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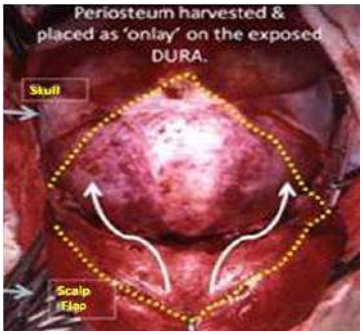
Challenges in Indian Health Care System

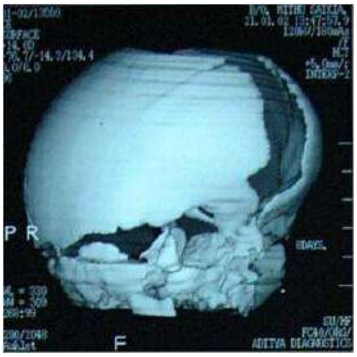
Intra-operative Neuromonitoring

Craniosynostosis: Triphyllocephaly

Partial Calvariectomy, Onlay Periosteoplasty



Bilateral coronal suture ossification – Brachycephaly



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EDITORIAL

Healthcare Infrastructure, Policy Support & Government Initiatives

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The healthcare sector in India has seen considerable increases in employment and earnings. The industry is growingexceptionally quickly as a result of its expanded coverage, enhanced services, and higher investment by both public and private enterprises. By 2022, it is projected that the industry would be worth $372 billion in total. By 2025, it is predicted that the e-health market would be worth US$10.6 billion. AUS$40 million health initiative for the state of Meghalaya was signed by the governments of India, Meghalaya, and the World Bank in November 2021. This initiative will raise the standard of healthcare and increase the state's ability to respond to emerging health crises, such as the COVID-19 pandemic [1].

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A rising trend in per capita healthcare expenditure

Increased knowledge of personal cleanliness and health, increased access to high-quality healthcare facilities, and risingmoney all contribute to this. Healthcare spending increased as a result of more people having health insurance, and this trend is expected to continue over the next 10 years. The increase in generic drug affordability on the market is being driven by the improvement in the economy. India's public healthcare spending was 2.1% of GDP in 2021–2022, up from 1.8% in 2020–2021 and 1.3% in 2019– 20, according to the Economic Survey of 2022. By 2025, the government wants to spend 2.5% of the nation's GDP on public health [2].

A rising trend in healthcare infrastructure

In the last few decades, India's infrastructure for medical education has

expanded quickly. Indian healthcare infrastructure is anticipated to cost $349.1 billion by FY22. There were 612 medical colleges in India as of July 2022. In November2021, there were 1.3 million allopathic doctorsregistered with state medical councils and the national medical council who have recognised medical degrees (under the NMC Act), up from 0.83 million in 2010. According to data given to the Lok Sabha, there are 1:834 doctors in the nation, assuming that 5.65 lakh AYUSH doctors and 12.68 lakh registered allopathic doctors are both available 80% of the time. Nitin Gadkari, Minister of Road Transport & Highways, stated that the nation requires at least 600 medical colleges, 50 institutes similar to AIIMS, and 200 super-specialty hospitals in September 2021. He also urged the healthcare industry to adopt the public-private partnership model used in the development of infrastructure [3].

Rising demand

- Rising income and affordability.
- Growing elderly population, changing disease patterns.
- Rise in medical tourism.
- Better awareness of wellness, preventive care and diagnosis.

Focus

- Expanding R&D and distribution facilitiesin India.
- Use of modern technology.
- Providing support to global projects from India.

Support

- Encouraging policies for FDI in the private sector.
- Reduction in customs duty and other taxes on life-saving equipment.
- NRHM allocated US$ 10 billion for healthcare facilities.
- National Health Insurance Mission tocover entire population.

Rising trend to choosing India as a preferred destination for medical tourism

India's position as a top destination for medical tourism has been bolstered by the country's availability of top-notch hospitals and qualified medical personnel. Indian medical tourism benefits from high standards of healthcare and affordable treatment prices compared to other nations, which has improved prospects for the Indian healthcare business. Major procedures in India cost about20% less than in industrialised nations. Due tothe dearth of modern medical facilities in many developing nations, India also draws medical tourists from these nations. In 2020, the Indian medical tourism market was estimated to be worth US$2.89 billion, and by2026, it is anticipated to be worth US$13.42 billion. Around 697,300 foreign tourists, or roughly 7% of all foreign visitors to India in FY19, came for medical treatment, according to the India Tourism Statistics at a Glance 2020 report. Out of 46 destinations, India is placed 10th in the Medical Tourism Index (MTI) for 2020–21 by the Medical Tourism Association. In July 2021, the National Medical & Wellness Tourism Board was founded by the Ministry of Tourism. In order to promote all forms of medical travel, the board will function as an umbrella organisation. A proposal of the "National Strategy and Roadmap for Medical and Wellness Tourism," which intends to provide a framework for governance and development ofthe industry, has also been made available by the Ministry [4].

The present structure of Indian healthcare industry

The healthcare sector in India is expanding at a compound annual growth rate (CAGR of 22% during 2016–22 with a target to achieve US$ 372 billion in 2022. Healthcare industry has become the largest sector of the Indian economy and providing direct employment to approximately 47 lakhs peoples. As per the estimate according to the National Skill Development Corporation

(NSDC), the Indian healthcare industry may create an additional 27 lakh employment. India's healthcare industry functions through five major segments which is hospital (government and private), Diagnostics and Interventions (imaging and laboratoryinvestigation), Pharma (synthesis, evaluation, extraction, toxicology, purification, processing, manufacturing, packaging and distribution of medications and vaccines), Devices and Equipments (manufacturing and establishment of medical equipments, devices, instruments etc.), health insurance, research, digital health programme (telemedicine) and medical tourism. The COVID-19 has catalyzed long-term shifts in perceptions of personal hygiene, health insurance, nutrition, and exercise, as well as health monitoring and physical examinations. The epidemic has also accelerated the uptake of telemedicine and other digital health technology [5] (Figure 1).

Fig. 1. Challenges in Indian Health Care System

Policy support and government initiatives

Pradhan Mantri Jan Arogya Yojana (PMJAY)

- The Union Budget for 2021–2022 included a Rs. 64,180 crore (US$ 8.80billion) outlay for the healthcare industry over a six-year period with the goal of bolstering the current "National Health Mission" by building primary, secondary, and tertiary care, healthcare systems, and institutions' capacities for the detection and treatment of new and emerging diseases.

Tax incentives

- There is no service tax on any healthcare education or training services.
- An increase in the tax break provided under Section 80-IB for private healthcare providers in non-metro hospitals with at least 50 beds.
- Telemedicine and remote radiology are examples of healthcare services made possible by technology, which is eligible for a 250% deduction for authorised operating expenses.
- A basic 5% customs tax exemption appliesto artificial hearts.
- A 15-year income tax exemption for medical technology items made in the country.
- New hospitals built in rural regions with 100 beds or more now qualify for section 80-IB's benefits. These hospitals are

eligible for a five-year period of 100% profit deduction [6].

