essential in guiding treatment decisions. The third classification type evaluate haemorrhoids on the basis of their anatomical position, where 3, 7 and 11 o'clock are referred as primary haemorrhoids, whereas the areas between them are secondary [3,4]. Hemorrhoids show different presentations clinically like pain, bleeding, itching, mucus discharge, and something projecting out of the rectum. The patient generally reports the dripping of blood in the toilet, mainly bright red in colour [5]. Conservative treatment, including lifestyle and dietary modifications, is typically recommended for Grade I and early Grade II hemorrhoids. Medications such as laxatives, stool softeners, calcium dobesilate, and oral flavonoids are commonly prescribed to alleviate symptoms [6]. When conservative treatment is insufficient, or in cases of more advanced hemorrhoids (Grades 3-4), surgical interventions become necessary. The most commonly performed surgical treatment is hemorrhoidectomy, with the Milligan-Morgan open hemorrhoidectomy, being the traditional technique. However, this procedure is associated with significant postoperative pain, longer recovery periods, and increased postoperative complications. Other surgical options include Ferguson's closed hemorrhoidectomy and newer, minimally invasive procedures like Stapled Hemorrhoidopexy, also known as Minimally Invasive Procedure for Hemorrhoids (MIPH) [7,8,9]. Stapled hemorrhoidopexy offers a minimally invasive alternative to traditional methods, with reduced pain and faster recovery [9]. Stapled hemorrhoidopexy, introduced by Dr. Antonio Longo in 1998, has become a popular alternative for managing prolapsing Grade III and IV hemorrhoids. By avoiding surgical intervention below the dentate line, this technique significantly reduces postoperative pain and shortens recovery time. Stapled hemorrhoidopexy is associated with fewer complications, a lower recurrence rate, and a faster return to normal activities compared to traditional hemorrhoidectomy [10,11]. This study aims to compare the outcomes of the Minimally Invasive Procedure for Hemorrhoids (MIPH) with Open Hemorrhoidectomy (Milligan-Morgan Hemorrhoidectomy).

Material and Methods

Type of Study

Prospective Randomised Study

Inclusion criteria

Grade 3 hemorrhoids

Grade 4 hemorrhoids

Exclusion criteria

Grade 1 & grade 2 hemorrhoids

Thrombosed & strangulated haemorrhoids

Prior hemorrhoidectomy

Intercurrent anal pathology (example: fistula in ano, anal fissure)

Patient's refusal

Patients' information

The study was conducted at Department of Surgery, Jawaharlal Nehru Medical College, Aligarh Muslim University, Uttar Pradesh, India, between August 2022 and July 2024 over a 24 months period. Ethical approval was obtained from the Institutional Ethical Committee before the commencement of the study, and informed and written consent was taken from all patients prior to surgery. The study aimed to assess the outcomes of two surgical techniques for hemorrhoids: Milligan-Morgan Open Hemorrhoidectomy and Minimally Invasive Procedure for Hemorrhoids (MIPH). This prospective study included 60 patients who were randomly assigned into two groups using the envelope method, with 30 patients in each group.

Prior to surgery, each patient underwent a thorough clinical evaluation, including history-taking, physical examination, and proctoscopy. Blood investigations were conducted to assess fitness for spinal anesthesia. Rectal enema was administered the night before the surgery. Both the surgical techniques were performed with the patient in the lithotomy position under spinal anesthesia. Following surgery, patients were monitored in the ward and given intravenous fluids. Oral feeds were introduced postoperatively, and pain was assessed using the Visual Analogue Scale (VAS) at day 0 and day 1 post operatively. The patients were evaluated for complications such as post-operative bleeding and infection. If no complications were observed, patients were discharged within 1-2 days. In the event of complications, the hospital stay was extended, and appropriate treatment was administered. Follow-up visits were scheduled after one week, and additional follow-up was done through outpatient visits or phone calls. Patients were instructed to report any complications immediately.

The study's key outcomes include operative time, postoperative pain, post operative bleeding, duration of hospital stay, duration of wound healing and return to work. Operative time was recorded from the start of the anal canal inspection to the completion of the procedure, including packing the anal canal with gauze.

Statistical analysis

Data were collected in Microsoft Excel and analyzed using SPSS software (Version 25.0). Categorical variables were presented as numbers and percentages, while continuous variables were reported as means and standard deviations. The chi-square test was used to compare categorical data, and an unpaired t-test was applied for continuous variables. A p-value <0.05 was considered statistically significant.

Results

The study compared MIPH and Open Hemorrhoidectomy procedures, showing that MIPH had a higher

percentage of Grade 3 hemorrhoids (83.3%) compared to Open Hemorrhoidectomy (66.7%), while Grade 4 hemorrhoids were more prevalent in the Open Hemorrhoidectomy group (33.3%) than in the MIPH group (16.7%), with no significant difference in gender distribution (P>0.05). However, age distribution was significant (P<0.01), with younger patients (<25 years) predominantly undergoing MIPH, while older patients (>50 years) were more likely to have Open Hemorrhoidectomy (33.3%). The overall findings suggest age significantly influenced the choice of procedure (Table 1).

Table 1: Comparison of operative time between the two surgery procedures

S.No.	Procedure	Duration of Surgery (Minute)	t- Value	P- Value
		Mean ± SD		
1	MIPH	23.83 ± 2.84	-6.251	P < 0.001
2	Open Hemorrhoidectomy	28.33 ± 2.73		
3	Total	26.08 ± 3.58		

Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids

The mean operative time for MIPH was 23.83 ±2.84 minutes, while for Open Hemorrhoidectomy, it was 28.33 ± 2.73 minutes. A t-value of -6.251 and a P-value of P<0.001 demonstrate a statistically highly significant difference, indicating that MIPH is faster (Table 2).

Table 2: Comparison of post – operative pain in Day 0 and Day 1 in different surgery procedures using VAS (Visual Analog Scale)

S.No.	Procedure	Day 0 Post Operative Pain (VAS)	Day 1 Post Operative Pain (VAS)
		Mean ± SD	Mean ± SD
1	MIPH	4.70 ± 1.36	2.80 ± 1.34
2	Open Hemorrhoidectomy	7.00 ± 1.36	5.10 ± 1.15
3	Total	5.85 ± 1.78	3.95 ± 1.70
4	t- Value	-6.519	-7.092
5	P- Value	P < 0.001	P < 0.001

(Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids, VAS = Visual Analog Scale)

On the day of surgery (Day 0), MIPH patients experienced a mean pain score of 4.70 ± 1.36, significantly lower than Open Hemorrhoidectomy at 7.00 ± 1.36, indicated by a t-value of -6.519 and P-value < 0.001. On Day 1, MIPH pain averaged 2.80 ± 1.34, compared to 5.10 ± 1.15 for Open Hemorrhoidectomy, with a t-value of -7.092 and P-value <0.001, reinforcing the less painful nature of MIPH (Table 3).

Table 3. Comparison of post operative bleeding in different surgery procedures

S.No.	Post Operative Bleeding	Procedure						Ch^2-Value	P-Value
		MIPH		Open Hemorrhoidectomy		Total			
		No. of Cases	(%)	No. of Cases	(%)	No. of Cases	(%)		
1	Present	3	10.0%	4	13.3 %	7	11.7 %	0.162	P > 0.05
2	Absent	27	90.0%	26	86.7 %	53	88.3 %		
3	Total	30	100.0 %	30	100.0 %	60	100. 0%		

(Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids)

Table 3 shows 10.0% of MIPH patients and 13.3% of Open Hemorrhoidectomy patients experienced post-operative bleeding, with a Chi-square value of 0.162 and a P-value > 0.05. This indicates no significant difference in the incidence of bleeding between the two procedures, suggesting that both carry similar risks for post-operative bleeding (Table 4).

Table 4. Comparison of duration of Hospital stay (days) in two study groups

S.No.	Procedure	Duartion of Hospital Stay (Days)	t- Value	P- Value
		Mean ± SD		
1	MIPH	1.40 ± 0.56	-2.898	P < 0.01
2	Open Hemorrhoidectomy	1.90 ± 0.76		
3	Total	1.65 ± 0.71		

(Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids)

Table 4 indicates that the average hospital stay for MIPH patients is 1.40 ± 0.56 days, shorter than the 1.90 ± 0.76 days for Open Hemorrhoidectomy patients. A t-value of -2.898 and a P-value < 0.01 demonstrate a significant difference, suggesting that MIPH results in a shorter hospital stay compared to Open Hemorrhoidectomy (Table 5).

Table 5. Comparison of duration of wound healing (Days) in two study groups

S.No.	Procedure	Duration of Wound Healing (Days)	t-Value	P- Value
		Mean ± SD		
1	MIPH	6.40 ± 1.61	-17.342	P < 0.001
2	Open Hemorrhoidectomy	21.47 ± 4.48		
3	Total	13.93 ± 8.30		

(Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids)

The comparison of wound healing duration between MIPH and Open Hemorrhoidectomy shows MIPH patients had a mean healing time of 6.40 ± 1.61 days, while Open Hemorrhoidectomy patients averaged 21.47 ± 4.48 days. The t-value of -17.342 and P-value of P<0.001 indicate a highly significant difference, confirming that wounds from MIPH heal much faster than those from Open Hemorrhoidectomy (Table 6).

Table 6. Comparison of duration of Return to Work (Days) in two study groups

S.No.	Procedure	Duration of Return to Work (Days)	t- Value	P- Value
		Mean ± SD		
1	MIPH	7.83 ± 2.48	-7.037	P < 0.001
2	Open Hemorrhoidectomy	17.70 ± 7.27		
3	Total	12.77 ± 7.33		

(Abbreviation: MIPH = Minimally Invasive Procedure for Hemorrhoids)

Table 6 compares the time taken to return to work post-surgery. MIPH patients returned to work in an average of 7.83 ± 2.48 days, while Open Hemorrhoidectomy patients took 17.70 ± 7.27 days. The t-value of -7.037 and P-value of P<0.001 indicate a highly significant difference, showing that MIPH patients resume normal activities much earlier than those who undergo Open Hemorrhoidectomy.

Discussion

Stapled hemorrhoidopexy, also known as minimally invasive procedure for hemorrhoids (MIPH), introduced by Dr. Antonio Longo, has become a popular alternative for managing prolapsing Grade III and IV hemorrhoids due to the technique's fewer complications, lower recurrence rate, and a faster return to normal activities as compared to traditional hemorrhoidectomy.

This present study aligns with those of Gupta S et al. (2019) and Symeonidis D et al. (2022), showing a higher prevalence of Grade 3 hemorrhoids in MIPH patients (83.3%) compared to Open Hemorrhoidectomy (66.7%), likely due to MIPH's less invasive nature, while Grade 4 hemorrhoids were seen more in Open Hemorrhoidectomy (33.3%) than MIPH (16.7%) [2,12]. The mean duration of surgery was significantly shorter for MIPH (23.83 ±2.84 minutes) compared to Open Hemorrhoidectomy (28.33 ± 2.73 minutes) (P<0.001). Studies by Symeonidis D et al. (2022) and Singh DK et al. (2023), reported similar finding for both procedures, highlighting MIPH's faster operative time and potential benefits for reducing anesthesia-related risks [12,13]. MIPH patients reported significantly less post-operative pain than Open Hemorrhoidectomy patients in this study. On Day 0, the mean pain score using VAS (Visual Analog Scale) for MIPH was 4.70 ± 1.36, compared to 7.00 ± 1.36 for Open Hemorrhoidectomy (P<0.001), supported by Gupta S et al. (2019) and Symeonidis D et al. (2022) [2,15]. On Day 1, MIPH patients had a mean score of 2.80 ± 1.34 versus 5.10 ± 1.15 for Open Hemorrhoidectomy (P<0.001), supported by Gupta S et al. (2019) and Singh DK et al. (2023) [2,13].

This study shows no significant difference in post-operative bleeding

between MIPH (10.0%) and Open Hemorrhoidectomy (13.3%), with a Chi-square value of 0.162 and P-value > 0.05, indicating similar risks. Comparable bleeding rates between the two procedures was reported by Singh DK et al. (2023) and Sharma B et al. (2018), suggesting that MIPH may have a slightly lower, though not statistically significant, bleeding risk [13,14]. Our findings show that MIPH patients had a significantly shorter hospital stay (1.40 ± 0.56 days) compared to Open Hemorrhoidectomy patients (1.90 ± 0.76 days), with a t-value of -2.898 and P-value < 0.01. This aligns with studies by Gupta S et al. (2019) reporting shorter hospital stays for MIPH. The reduced stay could lower healthcare costs and minimize the risk of hospital-acquired infections [2]. MIPH patients had significantly faster wound healing (6.40 ± 1.61 days) compared to Open Hemorrhoidectomy patients (21.47 ± 4.48 days), with a t-value of -17.342 and P < 0.001. This corresponds with Gupta S et al. (2019) and Singh DK et al. (2023), all reporting faster healing times for MIPH. The quicker healing in MIPH may be due to anal mucosa preservation and improved tissue approximation from staples [2,13]. MIPH patients returned to work significantly sooner (7.83 ± 2.48 days) compared to Open Hemorrhoidectomy patients (17.70 ± 7.27 days), with P<0.001, supported by Gupta et al. (2019) and Singh et al. (2023) [2,13]. There was no incidence of incontinence and anal or rectal stenosis at 3 months post-operatively for both MIPH and Open Hemorrhoidectomy, consistent with Singh DK et al. (2023) and Sharma et al. [13,14]. Regarding recurrence, MIPH had 0% recurrence, while Open Hemorrhoidectomy had 3.3%, with no significant difference (P=0.313). Similar trends were reported by Gupta S et al. (2019), suggesting MIPH may have a lower recurrence rate due to precise suture placement [2].

Conclusion

The study highlights several advantages of the Minimally Invasive Procedure for Hemorrhoids (MIPH) over the traditional Open Hemorrhoidectomy (Milligan-Morgan Hemorrhoidectomy). MIPH was associated with a shorter operative time, less post-operative pain, quicker wound healing, shorter hospital stays, and a faster return to work, making it a highly favourable option for patients. Importantly, both procedures yielded comparable results in terms of post-operative complications, including bleeding, residual prolapse, incontinence, recurrence, and anal or rectal stenosis.

MIPH, therefore, emerges as a superior alternative to Open Hemorrhoidectomy, especially for treating grade III and IV hemorrhoids. Its minimally invasive nature leads to significantly improved patient recovery and a more favourable post-operative experience. Notably, the absence of serious complications, such as incontinence and anal stenosis, further supports the use of MIPH as a preferred surgical option. These findings suggest that MIPH should be considered the procedure of choice for patients requiring surgical intervention for hemorrhoids. Overall, MIPH offers a less invasive approach with better outcomes, enhancing patient's quality of care and recovery.

Ethical Approval

The study was conducted after approval from institutional ethical committee.

Conflicts of interest

The authors declare that they do not have conflict of interest.

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ORIGINAL ARTICLE

Urokinase in Hypertensive Capsuloganglionic Hemorrhage with Intraventricular Hemorrhage: A Randomized Control Trial

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Abstract

Background: Capsuloganglionic hemorrhage with intraventricular hemorrhage (IVH) is always associated with higher mortality and morbidity [12]. So, we did a randomized control trail in patients requiring External ventricular Drain (EVD) for hypertensive IVH with and without instilling Urokinase; to know it's effectiveness [19]. **Methods**: A computerized randomized controlled trial was carried out on 30 patients who needed EVD for hypertensive capsuloganglionic hemorrhage with IVH. Patients were randomly assigned to one of two groups: test (EVD + urokinase) or control (EVD only). Graeb scores, Glasgow Outcome Scale (GOS), ICU stay, GCS, and complications were compared before and after treatment. **Results**: The EVD + urokinase group had better functional outcomes, a shorter ICU stay (5.8 vs. 7.8 days, p=0.044), and a much larger drop in Graeb scores (p<0.001). There was no increased risk of infection or rebleeding. **Conclusion**: In Hypertensive Capsuloganglionic Hemorrhage with IVH, intraventricular fibrinolysis with urokinase is a safe and effective to improve the outcome of the patient.

Keywords: IVH, Gareb score, Urokinase fibrinolysis, Capsuloganglionic ICH with IVH

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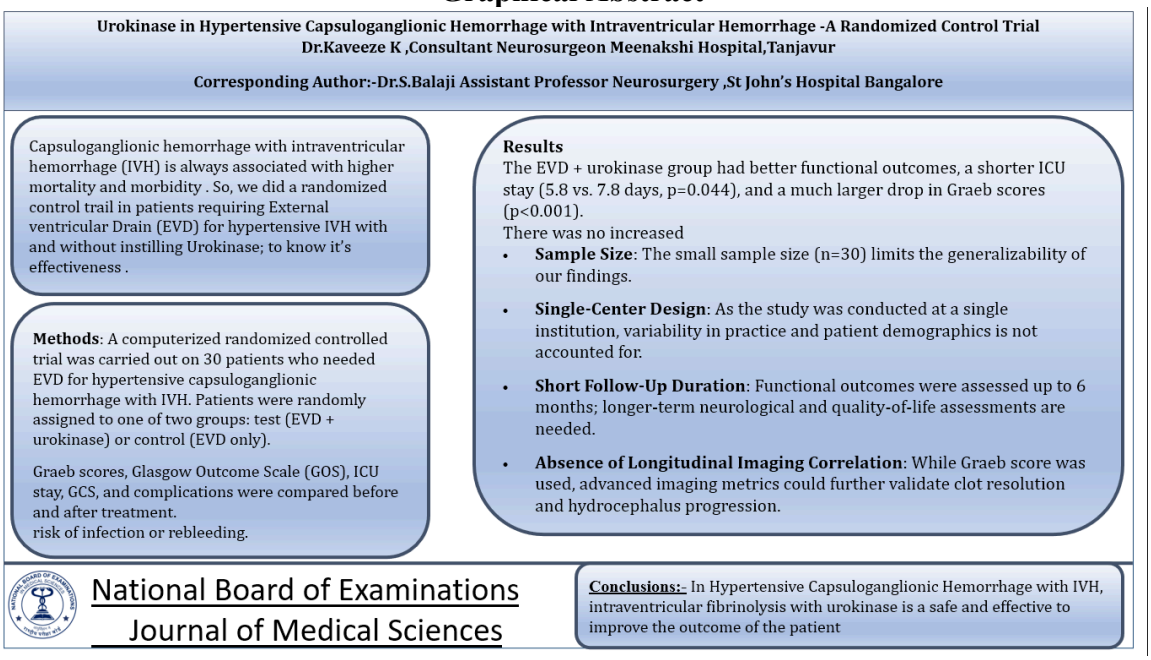
Graphical Abstract



Introduction

The term "hypertensive capsuloganglionic hemorrhage with intraventricular hemorrhage" (IVH) describes bleeding into the intra ventricular system of the brain, due to subarachnoid or intra parenchymal hemorrhage [2,3]. It gives rise to grave prognosis due to increase in intra cranial pressure and development of hydrocephalus [4,5], due to catheter blockage and need of aseptic precaution patients with EVD usually kept in Neuro Critical Care ICU [6,7].

Urokinase helps in prevention of catheter blockage and helps in faster clearance of IVH[10,11]. The usefulness of EVD alone and EVD plus urokinase-assisted intraventricular fibrinolysis in patients with hypertensive capsuloganglionic hemorrhage with IVH is studied in this article [19,20].

Materials and Methods

At Meenakshi Mission Hospital, a computerized randomized controlled trial was carried out on 30 patients who needed EVD for hypertensive capsuloganglionic hemorrhage with IVH. Patients were randomly assigned to one of two groups: test (EVD + urokinase) or control (EVD only).

Inclusion criteria encompassed adults aged 18–70 years with Hypertensive Capsuloganglionic Hemorrhage with IVH.

Exclusion criteria included traumatic IVH[21], vascular malformations, pregnancy, and delayed presentation (>48 hours).

Urokinase was administered intraventricularly at a dose of 10,000 IU every 12 hours for 5 days. Graeb scores [1], GCS, ICU stay, GOS, and complications were analyzed (Figure 1).

Results

Significant reduction in post-operative Graeb scores was observed in the urokinase group compared to the control group (mean 2.47 vs 6.6; $p<0.001$) (Figs 1 and 2).

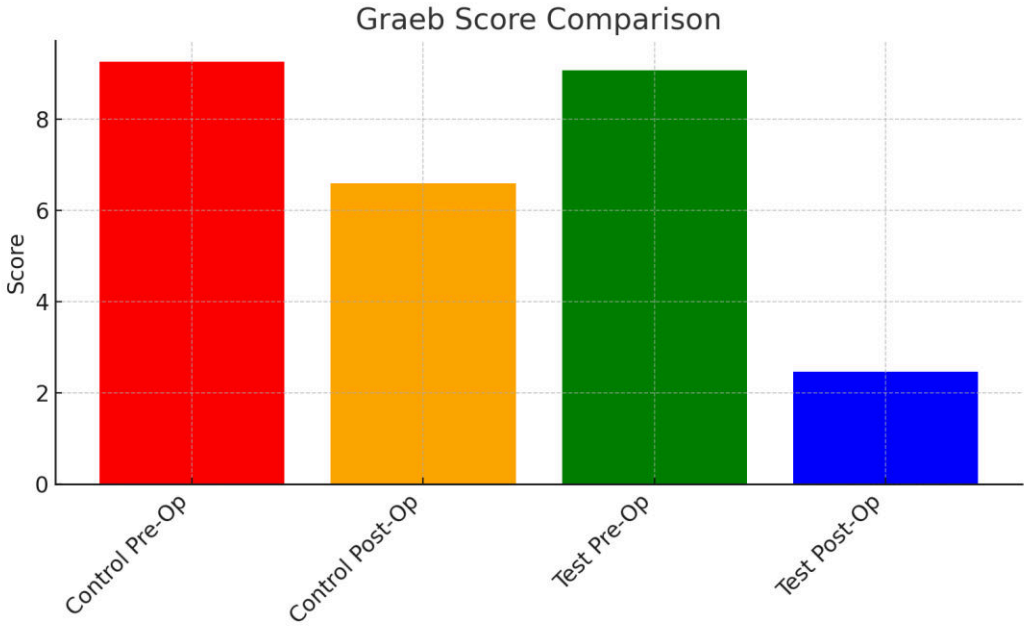


Figure 1. Graeb Score Comparison

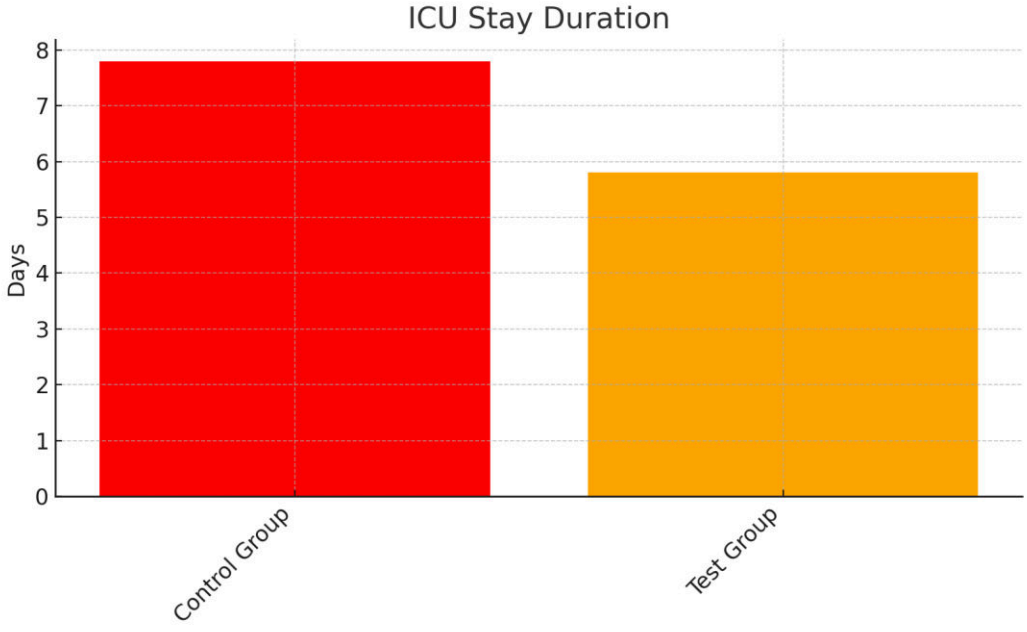


Figure 2. ICU Stay Duration

Patients in the urokinase group had significantly shorter ICU stays than those in the control group (5.8 vs 7.8 days; p=0.044) [14,26] (Figure 3).

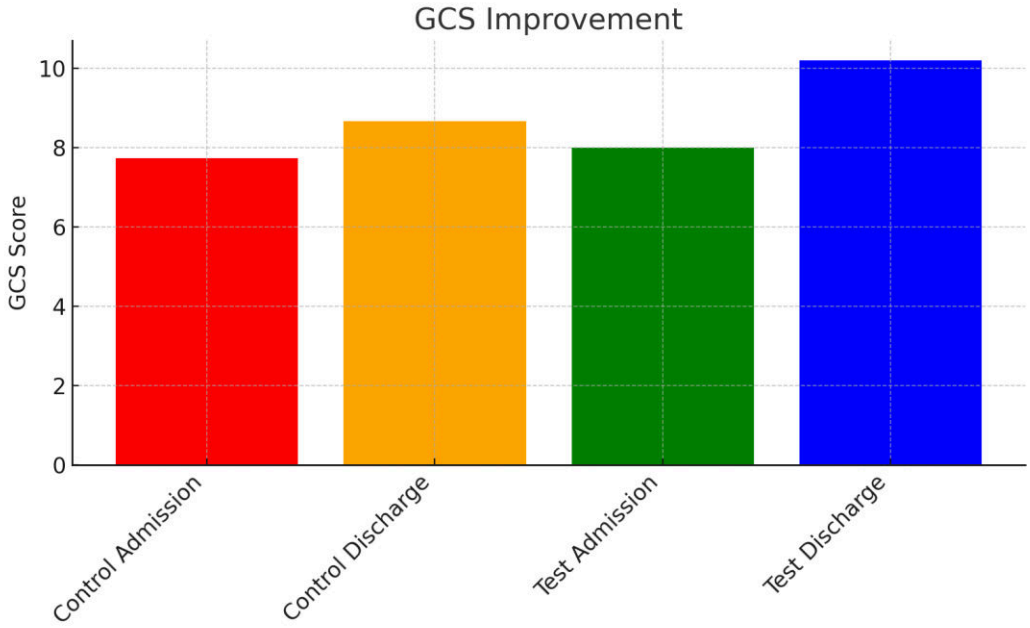


Figure 3. GCS Improvement

Both groups showed GCS improvement at discharge, with a higher mean GCS in the urokinase group (10.2 vs 8.7), though not statistically significant [24,25] (Figure 4).

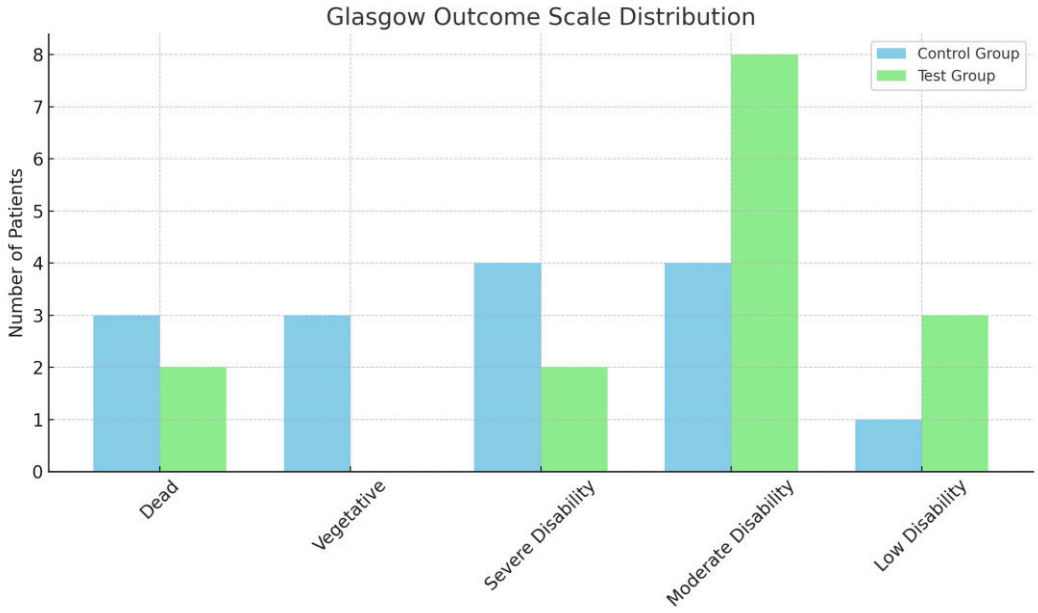


Figure 4. Glasgow Outcome Scale Distribution

The urokinase group had more patients with favorable outcomes (moderate to low disability), while the control group had higher mortality and vegetative states [13,15,27].

