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ROLE OF TELEMEDICINE IN FOLLOW UP AFTER SPINE SURGERY

Thesis

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

MAGISTER OF CHIRURGIAE (MCh) (NEUROSURGERY)

JUNE, 2023 **DR. TOTALA PANKAJ RAJENDRAKUMAR**

AIIMS, JODHPUR

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DECLARATION

I hereby declare that this project, titled **"Role of Telemedicine in Follow Up after Spine Surgery"** is a bonafide record of my original research work. It has not been submitted to any other institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

This is to certify that this thesis, titled **"ROLE OF TELEMEDICINE IN FOLLOW UP AFTER SPINE SURGERY"** is a bonafide work of **Dr. Totala Pankaj Rajendrakumar**, performed under our guidance and supervision, in the Department of Neurosurgery at All India Institute of Medical Sciences (AIIMS), Jodhpur, during the period of study for degree of **Magister Chirurgiae (MCh) Neurosurgery,** from July 2020 to June 2023.

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Dedicated to
my beloved parents,
Teachers & Friends

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Although it is my name that appears on the cover of this dissertation, a great many people have contributed to its successful fruition, and I take this opportunity to express my heartfelt gratitude towards these people –

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"From inability to let well alone;

From too much zeal for the new and contempt for what is old;

From putting knowledge before wisdom, science before art and cleverness before commonsense;

From treating patients as cases;

And from making the cure of the disease more grievous than the endurance of the same,Good Lord, deliver us".

Dr. Totala Pankaj Rajendrakumar

SYNOPSIS

Introduction: It is well documented that there is an acute shortage of Neurosurgeons and Spine surgeons especially in rural areas of developing countries. Aim of this study is to evaluate role of telemedicine in follow up after spine surgery, to correlate success rate of telemedicine with patients' diagnosis and demographics also to identify barriers for successful telemedicine consultations.

Methods: All patients undergoing spine surgeries including Cranio-vertebral junction surgeries from January 2021 to June 2022 were included in study. Success rate of telemedicine was calculated using simple formula: Success rate of telemedicine = successful telemedicine consultations/Total number of telemedicine consultation x 100. Success rate was evaluated with respect to demographic features and underlying disease related factors.

Results: Eighty-four patients formed the study group in which a total of 181 video tele-consultations were done. Overall success rate of telemedicine was 82.87%. Higher socioeconomic and educational statuses were related to higher success rates of tele-consultations (p-Value < 0.05). Issue related to internet communication network leading to failure in video calling and failure to share image/videos was another major cause of failure.

Conclusions: Success rate of telemedicine follow up after spine surgery is less compared to developed countries. Success rate was significantly better in patients with higher educational and socioeconomic status. Given recent evidence attesting to the feasibility of telemedicine in spine surgery and promising patient results, telemedicine may remain as a viable follow up option after spine surgeries in the future.

LIST OF ABBREVIATIONS:

ATA	American Telemedicine Association
CPA	Consumer Protection Act
CVJ	Cranio-Vertebral Junction
DIT	Department of Information Technology
EMRs	Electronic medical records
EHR	Electronic Health Records
HIPAA	Health Insurance Portability and Accountability Act
ISRO	Indian Space Research Organization
IDSP	Integrated Disease Surveillance Project
ICMR	Indian Council of Medical Research
ICTs	Information and communication technology
MoHFW	Ministry of Health and Family Welfare
MCI	Medical Council of India
NMCN	National Medical College Network
NDHAI	National Digital Health Authority of India
NeHA	National eHealth Authority
NHP	National Health Portal's
NCN	National Cancer Network
SAARC	South Asian Association for Regional Cooperation
TM	Telemedicine
TC	Tele-consultation
VC	Virtual consultations

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Introduction

1. INTRODUCTION

Telemedicine is the use of medical information exchanged from one site to another through electronic communications to improve a patient's clinical health status. WHO has adopted the following description of telemedicine: 'The delivery of health care services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities 'Telemedicine is a method by which patients can be examined, investigated, monitored and treated, with the patient and the doctor in different physical locations. [1] Tele is a Greek word meaning ''distance'' and Mederi is a Latin word meaning ''to heal''. In telemedicine one transfers the expertise, not the patient.[2]

There is a severe scarcity of neurologists and neurosurgeons both in India and around the world. It will be impossible to provide neurospecialists in every suburban and rural location despite best efforts. Information and communication technology (ICT) has simultaneously grown and developed at an exponential rate. Distance is becoming meaningless due to falling prices, incredible sophistication and the availability of user-friendly mobile video conferencing gadgets. Geography has become history! The medical profession, which is notoriously ultraconservative, has been particularly sluggish to adopt and embrace the use of ICT to broaden their clinical reach. But over the past ten years, experts in all fields of neuroscience have begun to gradually accept the necessity and future of telemedicine.[3]

Since the majority of neurosurgery experts work in urban settings and the majority of rural areas lack access to neurosurgical treatment, telemedicine has become crucial for treating neurosurgical crises. In a big nation like India, where the bulk of the population lives in distant areas without access to even the most basic healthcare, telemedicine offers significant benefits.[4]

Patients who can be treated without having to travel back to a regional specialist centre can have better access to the treatments they need by using the available telemedicine technologies. Structured telemedicine consultations for post-neurosurgical follow-up care can save patients and their families money and time on travel while also lowering stress. The primary goal of telemedicine and virtual consultation is to deliver high-quality healthcare services throughout India. This involves facilitating faster, less expensive and better communication for treatment, expert follow-up and the storage of information, as well as improving access to healthcare for both rich and impoverished populations. By reaching remote places with weak transportation connections, it especially aids in removing geographic barriers to healthcare. [2]

While several studies have been published regarding patient satisfaction and physical examination techniques to our knowledge, throughout spine and neurosurgery, no data-driven study has assessed the challenges and benefits of telemedicine from an Indian spine surgeon perspective. [5] This study sought to address this deficiency by analyzing the overall and regionally reported challenges and perceived benefits of telemedicine among neurosurgeons/spine surgeons, and investigating how additional factors, such as patient's demographics and underlying disease could affect success of telemedicine.

Aims & Objectives

2. AIMS AND OBJECTIVES

Aim: Role of telemedicine for follow up after spine surgery.

Objectives:

- Relationship of success rate of telemedicine with patients diagnosis (Trauma, Degenerative, Vascular, Tumour)
- Relationship of success rate of telemedicine with patients demographics (Age, Sex, Educational status, Socioeconomic status, address)
- To identify barriers for successful telemedicine consultations. (Technological issues, communication problem, unsatisfactory evaluation of the patient, patient choice or doctors' choice for in-person visit, others)

Review of Literature

3. REVIEW OF LITERATURE

Historical perspectives:

One of the first cutting-edge information systems to be included into healthcare services in the past 50 years is telemedicine.[6,7,8] Since the late 1960s, it has been a significant technology in healthcare long before the information system industry understood what it was or how significant it would become.[9] The invention of the telephone in 1876 served as the foundation for telemedicine. The electrocardiogram's creator wrote a paper on the telecardiogram and published it in 1906. Radio has been used to communicate medical advice to shipboard clinics since the 1920s.[10] The idea of connecting patients and doctors virtually without both parties being present at the same location first became public knowledge in the 1920s and 1930s. The cover of the magazine "Radio News" in 1924 featured a picture of a patient speaking with a doctor while watching television.[11] Interestingly, it wasn't until 1927—three years later—that the first television transmission took place. Even in modern times, telemedicine relies heavily on the telephone. Previously, when it was primarily available to those with resources, doctors and pharmacists used it to conduct virtual consultations regarding their patients.

Generally speaking, three historical eras can be used to assess key advancements in the spread of telemedicine.[12] The majority of the studies in this stage were proof-of-concept research in the form of technological feasibility studies, with the first period focusing on the improvement of clinical treatment in speciality areas such as teleradiology, telecardiology, teledermatology, and telepsychiatry.[13] The second historical period was characterized by the development of digital technology.[7,9] Studies in this stage began during the development of computer-based digital teleconferencing systems. In this

stage, computers became widely used and digital communication methods merged quickly. They also discovered that interactive video could be used over wide area surface networks at a much lower cost than the analogue television system of the first stage.[13] We are currently in the third diffusion phase of telemedicine. In the third historical period, attention was given to raising standards, utilising wireless technology, security, secrecy, and privacy concerns, as well as to legal issues regarding jurisdiction and payment for telemedicine services.