A roadmap for missing 'middle'

India has made large strides towards universal health coverage (UHC) with the launch of Ayushman Bharat – Pradhan Mantri Jan Arogya Yojna (AB-PMJAY). It is the largest fully Government subsidized scheme inthe world, covering nearly 40% of the India's population at the bottom of the pyramid. Nearly 70% of India's population is now estimated to be protected by some health insurance coverage including State Government scheme, social insurance schemes, and private insurance [7,8].

Despite this progress, 30% of the population and over 40 crore people still don't have access to any type of financial health insurance. Financial difficulties and evenpoverty might result from adverse health situations. Because they are neither wealthy enough to purchase private insurance nor sufficiently poor to qualify for government- subsidized coverage, this group is known as the "missing middle." Lack of social security benefits and informal employment with variable revenues are characteristics of the missing middle [10,11].

The missing middle has the financial capacity to pay for health insurance cover. However, the current insurance products are targeted towards high-income groups. A well-designed appropriately priced, voluntary, and contributory insurance product catering to this segment will accelerate India's progress towards universal health coverage (UHC) while expanding the market for private insurance. The product needs to be built on principles of standardization, and simplicity. The Arogya Sanjivani policy is a first step in this direction. However, presently it does not include any out-patient care [12,13].

In the absence of a low-cost health insurance product, the missing middle remains uncovered despite the ability to pay nominal premiums. A comprehensive product designed for this segment – improving upon the existing *Arogya Sanjeevani* plan and offering **out-patient cover –can expand health insurance coverage.** Most health insurance schemes and products in the Indian market are not designed for the missing middle. Private evolutionary healthinsurance is designed for high-income groups – it costs at least two to three times the affordable level for the missing middle. Affordable contributory products such as ESIC, and Government subsidized insurance including PMJAY are closed products. They are not available to the general population due to the risk of adverse selection. A modified, standardized product which builds on the *Aarogya Sanjeevani* hospitalization insurance product–launched by IRDAI in April 2020–can be appealing to the missing middle. Arogya Sanjeevani has laid the foundation for a standardized health insurance product; it offers a basic benefits package which is common across insurers [9].

Universal Health-Care is affordable and feasible

Global experience has demonstratedthe affordability and viability of universal health care. The political will demonstrated by the government's commitment to increased resource allocation, recent audacious social policy initiatives, and legislation like the Clinical Establishments (Registration Regulation) Act, Disaster Management Act,and Mahatma Gandhi National Rural Employment Guarantee Act Fundamental Right to Education Act of 2012 and the Food Security Bill 2012 will contribute to lessening the burden of illness and suffering through increasing employment, reducing poverty, enhancing literacy, etc. UHC can be accomplished by 2022 thanks to increased civil society involvement, the elimination of polio, smallpox, and guinea worms, and a significant effort to introduce strict quality control methods in Maternal and Child Healthservices at Primary Health Centers in Tamil Nadu [14]. Becoming a welfare state the government of India (central and state) has the

general obligation to provide universal health care services to its citizens at no cost basis. The government also has the responsibility to ensure that laying down minimum standards and appropriate regulatory mechanism [15]. The government is bound to provide a safe and healthy environment to its people, delivering universal access to basic health services, medicines and regular evaluation of the health system [16,17].

Universal health coverage: an investment in human capital

The planning commission of India established the high level expert group (HLEG) on universal health coverage (UHC) in October 2010 with the goal of creating a framework for making health care conveniently accessible and affordable for all Indians [18]. The HLEG recommendations the ability of everyone to obtain the health care they require without experiencing financial hardship is essential to raising national well- being. But universal health care is **more than that;** it is a foundational factor in equitable and sustainable economic growth and development as well as an investment in human capital. It is a means of assisting peoplein realising their full potential and achieving their goals. According to the UHC Global Monitoring Report 2017, at least 50% of the world's population still does not have access to basic healthcare services. In addition, almost 800 million individuals spend more than 10% of their family income on health care, and every year, some 100 million people are forcedinto extreme poverty as a result of uninsured medical costs [19].

Conclusion

The Indian healthcare sector is one of the largest in the world in terms of revenue and jobs in largest economic sectors among others. We are emerging as fastest growing economy with several opportunities for investment. We have elaborated the growthpotential and investment opportunity in healthcare sector, including insights about its employment generation potential, overarching policy landscape, enabling policies and investment opportunities in hospitals and infrastructure, drug and vaccine development, medical devices, medical tourism, digital healthcare industry with telemedicine and health insurance. The abundance of highly qualified medical personnel in India is a competitive advantage. India's costs are competitive with those of its neighbours in Asia and the West. The low cost of healthcarehas led to an increase in medical tourism in the nation, drawing people from all over the world. Moreover, because to its relatively lowcost of clinical research, India has become a centre for R&D activity for foreign businesses.

Conflicts of interest

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

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EDITORIAL

Digital Healthcare –Paving the Road to "One World, One Health"

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Our world today is not defined as 7 continents, 5 oceans and 193 countries; it is rather a global village. A unified population, connected extensively thanks to the existing and forever evolving technology.

To keep at pace with this evolving nature of society, healthcare sectors must evolve too. Digital healthcare (DH) is the pacemaker of our new world.

A recent event which unified all the members of society and diluted all borders of the world as we know it, is the much talked about COVID-19 pandemic. The pandemic has been a teacher to all of us, explaining by example how important preparedness for any event is for the healthcare sector and how the concept of "One world, one health" rises above all.

With knowledge comes power. Awareness and information are tools of primary importance in any novel challenge that a nation faces. The pandemic was no different. Communicating the right information about the pandemic in terms of its spread, the course of the disease, outcomes of the patients and preventing & testing strategies were the most sensitive and critical steps in handling the response of the citizens.

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From the very first diagnosed case to the current status of the disease in the population, our nation handled the COVID-19 situation with great maturity. The first step was to spread awareness without creating chaos. Contact tracing was a major challenge which has been well tackled with a phone app, Aarogya Setu which has now transformed into a national health app allowing citizens access to not only COVID-19 contact tracing, testing, vaccinations, and updates, but also to other digital health services. The application has been downloaded by roughly 217 million users and is a nationally and internationally lauded effort towards the pandemic.

Numerous government and private laboratories were rapidly set up for COVID testing during the pandemic and over approximately 90 Cr samples have been tested till date. All the reports were centralized under the Indian Council of Medical Research (ICMR) to maintain a database to assess disease patterns, contact tracing and patient follow ups.