Discussion

This prospective comparative study supports the growing evidence that intraventricular fibrinolysis (IVF) using urokinase can significantly improve outcomes in patients with Hypertensive Capsuloganglionic Hemorrhage with intraventricular hemorrhage (IVH). Despite equivalent baseline characteristics between groups, the test group (EVD + urokinase) showed a greater reduction in ventricular blood burden (Graeb score), shorter ICU stay, and a trend toward improved GCS scores and GOS at discharge. These findings are in agreement with prior studies suggesting that timely clot removal can reduce secondary injury from hemoglobin breakdown products, inflammation, and elevated intracranial pressure (ICP) [8,9] (Figure 5 and 6) (Table 1).

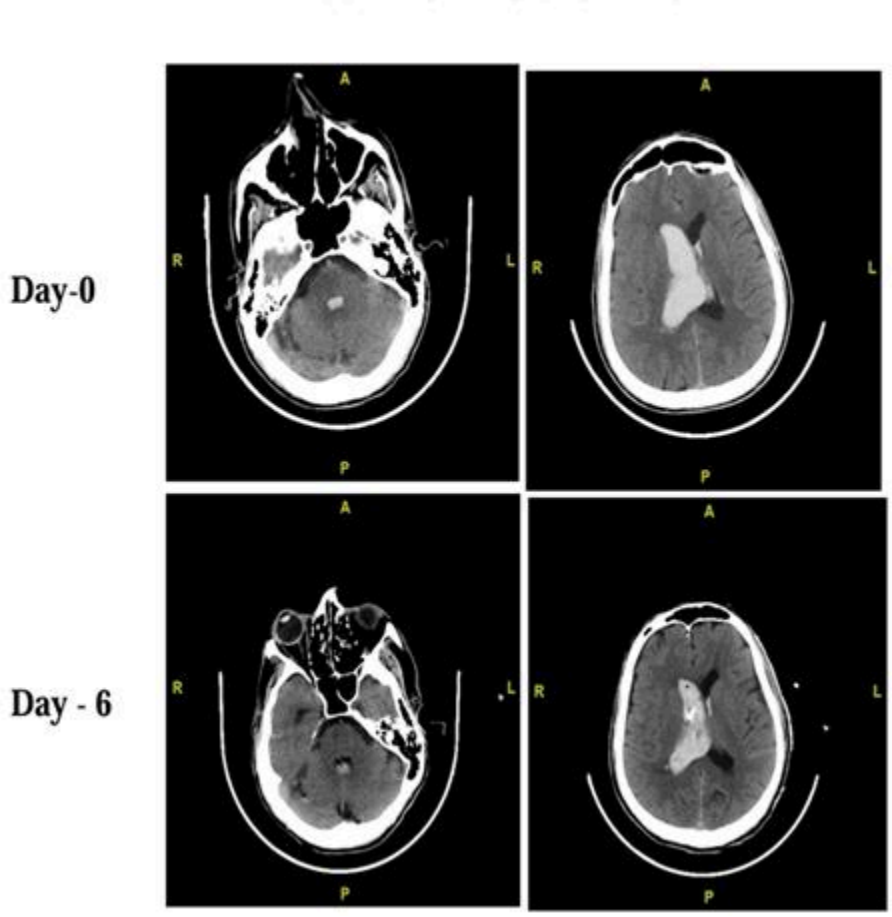


Figure 5. Non contrast CT of Primary IVH which was treated with EVD alone and the grab et al. score remains the same -7 even after 6 days of EVD

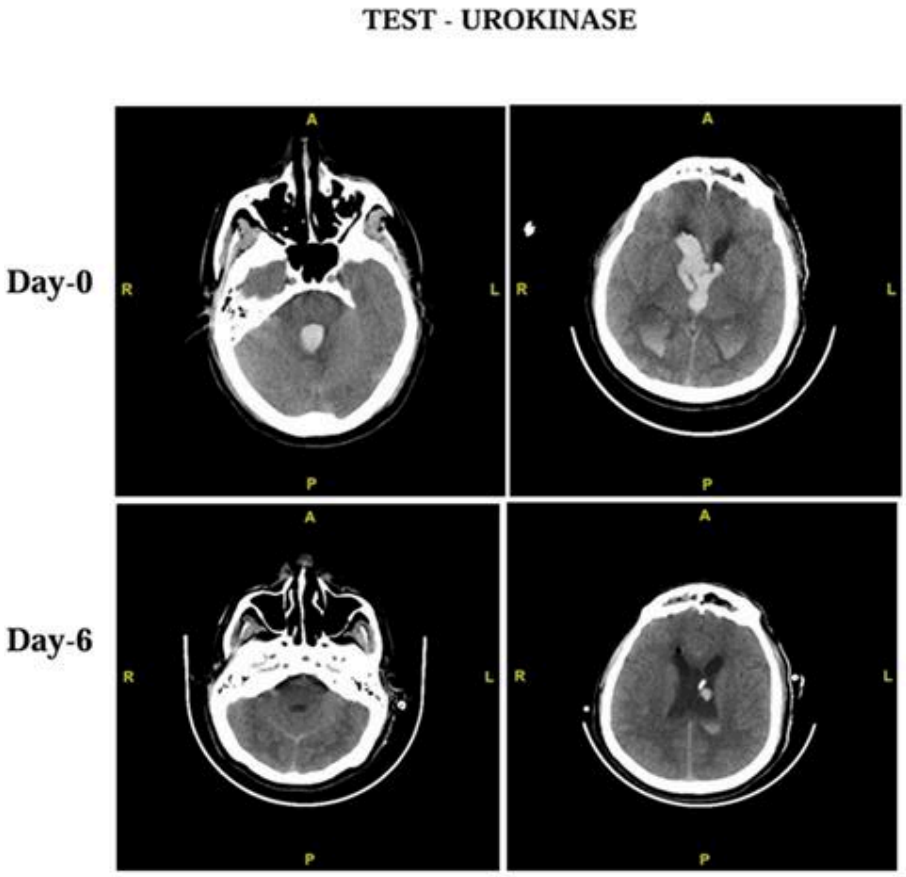


Figure 6. Non contrast CT of Primary IVH which was treated with EVD and intra ventricular fibrinolysis using urokinase and gareb et al. score pre operatively and post operatively are 11 and 2, respectively

Table 1. Intraventricular Haemorrhage Scoring

Localization	Number of points
Lateral ventricles (each ventricle was counted separately)	0 – no blood
	1 – traces of blood or minor hemorrhage
	2 – less than half of the ventricle is filled with blood
	3 – more than half of the ventricle is filled with blood
	4 – the ventricle is filled and stretched with blood
The third and the fourth ventricles	0 – no blood
	1 – the presence of blood, the ventricle is not enlarged
	2 – the ventricle is filled and stretched with blood
Number of points	0 - 12

Tuhrim et al. and Young et al. have previously emphasized the prognostic importance of intraventricular clot volume in the context of intracerebral hemorrhage. Our results affirm their findings and highlight that intraventricular administration of urokinase leads to a more substantial reduction in clot volume compared to EVD alone. Importantly, no increase in rebleeding or infections was observed, echoing findings by Coplin et al. on the safety of urokinase in this setting [16,17,18].

The increased incidence of shunt dependence in the urokinase group, although unexpected, may be linked to faster clot resolution leading to earlier assessment and decision for permanent CSF diversion. This observation warrants further investigation in larger cohorts [23,24,28].

Conclusion

Intraventricular fibrinolysis using urokinase is an effective adjunct to external ventricular drainage for the management of intraventricular hemorrhage. The approach facilitates faster blood clot clearance, reduces ICU stay, and improves functional outcomes, without increasing the risk of adverse events such as infection or rebleeding.

Our findings support the inclusion of urokinase in the management algorithm for Hypertensive Capsuloganglionic Hemorrhage with IVH in appropriately selected patients. Further large-scale, randomized controlled trials are necessary to establish optimal dosing protocols and long-term outcomes.

Limitations

- **Sample Size**: The small sample size (n=30) limits the generalizability of our findings.
- **Single-Center Design**: As the study was conducted at a single institution, variability in practice and patient demographics is not accounted for.
- **Short Follow-Up Duration**: Functional outcomes were assessed up to 6 months; longer-term neurological and quality-of-life assessments are needed.
- **Absence of Longitudinal Imaging Correlation**: While Graeb score was used, advanced imaging metrics could further validate clot resolution and hydrocephalus progression.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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ORIGINAL ARTICLE

Running Subcuticular Sutures Versus Simple Interrupted Suture in Wound Healing of Fibroadenoma Patients: A Randomised Control Trial

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Abstract

Objectives: To compare wound healing in post-operative patients of fibroadenoma when skin closure is done with running subcuticular suture as compared to simple interrupted suture. **Methods:** This was a prospective, randomized controlled clinical trial conducted in a hospital setting. Here, the scar quality, patient comfort, time taken for wound closure and postoperative complications were compared when the incision was closed with running subcuticular suture as compared to simple interrupted suture. Data was collected on postoperative day 7 when the patient came for stitch removal using the VAS (Visual Analogue Scale) and Modified HWES (Hollander Wound Evaluation Scale) scoring systems. The data were collected and analysed by using the statistical software 'R'. The key outcome measures included VAS scores, HWES, and time. **Results:** This study included a total of 60 patients. Out of the these, 54 met the inclusion and exclusion criteria, while the remaining patients were lost in follow-up. 24 were enrolled into group A (Running Subcuticular) and 30 in group B (Simple Interrupted). The mean VAS score for Scar quality (as given by the patients) for Group A was 9.6667 and 9.1 for Group B. The mean VAS score for patient comfort was 0.125 for Group A and 0.5 for Group B. The mean HWES score for Group A was 0.66667 and for Group B was 0.73333. The mean closure time was 5.2083 minutes for Group A and 2.7333 minutes for Group B. 2 cases (8.333%) of wound dehiscence following superficial wound infection were observed in Group A and 1 case (3.333%) in Group B. **Conclusion:** The cosmetic outcome showed better results with running subcuticular sutures as compared to simple interrupted sutures. Patient comfort was more postoperatively with running subcuticular sutures. However, simple interrupted sutures appear to be more time saving. No comment could be satisfactorily made on the postoperative complications as the sample size was too small in this study.

Key Words: Wound healing, Suture techniques, Scar quality, Running subcuticular suture, simple interrupted suture

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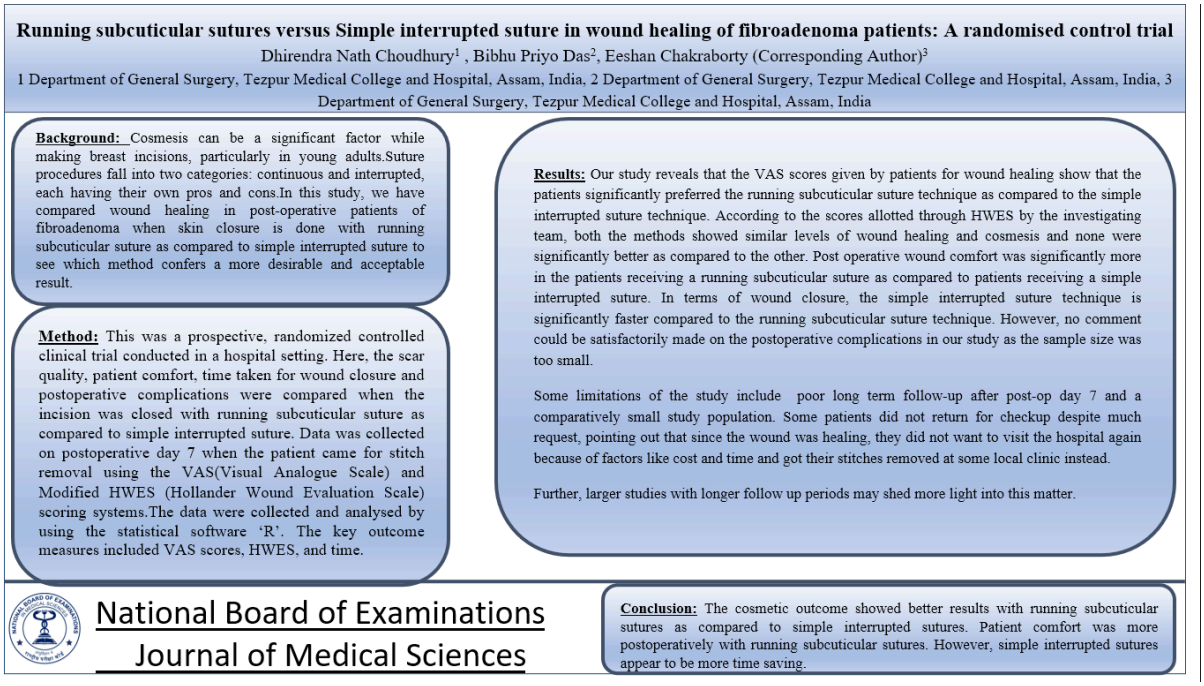
Graphical Abstract



Introduction

One of the most basic surgical techniques is skin suturing. It promotes early healing, which is an essential part of scar development. Scars developed following wound healing have a negative impact on patients' quality of life, mental health, and interpersonal connections [1]. The proper suture and technique can prevent complications and scar hyperplasia, resulting in better cosmetic results [2].

Cosmesis can be a significant factor while making breast incisions, particularly in young adults.

Suture procedures fall into two categories: continuous and interrupted. Interrupted sutures, created from a single piece of material, allow surgeons to adjust the spacing between the two ends of the wound. Continuous sutures provide consistent tension throughout the incision.

Dehiscence and infection are two common short-term side effects of skin sutures. Scar appearance and pigmentation development have been concerns for both surgeons and patients with improvements and advances in surgical abilities. The majority of cosmetic scar evaluation result reports are based on subjective scar scores. The visual analogue scale (VAS) is a reliable and helpful instrument for evaluating differences in scar quality [3].

In addition to continuous or interrupted suture procedures, the skin layers involved and the type of suture material used may have an impact on the results. In general, interrupted sutures include all the layers of the skin, whereas running subcuticular sutures are stitched straight beneath the outer skin layer.

Currently, academicians have mixed viewpoints when comparing these two suture procedures as to which offers better wound healing and will thus be both more acceptable and desirable by the patients.

In this study, we have compared wound healing in post-operative patients of fibroadenoma when skin closure is done with running subcuticular suture as compared to simple interrupted suture in a tertiary care government hospital setting in Tezpur, Assam, India.

Aims and objectives

1. To assess scar quality from patient and surgeon perspective.
2. To assess patient comfort in the days immediately following surgery.
3. To assess the time taken to complete closure in the operating room.
4. To assess short term complications.

Materials and Methods

This was a hospital based prospective, randomised controlled clinical study done in the Department of General Surgery in Tezpur Medical College and Hospital, Tezpur, Assam involving sixty patients with fibroadenoma who were treated by surgical excision of the same. Patients who matched the set inclusion and exclusion criteria were then selected for data analysis and further study.

Inclusion criteria

Patients were eligible for enrolment if

1. They were at least 18 years of age
2. They agreed to provide written consent
3. They were in general good health
4. They were available for follow up for at least 7 days after surgery
5. The size of the fibroadenoma was <5 cm in diameter.

Exclusion criteria

Patients were excluded from the study if

1. They were pregnant
2. They were minors
3. They had some pre-existing comorbidity which may impede wound healing.
4. They were incompetent to give written consent to enroll in the study
5. They were not willing for subsequent follow ups
6. They had Giant fibroadenomas (>5 cm in diameter).

The scar quality was assessed post-operatively from both patient and surgeon's point of view along with analysis of patient comfort post operatively, time taken for wound closure and short term complications for each wound in all the patients operated for fibroadenoma in a period of six months (January 2023 to June 2023).

Wounds of these patients were closed using running subcuticular technique or simple interrupted technique using nylon (Ethilon®) 3-0 sutures. Only one suture was used in each wound in either type of suture technique.

Out of the sixty patients enrolled, fifty four patients met the inclusion and exclusion criteria within this period and were enrolled and operated for fibroadenomas. The rest were lost in follow up.

The patients were randomised by means of a method of random selection, i.e., the patient was randomly allotted a procedure by the treating team. Each half of the bilateral case was closed differently.

Local anaesthesia (10 ml of 2% Lignocaine Hydrochloride solution) was infiltrated into the wound in each patient before incision was placed. Post excision and wound closure, careful dressing with povidone iodine solution and sterile gauze

was done. Time for wound closure was meticulously measured during each of the procedures.

There was no expense borne by the patients except for some pre-operative investigations like random blood sugar and viral markers (for HIV, HBsAg and Anti-HCV) and a minor OT charge (in accordance with government rules).

Sutures were provided from the hospital at no extra cost. All patients were discharged as per standard daycare procedure protocols and given medications with written and verbal instructions regarding wound care.

Data Collection

The wounds were examined by the treating team at the Surgery out-patient department on the 7th postoperative day or earlier if any complication developed. The wounds were then reviewed by the treating team and inspected thoroughly and stitches removed if the wounds healed properly.

Patients were then asked about their satisfaction regarding the scar, and the VAS Scale [4] was used to assess their opinion on scar quality, with a score from 0 to 10, where 10 represents the finest scar possible and 0 represents the worst.

Post-operative comfort including localised pain and tenderness were also assessed using the VAS score [5,6] out of 0-10, 0 denoting no pain and 10 being unbearable pain. Rescue analgesics were advised to the patients if they complained that the pain was at least above a score of 5.

The VAS score [5,6] out of 0-10 was used to quantify post-operative comfort, including localized pain and discomfort, with 0 representing no pain or discomfort and 10 indicating excruciating pain. Patients were recommended to take rescue analgesics if their pain score was at least above 5.

Physical examination and palpation were employed to establish complete healing of the wound, described as a dry wound with entirely viable tissue firmly adhered to the wound base, pinkish in color, and odorless. Clinical images were obtained at this point and a number was assigned to each photograph, which was then utilized by the investigating team at the end of data collection to randomly assess the wounds using the Modified Hollander Wound Evaluation Scale [7-10].

The modified HWES score includes six clinical criteria: step-off borders, contour irregularities, margin separation, edge inversion, excessive distortion, and overall look, with a maximum score of one for each. The total cosmetic score was calculated by summing the results for the six classified variables. A score of 0 was regarded the best, a score of 3 or lower was considered unsatisfactory, and a score of 6 was the lowest imaginable. This was done to avoid any score or observer prejudice on the part of the investigating team. The wounds were independently examined for complications, and those that were discovered were treated accordingly.

Data Analysis

The data were collected and processed using the statistical program 'R'.

The 'permutation test' was used to compare ordinal values, whereas the 'Student's t-test' was used to evaluate continuous variables. The key outcome variables were VAS scores, HWES, and time. Unless specified otherwise, statistical significance was kept at $\alpha = 0.05$.

Results

A total of 60 patients participated in this study. 54 of these patients met the inclusion and exclusion criteria and the rest were lost in follow-up. 24 wounds were enrolled into group A (Running Subcuticular) and thirty in group B (Simple Interrupted). The subjects were aged 18-29 years with an average age of 22.867 years (Table 1).

In the running subcuticular group, the mean VAS score for Scar quality (as given by the patients) was 9.6667. The mean VAS score for patient comfort was 0.125. The mean HWES score for this group (as given by the investigating team) was 0.66667.

The mean closure time was 5.2083 minutes for this group. Out of this sample size, 2 cases (8.333%) of wound dehiscence following superficial wound infection were observed.

In the simple interrupted group, the mean VAS score for Scar quality was 9.1. The mean VAS score for patient comfort was 0.5. The mean HWES score for this group (as given by the investigating team) was 0.73333.

The mean closure time was 2.7333 minutes for this group. Out of this sample size, 1 case (3.333%) of wound dehiscence was observed.

All wounds had epithelialized by the seventh day, regardless of closure method (excluding those with problems). The difficulties arose on the fifth day in three cases. All three dehisced wounds were cleansed, redressed, and left to heal with tertiary purpose, and oral antibiotics were provided (Figures 1 to 8).

Table 1. Comparison of wound outcomes using Running subcuticular and simple interrupted suture techniques

	Running Subcuticular Technique	Simple interrupted Technique
Mean VAS score for Scar Quality (0-10)	9.6667	9.1
Mean HWES score (0-6)	0.66667	0.73333
Mean VAS score for Patient Comfort (0-10)	0.125	0.5
Mean Closure Time (Mins)	5.2083	2.7333
Complications (Nos.)	2	1

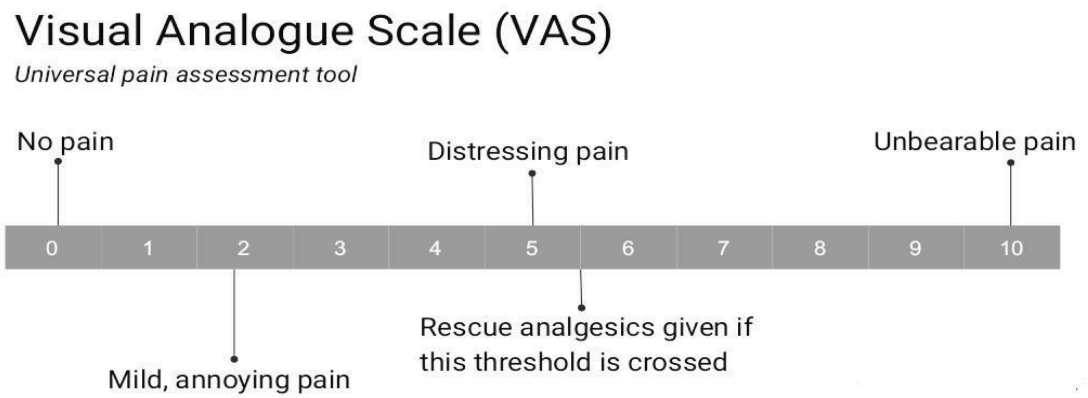


Figure 1. Visual Analogue Scale for Pain

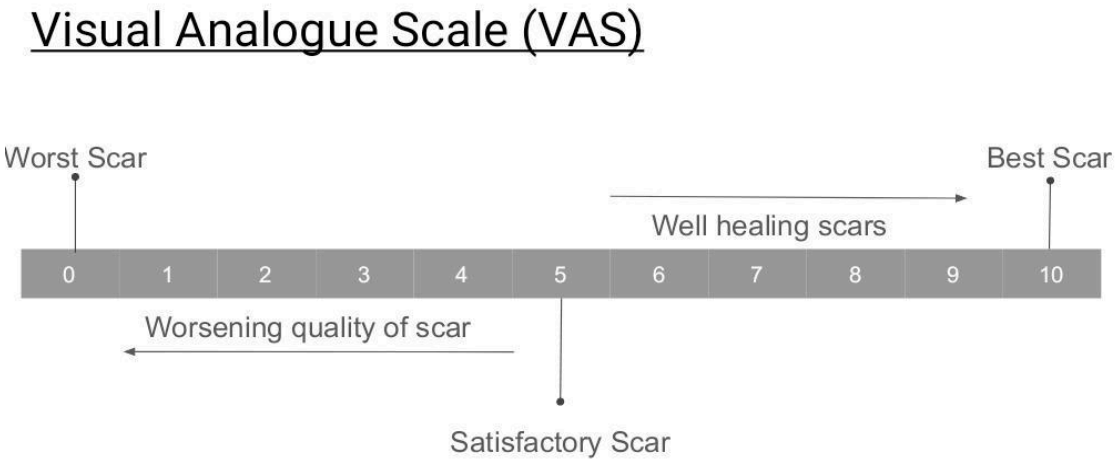


Figure 2. Visual Analogue Scale for Quality of Scar

Modified Hollander Wound Evaluation Scale(HWES)

Incision attribute	Score if absent	Score if present
Step-off borders	0	1
Contour Irregularities	0	1
Margin Separation	0	1
Edge inversion	0	1
Excessive Distortion	0	1
Overall appearance	0 (satisfactory)	1 (unsatisfactory)
Total Hollander score	**0 (best)**	**6 (worse)**

Figure 3. Modified Hollander Wound Evaluation Scale

Figure 4. Wound closed using Running Subcuticular Technique

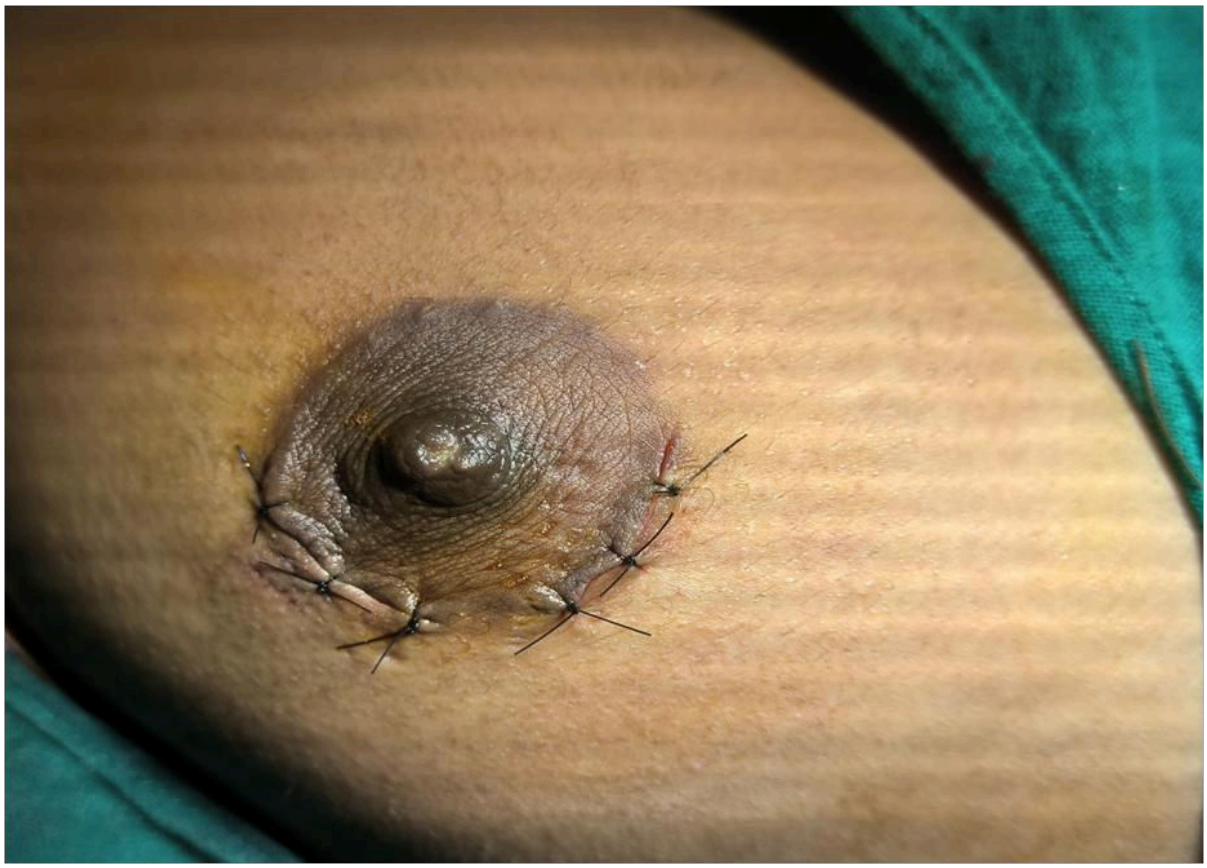


Figure 5. Wound closed using Simple Interrupted Technique

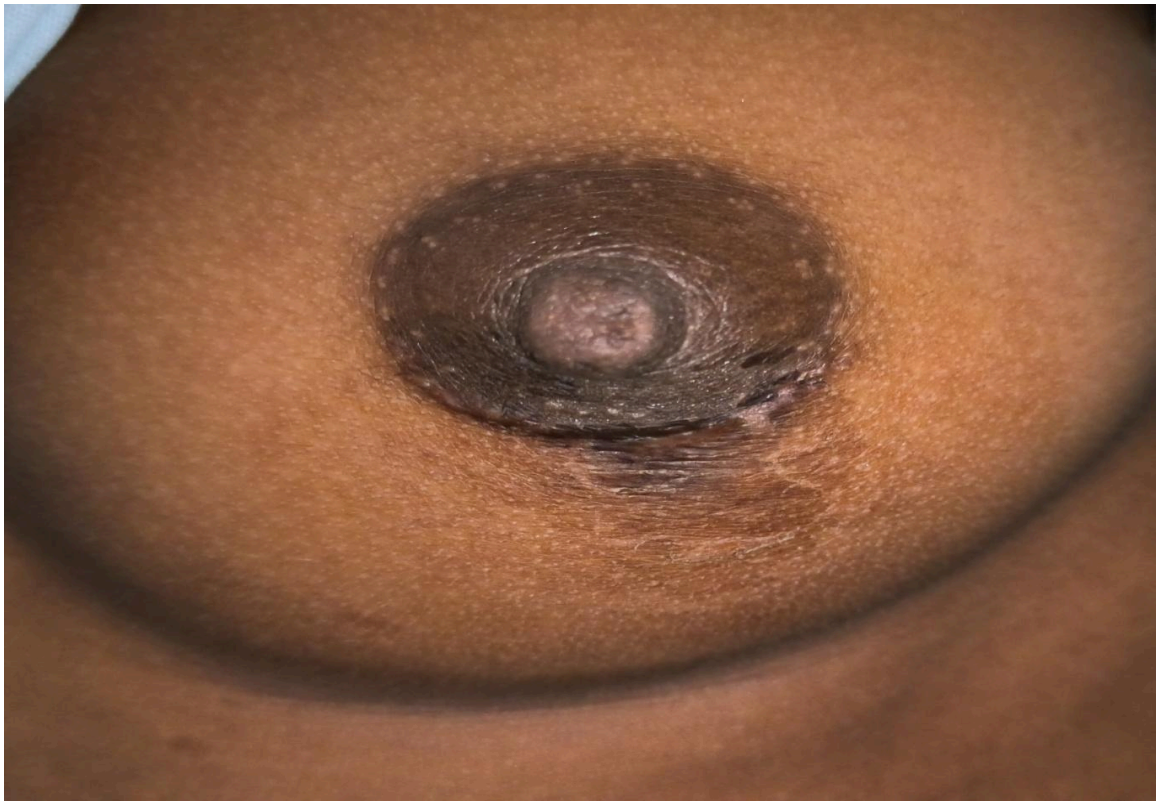


Figure 6. Wound post-Stitch Removal on Postoperative Day 7 for Running Subcuticular suture