Modern Telemedicine:

The use of cell phones and the internet has virtually reached ubiquity during the past few decades as wireless broadband technology has evolved.[14] Real-time voice and video consultations, the transfer of medical images including X-rays and scans, and patient education using images and videos all become commonplace.[15] Infrastructure improvements for the internet, including increased bandwidth, communication rates, information databases, web service backups, standard formats for data transfer, encryption, password protection, and HIPAA (Health Insurance Portability and Accountability Act of 1996) regulations, Electronic medical records (EMRs) were created, information was digitalized, and this resulted in stress-free and affordable telemedicine and e-health.[15,16] Modern telemedicine collects clinical data using already-owned, low-cost technologies like smartphone cameras, wearable biosensors, etc., making it simpler to use without specialised training. These devices might be owned by the patient or doctor.[15] Modern telemedicine techniques save money on travel, time and medical bills while making it simpler for the average person to access specialised doctors without interfering with their everyday obligations. By reducing the number of missed and cancelled appointments, increasing revenue and patient volume, enhancing

follow-up and enhancing health outcomes, it also makes the lives of healthcare practitioners easier.[17] As we enter the twenty-first century, numerous national and international organisations have been established, such as the American Telemedicine Association(ATA) in Washington, DC, which is completely focused on the provision of telemedicine services.[18]

The field of telemedicine is evolving more quickly than ever nowadays. The affordability and accessibility of basic telemedicine technologies are increasing dramatically as technology progresses at an exponential rate. For instance, a large portion of the population in India is familiar with utilising online video chat programmes, and we now have the technology for live video telemedicine (like WhatsApp, Skype or Facetime) and the ability to use computers or mobile devices. [19,20]

In the beginning, telemedicine was developed as a tool to treat patients who lived in distant areas far from nearby medical facilities or in situations where there were a lack of qualified medical personnel. Even though telemedicine is still utilised to solve these issues, it has become a tool for quick access to healthcare. Nowadays patients wants to spend less time in the waiting room at the doctor's office and obtain help right away when they need it for minor but urgent conditions.[11]

Telemedicine businesses have become increasingly popular as a result of patient expectations for more convenient care and the unavailability of many overworked medical professionals particularly primary care doctors. Many provide people with 24/7 access to medical care with a doctor on call that company has engaged. Others provide access to additional clinical staff and specialists, allowing hospitals and larger health institutions to outsource treating specific patients (common model among teleradiology companies). Others give doctors a telemedicine platform they can use to conduct virtual

consultations with their own patients. Telemedicine is increasingly being used to give medical practises an advantage in the competitive healthcare market, where it can be challenging to remain independent or keep a healthy bottom line.[11]

The expanding mobile health industry has an impact on the development of telemedicine today. Thanks to the abundance of mobile health apps & consumer-friendly mobile medical equipment, patients are beginning to use technology to monitor and track their health. Simple home medical equipment that can diagnose ear infections, measure blood pressure, or capture vital signs allows people to acquire the necessary medical data for a doctor's diagnosis without having to visit the doctor's office. And once more, as more patients become proactive in using technology to manage their health, they will also be more receptive to alternative methods of receiving care, such as telemedicine![21]

Telemedicine in India:

With a population of more than 1.39 billion people, India is a sizable country.[22] As a result, distributing healthcare services has consistently shown to be a top priority in public health management. The current tendency of moving healthcare facilities away from rural India, where 68.84 percent of the population lives and toward cities and towns (including 75 percent of the doctor population), adds to this.[22] ISRO (Indian Space Research Organization) made a modest beginning in telemedicine in India with a Telemedicine Pilot Project in 2001, linking Chennai's Apollo Hospital with the Apollo Rural Hospital at Aragonda village in the Chittoor district of Andhra Pradesh.[23] The development of telemedicine services in India was greatly aided by initiatives taken by ISRO, the Department of Information Technology (DIT), the Ministry of External Affairs, the Ministry of Health and Family Welfare and the state governments. The

Ministry of Health in the Government of India has undertaken initiatives like the Integrated Disease Surveillance Project (IDSP), National Cancer Network (ONCONET), National Rural Telemedicine Network, National Medical College Network, and the Digital Medical Library Network in an effort to consolidate the public health data that is currently available and provide simple access.[24] A National Telemedicine Task Force was established by the Health Ministry in 2005, and the Department of Information Technology of the Government of India established standardised telemedicine practise guidelines in 2005. The External Affairs Ministry has also taken on international initiatives like the PanAfrican eNetwork Project and the SAARC (South Asian Association for Regional Cooperation) Telemedicine Network Projects.[25] strategically placing Indian telemedicine in the global scenario. A few noteworthy examples of the successfully established telemedicine services in India include mammography services at Sri Ganga Ram Hospital, Delhi; oncology at Regional cancer centre, Trivandrum; surgical services at Sanjay Gandhi Postgraduate Institute of Medical Sciences, School of Telemedicine and Biomedical Informatics, and many more. [15,26] When providing medical care becomes urgently necessary, telemedicine is also used in locations where huge people occasionally or regularly congregate; for instance, the government of Uttar Pradesh uses it during Maha Kumbhamelas.[15] One field that has been successful at piquing the commercial sector's attention and encouraging them to participate actively in public health management is telemedicine. Narayana Hrudayalaya, Apollo Telemedicine Enterprises, Asia Heart Foundation, Escorts Heart Institute, Amrita Institute of Medical Sciences, and Aravind Eye Care are a few of the country's current top private telemedicine companies.[27] They function with support from the central and state governments and from organizations like ISRO who guide them with appropriate and updated technology.[28] The ISRO

telemedicine network has advanced significantly over the past few years. It has grown to connect 15 super specialised hospitals and 45 remote and rural hospitals. The Andaman & Nicobar and Lakshadweep Islands, the mountainous areas of Jammu and Kashmir, the Medical College Hospitals in Orissa, and some of the rural/district hospitals in other states are among the remote nodes.[15]

Current scenario in India:

WHO recommends a doctor-population ratio of 1:1000 while the current doctor population ratio in India is only 0.62:1000. [29,30] Since training new doctors takes time and money, the doctor-to-patient ratio is likely to stay low for a very long time. The active telemedicine services in various sections of the nation help to fill this shortfall in part. The Ministry of Health and Family Welfare and the Department of Information Technology jointly oversee telemedicine services in the nation. A National Telemedicine Portal has been established by the MoHFW, GOI's Telemedicine Division [31] for implementing a green field project on e-health establishing a National Medical College Network (NMCN) for interlinking the Medical Colleges across the country with the purpose of e-Education and a National Rural Telemedicine Network for e-Healthcare delivery.[25] The National Digital Health Authority of India (NDHAI)/National eHealth Authority (NeHA) is being established as a part of the National Health Portal's (NHP) eHealth division with the goal of providing high-quality health services to all Indians by using ICTs in cost-efficient and secure ways in the fields of health and health-related fields.[32] In 2013 and 2016, the MoHFW created a set of Electronic Health Records (EHR) standards to ensure secure data transmission during telemedicine activities.[32] In India, traditional medical specialties are included in the use of telemedicine. The National Rural AYUSH Telemedicine Network seeks to

use telemedicine to spread awareness of the value of conventional treatments across a bigger population.[33] Village Resource Center (VRC): ISRO created the VRC concept to offer a range of services, including weather forecasting, telemedicine, online decision assistance, interactive farmers' advisory services, telefishing, and water management. The VRCs serve as both learning facilities and connecting points to speciality hospitals, offering specialized medical care to the villages. Such VRCs have been constructed nationwide, numbering around 500.[15] Another internet-based mobile telemedicine conglomerate AROGYASREE, unites numerous hospitals, mobile doctors' offices and outlying mobile units/clinics. The idea behind the study is the Indian Council of Medical Research (ICMR). They have worked along with a group of researchers from the University of Karlsruhe in Germany who are developing an ECG jacket that will allow for continuous patient ECG monitoring without the need for hospitalization.[34]

Types and applications of telemedicine

Five fundamental categories can be used to categories telemedicine: Depending on when the information was transmitted: (i) Real-time or synchronous telemedicine (when information is transferred "live" and both sender and recipient are online at the same time) (ii) Asynchronous or store-and-forward telemedicine (where the sender stores the information databases and sends it to the receiver at a convenient point of time, and the receiver can review the data according to his convenience)(iii)Remote Monitoring type of telemedicine, commonly referred to as self-testing or self-monitoring. The health and clinical indications of a patient are remotely monitored using a variety of technology tools. According to the interaction between the individuals involved: (iv)Health professional to health professional (giving easier access to specialty care, referral and consultation services)(v) Health professional to patient

(offering the unreached population direct access to a doctor in order to provide them with medical care).

Pros of Telemedicine:

The majority of the time telemedicine is advantageous. It provides individuals with mobility challenges such as the elderly and those in rural places with access to healthcare services. As a result, it has the ability to provide healthcare services despite regional limitations. It might present a chance to cut back on healthcare expenses while also saving the patient and caregiver time. With the development of telemedicine, a doctor or hospital can consult with several specialists no matter where they are located. Telemedicine enables patients to communicate more regularly and conveniently with their healthcare professionals, which may lead to an improvement in the doctor-patient relationship. Patients will likely receive better follow-up, which could lead to improved results. Overall, telemedicine has the ability to offer the general public better healthcare services.[35]

Cons of Telemedicine:

Because telemedicine is virtual, there are some drawbacks. Infrastructure and technical training are needed. Because online interactions are impersonal and a physical examination is required to give a full diagnosis, it may result in less direct patient-doctor connection. The medical curriculum still does not cover telemedicine. Concerns about privacy, confidentiality, the security of patient information, and treatment are present in addition to ambiguity surrounding obligations in cases of carelessness. Regarding medicolegal difficulties resulting from telemedicine, there is no clarification. Telemedicine is not yet covered by any health insurance policies in India.[36]

Importance of Follow up in spine surgery:

The maintenance of a successful follow-up after spinal intervention is essential to justify the investment that spine specialty care entails. In the developing world and in underserved areas in the more developed nations, transportation, limited medical resources and occasionally, social stigma can pose significant challenges with regard to diagnosis and follow-up care of patients with spinal diseases. Telemedicine (TM) can help in overcoming some of these limitations by cutting down on the travel time and travel expenses incurred by the patient during follow-up care, but they remain largely unexplored in elective spine surgery. [37]