A National Covid Registry has been established for real-time hospital data. It involves 50 centers under 14 COVID-19 clinical registration sites, which finally fall under the ICMR and Ministry of Health and Family Welfare (MoHFW). The registry aims to collect data regarding clinical and laboratory features, treatments, follow up and outcomes of

hospitalized COVID-19 patients in India. The details recorded by the registry will also aid in studying the natural course of the disease, its spectrum, prognostic factors, outcomes data, medications, health systems and context specific questions such as COVID-19 in tuberculosis, malnutrition.

Anytime a person tests positive for COVID and is assessed to be stable enough for home isolation, home isolation monitoring kits and medications are provided to patients. Regular telephonic follow up and online consultations are given to ensure that any danger sign or symptom is promptly identified, and the patient is advised a hospital visit. Special care is offered to elderly patients or to those who do not have an adequate care giver during isolation.

India also has a very robust and successful vaccination drive and since its inception, approximately 70% of India's population has been fully vaccinated. The vaccination details, certificates and records are stringently and systematically maintained with easy access and user interface for citizens.

Universal healthcare by 2030 is a pivotal commitment for India because it will promise digitized healthcare making it accessible, equitable and affordable.

The principles of the National Health Policy 2017 include universality, citizen-centricity, quality of care and accountability of performance. The core of the policy lies in the paradigm shift towards digital health to realize the dream of Universal healthcare. The National Digital Health Mission (NDHM) now rechristened as the Ayushman Bharat Digital Health Mission (ABDM) was initially launched as a pilot project in 6 union territories in 2020 and then expanded nation-wide in September 2021 focusing on initiatives like Ayushman Bharat Health Account (ABHA) No., Health Facility Registry, ABHA App, Healthcare Professionals Registry and Unified Health Interface (UHI). As of September 2022, an impressive 24 crore plus ABHA numbers have been created with 1,44,371 health facilities and 69,312 health professionals have been registered. The mobile application has been downloaded with over 7 lakh health records. The ABDM uses the approach – "Think Big, Start Small, Scale Fast" and aims to develop the backbone necessary to support the integrated digital health infrastructure of the country.

During the lockdown period, the adoption of virtual health care was accelerated throughout the nation, including teleconsultation, teleradiology, telepathology and e-pharmacy. Since 2010, the telemedicine market size has seen a gradual increase and is expected to grow at a compound annual growth rate (CAGR) of 31% from 2020 to 2025. Over 5 Crore Indians accessed healthcare online in March-May 2020. The national telemedicine service, e-Sanjeevani, completed more than 1,50,000 teleconsultations in August 2020.

A recent effort which is ongoing to enhance accessibility, is a QR Code-based OPD registration service which allows patients to scan QR codes with their mobile phones and register for OPD appointments. It helped over 2200 patients at 2 major government hospitals within 15 days to avoid long queues at the registration counters.

While the numbers look promising, and 24 crore ABHA numbers constitute one-sixth of India's population, a large part of the healthcare value chain remains outside of the ABDM-initiative. According to the National Health Profile 2019, an alarming 65% of rural India still has no internet access and only 65% of primary health centers in rural India have computers. This poses a challenge for the wide spread of the digital mission, but as our nation has proven time and again, no dream is too big to achieve.

The World Health Organization (WHO) defines public health surveillance as, "the continuous, systematic collection, analysis, and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice". Advancements in information technology and information sharing is giving rise to a new field of *infodemiology*. Infodemiology is defined as, "the science of distribution and determinants of information in an electronic medium, specifically the internet, with the ultimate aim to inform public health and public policy". Online surveillance-mapping tools like the Surveillance and Outbreak Response Management and Analysis System (SORMAS), as well as HealthMap, have the potential to improve the early detection of infectious diseases in comparison to traditional epidemiological tools. SORMAS and HealthMap have also been in use for COVID-19 surveillance.

Healthcare systems have experienced a proliferation of innovations aimed at enhancing life expectancy, quality of life, diagnostic and treatment options, as well as the efficiency and cost effectiveness of the healthcare system. Taking inspiration from the National Health Mission, various states have made efforts towards advanced health care. 'Making a Difference: Good Replicable and Innovative Practices' (GRIP) is a compilation of 85 innovations across the states and 8 central government initiatives from different areas of the health systems.

The government of Madhya Pradesh started an integrated referral transport system including mobile medical units and Janani express vehicles which are operated through district level call centers. An Emergency Medical Ambulance Service popularly known as "108 Ambulance Service" has a daunting fleet of 554 Basic Life Support (BLS) ambulances and 50 Advanced Life Support (ALS) ambulances. Supported and deployed by a centralized call center which receives more than 25000 calls per day and handling 1800 emergencies a day. Such a system of organized healthcare transport provision has been monumental in improving outcomes of patients living in remote areas in our developing country.

In Rajashthan, a free supply of generic medicines is given under the Mukhyamantri Nishulk Dava Yojana. Not only does the programme aid less privileged patients in getting access to quality medications but also aids in the strengthening of supply chain management. Right from the procurement of drugs to their distribution to various institutions via District Drug Warehouses (DDW), a complete supply chain tracking mechanism has been deployed using e-Aushadhi which is a software for inventory management. The software covers – online demand, rate contract desk, online PO generation, supplier interface, stock ledger, inter-DDW transfer, lab interface, quality control, supplier performance detail report, NA hit report and expiry drugs detail.

An additional advantage of the e-Aushadhi software, under the Mukhyamantri Nishulk Janch Yojana, is the daily online reporting of investigations and for information to non-reporting institutions via SMS message.

ASHA workers form an essential part of rural healthcare and since they are volunteering for the betterment of their respective villages, it is important to keep their motivation alive. Delays and lack of transparency in payment of ASHA incentives are a deterrent in motivating these activists. In Jharkhand, a fixed day was decided to make payments to ASHA workers through NEFT transfers directly from the block. The key components of this model were to establish a robust system of claim submission, collection, verification, and authentication leading to timely payments under the Public Financial Management System (PFMS). The PFMS system provides both online and offline data entry options for ASHA payment. Another effort directed towards the encouragement of ASHA workers by transparent access for them to incentives is ASHA Soft which is a web-based software which was launched on December 26th 2014.

The state of Gujarat implemented the Mobile Mamta Diwas scheme which was a platform for creating health related awareness targeted for the far-flung and poorly accessible areas of the state. Information generated by the software has influenced policy decisions and nearly 2 lac newborn admissions, discharges, deaths and follow up visits have been captured by the software.

The Mother and Child Tracking System (MTCS) is an initiative of the MoHFW for ensuring delivery of full spectrum of healthcare and immunization services to pregnant women and children up to 5 years of age. It is an innovative, web-based application to facilitate and monitor service delivery as well as to establish a two-way communication between the health service provider and beneficiary. Near real time data uploading ensures real time work plans and goals for ANMs, and timely delivery of services to all pregnant women and children.

When we examine some of these successful technological trends and developments in healthcare in India over the past decade, the accomplishment report card is an impressive one. So too is the roadmap for what lies ahead. Yes, challenges remain, but the elements are in place for an enduring transformation.