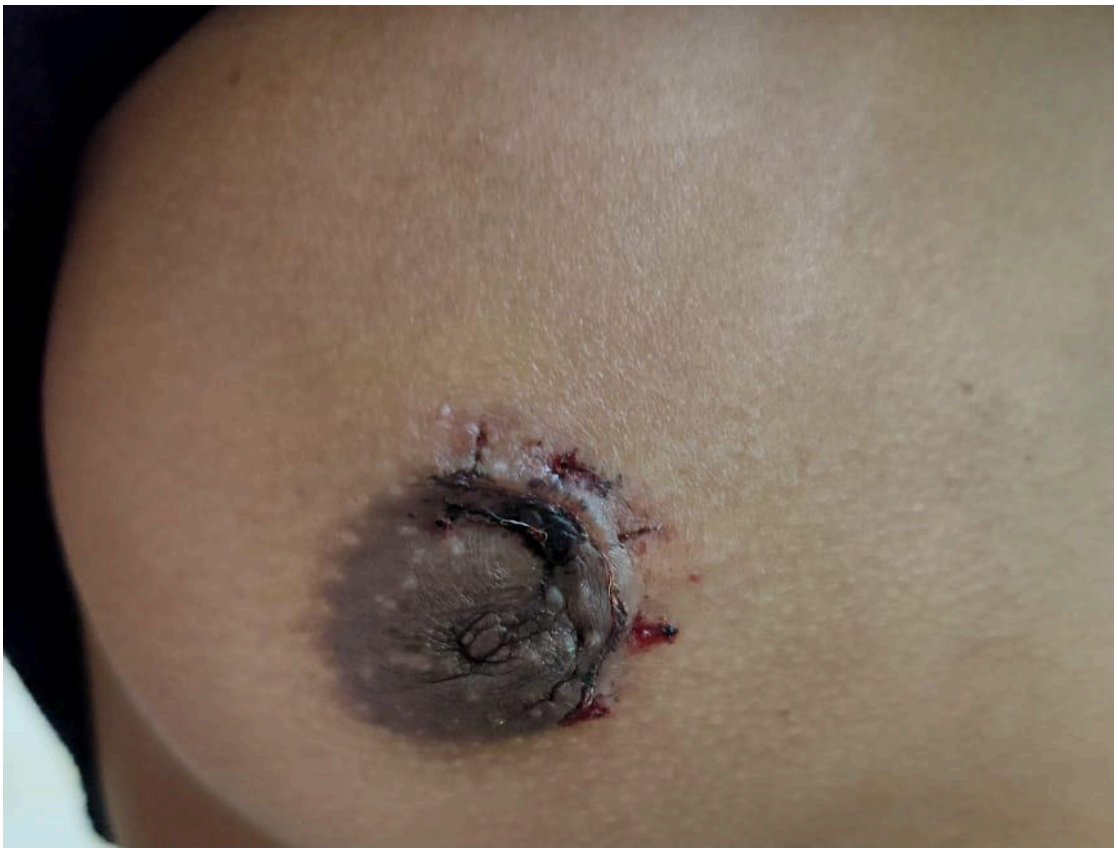


Figure 7. Wound post-Stitch Removal on Postoperative Day 7 for Simple Interrupted suture

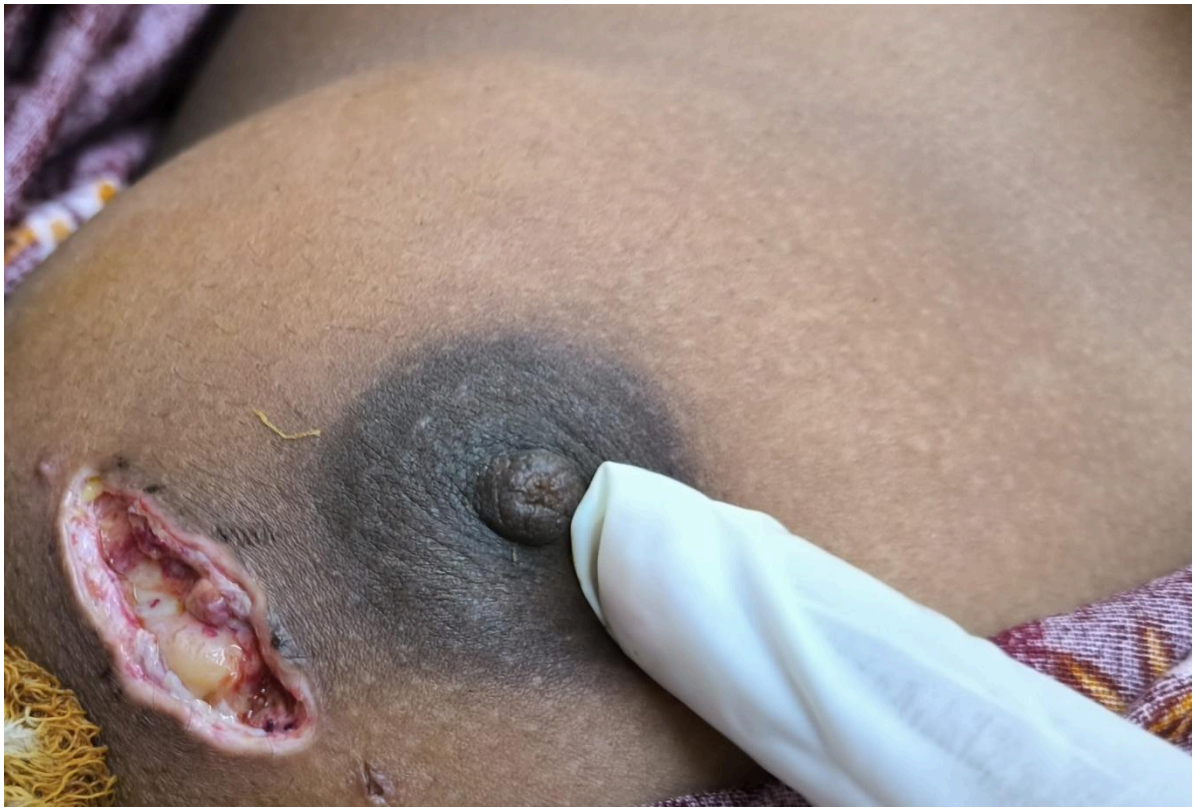


Figure 8. Wound Dehiscence on Postoperative Day 5

Discussion

Both the surgeon and the patient want a cosmetically attractive scar after surgery. The scar that forms as a result of wound healing has a substantial impact on patients' mental health, personal relationships, and quality of life [1]. Cosmesis is a critical factor to consider while making breast incisions, particularly in young adults.

Our study reveals that the VAS scores given by patients for wound healing show that the patients significantly preferred the running subcuticular suture technique as compared to the simple interrupted suture technique.

According to the scores allotted through HWES by the investigating team, both the methods showed similar levels of wound healing and cosmesis and none were significantly better as compared to the other.

Post operative wound comfort was significantly more in the patients receiving a running subcuticular suture as compared to patients receiving a simple interrupted suture.

In terms of wound closure, the simple interrupted suture technique is significantly faster compared to the running subcuticular suture technique.

Scar appearance is essential for a variety of reasons. It can assess the level of care delivered to the patient. It is also useful to compare the outcomes of several therapies in order to determine which is more effective. As a result, our wound outcome data may be beneficial to clinicians and patients both.

Other investigations comparing wound healing after running subcuticular sutures vs basic interrupted skin sutures for wound closure have produced comparable and similar outcomes across

the scalp, wrist, abdominal wall, upper or lower extremities, face, groin area, and sacral region [11-14]. Different suturing techniques may have different impacts on the incidence of surgical site infection as concluded by other researchers [15].

Continuous sutures have the disadvantage of requiring the entire stitch to be removed if infection occurs, as opposed to interrupted sutures, which only require the removal of stitches in the appropriate area.

Participants in prior trials also experienced a few cases of superficial wound dehiscence. Overall, the two groups differed significantly, indicating that interrupted sutures were more likely to produce wound dehiscence than continuous subcutaneous sutures. Four further independent abdominal wall trials revealed a substantial difference [11,13,16,17]. But, in another study, when the wound on the face was sutured, there was no notable difference by either procedure of wound closure [14]. One probable explanation is that in surgical wounds with high tensions, such as the abdominal wall, scalp or extremities, interrupted sutures may struggle to close a defect when used under high skin stress because of increased tension at the wound borders [18,19]. The facial area has less strain, resulting in similar wound dehiscence rates between the groups. The discrepancy between the two groups could be explained by overlapping wound edges generated by interrupted sutures, which can be avoided using continuous subcuticular sutures. There are several causes that can contribute to wound dehiscence. More research is needed to support these theories.

However, no comment could be satisfactorily made on the postoperative complications in our study as the sample size was too small.

Previous research on the relationship between suture methods and cosmetic outcomes is sparse.

Cosmetic satisfaction can often be more important than functional success in treatment [20] and can influence every area of our social lives [1]. The VAS score for scar aesthetic appearance was reported in six trials by both expert assessors and patients. Continuous subcuticular sutures resulted in a better cosmetic outcome in these investigations. Only one trial indicated that disrupted suture was slightly more associated with a cosmetically superior outcome, but not statistically significant [14]. The method of skin closure is the one of the most important factors influencing the cosmetic look of a scar [21].

Suture marks are commonly related with tissue inflammation at the macro level [21] and collagen fiber degradation at the micro level [22]. Running subcuticular sutures do not comprise stitches across the epidermal layer, hence there is no punctate scarring. In simple interrupted sutures, the suture must penetrate the epidermis, which causes further inflammation. Continuous cutting and compression of soft tissue beneath normal skin might lead to increased fibrous tissue during healing and scarring. Furthermore, because individual stitches are used, determining suturing depth, width, and tensile strength can be challenging, leading in less precise epidermal alignment and a reduced cosmetic result [22]. Interrupted sutures are more prone to cause dehiscence and cross-scarring, potentially affecting the cosmetic outcome [17,23].

We accept that there are some limitations of the study, such as poor long

term follow-up after post-op day 7 and a comparatively small study population. Some patients did not return for checkup despite much request, pointing out that since the wound was healing, they did not want to visit the hospital again because of factors like cost and time and got their stitches removed at some local clinic instead.

As far as we know, at the time of writing, even though there are some comparative studies between the two suture techniques that we studied, there are no studies conducted for wound healing over the breast post fibroadenoma excision.

However, in our research, we could not come to a satisfactory conclusion about all the study parameters as our sample size was small.

Conclusion

Our study demonstrates that the cosmetic outcome is better with running subcuticular sutures as compared to simple interrupted sutures. Patient comfort is more postoperatively with running subcuticular sutures. However, simple interrupted sutures appear to be more time saving as demonstrated by our findings. However, no comment could be satisfactorily made on the postoperative complications as the sample size was too small in this study. The study had a few drawbacks including poor long-term wound assessment and a limited sample size. We may have also used more detailed and thorough scar evaluation techniques to have a better understanding and analysis of wound healing. Future trials with longer follow-up periods are necessary to fully evaluate the impact of different skin suturing procedures.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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ORIGINAL ARTICLE

Anticonvulsant Activity of Aqueous Extract of *Andrographis paniculata* Leaves in Wistar Albino Rats

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Abstract

Background: The anticonvulsant effect of Aqueous Extract of *Andrographis paniculata* leaves (AEAP) and its synergistic action with Sodium valproate were evaluated in this research. **Methods:** Anticonvulsant activity of AEAP 500 mg/kg b.w. was evaluated in Wistar albino rats using the Maximal Electroshock Seizure (MES) model and the Pentylenetetrazol (PTZ) seizure model. **Results:** The Extract demonstrated significant anticonvulsant activity in both MES and PTZ seizure models. In the MES model, the anticonvulsant action of plant extract was comparable to that of the standard drug Sodium valproate 300 mg/kg in reducing the duration of Tonic hind limb extension (THLE). AEAP exhibited a synergistic effect with sodium valproate in both MES and PTZ seizure models, resulting in 100% protection. **Conclusion:** AEAP exhibits anticonvulsant action. Additional research is needed to elucidate the precise mechanisms through which *Andrographis paniculata* mediates its anticonvulsant activity.

Keywords: *Andrographis paniculata*, Anticonvulsant action, MES, PTZ

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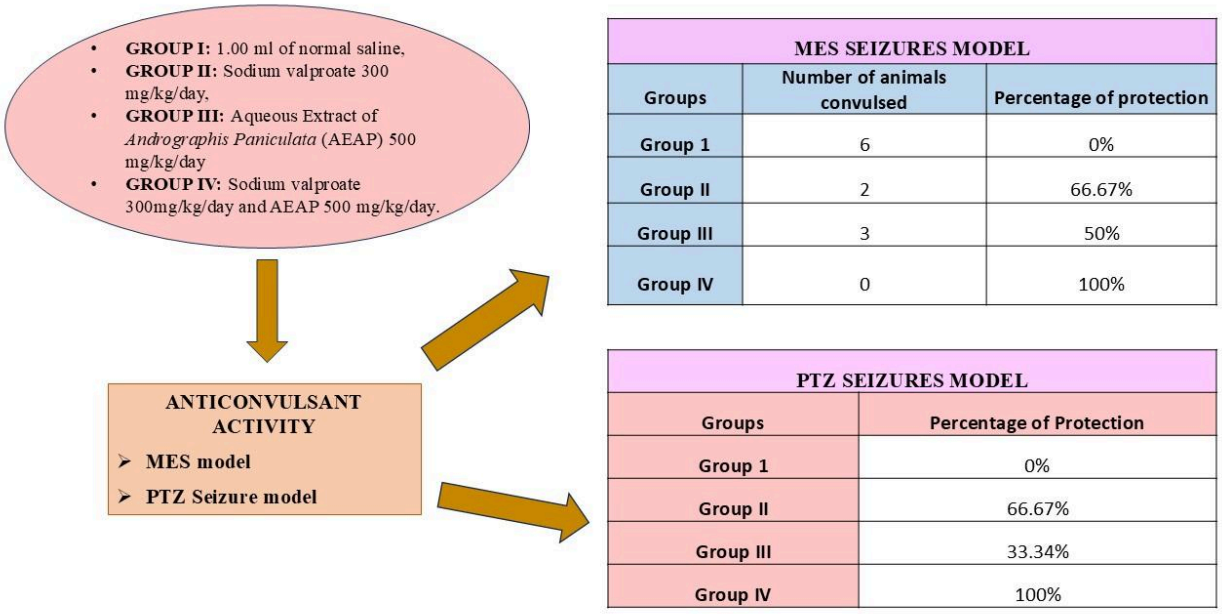
Graphical Abstract



MES SEIZURES MODEL		
Groups	Number of animals convulsed	Percentage of protection
Group 1	6	0%
Group II	2	66.67%
Group III	3	50%
Group IV	0	100%

PTZ SEIZURES MODEL	
Groups	Percentage of Protection
Group 1	0%
Group II	66.67%
Group III	33.34%
Group IV	100%

Introduction

A seizure is a paroxysmal event caused by abnormal, excessive, and asynchronous neuronal activity in the brain. Among the general population, 5-10% has experienced at least one seizure episode in their lifetime. The highest occurrence arises in early childhood and late adulthood. Epilepsy is a neurological condition involving recurrent, unprovoked seizures due to an underlying chronic disorder. The global prevalence of epilepsy is estimated to range from 5 to 10 cases per 1,000 individuals, with an incidence rate between 0.3% and 0.5%. According to the International League Against Epilepsy (ILAE) Commission, seizures are classified into three categories: focal seizures, generalized seizures, and seizures of unknown origin. Absence seizures and tonic-clonic seizures fall under generalized seizures, as they involve widespread electrical discharges throughout the brain [1].

Andrographis paniculata pertains to the family Acanthaceae [2]. It is commonly known as Nilavembu in Tamil and Kalmegh in Hindi. *Andrographis paniculata* and its major bioactive phytoconstituent Andrographolide, exhibit wide range of pharmacological activities. These include anti-inflammatory, analgesic, antipyretic, antimicrobial (active against bacteria, virus, retrovirus, malaria, larva), antidiabetic, hypolipidemic, anti-obesity, anticancer, hepatoprotective, immunomodulator, neuroprotective (effective in Parkinsonism, Alzheimer's, and ischemic conditions), and anti-fertility effects [3-5].

Andrographis paniculata is a widely recognized traditional medicinal plant in many countries, including India. Ethnobotanically, this herb has been used for the treatment of snake bite and bug bite [6,7].

Methanolic extracts of *Andrographis paniculata* leaves demonstrate immunostimulant, antioxidative and nootropic effects (improving cognitive function) in both normal and diabetic rat models [8].

The majority of routinely used anti-epileptic drugs do not prevent or reverse the underlying pathological changes that cause seizures, prompting continued research into newer antiepileptic therapies with improved efficacy and tolerance. 30–40% of patients develop into pharmaco-resistant or intractable epilepsy necessitating the search for alternative treatment options. Herbal medicine plays a vital role in the primary health care in many countries, including India, due to its wide availability and cultural acceptance. In the search for herbal medicines for epilepsy, some of the medicinal plants have potential as safe and effective alternatives [9]. Ajit Kumar Thakur et al. reported that, andrographolide, the active constituent of *Andrographis paniculata, exhibits* Benzodiazepine-like potentiation of pentobarbital induced hypnosis [6,10].

Based on the above considerations, the present study was conducted with the aim of investigating the anticonvulsant potential of the aqueous extract of *Andrographis paniculata* leaves in Wistar albino rats using Maximal Electroshock Seizure and Pentylenetetrazol seizure models, and to evaluate the synergistic effects of combining this extract with sodium valproate in these models.

Materials and Methods

Place and study duration

The study was conducted over a period of three months, from September 2023 to November 2023, at KMCH Institute of Health Sciences and Research, Coimbatore, Tamil Nadu. The study was carried out after obtaining approval from the Institutional Animal Ethics Committee (Approval number: 02/IAEC/2022) of KMCH Institute of Health Sciences and Research, Coimbatore, Tamil Nadu.

Animals

A total of 48 female Wistar albino rats, weighing between 200–220 g, were procured from the institutional animal house. The animals were housed in groups of six per cage under standard laboratory conditions, with a controlled room temperature of 25 ± 1°C. They were provided with free access to food and water *ad libitum*. On the day of the experiment, the animals were fasted for four hours, with no access to food or water prior to the procedure.

Preparation of extract

Fresh *Andrographis paniculata* leaves were collected locally from the Coimbatore district, Tamil Nadu, in September 2023. The aqueous extract was prepared using the maceration method. The collected leaves were shade dried and ground into a coarse powder. A total of 500 g of the coarse powder was boiled in hot water for 30 minutes and then allowed to cool. The decoction was filtered using cotton gauze. The filtrate was then poured into small Petri dishes and dried at room temperature to yield solid residues. The dried extract was stored in an airtight container at 4°C in a refrigerator. Fresh preparations were made from this stock as needed [11].

Drugs

For this study, pentylenetetrazol (PTZ) was obtained from Sigma (USA), and sodium valproate was sourced from Sanofi India Ltd. PTZ was administered intraperitoneally to induce seizures, while sodium valproate, served as the standard reference drug, was given orally. All drug solutions were freshly prepared using distilled water prior to administration.

Anticonvulsant activity:

Maximal Electroshock Seizures (MES) Model

This anticonvulsant model was employed to study grand mal (generalized tonic-clonic) seizures. In this model, electrical stimulation induces Tonic Hind Limb Extension (THLE), which serves as an indicator of seizure activity. A drug was considered to exhibit antiepileptic activity if it was able to abolish or significantly reduce THLE. Seizures were induced using ear electrodes delivering an electrical stimulus of 150 mA at 50 Hz for a duration of 0.2 seconds.

Twenty-four Wistar albino rats were randomly allocated to four groups, comprising six rats per group (n = 6). Group I (Control): Received 1.0 mL of 0.9% normal saline, Group II (Standard): Received sodium valproate at 300 mg/kg/day [12], Group III: Received the aqueous extract of *Andrographis paniculata* leaves (AEAP) at 500 mg/kg/day and Group IV: Received a combination of sodium valproate (300 mg/kg/day) and AEAP (500 mg/kg/day).

All treatments were given orally once daily for a duration of 15 days. On the day of experiment, MES seizures were evaluated by observing the time of onset and duration of THLE, along with the number of animals that experienced convulsions [13]. The percentage of protection was calculated [11] (Table 1 and Figure 1).

Table 1. Maximal electroshock seizure (MES) model

Groups	Name	Onset of THLE (Sec)	Duration of THLE (Sec)	Duration of PID (Sec)	Number of animals convulsed
I	Normal saline	3.79± 0.25	8.77±0.89	138.37±2.16	6
II	Sodium valproate	5.82±0.24***	1.25±0.83***	23.19±4.19***	2
III	*Andrographis paniculata*	6.08±0.2***	1.93±0.89***	29.51±2.16***	3
IV	Sodium valproate + *Andrographis paniculata*	0***	0***	7.3±1.14***	0

*p < 0.05, **p < 0.01, ***p < 0.001 (ANOVA followed by Dunnett's test); Results are stated as mean ± SEM
THLE: Tonic Hind Limb Extension, PID – Postictal depression

Pentylenetetrazol (PTZ) induced seizure

The pentylenetetrazol (PTZ)-induced seizure model is a well-established method for studying absence seizures [13]. Twenty-four Wistar albino rats were randomly assigned to four experimental groups, with six animals in each group (n = 6). Group I: received 1.00 mL of 0.9% normal saline, Group II: received sodium valproate at a dose of 300 mg/kg/day, Group III: received AEAP at 500 mg/kg/day, and Group IV: received a combination of sodium valproate (300 mg/kg/day) and AEAP (500 mg/kg/day). The standard and test drugs were administered orally for 15 consecutive days. Following a 12-hour fasting period, an intraperitoneal injection of PTZ (70 mg/kg body weight) was administered on the day of the experiment. Post-injection, the rats were observed for 30 minutes to record the latency to onset of the first forelimb clonus, the number of animals that exhibited convulsions, and mortality rates [11,14]. The percentage of protection was calculated [7] (Table 2 and Figure 1).

.

Table 2. Pentylenetetrazol (PTZ) seizure model

Group	Drug	Latency (Sec)	Number of animals died
I	Normal saline	46.77 ± 4.18	6
II	Sodium valproate	82.155 ± 2.349***	2
III	*Andrographis paniculata*	75.291 ± 6.148**	4
IV	Sodium valproate + *Andrographis paniculata*	330.166 ± 22.928***	0

*P < 0.05, **p < 0.01, ***p < 0.001 (ANOVA followed by Dunnett's test)
Results are stated as mean ± SEM

Statistical analysis

Data were analysed using one-way analysis of variance (ANOVA) followed by Dunnett's post hoc test, employing SPSS version 21. A p-value of <0.05 was considered statistically significant. Data are expressed as mean ± standard error of the mean (SEM) [15].

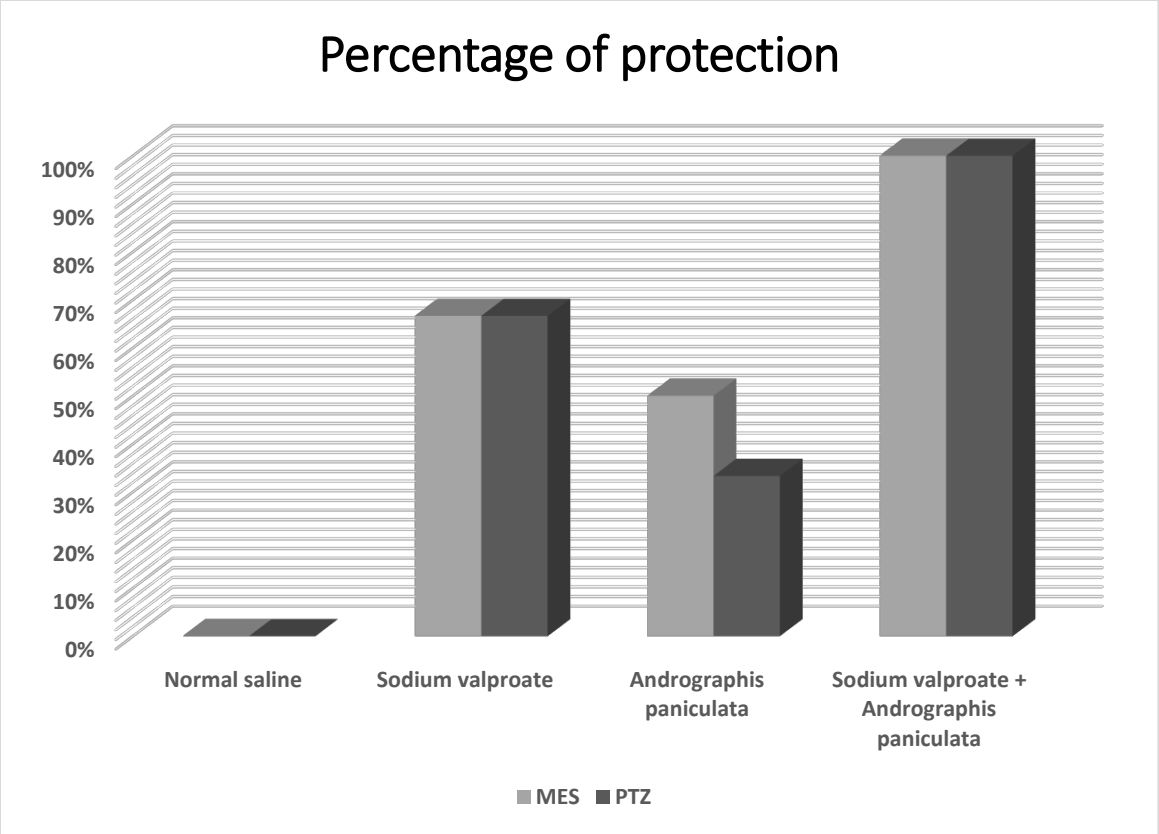


Figure 1. Percentage of Protection in MES and PTZ seizure models:

Discussion

The present study evaluated the anticonvulsant efficacy of AEAP and its potential synergistic action with sodium valproate. AEAP at a dose of 500 mg/kg body weight (Group III) demonstrated a statistically significant inhibition of THLE in the MES seizure model and a significant delay in the onset of clonic seizures in the PTZ-seizure model, which is comparable to the effects observed with sodium valproate at 300 mg/kg body weight (Group II). The combination treatment (Group IV), comprising sodium valproate (300 mg/kg) and AEAP (500 mg/kg), produced a highly significant inhibition of THLE in the MES model and further delayed the latency to PTZ seizures compared to Groups II & Group III. These findings suggest that *Andrographis paniculata* possesses notable anticonvulsant activity and potentiates the therapeutic efficacy of sodium valproate when used in combination.