Medicolegal Issues:

Doctor–patient relationship:

When seeking therapy, patients confide in and trust healthcare experts. Some forms of telemedicine are seen to hinder the proper growth of the doctor-patient bond because there is no face-to-face interaction.[38] To fulfil legal standards, it's crucial to keep the patient's trust. The establishment of positive doctor-patient interactions is required among healthcare providers.[39]

Informed consent:

A crucial medical legal need for treating a patient is informed consent; failing to get it is both a tort and a criminal offence.[39] Whether a medical encounter takes place face-to-face or remotely via telemedicine or virtual consultation, consent should always be acquired.[40] For telemedicine interactions, data transmission, treatment, monitoring and consulting, consent should be sought. It is also critical to specify whether the

medicolegal significance of informed consent in telemedicine is equivalent to or dissimilar from that in conventional face-to-face contacts.[41] There is sufficient data to conclude that virtual consultations, such video conferences, are clinically equivalent to in-person consultations in many specialities.[42] Thus, informed consent can be obtained in the conventional manner and properly documented. The World Medical Association's statement of the Guiding Principles for the Use of Telemedicine for the Provision of Health Care also emphasises this (2009). In Malaysia, France, UK, South Africa, and California (USA), informed consent for telemedicine is required.[40]

Malpractice and liability

Once a doctor-patient connection has been established, it is the doctor's duty to deliver the appropriate care and treatment that may reasonably be anticipated of a professional in the specific situation.[41] Can physicians be sued for medical malpractice in telemedicine and virtual consultation and can they be protected by medical indemnity insurance?[38] The following are some important points in this context.

1. The ‘duty of care’ must be established in all telemedicine encounters to clarify responsibility(s) for the patient/caregiver as well as other involved healthcare providers.

2. Healthcare professionals should clearly define their roles and responsibilities regarding the various aspects and extent of treatment.

Privacy:

Since the time of Hippocrates, the right to privacy has been an essential component of medical ethics. This principle is backed by numerous codes, including the International

Code of Medical Ethics.[43] It stipulates that the medical professional shall continue to respect patient privacy even after the patient has passed away. Even with telemedicine, each person has a right to privacy.[39] There is the potential for leakage of electronic records of a patient. The onus for safeguarding this information has to be on the medical practitioner.[5] Information must be transmitted in a secure way. Password security should be maintained to avoid unauthorized access to the information. However, privacy cannot be guaranteed with the use of telemedicine.[42] Even with telemedicine, each person has a right to privacy. Any injury to the patient brought on by a defective product is the manufacturer's responsibility. As a result, it follows that the manufacturer, including the maker of the telemedicine-compatible computer system, the maker of the telemedicine-compatible software, the maker or supplier of various telemedicine-related accessories, the network provider, the healthcare provider using the technology, and the service provider in charge of maintaining the entire telemedicine system, is responsible for upholding the duty of care.[39]

Rights of patients

In traditional medical practice, certain rights of patients have been recognized, such as the right to get treatment, choose a doctor freely, change doctor at any stage of treatment, right of compensation, right of confidentiality, right of dignity, right of grievance redressal, right of information and right to refuse treatment. The same applies to the practice of telemedicine and virtual consultation. The patient has a right to receive one's medical record in the electronic format, to know standards and safety guidelines. He/she has the right to be informed regarding authorization or registration status of the service provider. Certain patient rights have been acknowledged in traditional medical practise, including the right to receive treatment, the freedom to select a doctor, the

ability to switch doctors at any point during treatment, the right to compensation, the right to confidentiality, the right to dignity, the right to a hearing for complaints, the right to information and the right to refuse treatment. The same is true for virtual consultations and telemedicine. The patient has a right to get their medical records electronically and to be informed of the standards and security precautions. He or she has a right to know the service provider's authorization or registration status and to know the various complaint processes which he/she can use in case he/she suffers any harm during the consultation.[44]

Reimbursement:

In the practise of telemedicine, there is not currently a provision for insurance reimbursement.[38] Whether telemedicine was required or not in the given situation is another condition which should be cleared for reimbursement.

Laws In India Applicable to Telemedicine:

Telemedicine guidelines in India are governed by recent guidelines. Information and communication technology (ICTs) and medical science are combined in telemedicine. The Indian government has acknowledged it and incorporated it into several programmes and policies. The rules governing the medical industry and information technology currently apply to telemedicine in India. Some of the laws relating to the medical profession include the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945, the Indian Medical Council Act, 1956, the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, and the Clinical Establishments (Registration and Regulation) Act, 2010 ('Clinical Establishments Act').[45,46,47]

Liability in civil negligence:

Civil suits could arise out of a breach of contractual obligations between the telemedicine service provider and the patient/user. The Supreme Court of India has explained negligence as 'Careless conduct in commission or omission of an act connoting duty ,breach and the damage thereby suffered by the person to whom the plaintiff owes.'[48] The integral components to prove negligence are establishment of duty and dereliction of duty, which are directly related to the damage caused.

Vicarious liability:

In cases where there is an employer-employee relationship and eHealth services are offered, such as telemedicine, the employer may be sued under the vicarious liability doctrine if found responsible for the employee's actions that occurred while they were working for the company. For criminal prosecutions, the vicarious liability idea does not hold true.[49]

Liability under the Consumer Protection Act, 1986:

In the event that a service is subpar, consumers may seek reimbursement from service providers under the Consumer Protection Act (CPA). Claims for faulty goods and unfair business practises can be made by consumers. To hear about these issues, consumer forums have been established at the local, state, and national levels. In the case of Indian Medical Association versus V.P. Shantha and others, the Supreme Court determined that medical services would be covered by the CPA as long as the patient is being charged for the service. The payment for the services is one of the crucial components of a claim because the CPA disallows free services.[50]

Disciplinary control by the Medical Council of India:

A patient has the right to file a complaint against a doctor for professional misconduct with the appropriate state medical council. The Medical Council of India (MCI) may independently or at the patient's request, ask the state medical council to rule on a complaint against a doctor if the state medical council has not done so within six months of the complaint's receipt date or it may refer the complaint to the MCI's Ethical Committee. A consumer who disagrees with the state medical council's decision also has the right to file an appeal with the MCI within 60 days of the state medical council's order date.[46]

Global perspectives and practices:

Before & during social distancing: Prior to COVID-19 and social distancing, spine surgeons utilized telemedicine for <10.0% of cases. During COVID-19 usage rose as providers performed a mean 39.3%-44.2% of all "new patient," "follow-up," and "postoperative" visits through telemedicine, with regional differences. Presently, there is little data in the literature regarding how spine surgeons use telemedicine, how often they use telemedicine, when this tool seems appropriate and (perhaps more importantly) when it seems inappropriate. While preliminary studies suggest that telemedicine can be an accurate and efficient tool for spine care with high patient satisfaction, a thorough exploration of these questions is critical to safely integrating telemedicine into the spine clinical workflow.[51]

Telemedicine platform: Overall, phone calls without video were the most common form of telemedicine (33.8%), followed by non-secure videoconferencing programs (Face-time, Skype, etc.) (25%), secure EMR-integrated systems (23.2%), secure non-EMR-

integrated systems (9.9%), and other (8.1%). Responses to "other" included: "Doximity," "Microsoft Teams," "WhatsApp," "Amwell," "Clickdoc," "WeChat," and "E-mail." Regional differences were observed in the type of platform.[51]

Previous Literature:

Thakkar et al (2018) Dept of Neurosurgery, Sri Satya Sai institute of higher medical sciences has compared telemedicine with in-person visit for follow up after elective Neurosurgery. Data from 1200 patients were collected for a 52 months period. In their result, Telemedicine care success rate was 97%, overall utility for TM scenario (89%) was found to be higher than utility of routine care (80%).TM was found to be more cost effective. (INR 2630 per patient In telemedicine vs INR 6848 per patient in routine care)[37]

Crawford et al (2021) included 87 patients who were seen exclusively via telemedicine encounters and indicated for an interventional procedure with documented procedural plans. Virtual plans were then compared with the actual procedures performed following in-person evaluation. In their result, preprocedural plan established by telemedicine, primarily videoconferencing, did not change for 76 individuals (87%) following in-person evaluation. Their findings suggest that telemedicine evaluations are a generally accurate means of preprocedural assessment and development of interventional spine procedure plans.[52]

Lovecchio et al (2021) evaluated provider confidence in telemedicine spine evaluation, four hundred and eighty-five surgeons participated in the survey. Providers felt that physical exam-based tasks were inferior to in person exams, while communication-based aspects were equivalent. Participants who performed greater

than 50 visits were more likely to believe telemedicine was at least equivalent to in-person visits in the ability to make an accurate diagnosis. Compared to in-person encounters, video (versus phone only) visits were associated with increased confidence in the ability of telemedicine to formulate and communicate a treatment plan.[53]

Greven et al (2021) retrospectively evaluated 346 patients in neurological spine patients who were managed with telemedicine, in their result Ninety-five percent were "satisfied" or "very satisfied" with their telemedicine visit with 62% stating it was "the same" or "better" than previous in-person appointments. Patients saved a median of 105 minutes by using telemedicine compared to in-person visits. Fifty-two percent of patients have to take off work for in-person visits, compared to 7% for telemedicine.[54]

Maurer et al (2021) conducted survey on 164 patients, 56.8% of patients were new while 24.4% were post-operative follow-up visits. Of all respondents, only 15.3% preferred the appointment via video telehealth. There was a significant difference between how far the patient traveled for the clinic appointment and their preference for a telehealth appointment, with patients traveling further distances favoring telehealth. They have concluded that most spine patients prefer in-person clinic appointments to virtual appointments.