On a global scale, health care has witnessed two macro trends driving the change impacting the healthcare industry. The first is the acceleration of healthcare systems to work towards value-based care models. Such models shift the focus away from treatment to

prevention and early intervention. This dynamic can in some ways be a shift from a thing — a product or a pill — to a process for solving health issues. It's less about reacting to disease and more about helping manage the disease, or better yet, developing predictive structures to help optimize wellness and health. The other dramatic shift that's taken place in healthcare is simply physical location, or point-of-care. Digital technology's capability to keep us connected, despite physical distance, has been one of the main stories in the world's response to the COVID-19 pandemic. Digital health enables healthcare providers to engage directly with their patients, regardless of the actual location. Sensors, trackers, remote patient monitoring (RPM) technologies and other elements of digital healthcare make the point-of-care the patient themselves. As such, it simultaneously closes the distance between the patient and healthcare provider while also opening up opportunities for how, when and where these interactions take place. Consideration of both these trends provides a broader framing for more specific insights into the exciting opportunities in healthcare today.

Future concepts now seem very achievable. Artificial Intelligence (AI) on its own one of the most potent accelerators of innovation and emergent capability in healthcare. The analysis provided by AI and machine learning can be purposed to enable a highly personalized healthcare where specific courses of action are recommended or automatically taken based on ongoing monitoring of patient status and compliance with, for instance, a digital twin or via engagement with a digital health monitoring platform. More than three-quarters of digital healthcare solution providers say they are either seriously considering options or already working with advanced technologies for delivering personalized medicine and precision healthcare solutions.

Another opportunity for explosive innovation by healthcare manufacturing companies is through delivery of additive manufacturing — sometimes referred to as 3D printing. In just the last few years, additive manufacturing has become essentially a medical technology, enabling extraordinary benefits within a variety of niches, for example in the orthopedics market. Corrosion-resistant and biocompatible structures 3D printed from both polymers and metals and incorporating complex and precise geometries unattainable by traditional machining and manufacturing process are revolutionizing the work being done with patients suffering orthopedic trauma or other health-compromising conditions. Quick design turns with minimal waste and maximum strength make additive manufacturing printed implants ideal for next-generation applications with capabilities for customization to a patient's specific anatomy.

Modular design architectures addressing the "non-therapy" portion of a medical device may be the optimal approach for minimizing the complexity of regulatory approvals and improving speed to market. In the pharma space, digital technologies can be leveraged to optimize clinical trials performance by improving adherence and compliance to study protocols, and lowering costs, all in support of accelerating the right candidates to market.

A lab-on-a-chip is a miniaturized device that integrates into a single chip one or several analyses, which are usually done in a laboratory; analyses such as DNA sequencing or biochemical detection. Research on lab-on-a-chip focuses on several applications including human diagnostics, DNA analysis and, to a lesser extent, the synthesis of chemicals. The miniaturization of biochemical operations normally handled in a laboratory has numerous advantages such as cost efficiency, parallelization, ergonomics, diagnostic speed and sensitivity. The emergence of the lab-on-a-chip field mainly relies on two core technologies: microfluidics and molecular biology.

The basis of the lab-on-a-chip dream is to integrate onto a single chip thousands of biochemical operations that could be done by splitting a single drop of blood collected from the patient in order to get a precise diagnosis of potential diseases. As we will see, we are currently quite far from this, but current technologies are already able to do several single tests with specialized lab-on-a-chip such as HIV or glucose detection, bringing us closer to the realization of this dream. In the following decades, lab-on-a-chip advancements will change diagnostic practices.

The word "transformation" is often used when describing the impact of digital technologies on the industry. What were once considered barriers are now opportunities? Digital healthcare's progress now tracks an

unmistakably upward sloping trend, but as impressive as that graph is, COVID-19's impact on healthcare delivery and legacy healthcare workflows is to a whole other degree.

The COVID-19 pandemic has catalysed a massive shift toward a more aggressive leverage of digital technologies in healthcare. Telehealth, virtual care and remote patient monitoring are helping to protect people's lives — and for medical staff, their livelihoods. The entire ecosystem is evolving to address limited resources: the people, places and things which make up our healthcare system. Direct access to our physicians and medical centres has changed. We are being triaged and treated differently. If something can be done remotely, or through a sensor with digital connectivity, it's being embraced to deliver us safely, and with more cost efficiency, through the bottlenecks.

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REVIEW ARTICLE

Craniosynostosis: Overview Update

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Craniosynostosis is a congenital condition when one or more of the baby's skull's sutures close earlier than usual. The premature result of a suture closing is an unnaturally formed head. Each year an estimated 84,665 and there are 72,857 non-syndromic craniosynostosis cases among the newborns with craniosynostosis. [1]. Further studies are needed to delineate prevalence in low & middle income countries (LMICs). This information would be needed to upscale training of personnel & augmenting necessary infrastructure [1].

The cranial vault sutures are distinctive, but other than that, the brain growth could be pathologically restricted with irreversible damage pathologically caused to it as the intracranial pressure increases the sutures were previously believed to be active growth sites that force the cranial plates apart, but further research has revealed that their function is passive. The neonatal brain doubles up in size in 6 months and quadruples by the 1st year of life, acquiring 80% of its adult size by 2nd years of age. Patent cranial sutures allow this rapid expansion with a minimal pressure of approximately 5 mm Hg provided by the growing brain. Bone is deposited at the borders of the sutures and the epicranium in response to the rapidly expanding brain, while resorption happens along the dural surface [2,3].

The cranial sutures are typically patent at birth and develop into a yielding fibrous union in the first year of life, allowing appositional bone growth to continue. The cranium reaches 90% of its adult size by the age of 6, although complete solid sutural bony union does not happen until at least the fifth decade. Virchow's law states that if a suture closes too soon, growth is stopped in a direction perpendicular to the fused suture, while compensatory expansion takes place in a plane parallel to the affected suture. Depending on which suture or sutures are closed, the subsequent deformity of the skull will occur [4].

There are significant hereditary and long-term growth implications for the two types of craniosynostosis. The non-

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syndromic fraction of malformations typically occurs infrequently, but the syndromic subset typically has a hereditary component. Additionally, normal craniofacial development is the norm following surgical correction for the non-syndromic patients, whereas those with syndromal attributes do not fare so well.

Epidemiology of craniosynostosis

With particular reference to low- and middle-income countries (LMICs), according to one estimate [5], 23,300 additional neurosurgeons are necessary to address about 5 million essential neurosurgical cases, hitherto, remaining attended. It needs to be recognized, that, neurocognitive impact of Craniosynostosis could be as significant while priority remains to be given to illnesses include hydrocephalus, tumor, and stroke [6-10].