The neuroprotective effects of andrographolide on the central nervous system were reviewed by Jiashu Lu et al., who concluded that andrographolide is capable of crossing the blood brain barrier and is distributed across various regions of the brain [16]. Sasi Kumar Murugan et al. conducted a toxicological safety assessment of *Andrographis paniculata* extract in rats, including both acute and 90-day repeated-dose sub-chronic toxicity studies. They

reported that the median lethal dose (LD_{50}) of AP-Bio® exceeded 5000 mg/kg of body weight, with no adverse effects observed at doses up to 900 mg/kg body weight [17]. Based on these findings, present study used an aqueous extract of *A. paniculata* leaves at a dose of 500 mg/kg body weight, administered for 15 days, assuming it to be within the no-observed-adverse-effect level for rats.

Ajit Kumar Thakur et al. conducted a preclinical study on the neuropsycho pharmacological effects of *Andrographis paniculata* extract in rodents and reported that oral administration of the extract was well tolerated at doses up to 800 mg/kg, with no observable behavioural alterations. A daily dose of 200 mg/kg body weight administered for 10 days potentiated pentobarbital-induced sleep and significantly antagonized seizures induced by both PTZ seizure and MES models. Additionally, anxiolytic, and antidepressant-like effects were observed following the 10-day dosing regimen. The study also documented suppression of central sensitivity to acute stressful stimuli and downregulation of central dopaminergic receptors after prolonged administration. The authors concluded that *A. paniculata* exhibits benzodiazepine-like anxiolytic and anticonvulsant properties when administered daily over an extended period [18].

Ramana et al. investigated the anti-kindling and antioxidant activities of *Andrographis paniculata* leaves and roots through both in silico and in vivo studies in rats, utilizing the bioactive compound andrographolide and its nano-formulation for enhanced delivery. The study employed a PTZ-induced kindling model, along with computational techniques such as network pharmacology and molecular docking, to explore the multi-target mechanisms underlying the antiepileptic effects of andrographolide. Their findings indicated that andrographolide exerts its antiepileptic action primarily by upregulating GABA levels. However, due to the compound's low bioavailability, the researchers opted to use andrographolide-loaded nanoparticles. In PTZ kindled rats, PTZ increased oxidative stress, as evidenced by elevated malondialdehyde levels and reduced levels of glutathione (GSH), superoxide dismutase (SOD), and GABA. Treatment with andrographolide effectively reduced these levels. The study concluded that andrographolide possesses significant antiepileptic potential, and its nano-formulated version may be a promising therapeutic strategy for managing kindled seizures [19].

Verma and Vinayak reported that the aqueous extract of *Andrographis paniculata* significantly elevated the levels of key antioxidant enzymes, including superoxide dismutase (SOD), catalase, and glutathione-S-transferase (GST), thereby contributing to its antioxidant potential [20]. In a longitudinal study conducted by Eduardo Beltrán-Sarmiento et al., the oxidant–antioxidant status of epileptic children prescribed on valproate monotherapy was evaluated in a Mexican cohort. The study found that, in comparison to healthy children, epileptic children exhibited decreased activity of antioxidant enzymes and elevated oxidative stress. However, valproic acid monotherapy significantly improved

antioxidant enzyme activities and reduced oxidative stress. The authors concluded that the antioxidant properties of valproic acid may contribute to its antiepileptic and neuroprotective effects, potentially through modulation of reactive oxygen species in a time-dependent manner [21].

Unhealthy gut microbiota can enhance the production of epilepsy-promoting metabolites and elevate inflammatory factors, leading to alteration in the GABA–glutamate ratio, which may contribute to the development of epilepsy. Chronic stress has also been identified as a potential trigger for this process [22].

Lerner-Natoli et al. observed an increased expression of Nuclear Factor kappa B (NF-κB) in the brain tissues of both animal models and epileptic patients. Similarly, Prasad et al. reported heightened NF-κB activity in hippocampal neurons of pentylenetetrazol (PTZ)-induced epilepsy models. Lerner-Natoli further demonstrated a significant upregulation of NF-κB expression in the hippocampus 24 hours after kainic acid injection, a response that may be linked to calcium influx mediated by N-methyl-D-aspartate (NMDA) and α-amino-3-hydroxy-5-methyl-4-isoxazole-propionic acid receptors (AMPA) [24,25]. Andrographolide, a bioactive compound derived from *Andrographis paniculata*, has been shown to inhibit NF-κB activation by preventing the binding of NF-κB oligonucleotides to nuclear proteins [3,26].

Su Jing Chan et al. conducted an experimental study to evaluate the neuroprotective effects of andrographolide in a rat model of cerebral ischemia. Their findings demonstrated that andrographolide exerts neuroprotective actions by suppressing NF-κB activation and inhibiting microglial activation, thereby reducing the production of pro-inflammatory cytokines such as TNF-α, IL-1β, and prostaglandin E2 (PGE2). Based on these results, the authors proposed that andrographolide may have therapeutic potential in the treatment of stroke [27].

Lerner-Natoli et al. work on the role of NF-κB in epilepsy suggests that the antiepileptic effects of *Andrographis paniculata* may, in part, be attributed to its ability to inhibit NF-κB in brain tissues [24].

According to Pradip Chauhan et al. (Chapter 2), brain regions specialized for learning and memory—particularly the neocortex and hippocampus regions—are more susceptible to seizures compared to other brain areas. Epilepsy is commonly associated with anatomical alterations in the hippocampus, amygdala, frontal cortex, temporal cortex, and olfactory cortex [28].

Eduitem Sunday Otong et al. investigated the neuroprotective effects of an aqueous extract of *Andrographis paniculata* against mercury chloride ($HgCl_2$)-induced oxidative damage in rat brain tissue. Their study demonstrated that $HgCl_2$ administration led to significant oxidative damage in the hippocampus and cerebellum, which was effectively mitigated by oral administration of *A. paniculata* extract at a dose of 500 mg/kg body weight for twenty eight days. Additionally, they observed that $HgCl_2$ exposure elevated glutamate concentrations in the brain, while treatment with *A. paniculata* significantly reduced these levels [29].

Eun-Ju Yang et al. investigated the neuroprotective effects of andrographolide

using a glutamate-induced HT22 mouse hippocampal neuronal cell death model. Their findings revealed that andrographolide significantly reduced apoptosis by inhibiting calcium influx, lipid peroxidation, and the formation of intracellular reactive oxygen species [30].

Meldrum et al. demonstrated, repeated electrical stimulation-induced 'kindling' limbic seizures is dependent on the activation of NMDA receptors, with enhanced function, observed particularly in the hippocampal region of kindled rats. Through micro-dialysis analysis, increased levels of extracellular glutamate and aspartate were detected in the brain both preceding and during seizure activity, suggesting a key role of excitatory neurotransmitters in seizure propagation. Anticonvulsant drugs such as lamotrigine have been shown to reduce ischemia-induced glutamate release [31,32]. Supporting this mechanism, studies by Eduitem Sunday Otong et al. and Eun-Ju Yang et al. demonstrated that *Andrographis paniculata* can reduce glutamate concentrations in the hippocampus—a brain region commonly affected in epilepsy [28-30].

Yan Pan et al. conducted an *in vitro* study to evaluate the effects of andrographolide and various extracts of *Andrographis paniculata* like aqueous, ethanolic, and methanolic extracts on human cDNA expressed hepatic cytochrome p450 (CYP450) enzymes. Specifically, they examined the enzymatic activity of CYP2C9, CYP2D6, and CYP3A4. The study concluded that *A. paniculata* extracts are significant inhibitors of CYP3A4 and CYP2C9, whereas andrographolide alone showed only weak inhibition of CYP3A4 activity [33].

Sodium valproate, the standard anticonvulsant used in this study, undergoes hepatic metabolism primarily through oxidation via cytochrome P450 enzymes, particularly CYP2C9 and CYP2C19 [31]. As reported by Yan Pan et al., *Andrographis paniculata* is a potent inhibitor of CYP2C9 activity [33]. Therefore, the observed potentiation of sodium valproate's anticonvulsant effect when combined with *A. paniculata* may be attributed to a pharmacokinetic interaction involving the inhibition of CYP2C9-mediated metabolism. However, this proposed mechanism warrants further investigation through comprehensive preclinical and clinical studies.

The anticonvulsant effect of the aqueous extract of *Andrographis paniculata* (AEAP) may be attributed to enhancement of GABAergic activity, antioxidant properties, inhibition of NF-κB signalling, as well as calcium and sodium channel blocking actions. These effects are likely mediated by its major bioactive compound, andrographolide. The observed potentiation of sodium valproate's anticonvulsant activity when combined with AEAP could be due to complementary GABA-enhancing effects, inhibition of CYP2C9-mediated metabolism, or other mechanisms. However, these possibilities require further detailed investigation through preclinical and clinical studies.

Limitations

The limitations of this study include the lack of evaluation of the proposed mechanisms of AEAP, its effects on pregnant

animals, its potential to potentiate other anticonvulsant drugs aside from sodium valproate, and its influence on CYP450 enzyme activity. These aspects warrant further investigation in future research.

Conclusion

Andrographis paniculata exhibits potent anticonvulsant activity. Its inhibition of the CYP2C9 enzyme may contribute to the potentiation of anticonvulsant effect of sodium valproate; however, this also raises concerns regarding potential pharmacokinetic drug interactions with chronic use. Therefore, further studies are needed to clarify its anticonvulsant mechanisms and to assess possible drug interactions.

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Conflicts of interest

The authors declare that they do not have conflict of interest.

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Data Availability Statement

The original data is available with the corresponding author

Statement of Informed Consent

This study did not involve human participants; therefore, informed consent was not applicable.

Ethics of Human and Animal Experimentation

This study was conducted following approval from the Institutional Animal Ethical Committee (IAEC approval number: 02/IAEC/2022) and adhered to the guidelines set forth by the Committee for the Control and Supervision of Experiments on Animals (CCSEA).

Authors Contribution

All authors contributed to the conceptualization and design of the study, data collection and analysis, manuscript revision, and gave final approval of the version to be published.

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ORIGINAL ARTICLE

Behavioral Symptoms of Premenstrual Syndrome Among Reproductive Age Group Women in a Rural Area of Tamil Nadu

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Abstract

Introduction: Seven to fourteen days before to the onset of menstruation, premenstrual syndrome is characterized by a recurring recurrence of severe physical and affective symptoms that ends when menstrual flow begins. A prevalent health issue among women in the reproductive age range is premenstrual syndrome. **Objective:** The purpose of this research was to determine the prevalence of premenstrual syndrome behavioral symptoms in the study population as well as the distribution of these symptoms. **Methodology:** 650 women of reproductive age participated in this descriptive cross-sectional survey, which was carried out in Parangipettai town, Cuddalore district. Data collection was done using a pretested proforma. Single-stage area-wise cluster sampling was the method of sampling that was employed. **Results:** Five hundred and nineteen of the 650 study participants experienced at least one premenstrual symptom. Confusion, difficulties concentrating, avoidance of social situations, and insomnia were the most prevalent behavioral symptoms. Two of the survey participants' top concerns were disorientation and insomnia. A score of two was assigned to each of the other behavioral abnormalities. **Conclusion:** Insomnia, confusion, avoid social activities and difficulty in concentrating are the most frequently occurring behavioural symptoms.

Keywords: Premenstrual syndrome, frequent, reproductive age group, behavioural symptom

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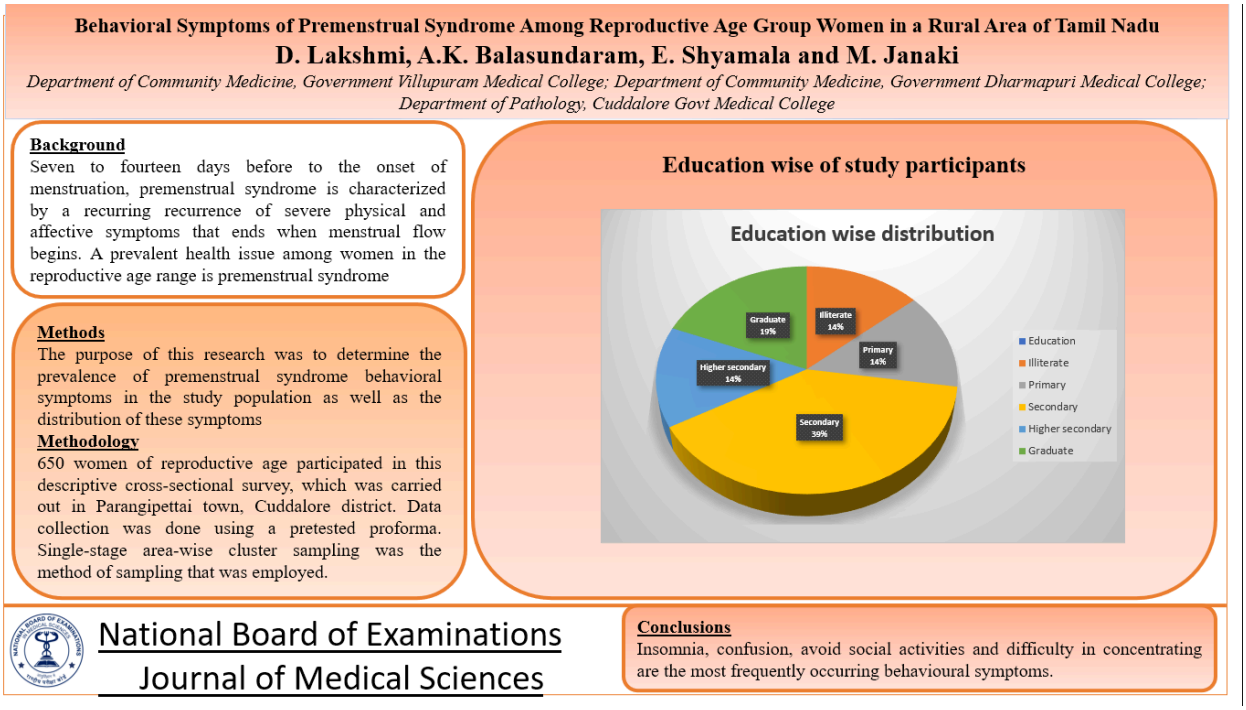
Graphical Abstract



Introduction

Millions of women from menarche through menopause suffer from premenstrual syndrome. A group of behavioral, psychological, and physical symptoms that appear during the leuteal phase of the menstrual cycle and go away after menstruation is known as PMS. PMS affects 90% of women during their reproductive years [1]. The severity of symptoms and their chronicity are the main causes of PMS morbidity, which can lead to emotional anguish or interfere with relationships and activities at work [2].

The etiopathogenesis of PMS is not known and till now there is no biochemical marker to confirm the diagnosis of PMS, but text book says Serotonin is an important neurotransmitter which place an important role in PMS. PMS-afflicted women exhibit reduced serotonin production during the luteal phase. The withdrawal of endorphins (neurotransmitters) from the central nervous system during the luteal phase is believed to be the cause of the PMS symptom complex. The brain's anxiety level is suppressed by y-aminobutyric acid (GABA). Changes in behavior may be caused by psychological and psychosocial causes [3]. GABA agonists are effective medications. Premenstrual Dysphoric Disorder (PMDD)4 was the term used to describe a severe type of PMS in the middle of the 1980s [4].

This context led to the study of PMS prevalence among reproductive-age women living in the rural field practice area under the rural health center of the Department of Community Medicine at Rajah Muthiah Medical College, Annamalai University.

This page discusses behavioral symptoms that are most commonly encountered.

Methods

The field practice area of Parangipettai, which is part of the rural health center of community medicine at Rajah Muthiah Medical College, Annamalai University, was the site of this descriptive cross-sectional study.

Sample size

According to a study by Enas H. Mohamed et al. on the prevalence of premenstrual syndrome and its contributing factors in the Algerian hamlet of Suez governorate, 80.8% of the sample population who were younger than childbearing age had PMS5. With this background knowledge in mind, the sample size was calculated with a 95% level of confidence and a 5% relative precision. In the field practice area of Parangipettai, there were 2934 women in the reproductive age group. It was determined that 325 was the necessary sample size. The clustering effect has been taken to be 2 since a house-to-house survey was conducted. As a result, 650 women were chosen as the study's sample.

Sampling technique

A survey of every household in the village was conducted from door to door. Six hundred and sixty women provided information for the first and second surveys. It was on the third visit that 650 samples were collected. The single-stage area-wise cluster sampling method was used for the sampling.

Data Collection

The study participants' social demographic information, menstruation history, housing details, and Moos menstrual distress questionnaire were gathered using a pretested proforma. There are two sections to the survey. Name, age, education, occupation, and other sociodemographic information were all asked about in the first section of the questionnaire. Other questions included physical activity, sleep disturbance, family history of premenstrual syndrome, number of children, nutrition history, and menstruation history. The second section contained the Moos Menstrual Distress Questionnaire, which was administered both before and after menstruation. It included 47 items, each of which was scored in the premenstrual phase10 and included descriptions of symptoms categorized into eight categories: pain (6), concentration (9), behavioral change (5), autonomic reaction (4), water retention (4), negative effect (8), arousal (5), and control (6). Participants can score the severity of their encounter using the MDQ's Never (0), Rare (1), Sometimes (2), Often (3), and Very often (4) options.

Interpretation and Scoring: Each item had five possible answers, each of which was assigned a score on the aforementioned 0–4 rating range. 188 was the final score. This was the spectrum of premenstrual syndrome levels.0: No symptoms are experienced. Mild (1–47), Moderate (48–94), Strong (95–144), and Severe (145–188). Operational Definition: Participants were classified as having premenstrual syndrome if their MOOS score was greater than 0. Data entry and statistical analysis were done using IBM SPSS version

21, a statistical program, after the collected data was loaded into an Excel spreadsheet. To analyze the Scoio demographic factors, descriptive statistics were employed. Both the Friedman's test and the multiple comparison test were used.

Results

The respondents' classification according to sociodemographic factors is displayed in Table 1. Of the study participants, 51.2% were under the 15–30 age range, while 43.5% were between the 31–45 age range. Seventy-seven percent of the study participants were married. The majority of research participants (43.2%) had completed secondary school. Fifty-six percent of the study participants were housewives. The majority of participants (41.3%) earned between Rs. 5001 and Rs. 30,000 per month. 519 of the 650 women had at least one of the behavioral signs listed below.

The most common behavioural symptoms are Insomnia, Confusion, Avoid social activities, Difficulty in concentrating, Take naps; stay in bed, Lowered school work or performance, Lowered motor coordination, Forgetfulness, Distractible, Accidents, etc. To determine whether there are any variances in the reported occurrence of behavioral symptoms, Friedman's test has been used. The Friedman's test's substantial p value shows that behavioral symptoms are statistically different. Therefore, the Friedman's multiple comparison test has been used to determine which behavioral symptoms are most commonly reported. Table 2 shows the most commonly occurring behavioral symptoms were Insomnia, confusion, avoid social activities and difficulty in concentrating. The other behavioral symptoms were occurring rarely. Among the study participants Insomnia and confusion was ranked as one. All the other behavioral symptoms were ranked as two (Table 3).

Table 1. Socio demographic characteristics of study participants

Socio demographic characteristics		**Frequency (n=350)**	**Percentage (%)**
Age group (in years)	30 – 39	128	36.6
	40 – 49	93	26.6
	50 – 59	66	18.8
	60 – 65	63	18
Marital status	Single	4	1.14
	Married	287	82
	Widow	59	16.86
Socio economic status	Class I	80	22.9%
	Class II	136	38.9%
	Class III	93	26.6%
	Class IV	34	9.7%
	Class V	7	1.9%

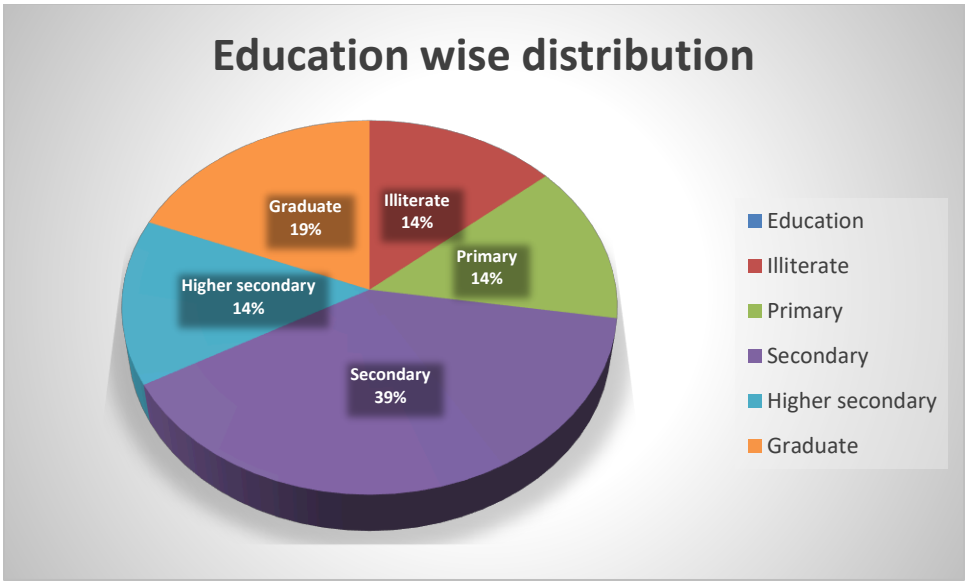


Figure 1. Education wise of study participants

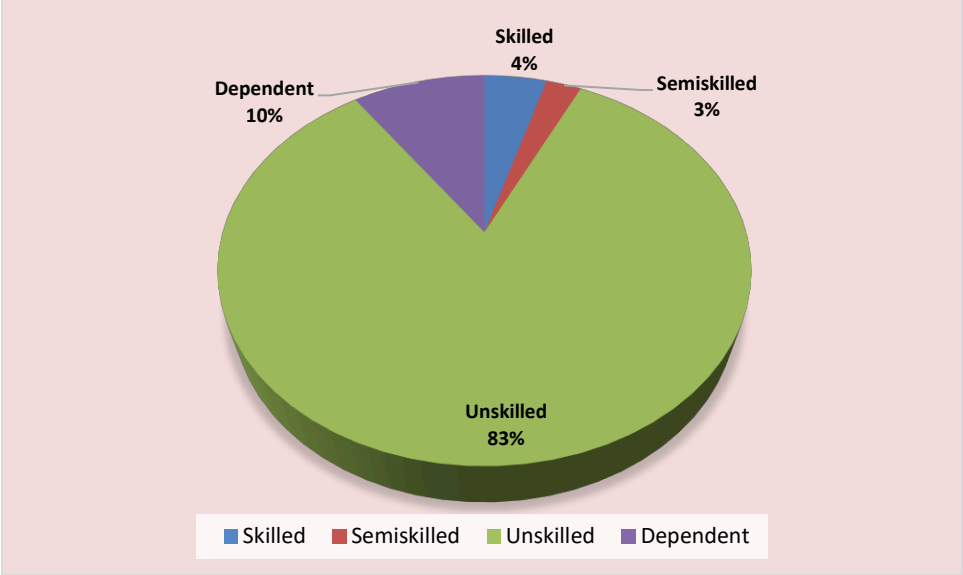


Figure 2. Occupation wise of study participants

Table 2. Distribution of Behavioural symptoms of the study participants

Symptoms	No. (n=519)	%
Insomnia	85	16.3
Confusion	67	12.9
Avoid social activities	40	7.7
Difficulty in concentrating	21	4
Take naps; stay in bed	4	0.8
Lowered school work or performance	3	0.6
Lowered motor coordination	3	0.6
Forgetfulness	1	0.2
Distractible	1	0.2
Accidents	1	0.2

Table 3. Most frequent Behavioural Symptoms of the study participants

Symptoms	Never		Rare		Sometimes		Often		Very often		Ranking after Friedman's multiple comparison tests
	N	%	N	%	N	%	N	%	N	%	
Lowered school work or performance	516	99.4	0	0	3	0.6	0	0	0	0	2
Take naps; stay in bed	515	99.2	0	0	4	0.8	0	0	0	0	2
Avoid social activities	479	92.3	13	2.5	24	4.6	1	0.2	2	0.4	2
Insomnia	434	83.6	21	4	63	12.1	0	0	1	0.2	1
Forgetfulness	518	99.8	0	0	1	0.2	0	0	0	0	2
Confusion	452	87.1	16	3.1	50	9.6	0	0	1	0.2	1
Difficulty in concentrating	498	96	0	0	21	4	0	0	0	0	2
Distractible	518	99.8	0	0	1	0.2	0	0	0	0	2
Accidents	518	99.8	0	0	1	0.2	0	0	0	0	2

Lowered motor coordination	516	99.4	1	0.2	2	0.4	0	0	0	0	2

Friedman's test value = 413.4; df=9; p value <0.001

Discussion

The Behavioural symptoms are Insomnia, Confusion, Avoid social activities, Difficulty in concentrating, Take naps; stay in bed, Lowered school work or performance, Lowered motor coordination, Forgetfulness, Distractible and Accidents.

In this study among the behavioral symptoms insomnia and confusion was ranked as one. All the other behavioral symptoms were ranked as two. The most commonly occurring symptoms were insomnia, confusion, avoid social activities and difficulty in concentrating in this study.

In contrast to this study a done by Aveen Fatah Haji et al reported behavioral symptoms such as social avoidance, poor concentration and confusion were commonly occurring among college of Nursing students [7].

Soo-Ho Chung et al., in (2014) from Korea, reported that among behavioural symptoms of PMS. Food cravings were reported by 44% of study participants reported followed by impaired concentration (20%), loss of interest (15%) and changes in sleep (15%) [8]. In a study done by Mahin Delera et al., (2013) in Iran, reported that the following behavioral symptoms were experienced by women with mild form of PMS, decreased interest (26.3%), concentration difficulty (23.4%), increased conflicts (21.9%) and no control on behaviour (22.3%) [9].

In contrast an observational study done by Nusrat Nisar et al. (2008) in Hydrabad, Sindh Pakistan, found out that in severe form of PMS lack of concentration was 12.1%, less participation in social activities was 14.1% and inefficiency to work at school and home was 11.1% [10].

Conclusion

Most frequent reported behavioral symptoms were Insomnia, Confusion, Avoid social activities and difficulty in concentrating. Health Education regarding Pre menstrual symptoms should be provided at adolescent age and school education. Higher level of awareness about Healthy life style which includes Balanced Diet, sleep, Exercises and yoga to be given as Community health care intervention to reduce the behavior symptoms of Premenstrual syndrome

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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Student-Doctor Method for Clinical Training Among Phase III Part II MBBS Students

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Abstract

Introduction: The Student–Doctor method, recommended by the National Medical Commission (NMC) under the Competency-Based Medical Education (CBME) curriculum, aims to bridge the gap between theoretical learning and practical clinical exposure. It provides medical students with longitudinal patient care experiences and fosters active participation in diagnosis, treatment, and patient communication. This study evaluated the feasibility and effectiveness of implementing the Student–Doctor method among Phase III Part II MBBS students in the Department of General Medicine at a medical college in Coimbatore. **Materials and Methods:** A mixed-methods study was conducted among 60 final-year MBBS students posted in General Medicine. Students were divided equally into five units and underwent a pre-test consisting of 25 multiple-choice questions (MCQs) via Google Forms. Cases were allotted for longitudinal follow-up under faculty supervision, following the Student–Doctor model. After a one-week clerkship experience, students presented their cases, and a post-test along with structured feedback questionnaires was administered. Quantitative data were analyzed using SPSS version 27, employing paired t-tests for pre- and post-test comparisons, while qualitative feedback was subjected to thematic content analysis. **Results:** The results demonstrated a statistically significant improvement in clinical knowledge. The mean pre-test score in the May batch increased from 16.3 to 20.26, and in the June batch from 17.13 to 21.26, with p-values <0.001 in both groups. Student feedback was highly positive, with the majority rating the teaching quality, faculty support, communication opportunities, and patient engagement as excellent or very good. **Conclusion:** The Student–Doctor method proved to be an effective and feasible model for clinical training, significantly enhancing clinical competencies and receiving favorable acceptance from students. This approach aligns with CBME goals and strengthens the development of patient-centered, competent future physicians.