Satin et al (2021) demonstrated techniques to evaluate gait, the cervical spine, the lumbar spine, adult spinal deformity patients and adolescent scoliosis patients via telemedicine. They have also reviewed limitations of spine telemedicine examination and discussed special considerations such as patient safety and criteria for in-person assessment. They have concluded that while there are limitations to the spine

telemedicine examination, unique strategies exist to provide important information to the examiner.

Eichberg et al (2020) have analysed 45801 patients in 52 studies where patient management was successful in 99.6 % of cases & telemedicine visit failed in 162 patients. 81.5% of which were due to technology failure and 18.5% of which were due to patients required further face to face evaluation.

Mrak et al has published his experiences with telemedicine in Zagreb, Croatia (1998) In the first three years of its use, the telemedicine network saved more than 400,000 km of patient transportation.

Reider-Demer et al (2018) examined if a videoconferencing visit could substitute for an in-person clinic visit for elective neurosurgical cases in the USA. Patients were offered telemedicine follow-up care by an allied health professional during the first 90 days after neurosurgery. Of the 57 prospective patients, 47 accepted telemedicine in lieu of an in-person clinic visit. Emergency room visits and readmission rates at 30 and 90 days postoperatively did not differ significantly between the study groups. Study concluded that telemedicine avoids unnecessary travel time and was welcomed by the majority of patients without compromising clinical or functional outcomes.[1]

Munusamy at al (2020) determined if telemedicine delivered through smart glasses was feasible and effective as an alternative method of conducting ward round on neurocritical care patients during the pandemic. Ten paired ward rounds were performed on 103 neurocritical care patients with excellent overall intrarater reliability. Nine out of 10 showed good to excellent internal consistency and 1

showed acceptable internal consistency. Qualitative analysis indicated wide user acceptance and high satisfaction rate with the alternative method.[2]

Hayward et al (2019) examined the socioeconomic benefits to the patients and families attending a regional pediatric neurosurgery telemedicine clinic. Clinic visits from August 2011 through January 2017 were reviewed. The families saved an average of 2.5 hours of travel time and 134 miles of travel distance per visit. The average transportation cost savings for all visits per family and for all families was $180 and $9711 respectively. They have concluded that managing pediatric neurosurgery patients and their families via telemedicine is feasible and saves families substantial travel time, travel cost and time away from work.[3]

Material & Methods

4. MATERIALS AND METHODS

Study design – Prospective, non-randomized, observational, cohort study.

Study participants – All patients undergoing spinal surgeries during the study period

Study duration – January 2021 to June 2022

Inclusion criteria:

- All patients undergoing spine surgeries including Cranio-Vertebral Junction (CVJ) surgeries.

Exclusion criteria:

- Patients not willing to participate in the study.
- Patients not having at least 2 tele-consultations and minimum 6 weeks of clinical follow up.
- Patients without access to necessary ICT.

Sampling and sample size:

All patients fulfilling the inclusion and exclusion criteria were serially included for the study, by consecutive sampling, until at least the desired sample size was achieved.

A retrospective analysis of follow up patients undergoing spine surgeries (emergency/elective spine surgeries including Cranio-vertebral junction surgeries) was done in our department from January 2020 to October 2020. A retrospective pilot study was conducted on 15 patients with success rate of 80%.

Using a 95% confidence interval and 10% absolute error, sample size was determined

to be 60.

Methodology

All enrolled patient's tele-consultation (TC) follow up was done at suitable intervals depending on patients condition and underlying problems. Valuable information was gained by asking the patient about current complaints, bladder and bowel habits. Patients were asked to demonstrate gait and power; sensations of the patient were checked with the help of patient's attendant/local health care worker over a video call. A dermatomal pain diagram was given to patient/attendant for reference at the time of discharge (Annexure 8) as well as a video demonstration of the examination technique was done. (Figure 5 to Figure 8)

A Telemedicine consultation was considered successful if the patient and doctor were completely satisfied with the tele-consultation without requiring in-person visit for further evaluation or treatment. It was considered unsuccessful if the patient needed to undergo in-person visit follow-up because of technological issues, further evaluation, patient's choice for in-person visits or other reasons.

Success rate of telemedicine was calculated by following formula:

Success rate of telemedicine= successful telemedicine consultations /Total number of telemedicine consultation x 100

Results

5. RESULTS

During the study period, a total of 139 patients were assessed for eligibility. Of these, 84 patients satisfied the selection criteria and were included in the study. The other 55 patients either did not participate or lost follow up.

The demographic features, clinical characteristics & success outcome among included 84 patients are summarized in detail in the successive tables.

Table 1 & Figure 1 Summarises distribution of age among enrolled patients in the study.

Age group (yrs)	No of patients (N-84)	Percent
1-10	4	4.76
11-20	7	8.33
21-30	**16**	**19.04**
31 – 40	15	17.85
41 – 50	**16**	**19.04**
51 – 60	10	11.90
61 – 70	11	13.09
>70	3	3.57
Total	84	100

Table 1: Distribution of age among enrolled patients in the study. (N-84)

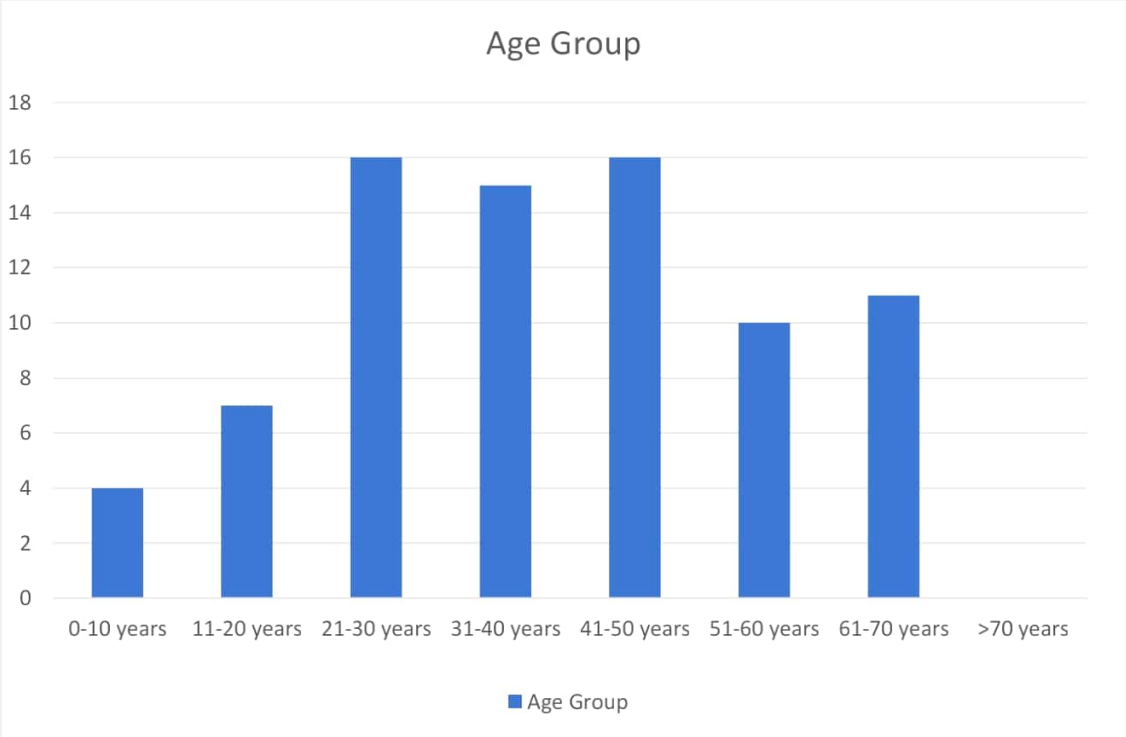

Figure 1: Distribution of age among enrolled patients in the study. (N-84)

Among the enrolled 84 patient's majority of study population who underwent surgery were between 21-31 year of age group (19.04 %) and between 41-51 year of age group (19.04%), followed by 31-41 year of age group (17.85 %) and 4.74 % of study population below age of 11 year. The mean age of the study population was 40.42 years (range 1 year to 81 years). (Table 1 & Figure 1)

Detailed demographic characteristics collected based on questionnaire are summarized in Table 2.