There paucity of trained manpower with only a handful of centres offering the expertise of this surgery in LMICs [11]. There is a need for early recognition of this condition by pediatricians followed by early intervention by trained pediatric surgeons [12-14]. Surgical workforce in managing craniosynostosis could be expanded by creating centres of excellence, particularly in LMICs where the disease burden is profound.

Nonsyndromic Craniosynostosis

One in every 1000 live infants is reported to have nonsyndromic premature stenosis of the cranial sutures. These statistics cover all single suture fusion types, with unilateral coronal, metopic, and lambdoidal areas most frequently impacted and the sagittal being the least frequently affected. Multiple sutures are also involved, as well as bilateral fusion of the coronal.

Based upon the suture involved, the following deformities present clinically:

Scaphocephaly (Boat shaped)

The sagittal suture is either partially or completely fused; when fusion is complete, there is frequently an exterior bony overgrowth that extends from lambda to bregma in the midline. On the interior surface, overgrowth might appear occasionally (Fig. 1). X-ray of the skull in an anteroposterior (AP) view shows sagittal suture fusion (Fig. 2).

Fig. 1. Scaphocephaly – Boat Shaped

Fig. 2. X-ray – Sagittal suture ossification – Scaphocephaly

Plagiocephaly (Unilateral coronal suture fusion)

The lateral section of the damaged coronal suture exhibits synostosis. The

suture's medical end is typically patent in early newborns. The synostosis is typically entire and reaches the anterior fontanelle, which may be modest or even absent, in cases where the patient is older than 6 months. The suture may then leave no visible external traces or appear as a shallow groove in the bone that resembles a constriction ring (Fig. 3). Sutural fusion shall seen on a plain X-ray or a 3-D CAT scan of the skull (Fig. 4).

Fig. 3. Unilateral coronal suture ossification – Plagiocephaly

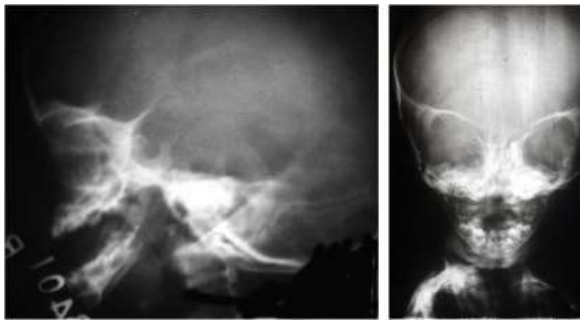

Fig. 4. X-ray – Unilateral coronal suture ossification — Plagiocephaly

Brachycephaly (Short-bilateral coronal suture fusion)

When both coronal sutures are involved the forehead becomes fore-shortened anterior-posteriorly (Fig. 5). The diagnosis can be confirmed by X-ray skull (Fig. 6) and 3-D CAT scan.

Fig. 5. Bilateral coronal suture ossification – Brachycephaly

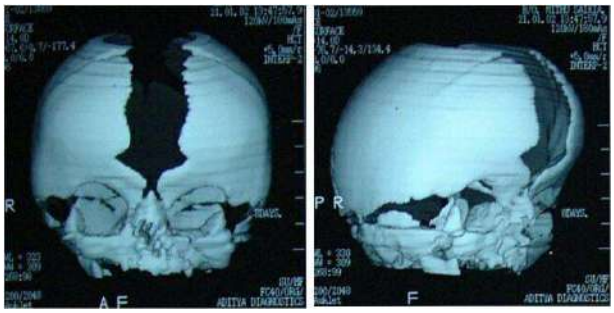

Fig. 6. Bilateral coronal suture ossification – Brachycephaly – 3-D CAT scan of the skull

Trigonocephaly (Triangular-metopic sutural fusion)

Premautre The metopic suture can fuse completely or not at all in the area around the anterior fontanelle, where it is typically most noticeable above the glabella. On the inner surface of the frontal bone near the lower end of the synostosis, there is frequently a noticeable bony outgrowth. (Fig. 7). X-ray of the skull (Fig. 8) or 3-D CAT scan is unmistakable.

Fig. 7. 3D Cat Scan — Trigonocephaly (Triangular-metopic suture ossification — Trigonocephaly

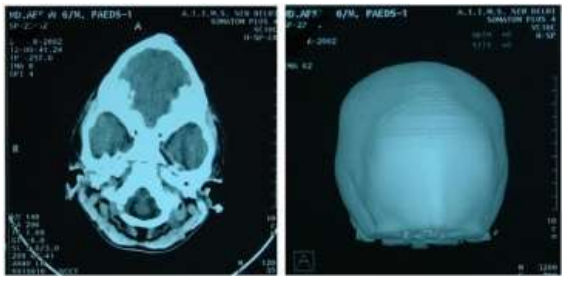

Fig. 8. 3D Cat Scan — Trigonocephaly (Triangular-metopic suture ossification— Trigonocephaly

Syndromal Craniosynostosis

In contrast to nonsyndromic fusions, syndromal craniosynostosis behave to these deformities differ from one other, have genetic ramifications, and an established pattern of inheritance. The most prevalent syndromal craniosynostosis anomaly, Crouzon's syndrome, with an estimated prevalence of up to 1 per 10,000 live births. The autosomal dominant inheritance pattern has almost full penetrance. [15].

Crouzon's Syndrome

Mid-face hypoplasia, parrot beak nose, lateral canthal dystopia, hypertelorism (Broad set orbits) and relative mandibular prognathism characterize the defect. High arched palate is also an associated finding. Although other head forms are seen, brachycephaly is the predominant skull malformation. Exorbitism is a serious warning. It may endanger sight and is frequently extremely prominent.

Apert's Syndrome

Also termed as acrocephalo syndactyly, the incidence of this anomaly has been estimated to be 1 in 1,60,000 live births. As with Crouzon's syndrome, exorbitism, midfacial retrusion with maxillary constriction, and pseudomandibular prognathism are present. Exorbitism is more asymmetrical and modest. The face also is transversely flattened. The distance between the orbits is greater. The cranial Premature fusion of the coronal sutures is nearly always linked to deformity, however the base of the skull is also affected. The severity of the syndactyly, which entails bone fusion of the phalanges of at least the index, middle, and ring fingers, separates the Apert's syndrome from other acrocephalosyndactylies. (Fig. 9). Autosomal dominant is the method of inheritance, albeit sporadic incidence is more common. Similarly to Crouzon's condition, a hereditary flaw has been identified [2].