Keywords: Student–Doctor method, clinical clerkship, competency-based medical education, longitudinal learning, medical education

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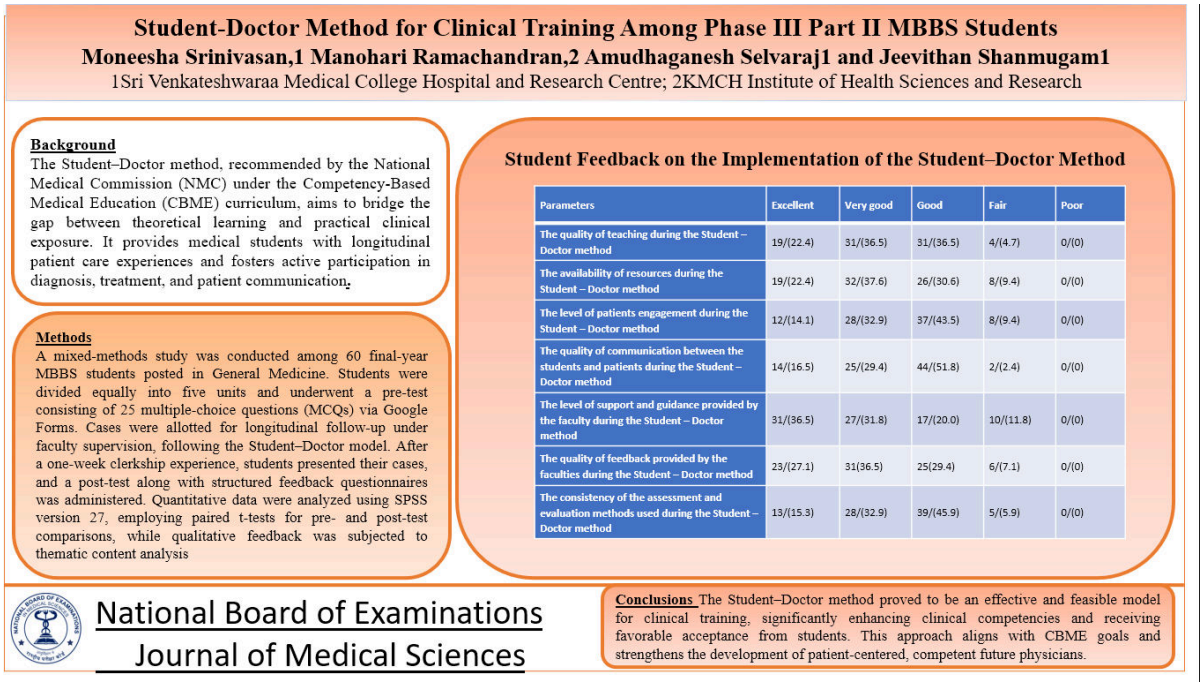
Graphical Abstract



Introduction

Clinical postings are a critical phase of medical education, bridging the gap between theoretical knowledge and real-world patient care. However, current clinical postings face several challenges that hinder optimal learning. A major issue is the lack of continuity in patient care: students often encounter patients briefly without following them through the full course of illness and recovery. Overcrowded teaching hospitals, time constraints, and fragmented teaching methods further limit meaningful patient interactions, preventing students from effectively integrating clinical skills with theoretical knowledge [1,2].

To address these limitations, the National Medical Commission (NMC) introduced the *Student-Doctor Method as part of the Competency-Based Medical Education* (CBME) curriculum reforms in India [1,2]. This method promotes active, longitudinal participation of students in patient care. In the Student-Doctor model, students are assigned to patients for extended periods, allowing them to witness the course of illness, management, and recovery. They work as part of the healthcare team under the supervision of faculty members, enhancing their hands-on clinical skills, communication abilities, decision-making, and professionalism [3–5]. Exposure to direct patient care and team-based learning is vital in preparing students for the dynamic, patient-centered demands of the 21st-century healthcare system [5].

Previous research supports the effectiveness of longitudinal clinical experiences. Cleland et al. emphasized that continuous patient engagement during clinical postings is highly valued by undergraduate students and improves their workplace learning experiences [3]. Teo, in a systematic review of medical education practices in Japan, observed that clerkships that promote active student participation strengthen clinical reasoning and professional development [4]. Gonzalo et

al. highlighted that integrating basic, clinical, and systems sciences in real clinical settings fosters interdependent learning and better prepares students for modern healthcare challenges [5]. Furthermore, Passi et al. stressed the importance of role modeling in clinical settings, showing that students benefit from close mentorship and observing professional behavior firsthand [6]. Dornan et al. described Experience-Based Learning (ExBL) during clerkships as crucial for the development of clinical competence and identity formation in medical students [7].

Despite the recognized benefits, limited research has specifically evaluated the *implementation challenges, student perceptions, and measurable outcomes* of the Student-Doctor Method in the Indian context, especially from both student and faculty perspectives. Understanding these aspects is essential to ensure effective execution and maximize the educational benefit of this approach.

Hence This study was planned to evaluate the efficacy of the Student-Doctor Method among Phase III Part II MBBS students posted in enhancement of clinical competencies at a tertiary care medical college in Western Tamilnadu.

Materials and Methods

The study was conducted in the Department of General Medicine at a Tertiary care Medical College in Western Tamil Nadu, India. A mixed-methods approach combining both quantitative and qualitative methodology was adopted. Phase III Part II MBBS students who were posted in the General Medicine department during the study period were recruited for the study. A total of 60 students were enrolled. Two batch of clinical batch students were included in the study. Institutional Ethics Committee approval was obtained before the commencement of the study, and written informed consent was obtained after explaining the need for the study, ethics involved and the rights of the participant from all participants before the start of the study.

As a routing, students were randomly divided into five groups corresponding to the five clinical units within the department. On Day 1, a pre-test consisting of 25 multiple-choice questions (MCQs) was conducted using Google Forms to assess their baseline clinical knowledge. Following the pre-test, students were assigned specific cases by the Assistant Professors and Senior Residents in their respective units for their evening clerkship apart from the routine sessions. The Student-Doctor method of learning was implemented and the students were asked to follow assigned patients longitudinally from admission to discharge. Case follow-up was performed during post-class hours in the evenings, and daily discussions with the supervising faculty which ensured ongoing guidance. Students were requested to maintain logbooks and document the patient progress and enter the clinical observations and experiences and faculty reviewed the same regularly.

After a week of longitudinal case follow-up, each Monday during the initial hour of clinical posting, students presented their cases before all faculty members. These case discussions aimed to consolidate theoretical knowledge with practical clinical experiences. Care was taken to ensure that all students were allotted cases of similar patterns and complexity to maintain uniformity across groups. On the last day of the posting, a

structured post-test was conducted using Google Forms, along with a structured feedback. A questionnaire was designed to capture students' perceptions on the Student-Doctor method of teaching. Feedback from the faculty regarding the feasibility and challenges of implementing this method was also obtained.

The data collected were coded into Microsoft Excel and analysed using SPSS version 27. Quantitative variables such as pre-test and post-test scores were summarized using mean and standard deviation (SD). The paired t-test was used to compare the pre-test and post-test scores, and a p-value of less than 0.05 was considered statistically significant. Qualitative data obtained from student and faculty feedback were analyzed using thematic content analysis to identify key themes and perceptions related to the Student-Doctor learning experience.

Results:

The feedback from students regarding the implementation of the Student–Doctor method was predominantly positive across all assessed parameters. In terms of the quality of teaching, a majority of students rated it as either excellent (22.4%) or very good (36.5%), with only 4% marking it as fair and none rating it poorly, indicating a high level of satisfaction with faculty teaching during the clerkship. The availability of resources was similarly well-rated, with 22.4% rating it excellent and 37.6% rating it very good, although 9.4% of students felt it was only fair, suggesting that resource allocation could be further optimized. Patient engagement during the Student–Doctor method was considered good by 43.5% of the students and very good by 32.9%, but a small proportion (9.4%) rated it as fair, highlighting a minor area for improvement in fostering active patient involvement.

Communication between students and patients received particularly strong feedback, with over half the students (51.8%) rating it as good and an additional 29.4% as very good, reflecting effective development of communication skills through this method. The support and guidance provided by the faculty were perceived very positively, with 36.5% rating it excellent and 31.8% as very good, although 11.8% rated it fair, indicating that consistency in faculty mentoring could be further strengthened. The quality of feedback provided by faculty was also rated favorably, with 27.1% of students rating it excellent and 36.5% very good, while only 7.1% rated it fair. The consistency of assessment and evaluation methods was well appreciated, with nearly half the students (45.9%) rating it as good, 32.9% as very good, and only 5.9% feeling it was fair. Importantly, no parameter received any poor ratings across the board. Overall, the findings suggest that the Student–Doctor method was effectively implemented, with high levels of student satisfaction in teaching quality, patient engagement, faculty support, and feedback processes, while also identifying minor areas where further enhancements could be made (Table 1).

Table 1. Student Feedback on the Implementation of the Student–Doctor Method Across Key Educational Parameters

Parameters	**Excellent**	**Very good**	**Good**	**Fair**	**Poor**
The quality of teaching during the Student – Doctor method	19/(22.4)	31/(36.5)	31/(36.5)	4/(4.7)	0/(0)
The availability of resources during the Student – Doctor method	19/(22.4)	32/(37.6)	26/(30.6)	8/(9.4)	0/(0)
The level of patients engagement during the Student – Doctor method	12/(14.1)	28/(32.9)	37/(43.5)	8/(9.4)	0/(0)
The quality of communication between the students and patients during the Student – Doctor method	14/(16.5)	25/(29.4)	44/(51.8)	2/(2.4)	0/(0)
The level of support and guidance provided by the faculty during the Student – Doctor method	31/(36.5)	27/(31.8)	17/(20.0)	10/(11.8)	0/(0)
The quality of feedback provided by the faculties during the Student – Doctor method	23/(27.1)	31(36.5)	25(29.4)	6/(7.1)	0/(0)
The consistency of the assessment and evaluation methods used during the Student – Doctor method	13/(15.3)	28/(32.9)	39/(45.9)	5/(5.9)	0/(0)

The comparison of pre-test and post-test scores among students who underwent the Student–Doctor method revealed a statistically significant improvement in clinical knowledge. In the May batch, the mean pre-test score observed was 16.3 (SD=1.24), which improved to a mean post-test score of 20.26 (SD=1.18). The mean difference was 3.96, with a t-value of -12.671 and a p-value of <0.001, indicating a highly significant improvement. Similarly, in the June batch, the mean pre-test score was 17.13 (SD=1.84), which rose to 21.26 (SD=0.98) in the post-test, with a mean difference of 4.13, a t-value of -10.851, and a p-value of <0.001 (Table 2).

Table 2: Comparison of Pre-Test and Post-Test Scores Among Students Undergoing the Student–Doctor Method

PARAMETERS	PRE TEST		POST TEST		MD	t Value	P Value
	M	SD	M	SD			
MAY	16.3	1.24	20.26	1.18	3.96	-12.671	<0.001
JUNE	17.13	1.84	21.26	0.98	4.13	-10.851	<0.001

Discussion

In terms of academic performance and student satisfaction, the findings demonstrated significant improvements in clinical knowledge. There was a notable increase in post-test scores compared to pre-test scores. The scored indicated the effectiveness of longitudinal patient engagement in enhancing clinical competencies.

Feedback analysis revealed that the quality of teaching, availability of resources, and faculty support were highly rated by the students. This aligns with previous literature emphasizing the role of structured clinical learning environments in promoting competency-based education [1,2]. The high ratings for patient engagement and communication skills reflect the success of the Student–Doctor method in fostering active student participation, improving clinical reasoning, and enhancing patient-centered communication skills, as highlighted by Dornan et al. in their experience-based learning model [7].

The students' perception of the consistency of assessment methods and feedback mechanisms was largely positive. Effective feedback is a cornerstone of clinical education, helping students refine their skills and professional behavior, a finding consistent with prior research by Passi et al., who emphasized the value of timely and structured feedback in medical training [6]. The role of faculty as role models and mentors was evident in this study, where supportive and continuous guidance significantly contributed to students' positive experiences, as previously noted by Gonzalo et al. in the context of interdependent learning frameworks in clinical education [5].

Despite the overall positive outcomes, some students rated the availability of resources and patient engagement as fair, highlighting a need for further efforts to ensure optimal resource allocation and enhanced patient participation. Similar results were identified by Cleland et al., who noted that inconsistencies in the clinical exposure and patient load impacted student experiences during their clerkships [3]. Furthermore, a structured weekly presentations and regular logbook maintenance promoted accountability and reflective learning among the students, for its role in reinforcing clinical reasoning through active participation [5].

Globally, the paradigm shift toward longitudinal clinical clerkships is supported by evidences from Japan and other countries, where the integration of community-based and hospital-based learning has shown a positive impact on clinical competencies and professional development [4]. Our study findings also resonate with the observations made by Teo et al., who reported that a structured clerkship experience improves clinical confidence and practical skills among undergraduate medical graduates [4].

This significant improvement observed between pre-test and post-test scores highlights the importance of the structured Student–Doctor method in enhancing clinical knowledge and skills among medical students. Overall the post-test scores was significantly higher than the pre-test scores. These findings were consistent with the goals of the Competency-Based Medical Education (CBME), as directed by the National Medical Commission which emphasizes active, longitudinal learning experiences that integrates clinical reasoning and patient-centered care [1,2]. Similar improvements in clinical competency following structured clerkship program has been reported in earlier studies also where in students exposed to longitudinal patient care demonstrated better clinical understanding and diagnostic abilities [4,7]. Greater patient engagement, faculty mentorship, and continuity of care play crucial roles in promoting deeper clinical learning and knowledge retention [3,5].

The Student–Doctor method of teaching provided students with a more holistic, continuous, and patient-centered learning experience compared to traditional fragmented postings [1,2].

Conclusions

The implementation of the Student-Doctor learning method among Phase III part II MBBS students has proved to be highly effective in enhancing their clinical skills and overall learning experience. The hands-on clinical training, continuous patient care exposure, and enhanced communication skills developed through regular patient follow-up in the Student–Doctor learning method significantly contribute in shaping students into competent, skilled, and compassionate healthcare professionals.

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Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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REVIEW ARTICLE

Comparative Insights into Vital Pulp Therapy Techniques

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Abstract

Vital pulp therapy encompasses a spectrum of biologically based procedures aimed at preserving the vitality of dental pulp following exposure due to caries, trauma, or mechanical factors. This narrative review provides a comprehensive overview of six core VPT techniques—indirect pulp capping, direct pulp capping, miniature pulpotomy, partial pulpotomy, full pulpotomy, and deep pulpotomy—with an emphasis on their historical development, clinical protocols, and reported success rates. Indirect and direct pulp capping remain foundational techniques, particularly in minimally or non-exposed pulps, with recent studies supporting high clinical success when appropriate sealing and case selection are observed. Miniature pulpotomy has emerged as a promising modification of direct capping, offering favourable outcomes through minimal pulp removal and improved material-pulp interaction. Partial and full pulpotomies continue to gain clinical relevance in managing both immature and mature permanent teeth, with comparable outcomes to root canal therapy in selected cases of irreversible pulpitis. Deep pulpotomy, though conceptually aligned with full pulpotomy, remains an underexplored technique with limited evidence supporting its use. Despite favourable clinical performance across various VPT modalities, inconsistencies in case selection, terminology, and treatment protocols highlight the need for standardized guidelines and further long-term investigations. This review underscores the evolving scope of VPT as a conservative and biologically driven alternative to conventional endodontic therapy.

Keywords: Indirect pulp capping, Direct pulp capping, Endodontics, Irreversible Pulpitis, Miniature Pulpotomy, Partial Pulpotomy, vital pulp therapy

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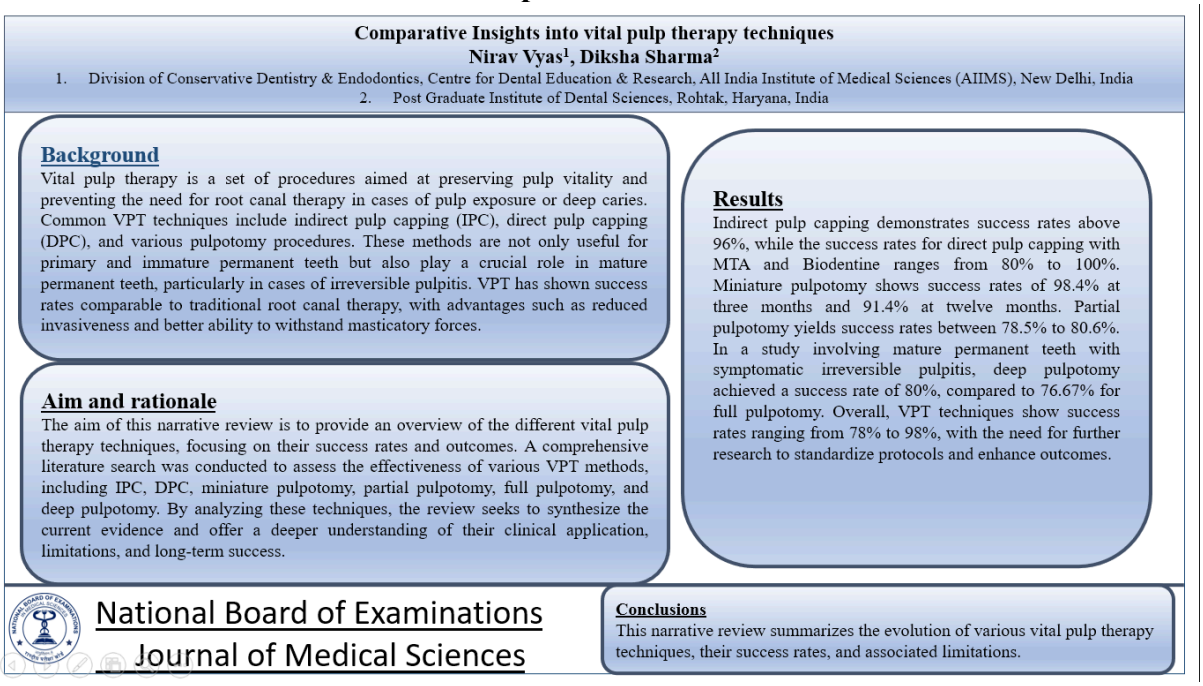
Graphical Abstract



Introduction

Vital pulp therapy (VPT) encompasses various approaches intended to protect pulpal vitality alongside maintaining tooth integrity in cases of pulp exposure/deep caries from mechanical factors/trauma [1]. VPT primarily includes direct pulp capping (DPC) and indirect pulp capping (IPC), along with various pulpotomy procedures. These procedures are routinely used in managing primary teeth for long-term retention and in immature permanent teeth to facilitate apexogenesis [2]. According to the AAE and ESE position statement over deep carious lesion management along with exposed pulp, VPT is considered a substitute method to traditional root canal therapy (RCT) aiming to maintain pulp vitality [3,4]. Another benefit of VPT over conventional RCT is its superior ability to withstand masticatory forces [5]. A study by Ghoddusi et al. (2014) highlighted vital pulp therapy's overall success rates in cariously exposed permanent teeth ranged between 87.5% and 95.4%, closely aligning with outcomes from iatrogenic exposures, which varied from 70% to 98% [6]. Therefore, the present study aimed to provide an overview of all 6 VPT technique and their respective success rate. A comprehensive literature search was conducted to identify all relevant studies on vital pulp therapy, from its inception up to April 2, 2025, utilizing the PubMed, Web of Science, and Scopus databases.

Vital Pulp Therapy techniques

Indirect Pulp capping

The concept of IPC had initially been presented by Hess in 1951 [7]. It was developed as a technique to maintain pulp vitality without exposing the pulp while treating carious dentine. IPC entails covering a thin layer of softened dentine close to the pulp with a protecting substance. It has been demonstrated that partial removal of carious dentine, followed by appropriate tooth sealing, will halt the progression of caries, suggesting that total caries removal is not necessarily required for efficient caries control. This technique

promotes the development of reparative dentine and pulp healing [8]. Three distinct IPC protocols— Dycal, TheraCal, and no liner—were examined in a recent randomized controlled experiment by Semprum-Clavier et al. (2024) in permanent teeth with deep carious lesions treated with resin composite. The findings demonstrated that all methods had effectiveness rates above 96%, and neither tooth sensitivity nor overall clinical outcomes revealed any significant variations [9].

Direct pulp capping

The term 'pulp capping' had initially been presented in literature by Barrett in 1877 [10]. The term DPC had been introduced by Hess in 1951, highlighting protective materials' use applied directly to exposed pulp tissue for facilitating healing as well as pulp function preservation [7]. Historically, DPC had been characterized as method employed for addressing pulp exposures caused by accidental trauma, in the absence of further signs of infection [11]. Nowadays, DPC is regarded as a Minimally invasive dentistry procedure that entails using a biocompatible substance to cover an exposed pulp directly, commonly trauma and carious lesions result [12]. Pinto et al.'s systematic review and meta-analysis from 2024 indicated that MTA had a greater success rate for DPC than calcium hydroxide. MTA and Biodentine showed similar success rate of 80-100% at 3 years follow-up. These findings suggest higher effectiveness of calcium silicate cement for DPC [13]. Even with improvements in materials and methods, DPC still has a lot of challenges that prevent it from being more widely used in clinical settings and from being as predictable.

Miniature pulpotomy

Asgary first used the VPT technique known as "miniature pulpotomy" (MP) in 2012. MP represents an advancement of the DPC technique by emphasizing effective debridement of the pulp wound, elimination of infected dentin and necrotic tissue, and improved interaction between capping materials and resident stem cells to enhance regenerative outcomes. MP is a conservative approach that involves careful removal of about 1mm inflamed superficial pulp tissue from exposure site while avoiding further enlargement of the wound. This method helps retain the vitality of the coronal pulp, supports effective bleeding control, and promotes better sealing of the capping material against the healthier underlying pulp, which contains mesenchymal stem cells capable of differentiating into odontoblast-like cells necessary for tissue regeneration [14]. A comparative study with 4 different pulpotomy techniques in mature permanent molar by Asgary et al. (2018) found that MP showed similar radiographical and clinical success compared to IPC, DPC and Full pulpotomy (FP). MP showed success rates of 98.4 and 91.4% at three- and twelve-month follow-up respectively which highlights its role as an alternative to conventional technique for VPT in permanent molars [15] Though there is a lack of large-scale studies and studies with prolonged follow-up.

Partial pulpotomy/Cvek pulpotomy

Cvek first introduced the term 'partial pulpotomy' (PP) in 1978 in permanent incisors for managing traumatic pulp exposures utilizing CH (calcium hydroxide) [16].

Bakland and Boyne later coined 'shallow pulpotomy' term as its synonym,

reinforcing its clinical relevance [17]. Cvek defined PP as elimination process of 1–2mm inflamed pulp in immature permanent teeth to preserve vitality. Fong and Davis later extended its application to carious exposures in vital teeth [18].

Lin et al. (2021) conducted a systematic review comparing PP and FP in cariously exposed mature molars. FP showed higher success (92.2%–99.4%) than PP (78.2%–80.6%). While the choice of capping agent didn't impact FP outcomes, it significantly influenced PP results [19]. Li et al. (2024) found that both PP and FP achieved outcomes comparable to RCT in mature teeth having irreversible pulpitis. At 24 months, PP had a radiographic success rate of 78.5% while 92.9% clinical success rate [20]. While FP marginally outperformed PP in one trial, Kumar et al. (2024) examined PP with FP in cases of irreversible pulpitis and found 0 significant difference in radiographic/clinical outcomes [21]. Umbrella review by Lin et al. (2022) analysed nine SRs on PP and FP published between 1970 and 2021. Success rates ranged from 88.5%–90.6%, though the effects of different medicaments and restorations were inconclusive [22].

Despite favourable outcomes, PP lacks a standardized definition, often described vaguely as ~2mm of inflamed pulp elimination. To validate PP as a reliable option, future studies must focus on well-designed clinical trials with standardized protocols, long-term outcomes, and better control of confounding variables.

Full/Coronal pulpotomy

The term FP was established by Aguilar and Linsuwanont in 2011 [23]. FP had 1st been utilized in treating non-inflamed pulp exposure, but it has demonstrated promising outcomes, even when treating irreversible pulpitis in primary as well as permanent teeth [24-26]. FP entails the coronal pulp being completely removed, with healthy radicular tissue preservation. Suitable bioactive material is then used to cover the pulp stump and seal the chamber. FP has been conservative and less invasive option than RCT to control exposure of carious pulp in permanent teeth. It offers comparable success rates while being more accessible, cost-effective, and simpler to perform [27]. Ather et al. (2022) showed 86% pooled success for FP in irreversible pulpitis, with Biodentine yielding better outcomes than MTA and CEM [28]. Li et al. (2024) further showed that mature teeth with irreversible pulpitis had combined radiographic as well as clinical success rates of 78.5% along with 92.9% over a 24-month period [20].

In a systematic review and meta-analysis by Wang et al. (2024), At 1- and 2-year follow-ups, FP employing CSCs and RCT achieved over 90% success, with no significant difference among 2 methods in mature teeth. Additionally, FP resulted in less postoperative pain during 1stweek, highlighting its advantage as a less invasive and more patient-friendly alternative [29]. Similarly, in a systematic review and meta-analysis by Li et al. (2024), which analysed 25 RCTs with ≥12 months follow-up, FP demonstrated an overall 86.7% success rate. In contrast to teeth having reversible/normal pulpitis, teeth with irreversible pulpitis demonstrated less success. The review also noted that MTA and Biodentine™ performed better than CH, with MTA exhibiting slightly superior results, although 0 significant difference had been found among MTA as well as other biomaterials [30]. While FP outcomes

were promising, standardization and higher-quality trials remain necessary to confirm long-term effectiveness.

Deep pulpotomy

Histologic research by Demant et al. (2021) observed that in teeth with extremely deep carious lesions, only 38% had unaffected radicular pulp tissue, while 62% showed inflammatory infiltrates in both the coronal and radicular pulps [31]. Another study by Ricucci et al. (2021) investigating invasion of pulp blood vessels by bacteria in teeth exhibiting symptoms of irreversible pulpitis reported that bacteria were present in the lumen of venules in one-third of cases, even in areas far from the necrotic focus in the root's coronal third [32]. The histological findings suggest that the success of partial or full pulpotomy procedures may be compromised by the presence of inflamed pulp tissue in the coronal third of the root in teeth with extremely deep caries and symptomatic irreversible pulpitis. Therefore, in such cases, it is advisable to remove 2–3 mm of the coronal radicular pulp to enhance the likelihood of successful outcomes [33]. Partial extirpation of the radicular pulp has been described in the literature using terms such as "high amputation," "radicular pulpotomy," or "deep pulpotomy" as a method for effectively managing teeth with traumatic or carious pulp exposure (Baume et al., 1971; Ingle et al., 2008; Tronstad, 2009). However, this approach is considered more invasive and technique-sensitive compared to FP [34-36]. A recent comparative study by Shah et al. (2025) on outcome of full vs deep pulpotomy in teeth with extremely deep carious lesions found that the success rate was 88.46% and 92.30% for per protocol analysis and 76.67 and 80% for ITT analysis for FP and deep pulpotomy, respectively [33]. Further long-term trials will require to evaluate the effectiveness of deep pulpotomy in extremely deep carious lesion.

Conclusion

VPT offers a conservative approach to preserving pulp vitality in cases of deep caries or pulp exposure, providing an effective alternative to more invasive treatment like root canal therapy. Techniques such as IPC and DPC, as well as MP, PP, and FP have demonstrated favourable success rates in both immature or primary teeth and mature permanent teeth. While VPT demonstrates promising clinical outcomes, the variability in treatment protocols and the need for more long-term, high-quality studies highlight areas for improvement. As VPT continues to evolve, further research is necessary to refine clinical techniques and establish standardized protocols for better long-term results.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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REVIEW ARTICLE

Exposure to Empowerment in COVID-19: Healthcare workers' resilience for future Pandemics

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Abstract

Background: The COVID Health Care Workers (HCWs) were committed to the treatment of COVID patients during the pandemic. In this process, there was a high chance of acquiring and/or carrying the deadly infection to themselves as well as to their family members. Hence it was imperative to take all the necessary steps to provide protection to the HCWs, confining the spread of the virus. Using the WHO (World Health Organization) risk assessment tool, many researchers had evaluated the probability of spreading of COVID infection. In this paper, we tried to assess the risk of HCWs exposed to COVID-19 patients during the pandemic. **Methods:** A prospective cross-sectional study was carried out from August 2020 to August 2021 using WHO (World Health Organization) risk assessment tool. A total of 1600 HCWs, who worked in the COVID hospital were included in the study. The HCWs were divided into two groups high-risk group and a low-risk group. The HCWs who got confirmed exposure to COVID patients or their infected material were included in the high-risk group and others were included in low-risk group. The chi-square test and binary logistic regression analysis were done by using the SPSS 24 statistics application. **Results:** Females were more prone to the risk of infection than their male counterparts [OR 1.9 (1.13-3.28), p=0.015]. HCWs with confirmed exposure to COVID-19 patients were more prone to the risk of infection [OR 196.9 (19.78-1960.7), p=0.001]. The HCWs who were exposed to the biological secretory materials of the COVID-patients were more prone to COVID-19 infection, including the needle stick injury [OR 0.229 (0.056-0.931), p=0.039]. **Conclusions:** The study revealed that HCWs in the high-risk group were less infected than the low-risk group, which contradicts the common perception of HCWs that they will get an infection after the COVID duty.