Demographic variables		No. of patients	Percentage
Gender	Male	42	50
	Female	42	50
Marital status	Married	**66**	**79**
	Unmarried	18	21
Residence area	Rural	**66**	**79**
	Urban	18	21
Educational status of patients	Educated	**45**	**53.57**
	Illiterate	33	39.28
	Not applicable	6	7.14
Pre-existing co morbidity	Yes	18	18.24
	No	66	81.76
Distance from hospital	<100 km	**33**	**39.28**
	100-200 km	30	35.71
	200-500 km	17	20.26
	>500 km	4	4.76

Table 2: Distribution of demographic variables among enrolled patients in the study. (N-84)

There were 42 (50%) male and 42(50%) female among which 66(79%) patients were married. Maximum of 66(79%) patients belonged to rural area. Highest education in the family was up to High School in majority of the population (38.02%), followed by primary school (18.85%) while nobody in family was literate in 5.96%. Most patients 33 (39.28%) were staying withing 100 km from hospital, followed by between 100-200 km 30 (35.71%). Only 4(4.74%) patients were staying more than 500 km away. Average distance of patients from hospital was 196.2 km and total distance of all patient together was 16677 km. (Table 2)

Demographic details are further studied and classified according to socioeconomic status based on the modified Kuppuswamy ‘s scale in Table 3 & Figure2.

Modified Kuppuswamy scale	Frequency	Percent
Upper class	4	4.76
Upper middle class	14	16.66
Lower middle class	26	30.95
Upper lower class	**29**	**34.52**
Lower	11	19.09
Total	84	100

Table 3: Distribution of the study group according to socioeconomic status based on the modified Kuppuswamy ‘s scale. (N-84)

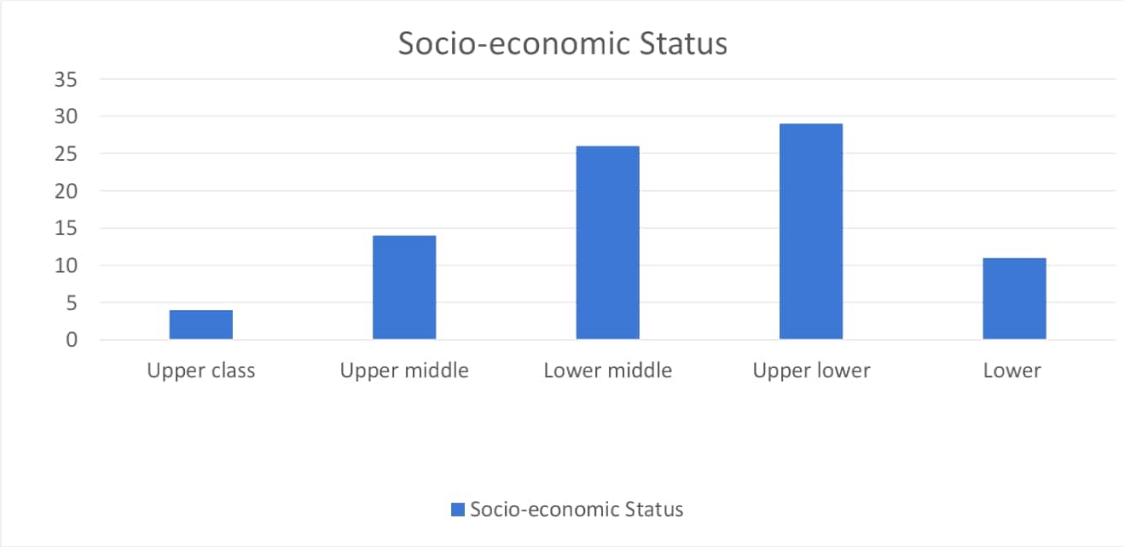

Figure 2: Distribution of the study group according to socioeconomic status based on the modified Kuppuswamy ‘s scale. (N-84)

In our study as per modified Kuppuswamy scale majority of study population belonged to Upper lower class 29(34.5%), followed by Lower middle class 26(30.95%). Only4 (4.74%) patients belonged to upper class family (Table 3 &Figure2).

Successive demographic feature based on education, occupation and per capita income are summarized as follows in Table 4.

Socioeconomic scale		No. of patients	Percentage
Education of head of family	Illiterate	12	14.28
	Primary	15	17.85
	Middle	13	15.47
	High school	**26**	**30.95**
	Intermediate/ diploma	11	13.09
	Graduate/ Professional degree	7	8.33
Occupation of head of family	Unemployed	2	2.38
	Unskilled worker	18	21.42
	Semi-skilled worker	11	13.09
	Skilled worker	18	21.42
	Clerical/Shop/Farm	**24**	**28.57**
	Semi professional	6	7.14
	Professional	5	5.96
Per capita income (per month)	≤1146	15	17.85
	1147-3404	**29**	**34.52**
	3405-5675	16	19.04
	5676-8512	9	10.71
	8513-11350	9	10.71
	11351-22702	4	4.7
	≥22703	2	2.38

Table 4: Distribution of the study group according to socioeconomic status. (N-84)

In majority of 26(30.95%) families education status of head of the family was up to high school & 24 (28.57%) were involved in occupation as a Clerk, Shopkeeper or Farmer. Per capita income per month was 1147-3404 INR (Indian National Rupees) in maximum number of patients i.e. 29(34.52%).

Enrolled patients were classified on the basis of indication of spinal surgery and details of which are mentioned in Table 5 &Figure 3

Indication of surgery	**Degenerative**	**Congenital**	**Tumor**	**Trauma**
Number	**52**	16	13	3
Percentage	**61.90**	19.04	15.47	3.57

Table 5: Distribution of enrolled patients according to indication of spinal surgery. (N-84)

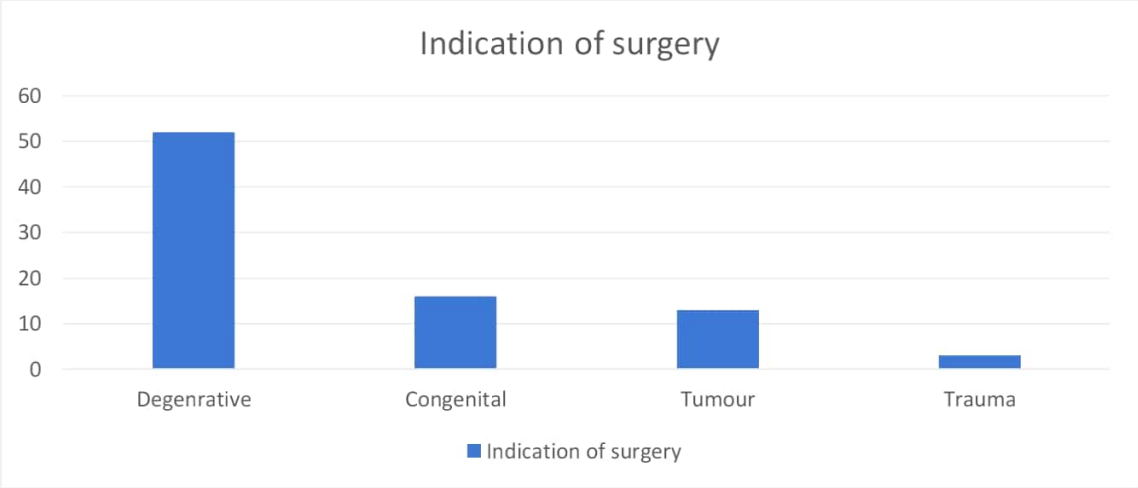

Figure 3: Distribution of enrolled patients according to indication of spinal surgery. (N-84)

Majority of the patients 52(61.90%) belonged to degenerative category followed by congenital 16(19.04%). Tumor was accounted for 13(15.47%) of patients while only 3(3.57%) patients belonged to trauma category.

These enrolled patients were further divided according to the level of spinal surgery which is summarized in Table 6 &Figure4.

Level of Surgery	CVJ	Cervical	Dorsal	Lumbar
Number	11	23	13	37
Percentage	13.09	27.38	15.47	44.04

Table 6: Distribution of enrolled patients according to level of spinal surgery. (N-84)

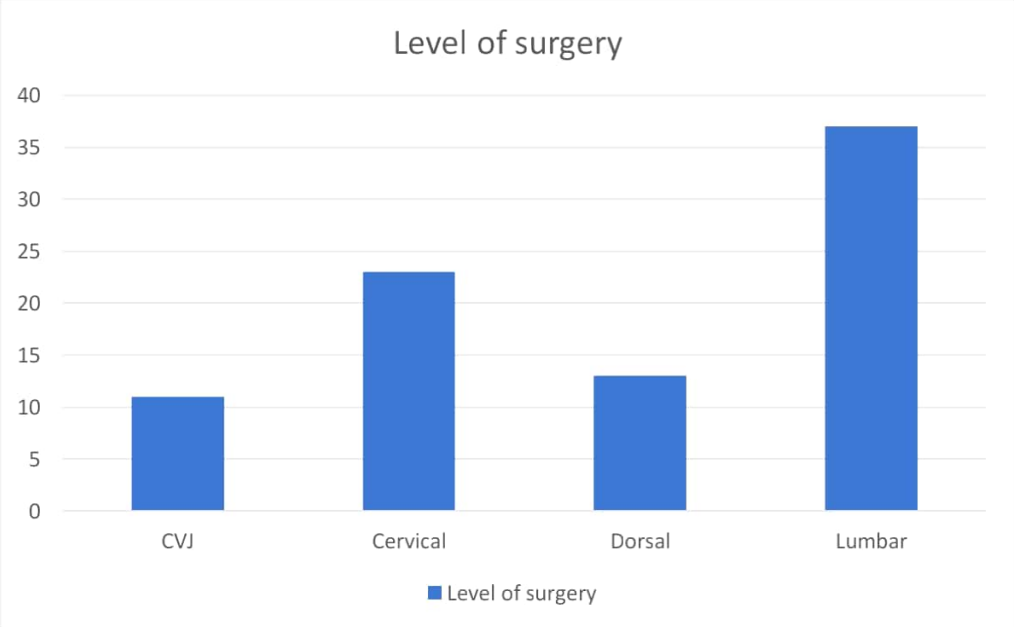

Figure 4: Distribution of enrolled patients according to level of spinal surgery. (N-84)

It was observed that maximum patient were operated for Lumbar spine 37(44.04%), while dorsal spine, cervical spine and CVJ accounted for 13(15.47%), 23(27.38%) and 11(13.09%) respectively. (Table 6 &Figure 4)

All teleconsultations were done using WhatsApp video calling. Wherever required

patient's attendant were involved for the help. Success rate of telemedicine was studied and summarized based on demographic features like type of visit, sex of the patient, economic status &education status of the patient details of which are mentioned below in Table 7.