Fig. 9. Apert's syndrome: The differentiating feature from other acro-cephalo-syndactyliesis highlighted by the severity of the syndactyly. There is bony fusion of the phalanges of the index, middle, and ring fingers

Others

More than 50 syndromes addition to the most prevalent Crouzon's and Apert's syndromes, there have also been described conditions connected with craniosynostosis. They are rare in number, therefore it is difficult to determine how frequently they occur. These syndromes include Pfeiffer's, Carpenter's, and Saethre-Chotzen Syndromes. Pfeiffer's is characterised by large toes and thumbs, Carpenter's by preaxial polysyndactyly and soft tissue syndactyly with shortened fingers, and Saethre-Chotzen by soft tissue webs between the second and third digits. These malformations are also with the exception of Carpenter's syndrome, which is autosomal recessive, all diseases are autosomal dominant. It is difficult to forget the unusual Kleeblattsschadel (cloverleaf skull) abnormality. The trilobular form of the skull cap features a projecting vertex and enlarged temporal regions (see Figs. 10 and Fig. 11 X-ray imaging).

Fig. 10. Cloverleaf skull — The skull cap assumes a tri-lobular configuration with a protruding vertex and bulging temporal regions.

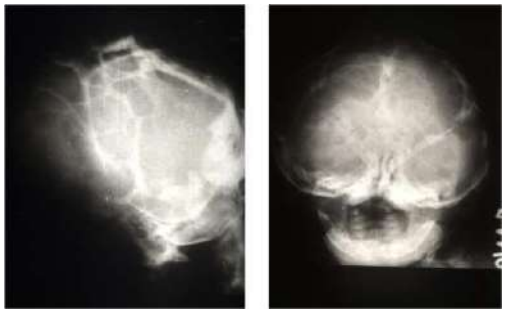

Fig. 11. X-ray — Cranio-lacunae & Cloverleaf skull

Multiple Suture Involvement

Oxycephaly or Turricephaly

The term "oxycephaly" refers to a condition in which the head is excessively high and conical. Whether seen from the front or the side, the vertex seems pointy in a case of typical oxycephaly. The coronal suture may also be involved in the deformation process, depending on which area of the cerebral capsule is initially affected.

Cloverleaf Skull

This is a constriction ring forms in the lambdoid-squamosal zone as a result of multiple sutural fusion, which permits disproportionate bulging in the frontal and temporal bones, resulting in deformity (triphyllocephaly). From the front, the head appears to trilobular (Fig. 10). There is almost always accompanying hydrocephalus Less severe variations of this syndrome may look pointedly oxycephalic.

Diagnosis

Diagnosis of craniosynostosis clinical examination in the majority of cases due of the distinctive deformity of the skull cap and indications of a ridge generated by the fused suture on palpation. Plain X-rays of the skull in different views should be performed in order to support the clinical impression. A radiographic linear opacity takes the place of a patent suture's wormian lucency. On a postero-anterior skull film, a characteristic "Harlequin" eye sign for unilateral coronal synostosis is created by the elevated ipsilateral lesser wing of the sphenoid. Typically, computed tomography (CT) scans are not diagnostically helpful unless reformatted in three-dimensionally. Detailed psychological assessment, ophthalmic evaluation for evidence of raised

ICT and dental examination should be carried out.

Differential Diagnosis

Positional distortions can be caused by muscular torticollis, cervical spinal abnormalities, and preferred sleeping postures. In these circumstances, the sutures are visible. Positional dyskinesia should be treated primarily for its underlying deformities. (Table 1)

Table 1: Differential diagnosis of craniosynostosis

- Primary microcephaly
- Hydrocephalus-sutural fusion secondary to decompression and overlapping of bones
- Postural Plagiocephaly

Table 2: Investigations

- Skull radiograph-Antero-posterior, lateral, Towne's and basal views
- CAT scan-3 dimensional
- Ophthalmological examination
- Psychological assessment
- Genetic evaluation
- Dental evaluation
- Clinical photograph

Posterior position when viewed from the vertex, a plagiocephaly features an obliquely oriented skull cap and an affected side ear that is pushed anteriorly and away from the flattened posterior side. True unilateral lambdoidal synostosis, on the other hand, results in a trapezoid deformity and draws the ipsilateral ear toward the damaged suture. It is critically important to distinguish positional deformations from those caused by true craniosynostosis.

Investigative workup has been summarized in Table 2.

Computer-aided design and manufacturing (CAD/CAM) technology

To accomplish a consistent, objective, and accurate correction of CS, Computer-aided design and manufacturing can be utilized. It helps in detailing and adds precision in realizing osteotomies which enable accurate positioning of bone segments, thus, eliminating subjectivity & allowing more reproducible surgical results [17,18]. This technology helps in identifying the precise location of dural venous sinuses during the surgical steps for Cranial surgery, such as appropriately plan burr holes and cuts& enhancing superior outcomes [19,20, 21].

Virtually Surgery Planning (VSP)

The surgical team is able to use VSP to achieve more predictable results and prepares the families for anticipating the postoperative results[17]. Devising VSP based, pre-surgical planning offers a near realistic visualization of the anatomy in a controlled environment.

3D printing/CNC machining

Adding further precision during surgical planning & its subsequent execution, 3D printing/CNC machining further help in eliminating anypresumption [17 21,22].

Resorbable plating system

Providing stable osteosynthesis, ultrasound-assisted, pinned resorbable plating system also saves time.[23]Resorbable plates are safe& stable with superior aesthetics & allow unhindered ongoing ossification which continues in the frontal area [24,25].

3D photogrammetry

3D photogrammetry/photography avoids radiation and is reproducible, thus,

minimizing operator dependent variation & errors [26,27,28].

3D simulation

Computer-aided simulated surgery& intraoperative navigation reduces operative time and facilitates surgery.[29]

Surgical Management

Non-syndromic craniosynostosis should be corrected because of the severe distortion the face is reflected. Other explanations discuss potential functional issues that the illness may bring about, all of which are related to increased intracranial pressure. Thirteen percent increased pressures in neonates with single suture synostosis, and 42% of those have multiple sutures involved. Visual impairment is possible but unusual when only one suture is united too soon.

Before the era of a linear strip craniectomy of the pathologic suture was the historically established form of treatment in craniofacial surgery. However, the rate of refusion and ongoing deformation was regrettably high.

Early intervention is encouraged to benefit from the infant brain's rapidly increasing development. Most centres advocate the window of time between 3 and 6 months old; some wait until after the sixth postnatal month. Early correction produces superior results than late intervention in the long term.

The concepts of treatment have constantly changed as a result of failures with strip craniectomy procedures. The focus has been on releasing the afflicted suture and promptly restoring the normal architecture by realigning and recontouring the malformed bones, regardless of the type of craniosynostosis. The prevalent surgical management globally and AIIMS technique (Table 3).

Table 3. Surgical management

Surgical Management	
Primary	**AIIMS Technique**
Linear Craniectomy Morcellation Cranioplasty Holfmann's Tongue–in–Groove Technique	Partial Calvariectomy with Onlay Periosteoplasty
Supplementary	
CSF Shunts Mid–Face Advancement	

Partial Calvariectomy and Onlay Pariosteoplasty

Partial calvariectomy and harvesting the periosteum is an alternative technique. in this procedure not only the involved sutures are removed but the adjacent deformed bones are also excised after separating and preserving the periosteum . Towards the end of the procedure this harvesting periosteum is laid down as an onlay over the exposed dure. Subsequently neocalvarium is formed by the periosteum according to the contour of growing brain. (Figs. 13 and 14).