Keywords: COVID-19, Risk of infection, Healthcare Workers, PPE, IPC practices, Risk ratio

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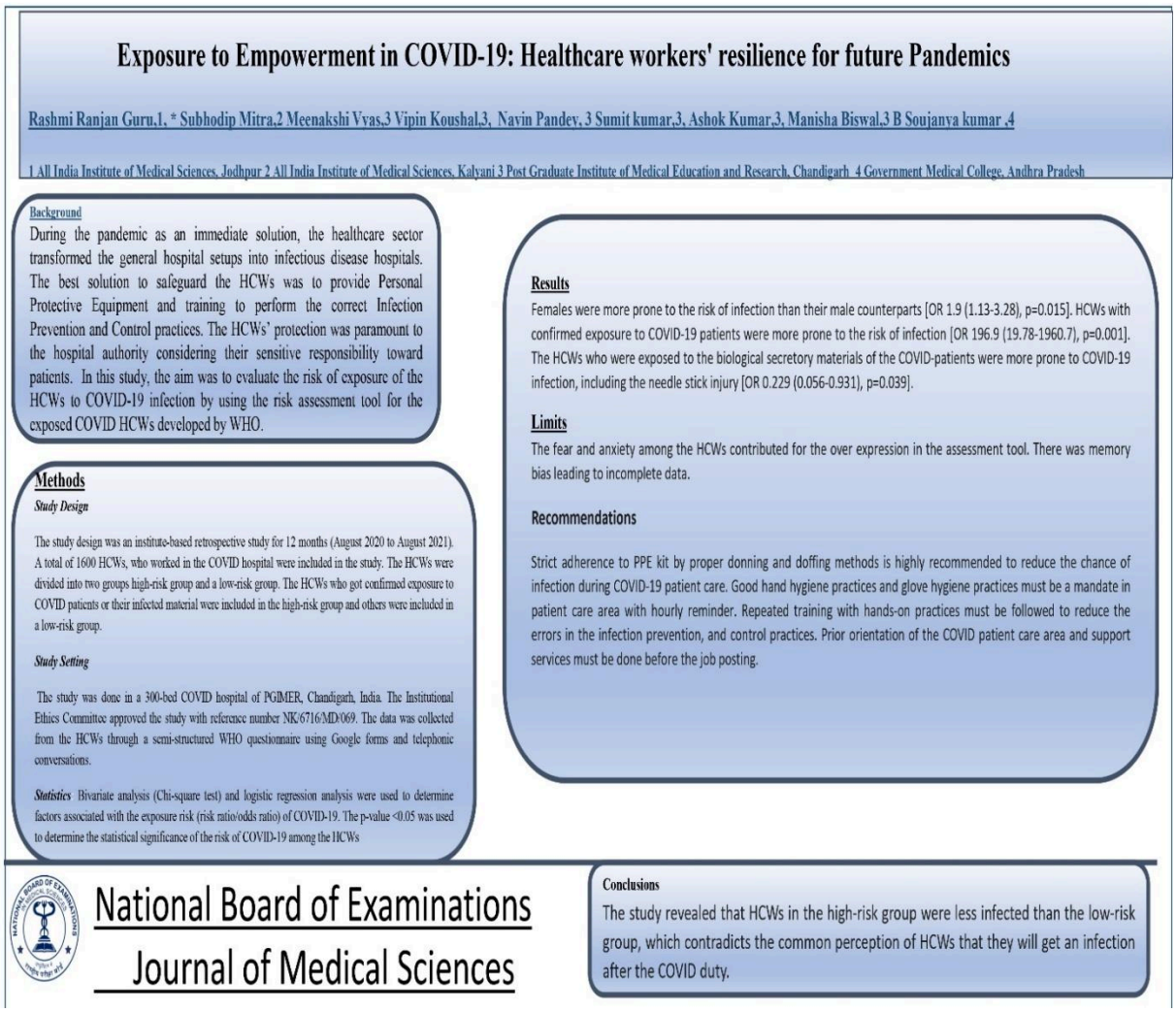
Graphical Abstract



Introduction

The Novel Coronavirus was first detected in Wuhan, China, in December 2019 [1]. World Health Organization declared COVID-19 as a pandemic after the spread of the infection in China in January 2020 [2]. HCWs were the direct targets of infection while attending the COVID struck patients. Protecting the HCWs from this deadly disease was an essential responsibility of society [3]. During the pandemic as an immediate solution, the healthcare sector transformed the general hospital setups into infectious disease hospitals [4]. The best solution to safeguard the HCWs was to provide Personal Protective Equipment and training to perform the correct Infection Prevention and Control practices [5]. The HCWs' protection was of utmost importance to the hospital authority considering their sensitive responsibility toward patients [6,7]. In this study, the aim was to evaluate the risk of exposure of the HCWs to COVID-19 infection by using the risk assessment tool for the exposed COVID HCWs developed by WHO [8].

Methods

Study design

The study design was an institute-based retrospective study for 12 months

(August 2020 to August 2021). A total of 1600 HCWs, who worked in the COVID hospital were included in the study. The HCWs were divided into two groups high-risk group and a low-risk group. The HCWs who got confirmed exposure to COVID patients or their infected material were included in the high-risk group and others were included in a low-risk group.

Study Setting

The study was done in a 300 bedded COVID hospital of PGIMER, Chandigarh, India. The Institutional Ethics Committee approved the study with reference number NK/6716/MD/069.

Data collection

The data was collected from the HCWs through a semi-structured WHO questionnaire using Google forms and telephonic conversations [8].

The questionnaire has three parts:
Part 1 - HCWs' socio-demographic information
Part 2 - Assessment of exposure to the COVID-19 virus
Part 3 - Adherence to infection prevention and control practices and use of PPE during healthcare interactions and procedures.

Statistics

Bivariate analysis (Chi-square test) and logistic regression analysis were used to determine factors associated with the exposure risk (risk ratio/odds ratio) of COVID-19. The p-value <0.05 was used to determine the statistical significance of the risk of COVID-19 among the HCWs.

Results

Part 1*: Socio-demographic data of HCWs*

Among the 1600 HCWs, 639 HCWs voluntarily replied to the questionnaire in the study. Among the participants, 123 became COVID-positive during patient care, and 516 successfully averted infection (COVID-negative). Of the study participants, 70 (56.91%) were male and 53 (43.09%) were female. Table 1 summarizes the socio-demographic characteristics of the participants.

Table 1. Socio-demographic Characteristics of participants

Variables	**% COVID +ve (N= 123)**	**% COVID -ve (N= 516)**	**Odds Ratio (CI=95%)**	**p-Value**
Sex				
Male	56.91	61.0	1.0(0.02-50.3)	*<0.001
Female	43.09	39.0	1	-
Age Group (Yrs.)				
18-24	10.57	26.0	1	-
25-34	59.35	58.7	2.4 (1.33-4.63)	*<0.003
35-44	22.76	13.0	4.3 (2.0-8.8)	*<0.001
45-54	7.32	2.3	7.7 (2.74-21.76)	*<0.001

Patient care Areas of the COVID Hospital				
WARD (HDU)	43.90	24.0	1	-
ICU (Intensive Care Unit)	26.82	37.0	1.80 (1.1-3.0)	*0.008
OT (Operation Theatre)	25.20	8.0	0.40 (0.2-0.7)	*0.003
Other Areas ****	4.06	31.0	8.15 (3.16-20.98)	*<0.001
Professional Status				
(Doctors)**	26.82	33.2	1	-
Nurses	36.58	26.2	1.73 (1.0-2.8)	*0.030
Technicians	7.31	3.8	2.34 (0.98-5.60)	*0.050
Others ***	29.26	36.8	0.9 (0.53-1.5)	0.725
Educational Status				
MD / MBBS / PhD	26.83	33.2	1	-
MSc. / BSc.	43.90	30.2	0.55 (0.33-0.89)	*0.015
Diploma / H.S.C /10+2	29.27	36.6	0.9 (0.53-1.5)	0.725
Experience				
<1 year	10.56	20.4	1	-
1-5yrs	59.34	54.3	2.0 (1.11-3.9)	*0.019
5-10yrs	22.76	17.8	2.4 (1.2-5.0)	*0.012
>10yrs	7.31	7.5	1.9 (0.75-4.83)	0.165

*p- value < 0.05; **Doctors- JR / SR / Faculty; ***Others – Hospital Attendant / Sanitary Attendant / Kitchen Bearer / Engineering staff; **** Other Areas- Ambulance / Resuscitation area / Dialysis / Radiology

***Part 2**: Assessment of Exposure status of the health professionals for COVID-19*

Out of 123 COVID-positive HCWs, 76.42% got COVID infection in the high-risk group and 23.57% of the low-risk group during the patient care (Table 2). Table 2 showed the Bivariate analysis of the COVID-19 HCWs Confirmed Exposure to the COVID-19 virus.

Table 2. Bivariate analysis of the HCWs with Confirmed Exposure to the COVID-19 virus

Variables	**% COVID +ve** (N=123)	**% COVID -ve** (N=516)	**Odds Ratio (CI=95%)**	**p-Value**
High risk	76.42	93.7	4.66 (2.6-8.0)	*<0.001
Low risk	23.57	6.3	1	-

*p- value < 0.05

Part 3: Adherence to IPC procedures during healthcare interactions

(i) Adherence to PPE kit
(ii) Adherence to Hand Hygiene
(iii) Accidental exposure with biological fluid material (Including Needle Stick injury)

In the study among the HCWs those who got COVID-positive infection, 18.70% were categorized as high risk, and 81.30% were categorized as low risk, with respect to adherence to the PPE. In the analysis of adherence to hand hygiene practice, 41.4% HCWs got COVID infection in the high-risk group and 58.53% in the low-risk group. In the analysis of the PPE adherence to aerosol generation procedure, among the COVID-positive HCWs, 17.07% were positive in the high-risk group, and 71.54% were positive in the low-risk group. In the analysis of adherence to hand hygiene during aerosol generation procedure among the COVID-positive HCWs, 27.64% were positive in the high-risk group, and 60.97% were positive in the low-risk group. In the analysis of exposure to biological fluid material including needle stick injury among the COVID-positive HCWs, 8.9% were positive in the high-risk group, and 91.05% were positive in the low-risk group. Table 3 showed a Bivariate analysis of the COVID-19 HCWs adherence to IPC procedures during healthcare interactions.

Table 3. Bivariate analysis of the COVID-19 HCWs Adherence to IPC procedures during healthcare interactions

Variables	**% COVID +VE** N=123	**% COVID -VE** N=516	**Odds Ratio** (CI=95%)	**p-Value**
Adherence to PPE				
High risk	18.70	12.02	0.59 (0.35-1.0)	*0.05
Low risk	81.30	87.98	1	-
Adherence to Hand Hygiene				
High risk	41.46	4.9	0.07 (0.04-0.123)	*<0.001
Low risk	58.53	95.1	1	-
Adherence to PPE (Aerosol-generating procedures) (N=109 +ve & N=475 -ve)				
High risk	17.07	4.8	0.23 (0.12-0.43)	*<0.001
Low risk	71.54	87.2	1	-
Adherence to Hand Hygiene (Aerosol-generating procedures) (N=109 +ve & N=438 -ve)				
High risk	27.64	7.3	0.17 (0.10-0.29)	*<0.001
Low risk	60.97	92.7	1	-
Accidents with biological fluid material (Including Needle Stick injury)				
High risk	8.9	24.0	3.0 (1.6-5.9)	*<0.001
Low risk	91.05	76.0	1	-

*p- value < 0.05

A binary logistic regression was done by considering the COVID status of the HCWs along with other factors such as age group, sex, area posting, type of HCWs, confirmed exposure to positive patients, exposure to the biological fluid of the patient, hand hygiene practice and adherence to PPE kit during the patient care and during aerosol-generating procedures taking as covariates. The females were 1.9 times more prone to COVID infection than their counterparts. Table 4 showed a Binary logistic regression analysis of the COVID-19 HCWs and associated factors in COVID Hospital, North India, 2021 (N=639).

Table 4. Binary logistic regression analysis of the COVID-19 HCWs and associated factors in COVID Hospital, North India, 2021 (N=639)

Covariates		**Adjusted Odds Ratio (CI=95%)**	**p-value**
Gender	Female	1.9(1.13-3.28)	*0.015
	Male	1	
Confirmed Exposure to COVID Patient	Yes	196.9(19.78-1960.7)	*0.001
	No	1	
Exposure To Biological Material	No	0.229(0.056-0.931)	*0.039
	Yes	1	

Discussion

The COVID-19 pandemic is a super spreading disease, which had created a crisis in the healthcare setup [9,10]. The HCWs were more prone to the infection of the COVID-19 virus because of their workplace and job responsibility [11,12]. In this study, 7.6% of HCWs got positive after the RT PCR report from the study place [13]. Similar studies were done on the infection rate of the COVID-19 HCWs found to be 3% in Italy, 9%in the Netherlands, and 18% in the UK [14]. To the best of the author's knowledge, this was the first study in the institute in north India, where the risk ratio (Odds ratio) of COVID-19 infection among the HCWs was calculated whereas limited similar studies were published globally [15].

Among the 639 HCWs, 123 HCWs got COVID-19 infection after seven days of duty (6hrs per day). The health professionals in the USA did studies that showed that the mean age of infection among the HCWs was 42yrs and in China was 37yrs [5]; wherein this study, the mean age of the HCWs was found to be 32yrs. Another study was done in the USA, suggesting the male sex was more likely to be infected than the female sex. In contrast, this study result showed that female HCWs were more prone to infection than male HCWs [16]. Our study results suggested similar high infectivity among the age group of 25-34 years compared to the age group of 18-24 years of the HCWs in a previous study done by Nguyen et al [17]. The HCWs with experience of 1-5 years were two times more likely to be infected than those with experience of less than 1year, and HCWs with 5-10years of experience were 2.4 times more likely to get the infection than those with less than 1year of experience. This explains that

experience and understanding the importance of the training is a vital factor in COVID-19 disease among HCWs [18].

The confirmed exposure of HCWs to COVID-19 patients, environment, and high-touch surfaces created a greater chance of infection; the results were statistically significant in this study and similar to previous studies [19-21]. HCWs with good adherence to PPE kits were less likely to be infected, which was similar to a study done in Bangladesh on adherence to PPE kits showed a protective factor against COVID-19 infection among the HCWs [22]. According to WHO recommendations, the N-95 mask exhibited a protective factor against COVID-19 infection among HCWs [23]. A previous study on ENT procedures showed an essential role of the N-95 mask in COVID-positive and COVID-19 suspected patients [24]. As reported by other studies, the HCWs with a habit of always hand hygiene practice were less likely to be infected, including those present during the aerosol-generating procedures [25]. A previous study stated that the decontamination of the patient care area and the high-touch surfaces had a significant role in preventing COVID infection; neglecting hand hygiene practice and decontamination practice will lead to infection among the HCWs [26]. Similar studies showed that using a PPE kit during aerosol-generating procedures became an asset to remain free from COVID infection [27][28]. The study showed proper use of goggles and face shields and following carefulness during needle use will prevent exposure to biological fluid and hence COVID-19 infection [29,30].

The result of binary logistic regression analysis showed female sex was two times more prone to infection than their counterparts. Confirmed exposure to COVID-19 patients showed a maximum chance of infectivity [19], and exposure to biological secretion materials of the positive patient showed a definite association with COVID-19 infection same as the results of other studies [30].

Interestingly, this study revealed that HCWs in high-risk groups were less infected than the low-risk group, which contradicts the common perception of HCWs that they will get an infection if they will go for the COVID-19 patient care.

Limitation of the study

The fear and anxiety among the HCWs contributed for the over expression in the assessment tool. There was memory bias leading to incomplete data.

Recommendations

Strict adherence to PPE kit by proper donning and doffing methods is highly recommended to reduce the chance of infection during COVID-19 patient care. Good hand hygiene practices and glove hygiene practices must be a mandate in patient care area with hourly reminder. Repeated training with hands-on practices must be followed to reduce the errors in the infection prevention, and control practices. Prior orientation of the COVID patient care area and support services must be done before the job posting.

Conclusion

The COVID-19 pandemic created fear and anxiety, particularly among the HCWs working in large healthcare setups. In developing countries like India, fewer HCWs provide care to the population so safeguarding the HCWs was a challenge for the administrators working in healthcare

setups. To protect the HCWs from COVID infection, the good practice of IPC was the utmost priority. A significant rate of infection among the HCWs was observed in the study. Poor adherence to PPE kit, improper use of N-95 masks, poor Hand Hygiene practice, exposure to biological fluid were analyzed and found significant to be significant contributory factors for the spread of the COVID-19 virus.

Statements and Declarations

Ethical Approval

The ethical approval of the study was approved by the Institute Ethics Committee, PGIMER, Chandigarh with approval no. NK/6716/MD/069.

Conflict of Interest

The authors declare no competing interests.

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REVIEW ARTICLE

A Scientometric Assessment of MAFLD in Children and Adolescents from 2007–2024

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Abstract

Purpose: Metabolic Dysfunction-Associated Fatty Liver Disease (MAFLD) is a growing concern in children and adolescents, with prevalence estimated between 7.6% and 9.6%. Given the significant rise in childhood obesity (up to 34%), early MAFLD identification and intervention are crucial to mitigate long-term health risks. **Methods:** This study conducted a scientometric assessment of global MAFLD publications from 2007–2024 to understand current research trends and future directions. Utilizing a targeted search strategy, 2,423 articles from 74 countries and 1,165 organizations were retrieved from the Scopus database. Bibliometric analysis and visualization, performed using MS-Excel and VOSviewer, explored co-authorship, co-occurrences of countries, organizations, authors, journals, and keywords. **Results:** The analysis revealed that the USA led in publications (29.63%), followed by China (15.02%) and Italy (13.83%). IRCCS Ospedale Pediatrica Gesu, Italy (141 publications)**,** and the University of California, San Diego, USA (92 publications)**,** were the most prolific institutions. Notably, Virginia Commonwealth University (13.08 CPP)**,** Columbia University (6.81 CPP)**,** and Indiana University School of Medicine (6.46 CPP) showed high citation per paper. Key journals publishing on MAFLD included the *Journal of Pediatric Gastroenterology & Nutrition* (n=70)**,** *Nutrients* (n=53)**,** and *Hepatology* (n=52)**.** Research predominantly focused on clinical studies (34.89%), complications (18.58%), and pathophysiology (18.58%). **Conclusion:** This comprehensive bibliometric analysis offers essential insights into MAFLD research, highlighting publication trends and identifying areas for future exploration. It serves as a valuable resource for researchers dedicated to developing effective MAFLD treatments.

Keywords: MAFLD; NAFLD; NASH; MASLD; Fatty Liver: Bibliometrics

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Introduction

Non-alcoholic fatty liver disease (NAFLD) is a progressive liver disorder characterized by hepatocellular steatosis, often linked to obesity, type 2 diabetes (T2D), and cardiovascular diseases. It is a significant public health concern globally, with a rising prevalence noted in younger populations, including children and adolescents, where it is the predominant cause of chronic liver disease (CLD) [1-3]. The prevalence of NAFLD in these demographic ranges from 3% to 10%, and nearly one-third of obese children and one-quarter of obese females are reportedly affected [4,5].

Moreover, pediatric metabolic dysfunction-associated fatty liver disease (MAFLD) has distinct etiological, pathological, and therapeutic attributes that warrant further investigation [6]. While there is a growing body of clinical and experimental research on MAFLD in children [7], capturing current trends remains challenging, as reviews and meta-analyses often do not project research trajectories or provide visualizations [8]. Hu et al. (2025) conducted an analysis of MAFLD research, examining 1,179 scholarly articles from the Web of Science database spanning from 1985 to 2024. They found a significant increase in publication volume, with contributions from 200 journals, 63 countries, 882 institutions, and 5,605 authors, including 84 core authors [9].

Bibliometrics has emerged as a useful tool for exploring research trends and guidelines, utilizing publication indicators across journals, authors, institutions, and countries to provide a comprehensive overview of the field [10]. Advanced bibliometric tools like Cite Space and VOSviewer facilitate the analysis of the scientific knowledge network and evolution in specific domains. This specialized field within information science has significant implications for scientific research assessment and academic communication, helping scholars understand the trends in the academic landscape [11,12].

Although many bibliometric studies on NAFLD and MAFLD exist, they primarily focus on the adult population. Previous studies have also addressed themes such as the "gut-liver axis in NAFLD," "NAFLD and insulin resistance," "nutrition associations with NAFLD," "macrophages associated with non-alcoholic fatty liver disease," and "vitamin D and non-alcoholic fatty liver disease" [13-15].

Based on existing literature, we conducted a comprehensive bibliometric study on MAFLD in children and adolescents. Our study analyzed 2,423 articles and reviews from the Scopus database, covering literature from 2007 to 2024. This research aims to summarize the current hotspots and trends in MAFLD among children, providing a reference for future scholars interested in this area of study.

Methods

Data Collection

Utilizing the “Advanced search” functionality of the Scopus online database, we used a combination of relevant keywords and their synonyms to identify literature pertaining to the “metabolic dysfunction-associated fatty liver disease (MAFLD) and

non-alcoholic fatty liver disease (NAFLD) and children & adolescents, in May 2025. These keywords were placed in Keyword tags with the help of Boolean operators of the Scopus search engine to accomplish the goals of our study: The research limits its scope to peer-reviewed scientific journal articles, excluding books, book chapters, retracted articles, and errata.

The search strategy used in this study is as follows:

(KEY (*"Metabolic dysfunction--associated fatty liver disease"* **OR** *"MAFLD"* **OR** *"non-alcoholic fatty liver disease"* **OR** *"NAFLD"*) **AND** KEY (*"child"* **OR** *"adolescent"* **OR** *"paed*"* **OR** *"pediat*"* **OR** *"juven*"* **OR** *"infant"* **OR** *teenager*)) **AND** (LIMIT-TO (DOCTYPE , *"ar"*) **OR** LIMIT-TO (DOCTYPE , *"re"*)) **AND** (EXCLUDE (PUBYEAR , *2025*)

Data Analysis

The connections or links between terms and collaborating countries were visualized using VOSviewer software version 1.6.20 (Leiden University, Leiden, The Netherlands). Network maps were constructed to depict the interplay of terms extracted from article titles or abstracts and the collaborative ties between countries. A co-occurrence analysis was simultaneously performed to segregate terms into distinct clusters, which were further enhanced by color coding based on their temporal distribution. To assess the emergence of new topics and identify evolving trends, the average publication year was calculated

Bibliometric indicators, including the total number of publications, publication years, types of publications, top ten funding agencies, top 15 countries, top 25 institutions and journals, top 25 journals, and the top ten most cited articles, were gathered using an Excel spreadsheet for detailed analysis.

Ethics Statement

Being a bibliometric study, based on the published literature, and not involving any human or animal intervention, ethical committee approval was not applicable for this research.

Results

Overall Results

The annual growth of publications on MAFLD in children & adolescents in last 18 years (2007-24) showed a systematic growth, increasing from 12 in 2007 to 246 in 2024, registering annual average growth rate of 25.93%. The maximum number of publications (263) was reported in 2022 (Table 1). The 2423 total publications on MAFLD together registered 95370 citations, averaging 39.36 citations per paper (CPP). The review articles registered higher CPP (45.76), compared to research articles (38.22).

Table 1. Annual Growth of publications on MAFLD in Children & Adolescents during 2007-2024

Year	TP	TC	CPP		Year	TP	TC	CPP
2007	12	560	46.67		**2018**	187	13809	73.84
2008	15	1734	115.60		**2019**	205	7781	37.96
2009	23	1097	47.70		**2020**	235	7438	31.65
2010	16	1208	75.50		**2021**	257	5562	21.64
2011	36	2942	81.72		**2022**	263	4567	17.37
2012	30	1269	42.30		**2023**	261	3642	13.95
2013	58	2251	38.81		**2024**	246	785	3.19
2014	126	7332	58.19		**2007-15**	470	27133	56.31
2015	154	8073	52.42		**2016-24**	1953	68237	31.47
2016	138	8961	64.93		**2007-24**	2423	95370	39.36
2017	161	8918	55.39					
	TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper							

The clinical studies accounted for the largest share (50.47%), followed by pathophysiology (17.38%), and epidemiology (13.25%) etc. External funding was received by 38.26% publications, from more than 150 research agencies. The leading funding agencies were National Institute of Health (n=309), US Department of Health & Human Sciences (n=248), and National Institute of Diabetes and Digestive and Kidney Diseases (n=186).

Leading Countries

A total of 115 countries participated in research on MAFLD in Children & Adolescents, with varying levels of contributions. Individually, the top 15 countries contributed 58 to 718 publications. Collectively they contributed 2521 papers and 151752 citations, constituting more than 100.0% share each in global publications and citations. Three out of top 15 countries contributed more than the average productivity (168.07): USA (718 papers), China (364 papers) and Italy (335 papers). Seven out of top 15 countries registered citation impact measured by CPP and Relative Citation Index (RCI), more than their average (60.2 and 1.53) (Table 2).

Table 2. Bibliometric Profile of the Top 15 countries with 57 or more papers

S. No.	Country	TP	TC	CPP	RCI	ICP	%ICP	TLS
1	United States	718	45493	63.36	1.61	268	37.33	586
2	China	364	11391	31.29	0.79	76	20.88	319
3	Italy	335	17984	53.68	1.36	139	41.49	536
4	United Kingdom	162	15708	96.96	2.46	121	74.69	455
5	South Korea	121	6799	56.19	1.43	32	26.45	257
6	Japan	120	6908	57.57	1.46	20	16.67	236
7	Germany	114	6804	59.68	1.52	78	68.42	391
8	Turkey	108	5492	50.85	1.29	16	14.81	246
9	Spain	86	6394	74.35	1.89	55	63.95	361
10	Canada	81	6452	79.65	2.02	54	66.67	179
11	India	71	5525	77.82	1.98	23	32.39	282
12	Australia	65	5991	92.17	2.34	43	66.15	292
13	France	59	6720	113.9	2.89	45	76.27	305
14	Brazil	59	1912	32.41	0.82	11	18.64	152
15	Poland	58	2179	37.57	0.95	16	27.59	164
	Total of top 15 countries	2521	151752	60.20	1.53	997	39.55	4761
	Global total	2423	95370	39.36	1.00			

TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; ICP: International Collaborative Papers; TLS: Total Link Strength

The research collaboration among the top 15 countries shows significant variation in Total Link Strength (TLS), ranging from 152 to 586. The USA led with a TLS of 586, followed by Italy (536) and the UK (455). Bilateral collaborations also varied, with the "USA-Italy" pair exhibiting the strongest link with 64 connections, followed by "USA-China" (45) and "USA-Germany" (35). A broader analysis of the top 30 most productive countries, visualized in a collaboration network, reveals two main clusters. Cluster 1 includes 16 countries like Italy, the UK, and Germany, while Cluster 2 consists of 7 countries such as the USA, China, and South Korea. The visualization highlights the USA, Germany, and France as particularly collaborative and productive (Figure 1). These 25 countries collectively demonstrate robust connectivity, evidenced by 435 links and a combined TLS of 2502 (Figure 1).