Patient Demographic Data		Successful		Unsuccessful			Chi square	P value
		Number	Percentage	Number	Percentage.	Total		
Type of visit	First visit	75	89.28	9	10.71	84	5.23	0.07
	Second visit	66	78.57	18	21.42	84		
	Third visit	9	69.29	4	30.76	13		
Sex	Male	80	87.91	11	12.09	91	3.27	0.07
	Female	70	77.77	20	22.23	90		
Socio-economic Status	Lower	11	44	14	56	25	21.01	<=**0.0001**
	Upper lower	51	83.60	10	16.4	61		
	Lower middle	49	87.5	7	12.5	56		
	Upper middle	30	100	0	0	30		
	Upper	9	100	0	0	9		
Educational Status	IL	5	41.66	7	58.34	12	23.53	**<=0.0001**
	PS	22	70.96	9	29.03	31		
	SS	22	78.57	6	21.42	28		
	HS	64	90.14	7	9.85	71		
	I	24	92.30	2	7.69	26		
	D	10	100	0	0	10		

Table 7: Success rate of telemedicine as per patient's demographic variables. (N-181)

Overall success rate of telemedicine was 82.87% (successful visit- 150, unsuccessful visit -31). Success rate in First visit was 75(89.28%), success rate in second visit was 66(78.57%), while success rate in third visit was 9(69.23%). Success rate in men was 87.91 while success rate in women was 77.77%. As per socio-economic status success rate was lowest in lower class (44%), in upper lower class success rate was 83.6%, success rate lower middle class was 87.5%, while 100% in upper middle class and upper class. Success rate was 41.66% in families where head of the family is illiterate,

70.96% if head of the family is educated up to primary school while it was 100% if head of the family holds a professional degree.

Success rate of telemedicine as per patients underlying pathology and level of surgery is explained below in Table 8.

Patient Demographic Data		Successful		Unsuccessful		Total	Chi square	P value
		Number	Percentage	Number	Percentage.			
Indication of surgery	Degenerative	91	80.53	22	19.47	113	1.18	0.55
	Congenital	28	83.60	6	16.4	34		
	Tumor	25	87.5	3	12.5	28		
	Trauma	6	100	0	0	6		
Level of surgery	CVJ	17	73.91	6	26.09	23	4.28	0.23
	Cervical	44	91.66	4	8.34	48		
	Dorsal	23	79.31	6	20.69	29		
	Lumbar	66	81.48	15	18.52	81		

Table 8: Success rate of telemedicine as per patients underlying pathology and level of surgery. (N-181)

Success rate was lowest in degenerative conditions 80.53%, followed by 83.6 in congenital condition while it was 100% in trauma. Success rate was lowest in CVJ surgery (73.91%) followed by dorsal spine (79.31%), maximum success rate was noted in cervical spine (91%) (Table 7)

Causes of unsuccessful Teleconsultation (TC) is explained in Table 9:

	Causes of unsuccessful TC			
	ICT	Physical visit	Sharing image	Total
First TC	7	2	0	9
second TC	4	5	9	18
Third TC	2	0	2	4

Table 9: Causes of unsuccessful Telemedicine(N-31)

Most common Reason for unsuccessful first visit was Network problem 77.77% while further evaluation/treatment was required in 22.22% of patients. Most common reason for unsuccessful second visit was difficulty in sharing post op imaging study (50%), further evaluation needed in 27.77% of patients while network problem was present in 22.22% of unsuccessful consultations.

Figure 5: Teleconsultations in spine follow up. A: Examination of CVJ patient with the help of attendant. B: Examination of post op patient with cervical laminectomy for OPLL. C: Examination of motor power with the help of attendant for a dorsal laminectomy patient for hypertrophied ligament flavum.

Figure 6: Examination of lumbar disc post-operative patients: A: Examination of bilateral EHL in a middle age lady with L4-5 lumbar disc prolapse. B: Examination of plantar flexion by asking the patient to walk on toes in a lady with L5-S1 lumbar disc prolapse.

Figure 7: Examination of post operative patients with tethered cord syndrome: A: Dorsiflexion against resistance in a child with tethered cord at 3 month follow up. B: Examination of sensation on dorsum of foot in a child with tethered cord at 2 month follow up. C: Examination of knee flexion with the help of parents in a child with tethered cord syndrome.

Figure 8: Troubleshooting while telemedicine: A: Low light making examination difficult in a patient with Foramen magnum decompression for Arnold Chiari Malformation. B: Poor internet connection in an operated patient for dorsal compressive myelopathy.

Discussion

6. DISCUSSION:

Spinal disorders are associated with a considerable healthcare burden and the need for frequent specialized medical consultations for symptomatic management.[55] Before COVID-19 pandemic, limited spine practices utilized telemedicine. Several challenges impeded adoption, including: a lack of perceived benefit, technology implementation costs, difficulty diagnosing musculoskeletal disorders, and concerns regarding reimbursement and liability. During the pandemic, however, as many as 35.6% of spine surgeons worldwide were performing over half of their clinical visits via telemedicine.[51]

It is estimated that there are around 7 billion mobile phone subscriptions worldwide.[20] Smartphone usage in developing countries such as India is in increasing trend. In 2022, 66.2% of Indian population use smartphone compared to only 7.1% of population used smartphone 10 years back. In future usage of smartphone is expected to grow and by 2040 penetration rate of smartphone usage is expected to reach 96%.[56] With increase in growth of smartphone there is increase usage of internet as well, India currently counts 825.3 million internet users. In 2022, India counts 487.5 million WhatsApp users. It is expected that growing use of smartphones and internet will allow surgeons to overcome some of the limitations that were exposed, thus allowing the generalization of telemedicine.[57]

The maintenance of a successful follow-up after spine surgery is essential to justify the investment that spine care entails. In the developing world and in underserved areas in the more developed nations, transportation, limited medical resources, and, occasionally, social stigma can pose significant challenges with regard to follow-up care of patients with spinal disease.[37] Telemedicine could help in overcoming some of

these limitations by cutting down on the travel time and travel expenses incurred by the patient during follow-up care, but they remain largely unexplored in Indian context follow up set up. Given the fact that telemedicine is going to be the future form of practice, it is important to assess spine patient success rate and identify related factors. Patient success rate is important to maintain a successful practice and increases follow-up.[58] Local clinics, patient homes, and facilities with appropriate telemedicine technology can be used during the postoperative period for 3 general purposes: for follow-up visits that replace those scheduled at distant sites, ongoing monitoring, and the remote identification of complications. Structured telemedicine visits for some post–neurosurgical follow-up care can reduce the time and travel costs to patients and their families, and they can reduce stress. To our knowledge, this is one of a few studies to address the feasibility of teleconsultations and video consultations for patients with spinal disorders in the real-life scenario of the public healthcare system of a developing country. Several studies have demonstrated the feasibility, cost reduction, satisfaction and effectiveness of telemedicine for patients with spinal disorders.[37,51,53] However, most were conducted in developed countries, had strict inclusion and exclusion criteria, or were performed using protocols that would facilitate telemedicine through the provision of the technological means necessary for it and instructions on how to use them. It is unknown how feasible it is to locate patients with spine disorders and perform teleconsultations for them in developing countries such as India, where limited access to the technological means to undergo a teleconsultation or video consultation or a low level of schooling could hinder this modality of care. Our study seeks to evaluate success rate of telemedicine after spine surgery in the Indian context.

In our study only 17.85% patients belonged to more than 60 years, as per previous study, most of the patients belonged to geriatric age group 60% (age more than 60

years).[58] In our study 50% patients were male and 50% patients were female which is comparable to previous study.[58]

In our study 47.61% patients belonged to lower, 52.3% belonged to middle and only 4.7% patients belonged to upper class category while in previous study 36.2% patients belonged to lower class, 55% belonged to medium class and 8% belonged to upper class, Total travel distance saved with successful consultation this study was 12322 kms. Considering average CO2 (carbon dioxide) emission per km in India, total amount of CO2 emission avoided with teleconsultation was 1763.2 Kg (kilogram).[4,60]

There was also no statistically significant difference between male and female patient's success rate. There was statistically significant decrease in success rate with decrease in level of education or decrease in socio-economic status of the patient. There was no statistical difference between indication of surgery and level of surgery. No other study in previous literature has compared patients success rate with demographic factors and clinicoradiological diagnosis.