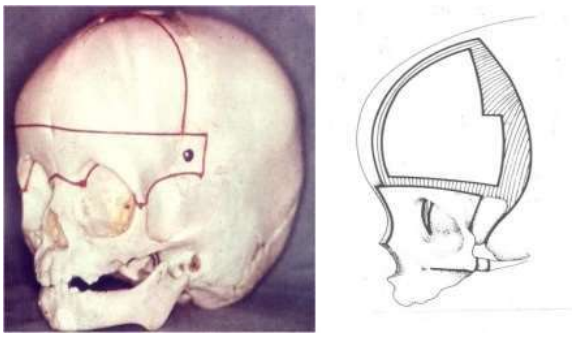

Fig. 13. Partial Calvariectomy, Onlayperiosteoplasty&Fronto-Orbital advancement.

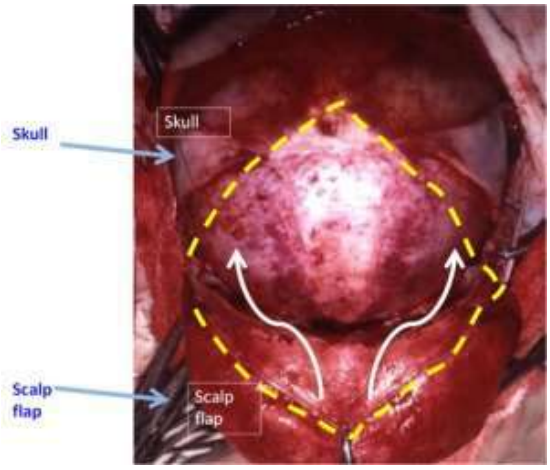

Fig. 14. Author's Technique: Periosteum harvested and placed as 'onlay' on the exposed DURA.

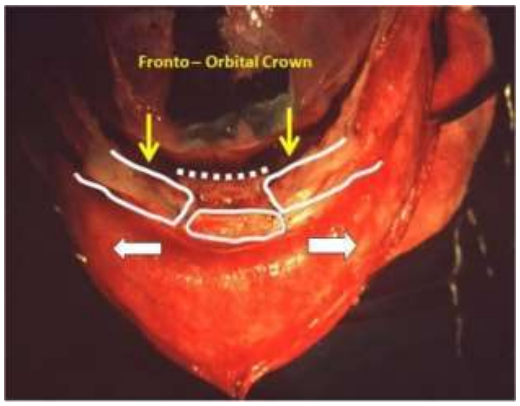

Fig. 15. Author's (MB) Technique: Fronto – orbital crown

All syndromic craniosynostosis abnormalities are surgically treated in one of three chronologic ways. In contrast to the non-syndromic variant in this group, surgical intervention does not result in the normalisation of facial growth. The urgent issue is the focus of treatment. A stepwise method is therefore utilised. Release of increased intracranial pressure brought on by the premature suture closure, airway impairment brought on by significant midfacial retrusion, and corneal protection due to exorbitism are all issues that need to be addressed. Additionally, the synostotic suture is loosened during the first year of life as well as fronto-orbital advancement (Fig 14 and 15). This results in more regular calvarial outlines, more protection for the canines, and a release of the quickly swelling brain.

Depending on the patient's preferences and experience, treatment schedules may change. Around the sixth year of life, when the orbits and skull cap have grown to 90% of their adult size, a second procedure is carried out. The traditional LeFort III midfacial advancement is utilised to advance the entire midface IF the forehead is of normal shape. The maxilla is purposefully positioned in an overcorrected anterior position because there is limited room for further midfacial expansion. This position corrects the exorbitism and unclogs the congested nasopharynx.

Two alternate routes can be taken if the forehead is seen to be sunken, as is frequently the case. A fronto-orbital advancement is done as the first procedure. An additional LeFort III is added around six months later. By separating a sterile intracranial operation from the contamination brought on by the subsequent extracranial midfacial advancement, this method maintains sterility, making it safer.

The other approach is the monobloc frontofacial advancement. The advantage of this technique is that only one operation is required to reposition the forehead.

When orbital hypertelorism is present, a facial bipartition either the frontofacial monobloc advancement or the LeFort III technique can be supplemented. This treatment is very useful for treating people with Apert's syndrome's distinctive flattened forehead and midface.

This last phase needs to wait till facial development is finished. A LeFort I (maxillary) advancement is used to treat the

pseudomandibular prognathism following presurgical orthodontic tooth alignment. Oftentimes, a simultaneous advancement osseous genioplasty correct the retruded chin. The result of pre and early post-operative technique of fronto-orbital advancement author's technique (MB): (Fig. 16a to Fig. 16c).

Figure 16 shows early post-operative result of fronto-orbital advancement.

Fig. 16a. Brachycephaly: Pre & Postop.

Fig. 16b. Scaphocephaly: Pre. & Postop-front views.

Fig. 16c. Scaphocephaly: Pre. & Postop- lateral views.

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ORIGINAL ARTICLE

A Prospective Study Comparing Billroth II and Roux-en-Y Gastrojejunostomy in Patients with Carcinoma Stomach

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Abstract

Aims and objectives: Comparison of the outcome of Roux-en-Y & Billroth II gastrojejunostomy in patients with gastric cancer specifically in terms of nutrition, gastric emptying and quality of life.
Methods: All good performance status patients (ECOG ≤2) aged less than 75 years old with distal gastric carcinoma presenting to the Department of GI Surgery, AIIMS, New Delhi between November 2012 and December 2013 were evaluated prospectively for inclusion in the study. Roux-en-Y gastrojejunostomy or Billroth II gastrojejunostomy was planned after distal gastrectomy and Billroth II gastrojejunostomy only in unresectable patients. Assessment was done 3 months after surgery.
Results: Thirty patients were recruited in the study. Twenty-four patients were offered distal resection. Roux-en-Y reconstruction was done in 16 patients & Billroth II reconstruction in 8 patients. Six unresectable cases were offered palliative Billroth II bypass only. Comparison of Roux-en-Y vs Billroth II gastrojejunostomy revealed following results. In the postoperative period, mean duration of nasogastric tube drainage and mean onset of regular oral diet were 3±0.8 days vs 4.5±2 days and 6.2±2.2 days vs 8.8±3.9 days respectively. At 3 months of follow up, physical parameters of WHOQOL-BREF assessment revealed score of 10.2±1.4 vs 8.2±2.5 respectively.
Conclusion: Reconstruction in patients with gastric cancer in the form of Roux-en-Y & Billroth II gastrojejunostomy revealed favourable short-term results like removal of nasogastric tube drain and initiation of enteral nutrition; and physical parameters of quality of life at the end of the third month. Rest of the results were similar in both groups.