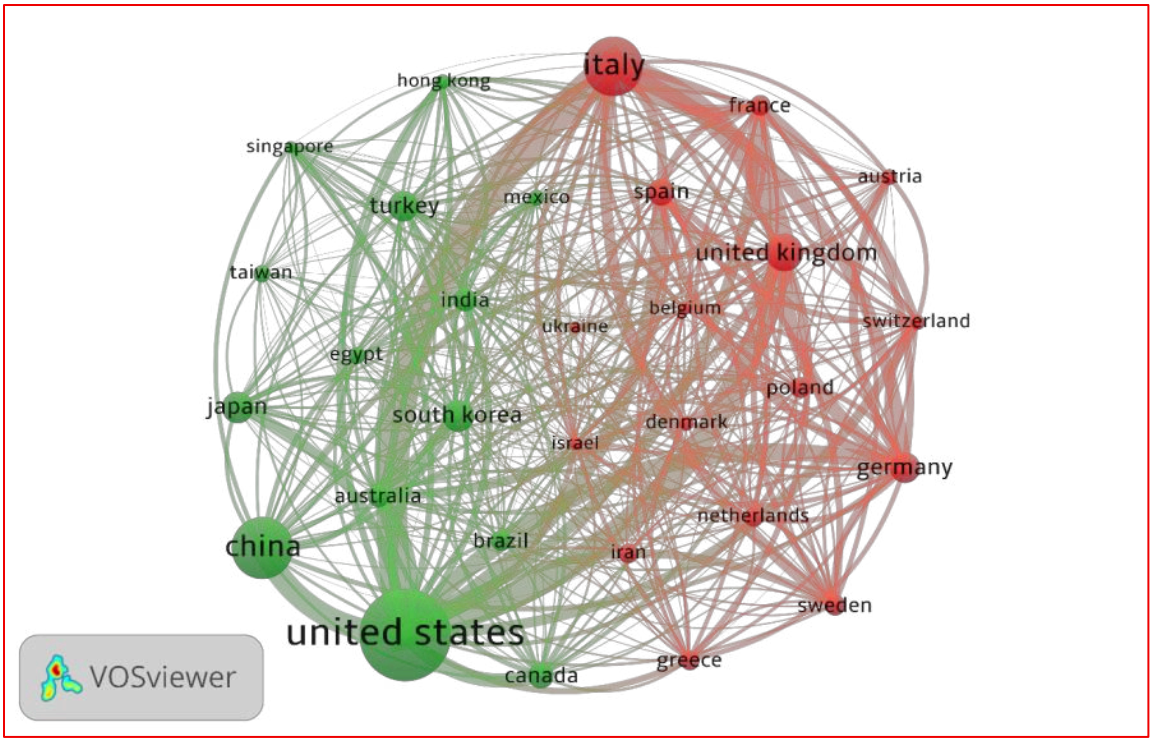

Figure 1. Collaboration network showing USA-Italy as the strongest bilateral link (TLS=64), suggesting shared clinical trial networks. Cluster 1 (16 countries) contributed 58% of publications, dominated by European nations, while Cluster 2 (7 countries) included China, reflecting its growing independence in MAFLD research

Leading Organizations

A total of 1165 organizations participated, with the top 25 contributing 1141 papers and 99,729 citations, accounting for 47.09% of global publications and over 100% of citations. Of these top 25, 19 were from the USA, 5 from Italy, and 1 from Sweden (**Supplementary Table 1**). Eight organizations, including IRCCS Ospedale Pediatrica Gesu (Italy) with 141 publications and the University of California, San Diego (USA) with 92, surpassed the average productivity. Similarly, eight organizations, such as Virginia Commonwealth University (USA)with a CPP of 515.0 and Columbia University (USA) with 267.86, exceeded the average citation impact. The proportion of international collaborative papers in individual organizational output ranged from 9.09% to 95.0%, averaging 32.16%. **Table 3** presents the bibliometric profile of the top six most productive and impactful organizations.

Table 3. Bibliometric details of the Top Six Productive and Impactful Organizations

S.No.	Name of the Organization	TP	TC	CPP	RCI	TLS
Six Most Productive Organizations						
1	IRCCS Ospedale Pediatrica Gesu, Italy	141	7120	50.50	1.28	370
2	University of California, San Diego, USA	92	9365	101.79	2.59	864
3	Sapienza Universita di Roma, Italy	76	4577	60.22	1.53	377
4	Cincinnati Children's Hospital Medical Center, USA	72	4741	65.85	1.67	671
5	Rady Children's Hospital, USA	58	3696	63.72	1.62	469
6	University of Cincinnati College of Medicine, USA	52	2724	52.38	1.33	413
Six Most Impactful Organizations						
1	Virginia Commonwealth University, USA	20	10,300	515	13.08	394
2	Columbia University, USA	29	7768	267.86	6.81	345
3	Indian University, School of Medicine, USA	35	8899	254.26	6.46	433
4	Universitadegli Studi dI Milano, Italy	37	4090	110.54	2.81	468
5	University of California, San Diego, USA	92	9365	101.79	2.59	864
6	Baylor College of Medicine, USA	40	3996	99.9	2.54	451
TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; RCI: Relative Citation Index; TLS: Total Link Strength						

Among the top 25 organizations, the TLS in research collaborations ranged from 149 to 864 (Supplementary Table 1). The University of California, San Diego, USA**,** exhibited the highest TLS at 864, followed by Cincinnati Children's Hospital Medical Center, USA (671), and the University of California San Diego, School of Medicine, USA (526). When examining bilateral collaborative links**,** the most frequent partnership was between Cincinnati Children's Hospital Medical Center, USA, and the University of Cincinnati College of Medicine, USA**,** with 51 links. Other strong collaborations included "IRCCS Ospedale Pediatrica Gesu, Italy, and Sapienza Universita di Roma, Italy" (45 links), and "University of California, San Diego, USA, and Rady Children's Hospital, USA" (43 links).

Leading Authors

Research on MAFLD in Children & Adolescents involved 12,633 authors, with the top 25 authors contributing significantly, accounting for 864 papers (35.66% of global publications) and 72,580 citations (76.10% of global citations) (Supplementary Table 2). These leading authors, primarily from the USA (15), Italy (9), and the UK (1),

published between 21 and 112 papers each. Notably, six authors—V. Nobili, A. Alisi, J.B. Schwimmer, M. Mouzaki, A. Mosca, and M.B. Vos—exceeded the average productivity. Additionally, eight of the top 25 organizations demonstrated above-average citation impact, with A.J. Sanyal (USA) showing the highest impact. International collaborations varied among individual authors, averaging 32.75% of their output. Supplementary Table 3 presents the bibliometric profile of the top six most productive and impactful authors.

Analysis of the top 25 authors in the field reveals varying TLS, with J.B. Schwimmer (USA) exhibiting the highest at 949. Collaborative links between author pairs ranged from 1 to 66, with the most frequent collaboration observed between "V. Nobili – A. Alisi" (66 links). When examining the top 30 authors, 172 inter-author links and a TLS of 1,092 were identified, forming four distinct collaborative clusters (Figure 2). Cluster 1, with 15 authors, is led by J.B. Schwimmer, M. Mouzaki, and M.B. Vos, while Cluster 2, comprising 9 authors, is headed by V. Nobili, A. Alisi, and A. Mosca, illustrating diverse collaborative patterns and leadership within the research network (Supplementary Figure 1).

Leading Journals

A total of 733 journals contributed to 2,423 papers, with a significant number (425) publishing only one paper, while a smaller group of 13 journals published between 26 and 66 papers each. The top 30 journals collectively produced 822 papers and received 46,573 citations, accounting for 33.92% of global publications and 48.83% of global citations. When ranked by productivity, the *Journal of Pediatric Gastroenterology & Nutrition* led with 70 papers. In terms of citation impact per paper, *Hepatology* stood out with 216.08 citations per paper (CPP), and by impact factor, the *Journal of Hepatology* had the highest at 26.8. The bibliometric profile of the top 25 journals with more than 17 papers each is presented in the Supplementary Table 4.

A co-citation analysis of the top 30 journals, each with 12 or more papers, revealed a network of 277 links and a TLS of 913. This analysis categorized the journals into four distinct clusters (Supplementary Figure 2), providing insight into their thematic groupings and collaborative relationships. Clusters 1 and 2 each contained 11 journals, while Cluster 3 had 5, and Cluster 4 contained 3, highlighting the significant influence these journals have in disseminating research and knowledge within the field.

Significant Keywords

Out of 12,409 keywords identified across 2,423 records, the most frequent were "nonalcoholic fatty liver" (2,124 occurrences) and "non-alcoholic fatty liver disease" (2,093 occurrences). A co-occurrence analysis of the top 50 keywords (those appearing 60 to 2,124 times) revealed three main thematic clusters (Figure 2). Cluster 1 (red) centered on biochemical markers and metabolic dysfunction**,** including terms like "triacylglycerol" and "alanine aminotransferase." Cluster 2 (green) focused on disease progression and comorbidities, with keywords such as "liver

biopsy" and "liver cirrhosis." Cluster 3 (blue) highlighted demographic and epidemiological aspects, featuring terms like "adolescent" and "childhood obesity." Bibliometric details of the top 50 keywords related to NAFLD in children is presented in the Supplementary Table 5.

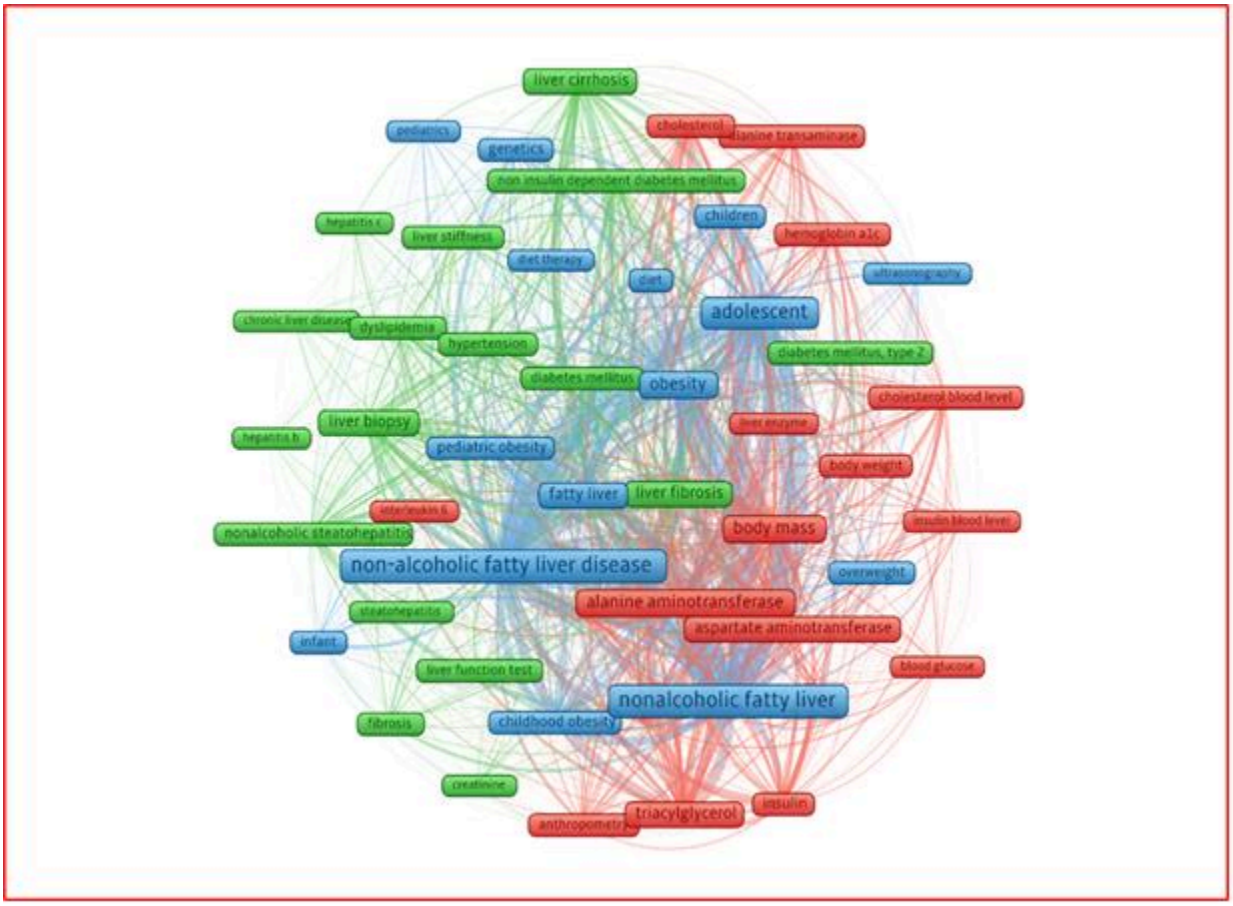

Figure 2. Network visualization of the top 50 author keywords

Highly-Cited Papers (HCPs)

Out of 2,423 papers, 190 (7.84%) were HCPs, garnering between 100 and 5,374 citations each, with a collective total of 51,127 citations and an average of 269.09 CPP. The majority of these HCPs (122 papers) fell within the 100-192 citation range, while a smaller, but impactful, group of 6 papers had 1,002 to 5,374 citations. The USA was the leading contributor to these HCPs with 100 papers, followed by Italy (42 papers) and the UK (33 papers). Institutions such as the University of California, San Diego, USA (23 papers) and IRCCS Ospedale Pediatrica Gesu, Italy (18 papers) were prominent in their contributions.

V. Nobili was the most prolific author among the HCPs, contributing to 17 papers, closely followed by A. Alisi and C.B. Sirlin (13 papers each). The *Journal of Hepatology* published the most HCPs (52 papers), with *Hepatology* (17 papers) and *Clinical*

Gastroenterology and *Hepatology* (13 papers) also being significant contributors. This highlights the key researchers, institutions, and journals driving impactful research in the field.

Discussion

The escalating global prevalence of obesity and metabolic syndrome has led to a critical increase in MAFLD among children and adolescents. This has established MAFLD as the most common chronic liver condition in this demographic. The reclassification from NAFLD to MAFLD in 2020 signified a pivotal shift in understanding, emphasizing the central role of metabolic dysfunction in the pathogenesis of hepatic steatosis [16]. This paradigm shift justifies the urgent need for early identification and intervention in pediatric MAFLD, as it can rapidly progress to severe outcomes, including cirrhosis and Hepatocellular Carcinoma (HCC), even in early childhood [17].

Our bibliometric analysis on MAFLD in children and adolescents has experienced significant growth from 2007 to 2024, as evidenced by a bibliometric analysis of 2,423 publications accumulating over 95,000 citations. Review articles notably show higher citation impact, indicating their crucial role in knowledge synthesis. The research landscape is heavily focused on clinical studies (50.47%), followed by pathophysiology and epidemiology, demonstrating a strong translational emphasis. Significant external funding supports a substantial portion of this research, highlighting considerable investment in the field. This global effort involves 115 countries, with the USA, China, and Italy leading in publication volume and demonstrating strong citation impacts, particularly the UK, France, and Australia. Collaborative networks are robust, with strong bilateral links observed between countries like the USA and Italy. Leading institutions in publication volume include IRCCS Ospedale Pediatrica Gesu and the University of California, San Diego, while institutions like Virginia Commonwealth University and Columbia University are recognized for highly cited research, affirming the dominance of North American and European contributions alongside growing Asian involvement.

The study also identified a highly productive author pool, with a small group of top authors contributing significantly to global publications and citations, forming strong collaborative partnerships. Research dissemination is primarily through 733 journals, with *The Journal of Pediatric Gastroenterology & Nutrition* being the most productive, and *Hepatology* and *The Journal of Hepatology* showing the highest citation impact and impact factor, respectively, indicating their central role in publishing influential research. Keyword analysis reveals dominant themes such as "nonalcoholic fatty liver," with co-occurrence analysis grouping terms into clusters related to biochemical markers, disease progression/comorbidities, and demographic/epidemiological aspects. A substantial number of HCPs, predominantly from the USA, Italy, and the UK, further underscore the impact of key institutions and authors, primarily published in *The Journal of Hepatology* and *Hepatology*, solidifying

their importance in advancing pediatric MAFLD research.

Pediatric MAFLD prevalence closely mirrors obesity rates, with studies indicating a 14-fold increased risk of severe liver disease or death in affected children compared to healthy peers [18]. While mortality rates have declined, hospitalizations continue to rise, highlighting the disease's growing burden. Key risk factors include obesity, insulin resistance, genetic predispositions (e.g., TM6SF2, PNPLA3, GCKR variants), and metabolic comorbidities like T2D and dyslipidemia [19]. The pathophysiological mechanisms involve a cascade of metabolic disturbances, including hepatic lipid accumulation, oxidative stress, endoplasmic reticulum stress, and inflammatory signaling. Pediatric MAFLD often shows distinct histologic patterns compared to adults, including predominant periportal inflammation and fibrosis [20].

Clinically, children with MAFLD often present with non-specific symptoms like fatigue, right upper quadrant pain, and hepatomegaly. Despite its insidious onset, MAFLD can progress rapidly in children, with documented cases of cirrhosis and HCC as early as age seven.[17] Management strategies primarily focus on lifestyle modifications, with some evidence for vitamin E improving histology, although effective pharmacotherapies remain elusive, as highlighted by trials like TONIC [21]. This highlights the need for developing age-specific treatment protocols and exploring emerging strategies targeting the gut-liver axis and genetic variants.

Despite the significant prevalence of MAFLD in South Asia, particularly among children and adolescents, research output from this region remains conspicuously limited. This disparity may stem from competing health priorities (e.g., infectious diseases), limited funding, or underrepresentation in global collaborations. Initiatives like the Global NAFLD/MAFLD Registry could incentivize participation from underrepresented regions. Funding bodies should prioritize grants for South Asian researchers, with mandates for international partnerships (e.g., USA-India consortia) to bridge this gap. Countries like India and Pakistan face escalating obesity rates and associated metabolic disorders, which contribute to the rising incidence of MAFLD among their younger populations. However, our analysis of the existing literature highlights a lack of comprehensive studies originating from South Asia, reflecting an urgent need for more focused research efforts. This gap is concerning, given that local dietary habits, genetic predispositions, and socio-economic factors may uniquely influence the epidemiology and management of MAFLD in these populations [22-25]. In 2021, an estimated 1.27 billion cases of MAFLD were reported globally, with an age-standardized prevalence rate of 15,018 per 100,000 people**.** The highest incidence of MAFLD during this period was concentrated in South and East Asia**.** This pervasive liver condition also contributed significantly to global mortality, with 138,328 deaths directly attributed to MAFLD and an additional 97,403 deaths stemming from MAFLD-related cirrhosis [26]. Increased research attention could not

only contribute to a better understanding of MAFLD in South Asian contexts but also inform tailored prevention and intervention strategies to combat this emerging health crisis.

Despite significant progress, substantial gaps in knowledge persist. There is a pressing need for standardizing non-invasive diagnostic biomarkers for pediatric populations, developing effective age-specific treatment protocols, and further investigating the role of epigenetic modifiers in disease progression [21]. The disproportionately limited research on pediatric MAFLD compared to adult populations, coupled with the lack of standardized diagnostic criteria and evidence-based therapeutic strategies, complicates disease management in children [27]. Future research should prioritize delineating the natural history of pediatric MAFLD, identifying risk factors for progression, and conducting well-designed clinical trials to determine optimal treatment approaches, including dietary interventions, exercise, and novel medications [21]. Ultimately, a shift towards multidisciplinary care models integrating hepatology, endocrinology, and nutritional

This study's reliance on Scopus, though justified by its coverage, may omit niche journals listed in other databases like in Web of Science. Citation metrics (CPP, RCI) favor highly cited topics like genetics over clinical guidelines, potentially skewing impact interpretation. We acknowledge that while citation counts (CPP, RCI) reflect academic influence, they may not correlate with clinical relevance or innovation. Furthermore, alternative metrics like altmetrics or clinical implementation indices could complement future analyses.

Conclusion

This bibliometric analysis provides a comprehensive overview of the research landscape concerning MAFLD in children and adolescents. The findings highlight the escalating global research interest, the pivotal contributions of key countries and institutions, the collaborative networks among authors, and the dominant thematic areas of study. While significant advancements have been made in understanding the epidemiology, pathophysiology, and clinical presentation of pediatric MAFLD, the persistent challenges in diagnosis, management, and the lack of effective pharmacotherapies underscore the urgency for continued, collaborative, and targeted research efforts. This study serves as a valuable resource for researchers and clinicians, informing future priorities to address this critical public health challenge and ultimately improve the long-term health outcomes for children and adolescents affected by MAFLD.

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Conflicts of Interest

The authors declare no conflicts of interest related to the content of this manuscript. No financial or personal relationships with other people or

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Author Contributions

RV: Conceptualization, Literature Search, Manuscript writing, editing and final approval; AS: Conceptualization, Manuscript writing, editing and final approval; BMG, GMNM: Methodology, Analysis, Manuscript writing, editing and final approval; AV: Literature Search, Manuscript writing, editing and final approval;

Ethical Considerations

This review did not involve any human or animal studies, and thus ethical approval was not required.

Data Availability

All data and materials utilized for this review are referenced within the manuscript and are available upon request.

Use of AI Tools

The authors utilized AI tools, Grammarly, to assist in the proofreading and editing of this manuscript to enhance clarity and coherence. The use of such tools was limited to language and stylistic improvements and did not influence the scientific content or analysis presented in the review.

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Supplementary Table 1: Bibliometric Profile of the Top 25 organizations with 28 and more papers

S.No	Name of the organization	TP	TC	CPP	RCI	HI	ICP	%ICP	TLS	HCP
1	IRCCS Ospedale Pediatrica Gesu, Italy	141	7120	50.50	1.28	47	60	42.55	370	18
2	University of California, San Diego, USA	92	9365	101.79	2.59	42	33	35.87	864	23
3	Sapienza Universita di Roma, Italy	76	4577	60.22	1.53	35	24	31.58	377	10
4	Cincinnati Children's Hospital Medical Center, USA	72	4741	65.85	1.67	24	14	19.44	671	8
5	Rady Children's Hospital, USA	58	3696	63.72	1.62	27	9	15.52	469	12
6	University of Cincinnati College of Medicine, USA	52	2724	52.38	1.33	16	12	23.08	413	3
7	Emory University School of Medicine, USA	47	2520	53.62	1.36	23	10	21.28	442	4
8	University of California San Diego, School of Medicine, USA	46	3253	70.72	1.80	23	6	13.04	526	11
9	Cleveland Clinic Foundation, USA	45	2452	54.49	1.38	25	22	48.89	290	5
10	Baylor College of Medicine, USA	40	3996	99.90	2.54	20	14	35.00	451	7
11	Emory University, USA	39	3590	92.05	2.34	20	11	28.21	372	6
12	Universitadegli Studi dI Milano, Italy	37	4090	110.54	2.81	26	18	48.65	468	9
13	Consiglio Nazionale delleRicerche, Italy	35	2346	67.03	1.70	27	4	11.43	149	6
14	Indian University, School of Medicine, USA	35	8899	254.26	6.46	20	12	34.29	433	5
15	University of California San Francisco, USA	33	2615	79.24	2.01	21	3	9.09	338	7
16	John Hopkins Bloomberg School of Public Health, USA	32	2923	91.34	2.32	21	3	9.38	409	6
17	Yale School of Medicine, USA	32	2079	64.97	1.65	18	22	68.75	186	4
18	Karolinska Institutet, Sweden	31	1932	62.32	1.58	31	24	77.42	405	4
19	Northwestern Universit Feinberg School of Medicine, USA	31	2634	84.97	2.16	18	9	29.03	315	6
20	Universitadegli Studi della Campania Luigi Vanvitelli, Italy	31	874	28.19	0.72	17	6	19.35	200	0
21	University of Colorado School of Medicine, USA	30	1891	63.03	1.60	16	4	13.33	261	3
22	Virginia Commonwealth University, USA	20	10,300	515.00	13.08	23	19	95.00	394	16
23	University of Colorado Anschutz Medical Campus, USA	29	1442	49.72	1.26	14	4	13.79	219	3
24	Columbia University, USA	29	7768	267.86	6.81	2	7	24.14	345	7
25	Harvard Medical School, USA	28	1902	67.93	1.73	16	17	60.71	229	5
	Total of top 25 organizations	1141	99729	87.40	2.22	572	367	32.16	9596	188
	Global total	2423	95370	39.36	1.00					

		47.09								

TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; RCI: Relative Citation Index; HI: H-Index; ICP: International Collaborative Papers; TLS: Total Link Strength; HCP: Highly Cited Papers

Supplementary Table 2: Bibliometric details of the top 25 authors

S.No	Name	Affiliation	TP	TC	CPP	RCI	HI	ICP	%ICP	TLS	HCP
1	V. Nobili	IRCCS Ospedale Pediatrico Bambino Gesù	112	6785	60.58	1.54	45	53	47.32	574	17
2	A. Alisi	IRCCS Ospedale Pediatrico Bambino Gesù	89	4993	56.10	1.43	39	35	39.33	648	13
3	J.B. Schwimmer,	Rady Children's Hospital	50	3071	61.42	1.56	24	8	16.00	949	11
4	M. Mouzaki	Cincinnati Children's Hospital Medical Center	47	1564	33.28	0.85	16	14	29.79	449	2
5	A. Mosca	IRCCS Ospedale Pediatrico Bambino Gesù	42	1424	33.90	0.86	21	18	42.86	315	2
6	M.B.Vos	Emory University School of Medicine	41	3652	89.07	2.26	20	9	21.95	572	7
7	S.A. Xanthakos	Cincinnati Children's Hospital Medical Center	38	1788	47.05	1.20	17	6	15.79	569	4
8	N. Alkhouri	Cleveland Clinic Foundation	36	2101	58.36	1.48	25	22	61.11	246	6
9	J.E. Lavine	Columbia University, USA	33	7664	232.24	5.90	23	4	12.12	676	7
10	R. Loomba	University of California, San Diego, USA	31	4213	135.90	3.45	22	13	41.94	376	8
11	K. Bramlage	Cincinnati children’s Hospital Medical Centre, USA	27	642	23.78	0.60	15	3	11.11	753	1
12	C.B. Sirlin	University of California, San Diego, USA	27	3648	135.11	3.43	23	6	22.22	904	13
13	K.P. Newton	Rady Children’s Hospital, USA	26	1884	72.46	1.84	18	2	7.69	484	8
14	R. Kohli	Cincinnati children’s Hospital Medical Centre, USA	25	1410	56.40	1.43	13	7	28.00	487	2
15	N. Panera	IRCCS Ospedale Pediatrico Bambino Gesù	24	924	38.50	0.98	16	6	25.00	232	2
16	A. Crudele	IRCCS Ospedale Pediatrico Bambino Gesù	23	784	34.09	0.87	14	7	30.43	228	2
17	M.S.Middleton	University of California, San Diego, USA	23	2394	104.09	2.64	17	4	17.39	339	10
18	D.E. Kleiner	National Cancer Institute, USA	22	2877	130.77	3.32	18	4	18.18	656	8
19	l. Valenti	Universitadegli Studi dI Milano, Italy	22	3486	158.45	4.03	19	14	63.64	457	8
20	A.C.Arce-Clachar	University of Cincinnati College of Medicine	21	216	10.29	0.26	9	1	4.76	240	1

21	C.D.Byrne	University Hospital Southampton NHS Foundation Trust, UK	21	3296	156.95	3.99	18	20	95.24	250	7
22	C. Chiesa	Consiglio Nazionale delleRicerche	21	1184	56.38	1.43	19	0	0.00	185	3
23	R. De Vito	IRCCS Ospedale Pediatrico Bambino Gesù	21	920	43.81	1.11	15	13	61.90	191	0
24	L. Pacifico	Consiglio Nazionale delleRicerche	21	1184	56.38	1.43	19	0	0.00	143	3
25	A.J. Sanyal	Virginia Commonwealth University	21	10476	498.86	12.67	17	14	66.67	480	12
			864	72580	84.00	2.13	502	283	32.75	11403	157
			2423	95370	39.36	1.00					
			35.66	76.10							
TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; RCI: Relative Citation Index; HI: H-Index; ICP: International Collaborative Papers; TLS: Total Link Strength; HCP: Highly Cited Papers											

Supplementary Table 3: Bibliometric profile of the Top Six Productive and Impactful Authors

S.No.	Name	Affiliation	TP	TC	CPP	RCI	TLS
Top Six Productive Authors							
1	V. Nobili	IRCCS Ospedale Pediatrico Bambino Gesù, Italy	112	6785	60.58	1.54	574
2	A. Alisi	IRCCS Ospedale Pediatrico Bambino Gesù, Italy	89	4993	56.10	1.43	648
3	J.B. Schwimmer	Rady Children's Hospital, USA	50	3071	61.42	1.56	949
4	M. Mouzaki	Cincinnati Children's Hospital Medical Center, USA	47	1564	33.28	0.85	449
5	A. Mosca	IRCCS Ospedale Pediatrico Bambino Gesù, Italy	42	1424	33.90	0.86	315
6	M.B.Vos	Emory University School of Medicine, USA	41	3652	89.07	2.26	572
Top Six Impactful Authors							
1	C.D. Byrne	University Hospital Southampton NHS Foundation Trust, UK	21	3296	156.95	3.99	250
2	A.J. Sanyal	Virginia Commonwealth University, USA	21	10476	498.86	12.67	480
3	l. Valenti	Universitadegli Studi dI Milano, Italy	22	3486	158.45	4.03	457
4	R. De Vito	IRCCS Ospedale Pediatrico Bambino Gesù, Italy	21	920	43.81	1.11	191
5	N. Alkhouri	Cleveland Clinic Foundation, USA	36	2101	58.36	1.48	246
6	V. Nobili	IRCCS Ospedale Pediatrico Bambino Gesù, Italy	112	6785	60.58	1.54	574

TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; RCI: Relative Citation Index; TLS: Total Link Strength

Supplementary Table 4: Bibliometric Profile of the Top 25 journals with 17 or more papers

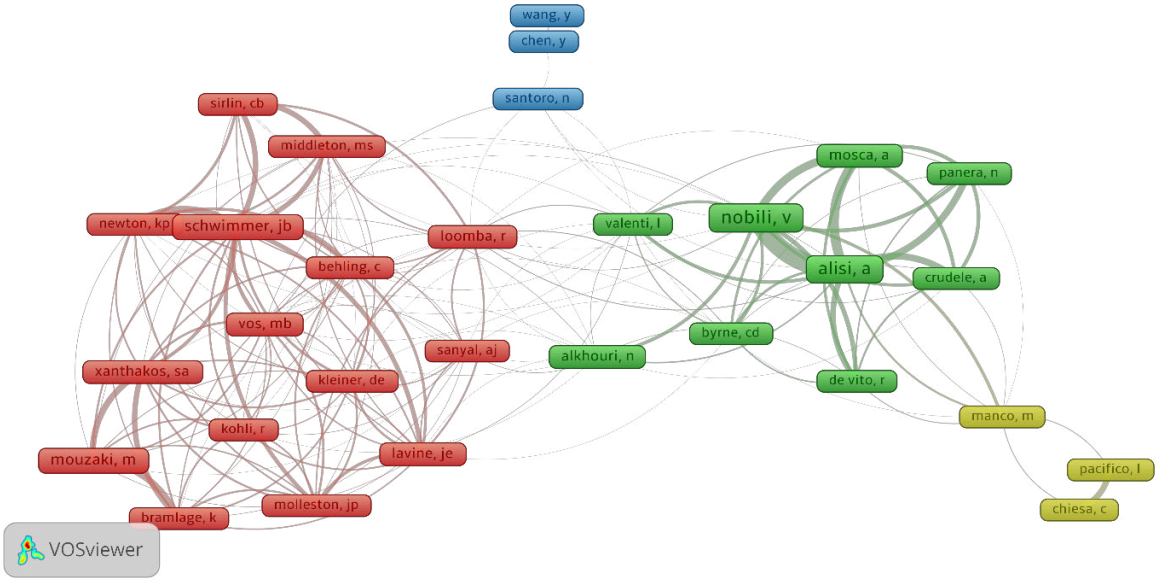
S.No.	**Name of the Journal**	**TP**	**TC**	**CPP**	**IF**	**HCP**
1	*Journal of Pediatric Gastroenterology and Nutrition*	70	2443	34.90	2.4	4
2	*Nutrients*	53	1468	27.70	4.8	3
3	*Hepatology*	52	11236	216.08	13.0	17
4	*Journal Of Hepatology*	52	8304	159.69	26.8	27
5	*Liver International*	50	1712	34.24	6.0	2
6	*Plos One*	50	1946	38.92	2.0	1
7	*Pediatric Obesity*	49	1073	21.90	4.0	0
8	*World Journal Of Gastroenterology*	49	3282	66.98	4.3	9
9	*Clinical Gastroenterology and Hepatology*	40	3996	99.90	11.6	13
10	*International Journal Of Molecular Sciences*	31	1125	36.29	4.9	4
11	*Journal Of Pediatrics*	29	1125	38.79	3.9	3
12	*Journal Of Pediatric Endocrinology and Metabolism*	28	562	20.07	1.3	0
13	*Scientific Reports*	26	741	28.50	3.8	1
14	*Journal Of*	25	1393	55.72	3.7	4

	Gastroenterology and Hepatology Australia					
15	*Digestive Diseases and Sciences*	24	701	29.21	2.5	0
16	*European Journal of Gastroenterology and Hepatology*	23	554	24.09	2.3	1
17	*Frontiers in Endocrinology*	22	309	14.05	3.9	0
18	*Journal of Clinical Endocrinology and Metabolism*	22	685	31.14	5.0	1
19	*European Journal Of Pediatrics*	20	553	27.65	3.0	2
20	*BMC Pediatrics*	19	449	23.63	2.05	0
21	*Annals of Hepatology*	18	519	28.83	3.7	1
22	*Journal of Gastroenterology*	18	674	37.44	6.9	1
23	*Nutrition Metabolism and Cardiovascular Diseases*	18	593	32.94	3.5	2
24	*Alimentary Pharmacology and Therapeutics*	17	762	44.82	6.6	3
25	*BMC Gastroenterology*	17	368	21.65	2.5	0
		822	46573	56.66		
		2423	95370	39.36		
		33.92	48.83			
TP: Total Papers; TC: Total Citations; CPP: Citations Per Paper; IF: Impact Factor; HCP: Highly Cited Papers						

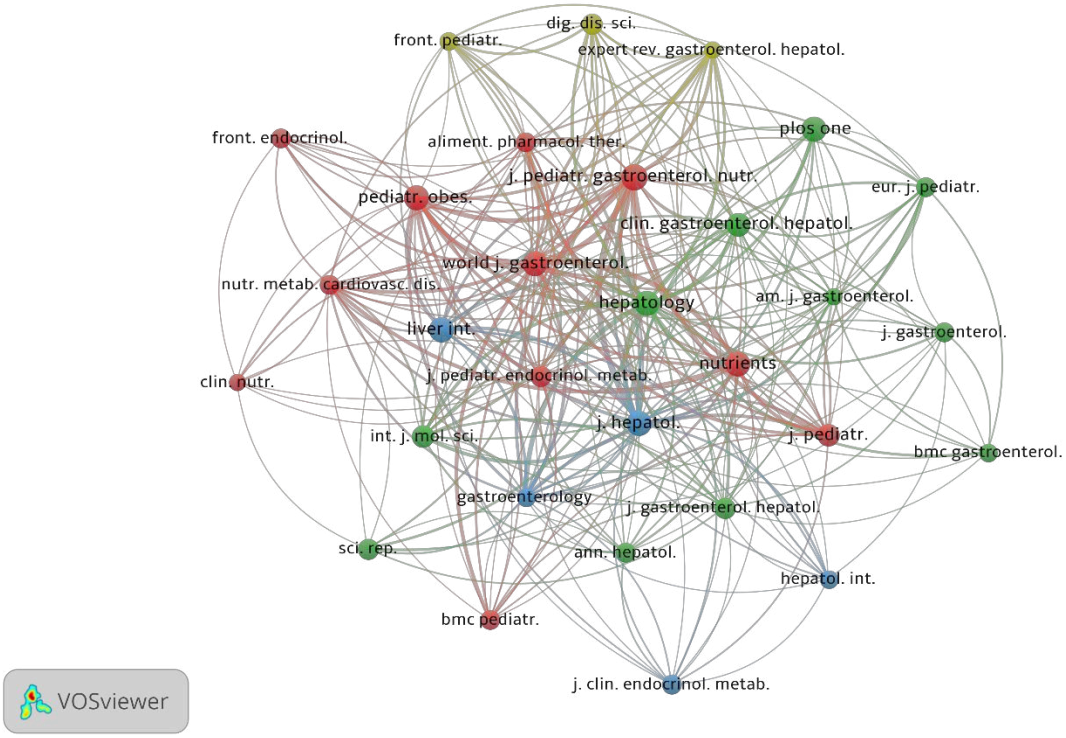
Supplementary Table 5: Bibliometric Details of the Top 50 keywords related to non-alcoholic fatty liver disease in children

Keyword	Occ.	TLS	Cluster	Links	Keyword	Occ.	TLS	Cluster	Links
nonalcoholic fatty liver	2124	15549	3	49	diabetes mellitus	204	1930	2	49
non-alcoholic fatty liver disease	2093	14939	3	49	Dyslipidemia	196	1953	2	49
Adolescent	1583	12132	3	49	Anthropometry	190	2096	1	49
Obesity	1068	8981	3	49	body weight	189	1884	1	49
body mass	904	8508	1	49	Infant	188	1132	3	48
alanine aminotransferase	866	8716	1	49	hemoglobin a1c	171	2036	1	49
fatty liver	700	5973	3	49	Fibrosis	161	1357	2	49
aspartate aminotransferase	634	6657	1	49	c reactive protein	139	1523	1	49
Triacylglycerol	626	6490	1	49	liver stiffness	137	1356	2	49
insulin resistance	552	5345	1	49	diabetes mellitus, type 2	135	1326	2	49
liver biopsy	494	4441	2	49	Overweight	128	1240	3	49
liver cirrhosis	492	3869	2	49	liver function test	127	1225	2	49
liver fibrosis	489	4344	2	49	Diet	120	926	3	46
childhood obesity	424	4073	3	49	insulin blood level	116	1423	1	49
Insulin	367	4057	1	49	Ultrasonography	113	983	3	49
Children	340	2705	3	49	blood glucose	109	1256	1	47
pediatric obesity	319	3070	3	49	Paediatrics	106	783	3	48
glucose blood level	303	3544	1	49	hepatitis c	93	704	2	47
nonalcoholic steatohepatitis	289	2312	2	49	interleukin 6	91	854	1	48
Genetics	278	2040	3	49	diet therapy	85	691	3	48
Hypertension	262	2664	2	49	chronic liver disease	83	670	2	48
non insulin dependent diabetes mellitus	262	2539	2	49	Steatohepatitis	76	640	2	48
Cholesterol	260	2945	1	49	Creatinine	74	782	2	48
cholesterol blood level	250	2901	1	49	liver enzyme	68	690	1	48
alanine transaminase	235	2300	1	49	hepatitis b	60	466	2	46

(Occ.: Occurrence; TLS: Total Link Strength)



Supplementary Figure 1: Collaboration Network of the Top 30 authors generated using VOSviewer



Supplementary Figure 2: Network visualization of the Top 30 journals

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TECHNICAL NOTE

Upper GI Endoscopy in a Patient with Submucous Fibrosis

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Abstract

Upper gastrointestinal (GI) endoscopy in a patient with submucous fibrosis is challenging and risky, as there is hardly any mouth opening for a mouth guard to be inserted. We devised a new innovative technique with the use of Guedel airway insertion for performing upper GI endoscopy in patients with small mouth opening(trismus) or restricted mouth opening

Keywords: Upper GI endoscopy, Trismus, Submucous Fibrosis

A 28-year-old male patient with a history of melena and loss of weight for the last few months came for an upper GI endoscopy. The patient had a history of having betel quid and chewing tobacco for almost a decade, with restricted mouth opening due to submucous fibrosis. It was impossible to insert the traditional mouth guard to be inserted prior to insertion of the endoscope due to the interincisor distance being less than two fingers. The patient was not willing to undergo any type of maxillofacial or dental surgical intervention to increase the mouth opening before endoscopy.

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Figure 1. Upper GI endoscopy being done with Guedel airway as a mouth guard

We devised our innovative technique of inserting Guedel airway, large adult 10 cm into the oral cavity for mouth opening and performed upper GI endoscopy from the side of the Guedel airway. The upper GI endoscopy was performed comfortably under light sedation without any discomfort or resistance from the patient (Figure 1).

Performing upper GI endoscopy in a patient with submucous fibrosis is often challenging and risky, as any resistance from the patient can lead to potential life-threatening complications during the procedure [1]. There are few case reports of using a Doyen mouth retractor or custom-made plastic syringe [2], the Guedel airway was never used. Since there is no previous literature or any published report available about this technique, this is probably the first such case, and we recommend this technique in all patients having extremely narrow mouth openings for upper GI endoscopy in the future.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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LETTER TO THE EDITOR

Fatal inhalational paraquat poisoning: Need for awareness among Indian Farmers

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Dear Editor,

Paraquat (1-methyl-4-(1-methylpyridin-1-ium-4-yl)pyridin-1-ium) is a non-selective herbicide extensively used in agricultural activities in India. Unfortunately, it is also a means of self-harm due to its high acute toxicity and the absence of an effective antidote [1]. Recently, paraquat has also been used in criminal poisonings [2-4]. While the suicidal and homicidal abuse of paraquat in India has received attention from the scientific community, accidental exposure among pesticide applicators and farmers remains a significant concern that needs to be addressed. The morbidity and mortality associated with accidental poisonings are high in vulnerable groups such as children and the elderly [5]. Here, we present a case of fatal acute inhalational paraquat poisoning.

A 55-year-old male farmer presented with fever and altered sensorium following occupational exposure to a pesticide during agricultural activity without appropriate personal protective equipment. Notwithstanding supportive medical intervention, his condition deteriorated, and he succumbed after 48 hours while undergoing treatment at a healthcare facility. During police investigation and subsequent verification of medical records, the herbicide inhaled turned out to be paraquat dichloride. Clinically, the deceased presented with breathlessness and abdominal pain. Laboratory investigation revealed elevated liver enzymes, urea and creatinine levels, indicating multiorgan organ involvement. Homogenous diffuse fluffy infiltrates were noted on chest X ray. All the above-mentioned findings were consistent with paraquat poisoning noticed in general medical practice.

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At autopsy, the deceased was lean-built, and the body showed a generalized yellowish hue, suggestive of liver failure. On internal examination, the brain was oedematous with a mild yellowish discoloration (Figure 1) and weighed 1150 grams. The lungs were markedly congested, haemorrhagic, and indurated in the upper lobes, with the right lung adherent to the thoracic cavity (Figure 2). The right lung weighed 774 grams, while the left lung weighed 738 grams. On histopathological examination, pulmonary oedema and interstitial haemorrhages were noted amidst hemosiderin-laden macrophages, and foci of congested blood vessels (Figure 3). The liver was enlarged, weighed 1274 grams, and exhibited a yellowish discoloration (Figure 4). On histopathological examination fatty changes with peripheral cellular infiltrates were present (Figure 5). The right kidney weighed 131 grams, and the left kidney weighed 130 grams, both showing yellowish discoloration (Figure 6). Histopathological examination demonstrated mild interstitial infiltrates and interstitial haemorrhages (Figure 7). The stomach contained approximately 100 mL of green fluid with no suspicious odour, and the gastric mucosa was normal. Chemical analysis of routine viscera, including the liver, kidneys, gastric contents, and blood, did not detect paraquat. Although preserving lungs would have yielded a positive result with respect to detection of paraquat we did not preserve lungs assuming good systemic distribution of paraquat in this case.

A common reason for the non-detection of paraquat in biological matrices is its rapid elimination from the body, particularly when there is a prolonged survival period following ingestion or exposure. Additionally, paraquat concentrations may fall below the analytical limit of detection, or the compound may undergo degradation prior to analysis. Furthermore, a significant time lapse between exposure and death can also contribute to undetectable levels in post-mortem samples. However, taking into account the history of exposure, a review of medical records from the time of initial treatment, and relevant toxic pathological findings showing characteristic *paraquat lung* with *hepatorenal* involvement, the cause of death was determined to be paraquat poisoning. The police investigation concluded the manner of death was accidental.

Since the exposure occurred in an informal setting and an open area, calculating the actual levels of paraquat in ambient air was difficult. However, the general levels at which paraquat becomes fatal are mentioned here. Time Weighted Average (TWA) for paraquat dichloride is 0.1 mg/m³ as respirable dust [6]. The Time Weighted Average (TWA) refers to the average exposure to a hazardous substance over a standard period, usually around 8 hours which is used in occupational health regulation [7]. The Threshold Limit Value (TLV) is the level of chemical concentration to which a worker can be exposed on a daily basis without experiencing adverse health effects [7]. Sadly, no such values are available for farming activities in our country since there is no corporate farming as well as large swathes of land are held by small and marginal farmers.

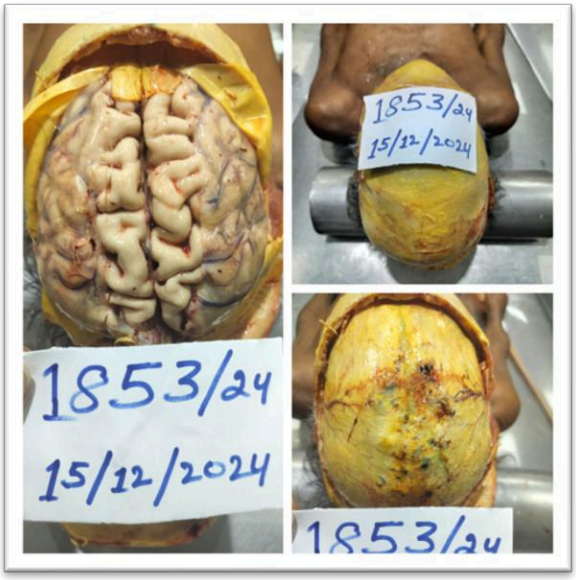

Figure 1. Icteric scalp, dura and oedematous brain

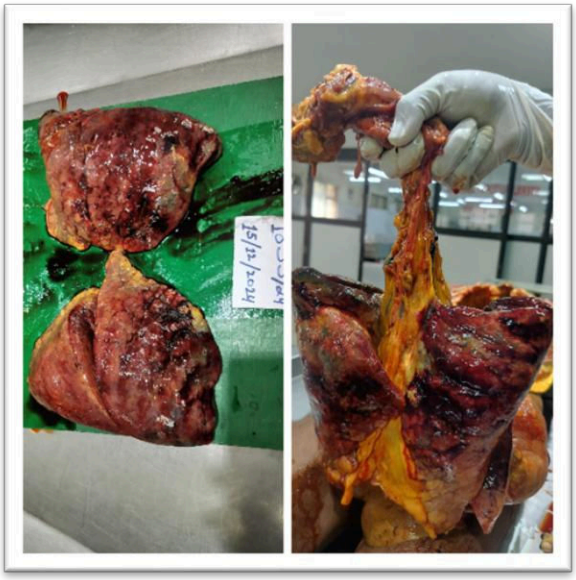

Figure 2. Haemorrhagic, heavily congested lungs

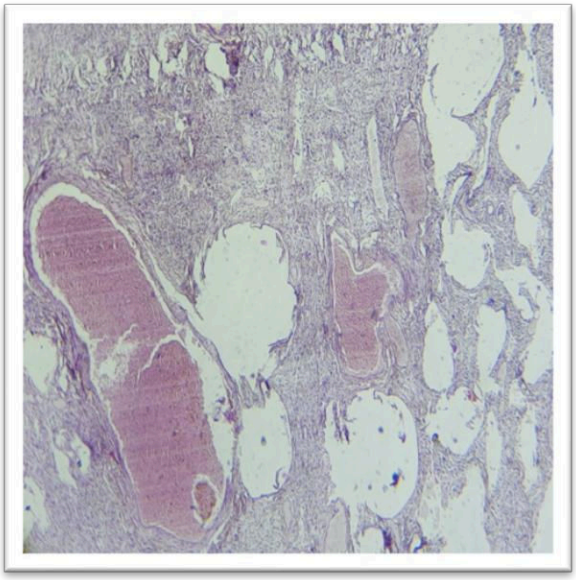

Figure 3. Histopathology lung (H & E, 400X), Pulmonary oedema and interstitial haemorrhages

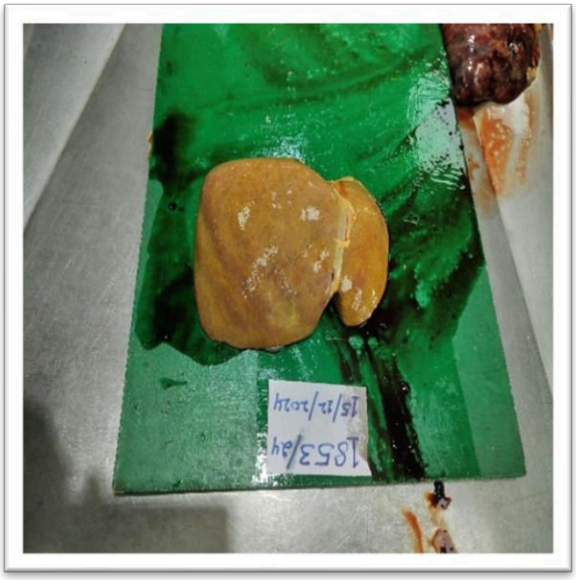

Figure 4. Yellowish liver

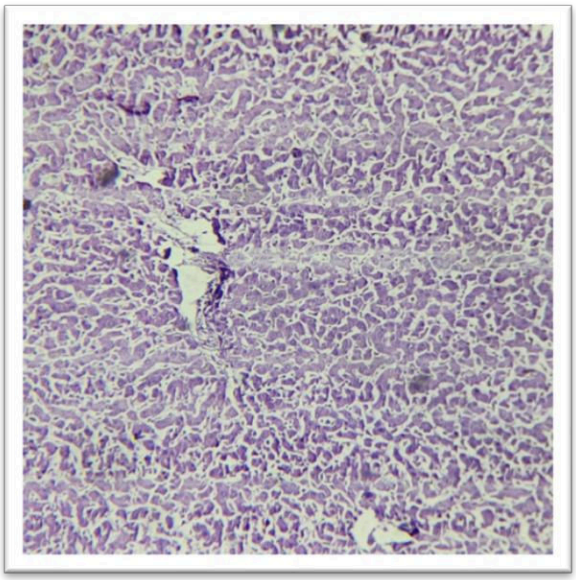

Figure 5. Histopathology liver (Haematoxylin and Eosin staining, 400X), Fatty changes with peripheral cell infiltration

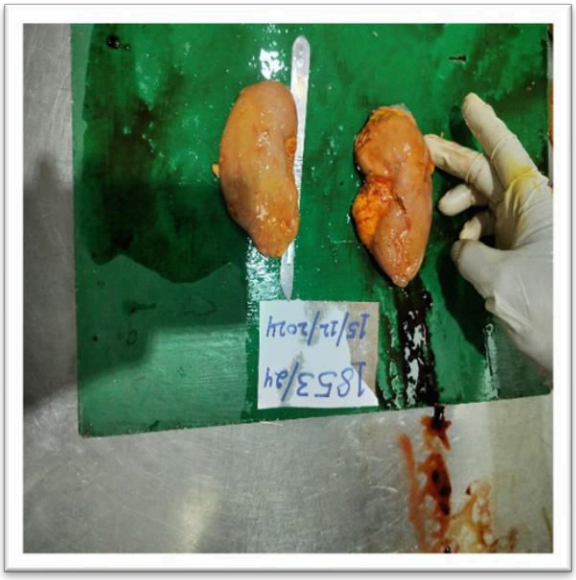

Figure 6. Yellowish discolouration of kidneys

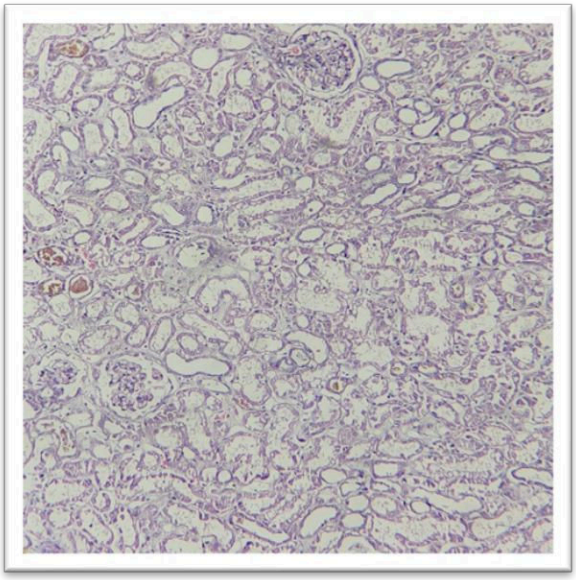

Figure 7. Histopathology Kidney (Haematoxylin and Eosin staining, 100X), Interstitial haemorrhages and infiltrates.

The lowest relevant inhalation no-observed-effect concentration (NOEC) for paraquat is 0.01 mg/m³, based on a 21-day whole-body exposure study in rats according to a recent risk assessment report [8]. With the lungs being one of the primary target organs for toxicity in paraquat poisoning [9], inhalational exposure—both in acute and chronic settings—can be fatal. It is common for Indian farmers to work without gloves or masks (unsafe pesticide use), leading to unintended exposure through both inhalation and dermal contact [10]. There have been instances of skin corrosion and burns due to occupational dermal exposure to paraquat [11]. However, this case emphasises the often-overlooked inhalational paraquat poisoning. From the Bhopal gas tragedy to the Yavatmal pesticide poisonings, there have been instances of mass casualties due to inhalational chemical exposures in India [12].

The history provided by the police and the relatives of the deceased was vague and lacked important details, making it unlikely quantify the inhalational paraquat exposure. There is limitation in measuring the paraquat concentration in air/body in these circumstances. The accurate estimation requires samples to be collected from the filtration system of the sprayers which are generally not used. In rural India, owing to poor financial support, knapsack/back pack sprayers are commonly used in agricultural activities. These sprayers are minimally motorized and does not have any air filters. Thus, it is impossible to sample and analyse airborne paraquat quantities.

In our country, farmers are exposed to a range of pesticides, including insecticides, herbicides, fungicides, and rodenticides. The extent of exposure and their adverse effects vary depending on the chemical composition of the pesticide and the target organ affected. This exposure can lead to a several health issues, including respiratory diseases, cardiovascular problems, gastrointestinal disturbances, and neurological conditions. Chemical pesticides, which include water-insoluble

chemicals such as nitrogen dioxide and phosgene, may cause toxic pulmonary damage and some pesticides may can cause skin corrosion [13].

A national survey in the United States identified farming as one of the most hazardous occupations, with pesticide use being a major contributing factor. Waggoner et al. analysed 338 injury-related fatalities over 727,543 person-years (1993–2008), noting an increasing trend in pesticide-related deaths. Pesticide dispersion and runoff pose risks to the environment and nearby individuals exposed during spraying. Five herbicides—2,4,5-T, paraquat, alachlor, metribuzin, and butylate—have been linked to a higher risk of fatal injuries [14]. Dermal absorption of organophosphates can cause severe neurological symptoms or death, while pesticides may also trigger anaphylaxis or contact dermatitis [15].

Although no protective gear or application technique can fully eliminate pesticide exposure, many farmers hesitate to use recommended protective equipment, increasing their risk. Pesticide-related risks can be minimized by taking precautions during transportation, storage, handling, application, and disposal. Formulations with a pH below 5 or above 8 can cause eye irritation and corneal opacity, especially in granular and dust forms. Oral exposure may result from poor hygiene practices, such as using the mouth to clear clogged nozzles, drinking from contaminated hoses, or handling food with pesticide-contaminated hands. Farmers can reduce exposure by using washable PPE, including goggles to prevent ocular exposure, respirator masks for inhalational protection, and rubber-lined clothing to prevent dermal contact. Clothes made of denim fabric have some protective effect [15]. In summary:

1. Try to avoid skin contact, wash hands thoroughly with water and soap after use.
2. Label the containers, use proper spraying equipment, check for any leaks and wear and tear changes in the spraying equipment.
3. Store the agrochemicals in a cool, dry and well-ventilated room, avoid spraying in windy conditions to prevent drift and inhalation.
4. Wash contaminated clothing and body parts and provide awareness to the farmers and the general public.

It is necessary to create awareness among Indian farmers about the hazards of unsafe pesticide handling as it can impact their health in multiple ways. Comprehensive intervention measures including awareness campaigns and safety training programs are a need of the hour [16]. Nevertheless, it is important to design novel risk communication strategies to inculcate a safety culture among the rural population.

We cannot always blame the farmer or pesticide applicator for this precarious situation. In fact, they are not in a financial position to purchase safety gear. The pesticide companies also have a responsibility to ensure the safe use of hazardous substances manufactured by them. It is time to think of designing agrochemicals that are effective but do not pose an occupational hazard. It would be great if the pesticide companies consider distributing washable personal protective equipment (PPE) free of cost during each crop season and actively promote their use as a corporate social responsibility in selected areas of the country where there is rampant use of pesticides in agriculture.

The local health care workers should work in collaboration with agriculture extension officers to spread the word on safe handling of pesticides. Practical demonstrations on wearing gloves and masks should be carried out before the crop season begins.

Limitations

Paraquat was not detected in biological matrices in this case due to lapse of time. Lungs were not preserved for chemical analysis. Quantitative analysis of viscera was not carried out due to lack of resources.

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Conflicts of interest

The authors declare that they do not have conflict of interest.

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Ethics committee approval

Addressed by the authors.

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