Our study has evaluated factors for unsuccessful telemedicine consultations, as per our study most common cause of failure in first visit is issues related to ICT, while in second and third visit most visit failed secondary to difficulty in sharing postoperative scans, as per Satin et al. Audio or Video were most common problems encountered during telemedicine accounting for 20% of telemedicine visits. while difficulty in taking history or examination occurred in 13% patients.[58]

Our study has evaluated success rate exclusively for follow up after spine surgery, no other study in previous literature for telemedicine in spine surgery has done the same. In other specialities Marsh at al evaluated success rate of telemedicine in follow up after

Arthroplasty. Kane et al completed a prospective, randomized clinical trial to evaluate telemedicine for postoperative follow-up after arthroscopic rotator cuff repair.[62]

Our Study has done 100% teleconsultations using video calls, while in other studies video calling accounted for 62.4% of patients while audio calls accounted for 37.6% of patients.[51]WhatsApp was used in all the cases as it is most common form of messaging app used in India accounting for 487.5 million users as of 2022.[19]

Strengths & Weakness of Study

7. STRENGTHS OF THE STUDY

- To the best of our knowledge, this is the first study till date that has been carried out inWestern region of Rajasthan to calculate success rate exclusively in follow up after spine surgery.
- The study is one of its kind from this region to draw attention emphasized on challenges during teleconsultation in follow up after spine surgery.
- The study also highlights correlation of success rate with patient's demographic factors, clinico-radiological diagnosis and level of the disease.

WEAKNESS OF THE STUDY:

- All teleconsultations in this study group were done only for follow up patient in spine surgery while new patients and cranial patients were excluded from study group as it is easy to do only spine examination compared to complete neurological examination in a set up with low socioeconomical and educational status.
- New patients were not enrolled in the study as many spine surgeons are not comfortable in deciding surgical plan without at least one physical consultation as suggested by previous studies.
- Since the study was conducted during the period of COVID-19 pandemic, telemedicine comparison study was not done with in person visits.

Conclusion

8. CONCLUSION

In conclusion, present study gives an insight about the success rate of telemedicine and barriers for successful teleconsultaions in western part of Rajasthan, India.

We conclude that teleconsultation is a viable option for follow up of patients undergoing spine surgeries. Obviating need to travel long distances for selected patients, especially of post-operative spine diseases, will be helpful for both patients/relatives and the environment. Though easier to do in developing countries, it appears essential in low and middle income countries due to poor healthcare and transport infrastructure facilities. Better availability of internet access is an important factor which may help in higher rates of success of overall tele-consultations and likely to improve in India in coming few years.

Success rate in Indian context is less compared to western countries and it is highly influenced by patient's educations and financial status. Given recent evidence attesting to the feasibility of telemedicine in spine surgery and promising patient results, telemedicine may remain as a viable care option in the future. Ultimately, weighing the challenges and benefits of telemedicine may help determine whether spine surgeons continue to use telemedicine in the post-pandemic world.

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Annexure

10. ANNEXURE 1: ETHICAL CLEARANCE CERTIFICATE

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
m
Institutional Ethics Committee

No. A IIMS/IEC/2021/ *y Nk o* **Date: 12/03/2021**

ETHICAL CLEARANCE **CERTIFICATE**

Certificate Reference Nuiiiber: A I I **MS/IEC/2021/3395**

Project title: "Role **of telemedicine** for follow **up after spine** surgery"

Nature of Project:	**Research Project** Submitted **for Expedited Review**
Submitted as:	**M.Ch. Dissertation**
Student Name:	Dr.Totala Pankaj Rajendraku mar
Guide:	Dr. Suryanarayanan Bhashar
Co-Guide:	Dr. Tanuj Kanchan, Dr. Vikas P Meshram & Dr. Jaska ran Singh Gosal

Institutional Ethics Committee aftei thorough consideration accorded its approval on above project.

The i nvestigator way therefore commence the research from the date ot th is certificate, using the reference number indicated above.

Please note that the AH MS IEC must be informed immediately of:

- « Any material change in the conditions or undertakings mentioned in the document.
- A ny material breaches of ethical undertakings or events that impact upon the ethical conduct ot the research.

l"lie Pri nci pal Investigator inrist report to the All MS I EC in the prescribed to mat, wider c appl icable, bi-annriall y. and at the end of the project, in respect of ethical compl iance,

AI I MS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or in isi epresented

A I IMS IEC shall leave an access to any information or data at any time d tiring the course or after colrlpletion of the project.

Please Note that this approval will be i ectified whenever it is possible to hold a rneeti rig in person of the Institutional Ethics Comm ittee. It is possible that the PI way be asked to give more clarifications or the Institutional Ethics Coiniiiittee may withhold the project. 4 lie Institiitional Ethics Loinn ittee is adopti rig this procedure due to COVID- 19 (Coi'ona Virus) situation.

If the Institutional Ethics Committee does not get back to you, tfiis uterus your project has been cleared by the IEC.

On behal f of Ethics Coliiinittee. t wish you success in j our research.

Dr. Praveen Korma
Member Secfetary

Basni Phase-2, Jodhpur, Rajasthan-342005; Website: www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE 2: CONSENT FORM (ENGLISH)

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation: Role of telemedicine in follow up after spine surgery.

Name of Investigator: **Dr. TOTALA PANKAJ RAJENDRAKUMAR**

Tel. No.8879076919

Patient/Volunteer Identification No.:_____
I,_____S/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of the study "**Role of telemedicine in follow up after spine surgery**.", the procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions. I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about me and any of my medical records may be looked at by responsible individuals from Department of Neurosurgery, AIIMS, Jodhpur or from regulatory authorities. I give permission to these individuals to have access to my records.

Date : _____ _____

Place :_____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place:_____ Signature of Student

1. Witness 1

_____
Signature
Name: _____
Address: _____

2. Witness 2

_____
Signature
Name: _____
Address: _____

ANNEXURE 3: CONSENT FORM (HINDI)

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान
सूचित सहमति प्रपत्र

थीसिस / शोध प्रबंध का शीर्षक: के लिए टेलीमेडिसिन परामर्श की सफलता दर का मूल्यांकन करना रीढ़ की सर्जरी के बाद का पालन करें।

अन्वेषक का नाम: डॉ। टोटाला पंकज राजेंद्रकुमार

दूरभाष। No.8879076919

रोगी / स्वयंसेवक पहचान संख्या:_____
मैं,_____ एस / ओ या डी / ओ_____
आर / ओ _____
रीढ़ की सर्जरी के बाद अनुवर्ती टेलीमेडिसिन परामर्श की सफलता दर का मूल्यांकन करने के लिए, मेरी पूरी, मुफ्त, स्वैच्छिक सहमति दे। संतुष्टि। मैं पुष्टि करता हूं कि मुझे सवाल पूछने का अवसर मिला है। मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय अध्ययन से बाहर निकलने के मेरे अधिकार से अवगत हूं।
मैं समझता हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को न्यूरोसर्जरी विभाग, एम्स, जोधपुर के जिम्मेदार व्यक्तियों या नियामक अधिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंच की अनुमति देता हूं।

दिनांक : _____
स्थान : _____ हस्ताक्षर / बाएं अंगूठे का निशान

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है।

दिनांक : _____

स्थान :_____ छात्र का हस्ताक्षर

1. गवाह 1

_____
हस्ताक्षर

नाम:_____

पता:_____

2. गवाह 2

_____
हस्ताक्षर

नाम:___

पता:___

ANNEXURE 4: PATIENT INFORMATION SHEET (ENGLISH)

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Patient information sheet

Name of the patient: Patient ID:

Title of the study: Role of telemedicine in follow up after spine surgery.

Aim of the study: This study is being carried out to evaluate role of telemedicine for follow up after spine surgery.

Study setting: This study shall be carried out in the Department of Neurosurgery at AIIMS, Jodhpur.

Study procedure:

All eligible participants shall be explained about the procedure in detail, and a written consent will be taken. All patients will be followed up at suitable intervals over a video call. Clinical finding of the patient will be noted for record and analysis of the data will be done.

Benefits from the study:

This study will help us to evaluate success rate of telemedicine consultations for follow up after spine surgery. Also this study will help us to understand different factors affecting success of telemedicine and barriers for the same.

Risks expected from the study

Enrolment in this study poses no substantial risk to the participants. Patients will be carefully monitored during the postoperative period, as is routinely done.

Confidentiality of records:

All data collected from the participants and his/her medical records will be kept strictly confidential.

Confidentiality will be maintained during data collection, analysis and publication. The records will be preserved for a minimum duration of 3 years.

Compensation for participation

No compensation will be provided to the participants for enrolment in this study.

Freedom to withdraw from the study

All participants are free to withdraw from the study at any point, without assigning any reason, and without the otherwise medical care being affected.

Contact details of the Principal Investigator

Dr. TOTALA PANAKJ RAJENDRAKUMAR
Senior Resident, Department of Neurosurgery, AIIMS, Jodhpur
Phone: 8879076919
Email: pankajtotala1992@gmail.com Signature of the Principal Investigator

ANNEXURE 5: PATIENT INFORMATION SHEET (HINDI)

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर, राजस्थान

सूचित सहमति प्रपत्र

रोगी का नाम: **रोगी आईडी:**

अध्ययन का शीर्षक: रीढ़ की सर्जरी के बाद अनुवर्ती टेलीमेडिसिन परामर्श की सफलता दर का मूल्यांकन करना।

अध्ययन का उद्देश्य: टेलीमेडिसिन परामर्श की सफलता दर का मूल्यांकन करने के लिए यह अध्ययन किया जा रहा है स्पाइन सर्जरी के बाद फॉलोअप के लिए।

अध्ययन सेटिंग: यह अध्ययन जोधपुर के एम्स में न्यूरोसर्जरी विभाग में किया जाएगा।

अध्ययन प्रक्रिया:
सभी योग्य प्रतिभागियों को प्रक्रिया के बारे में विस्तार से बताया जाएगा, और एक लिखित सहमति ली जाएगी। वीडियो कॉल पर उपयुक्त अंतराल पर सभी रोगियों का पालन किया जाएगा। रोगी के नैदानिक खोज को रिकॉर्ड के लिए नोट किया जाएगा और डेटा का विश्लेषण किया जाएगा।

भागीदारी की अपेक्षित अवधि: सर्जरी की तारीख से तीन महीने।

अध्ययन से लाभ:
यह अध्ययन रीढ़ की सर्जरी के बाद अनुवर्ती टेलीमेडिसिन परामर्श की सफलता दर का मूल्यांकन करने में हमारी मदद करेगा। साथ ही यह अध्ययन हमें टेलीमेडिसिन की सफलता को प्रभावित करने वाले विभिन्न कारकों को समझने में मदद करेगा और उसी के लिए बाधाओं को दूर करेगा।

अध्ययन से जोखिम की उम्मीद है :
इस अध्ययन में नामांकन प्रतिभागियों के लिए कोई महत्वपूर्ण जोखिम नहीं है। नियमित रूप से पोस्टऑपरेटिव अवधि के दौरान मरीजों की सावधानीपूर्वक निगरानी की जाएगी।

अभिलेखों की गोपनीयता:
प्रतिभागियों से एकत्र किए गए सभी डेटा और उसके मेडिकल रिकॉर्ड को कड़ाई से गोपनीय रखा जाएगा।
डेटा संग्रह, विश्लेषण और प्रकाशन के दौरान गोपनीयता बनाए रखी जाएगी। रिकॉर्ड करेंगे
3 साल की न्यूनतम अवधि के लिए संरक्षित किया जाना चाहिए।

भागीदारी के लिए मुआवजा :
इस अध्ययन में नामांकन के लिए प्रतिभागियों को कोई मुआवजा प्रदान नहीं किया जाएगा।

अध्ययन से पीछे हटने की स्वतंत्रता :
सभी प्रतिभागी बिना किसी कारण बताए और बिना चिकित्सकीय देखभाल के प्रभावित हुए किसी भी बिंदु पर अध्ययन से हटने के लिए स्वतंत्र हैं।

प्रधान अन्वेषक का संपर्क विवरण
डॉ। टोटाला पंकज राजेंद्रकुमार
वरिष्ठ निवासी, न्यूरोसर्जरी विभाग, एम्स, जोधपुर
फोन: 8879076919

ईमेल: pankajtotala1992@gmail.com

प्रधान अन्वेषक का हस्ताक्षर

ANNEXURE 6: DECLARATION BY THE STUDENT

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Declaration by the Student

I hereby declare that:

1. The study will be done as per ICMR/ GCP guidelines.
2. The study has not been initiated and shall be initiated only after ethical clearance
3. Voluntary written consent of the volunteers/ patients will be obtained.
4. In case of children or mentally handicapped volunteers/patients, voluntary written informed consent of the parents/ guardians will be obtained.
5. The probable risks involved in the study will be explained in full to the subjects/ parents/ guardians in their own language.
6. Volunteers/ patients/ parents/ guardians will be at liberty to opt out of the study at any time without assigning reason.
7. I will terminate the study at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the study/ experiment is likely to result in injury/ disability/ death to the volunteers/subject.

Date: _____ (Signature of Student) Department __

(Signature of Guide) Department _____

ANNEXURE 7: DATA COLLECTION PRO FORMA

Serial number:

Demographic details

- Name: Age/sex:
- Hospital number: Contact number:
- Socioeconomic status
- Educational status
- Address
- Comorbidities
- Preoperative complaints
- Preoperative positive clinical findings
- Clinical diagnosis
- Radiological diagnosis

Operation details

- Date of surgery:
- Surgery performed:
- Surgical approach:
- Intraoperative findings:

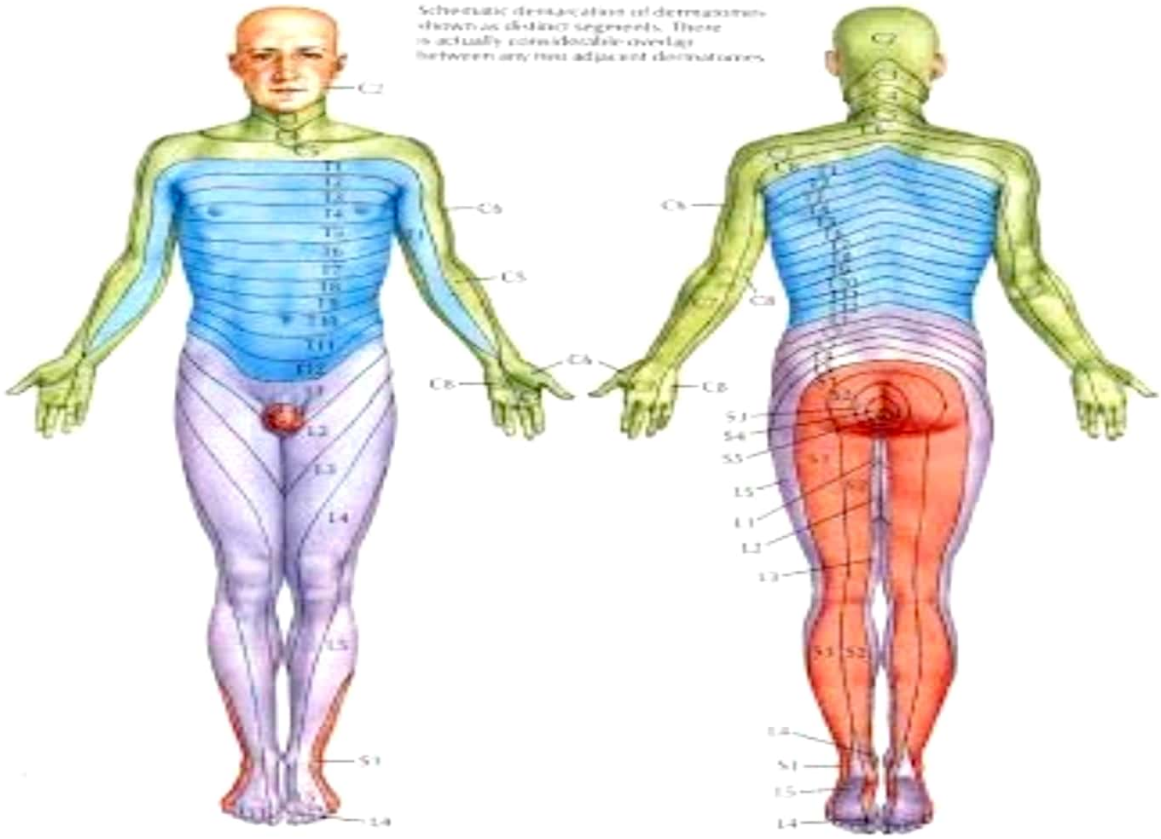
Postoperative:

- Complaints
- Positive clinical findings

Follow up:

- Platform for teleconsultation: WhatsApp video call/ skype/ zoom
- Follow up duration:
- Assisted clinical examination by: Patient / relative/ healthcare worker
- Complaints
- Positive clinical findings
- Remark: successful or unsuccessful telemedicine consultation
- Reason for unsuccessful telemedicine consultation (if applicable):

ANNEXURE 8: <u>DERMATOMAL DIAGRAM PROVIDED TO THE PATIENT</u>.



Levels of principal dermatomes

C5	Clavicles
C5, 6, 7	Lateral parts of upper limbs
C8, T1	Medial sides of upper limbs
C6	Thumb
C6, 7, 8	Hand
C8	Ring and little fingers
T4	Level of nipples
T10	Level of umbilicus
T12	Inguinal or groin regions
L1, 2, 3, 4	Anterior and medial surfaces of lower limbs
L4, 5, S1	Foot
L4	Medial side of great toe
S1, 2, L5	Posterior and outer surfaces of lower limbs
S1	Lateral margin of foot and little toe
S2, 3, 4	Perineum

ANNEXURE 9: MODIFIED KUPPUSWAMY SCALE

Education of head of family	Score	Occupation of head of family	Score
Professional degree	7	Professional	10
Graduate	6	Semi profession	6
Intermediate/diploma	5	Clerical/shop/farm	5
High school	4	Skilled worker	4
Middle school	3	Semiskilled worker	3
Primary school	2	Unskilled worker	2
Illiterate	1	Unemployed	1

Total score	Socioeconomic class
26–29	Upper class
16–25	Upper middle
11–15	Lower middle
5–10	Upper lower
Below 5	Lower

Current total per capita income per month according to Current Price Index of India in October 2019.

Sr.No	Total income	Score
1	22703 and above	12
2	11351-22702	10
3	8513-11350	6
4	5676- 8512	4
5	3405-5675	3
6	1147-3404	2