Keywords: Roux-en-Y gastrojejunostomy, Billroth II gastrojejunostomy, Gastric emptying, WHOQOL-BREF.

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Introduction

Gastric cancer is one of the common cancers of the digestive system. In the year 2008, 989,600 new cases were detected and 738,000 deaths were estimated to have occurred globally due to gastric cancer. Over 70% of new cases and deaths occur in developing countries. The highest incidence is in Eastern Asia, Eastern Europe and South America and the lowest rates in North America and Africa [1]. In USA, about 21,000 new cases are detected each year, and 10,570 deaths related to gastric cancer occur [2]. In India, the age-adjusted rate is 4.6–11.1 per 100,000 population, with the incidence being more in the southern states [3].

Worldwide, gastric cancer is commonly seen in the antrum/body of the stomach and requires a distal/subtotal gastrectomy. In western countries, the proximal stomach is the most common site requiring a total or proximal gastrectomy. Distal or subtotal gastric resection is followed by one of the reconstructive procedures like gastro-duodenal anastomosis (Billroth I), loop gastrojejunal anastomosis (Billroth II), or a Roux-en-Y gastrojejunostomy. The more commonly performed reconstructions are Billroth II and Roux-en-Y gastrojejunostomy. The choice of reconstructive procedure after distal/subtotal gastrectomy for gastric cancer remains controversial. Billroth II reconstruction requires a single anastomosis and is technically simpler, but has been shown to have bile reflux into the gastric remnant by some authors, causing histological alterations in the gastric mucosa and a clinical syndrome called alkaline gastritis. It may also be associated with afferent limb complications like afferent loop syndrome. Roux-en-Y gastrojejunostomy requires two anastomoses and may be associated with complications like Roux stasis syndrome.

In a randomized controlled trial, Csendes et al. compared the results of Billroth II and Roux-en-Y gastrojejunostomy after distal gastrectomy for peptic ulcer disease [4]. The Roux-en-Y gastrojejunostomy group had significantly better clinical results than Billroth II reconstruction, in terms of less symptoms of gastroesophageal reflux. Also, after Billroth II anastomosis endoscopy showed the presence of erosive esophagitis and Barrett`s metaplasia more frequently than after a Roux-en-Y reconstruction. The Visick grading showed a significantly better result after Roux-en-Y reconstruction ($P < 0.001$).

Fukuhara et al., in a retrospective study, observed that bile reflux periods in the gastric remnant and esophagus were significantly less with Roux-en-Y reconstruction than with Billroth II and Billroth I reconstruction after distal gastrectomy for gastric cancer, [5]. They also found a correlation between the incidence of reflux symptoms and the duration of reflux exposure. Mine et al. found the incidence of early and late dumping to be significantly less with Roux-en-Y than with other forms of reconstruction in patients with gastric cancer [6].

In peptic ulcer surgery it has been shown that Roux-en-Y gastrojejunal reconstruction is superior to Billroth II anastomosis, but in gastric cancer few studies have compared Billroth I with Roux-en-Y gastrojejunostomy, and there are no studies with a head-to-head comparison between Billroth II gastrojejunostomy and Roux-en-Y gastrojejunostomy.

Aims and Objectives

The aim of this study was to compare the outcome of Billroth II and Roux-en-Y gastrojejunostomy in patients with gastric cancer specifically in terms of nutrition, gastric emptying and quality of life.

Methods

All patients with carcinoma of the stomach presenting to the Department of Gastrointestinal Surgery, All India Institute of Medical Sciences, New Delhi between November 2012 and December 2013 were evaluated for inclusion in the study. This study was registered in clinical trials registry of India (CTRI/2013/11/004126).

Inclusion Criteria

1. Age <75 years
2. Adenocarcinoma of stomach body/antrum
3. Good performance status, i.e., Eastern Cooperative Oncology Group (ECOG) grades 0, 1 and 2

Exclusion Criteria

1. Patients who refused to give consent for the study
2. Comorbid conditions which would preclude gastrectomy
3. Patients with previous gastrectomy

4. Patients with stomach cancer or previous small bowel surgery precluding either form of reconstruction

Staging

All patients assessed for inclusion in the trial were evaluated with a detailed history and complete clinical examination. Patients were investigated with complete blood counts, renal and liver function tests, serum electrolytes, blood sugar, chest X-ray and electrocardiogram. The performance status was assessed using the ECOG scale [7]. Tumor assessment was done by upper GI endoscopy and staging was done by CECT scan. TNM Staging was done as per AJCC 7th edition [8].

Surgery

Patients diagnosed with distal gastric cancers after evaluation and informed consent were enrolled in the study and underwent subtotal gastrectomy depending on the location and extent in resectable cases and palliative bypass in unresectable/advanced cases.

Patients underwent Billroth II gastrojejunostomy in one arm using a jejunal loop with a short afferent limb in an iso-peristaltic manner in either antecolic or retrocolic position and in the other arm patients underwent Roux-en-Y gastrojejunostomy using a jejunal limb length of 15–20 cm distal to the duodenojejunal flexure, and a Roux limb length of 45 cm. The type of reconstruction was chosen by the operating surgeon. Feeding jejunostomy was done using a 12 Fr Malecot tube by Witzel's method. Postoperative complications were noted. Operative mortality was defined as death from any cause within 30 days of surgery or during the same hospital admission.

Follow up

All patients were assessed at the visit 3 months after surgery. Apart from a complete clinical evaluation to rule out recurrence or metastasis, gastric emptying scan was done. Clinical symptoms such as epigastric pain, heartburn, bilious vomiting, postprandial bloating and nausea were recorded in both the groups. An assessment of the daily intake of calorie and protein was done by an experienced dietician. Nutritional status was assessed by measuring the weight in kilograms, BMI in kg/m^2. Serum albumin, also a nutritional parameter, was measured both preoperatively and at 3 months postoperatively. Post-operative adjuvant treatment was given in advanced and node positive disease.

Gastric emptying study

This was done using a radionuclide gastric emptying scan. The patient was kept nil per oral for a minimum of 4 hours prior to the study. Steamed rice cake (Idli) prepared from a commercially available ready-mix rice powder (Gits, India) was used. Each packet contained 200 g of ready-mix rice powder which was dissolved in 320 ml of water. A total of 15-20 mCi of Tc99m sulphur colloid was added to the mixture. The Mixture was steamed after putting it in moulds thereby making 18 pancakes of 30 g each. Patients were encouraged to consume the meal within 10 minutes. The images were in a format of 64 x 64 pixels using a low-energy high-resolution collimator. Photopeak settings were at 20% at 140 keV for Tc99m. At the end of consumption of the rice cake, the first image was obtained. Subsequent images were taken every 15 minutes for at least 60 minutes. Data was analysed with gastric emptying software and the result was expressed as emptying half time (t½) in minutes. The emptying half time (t½) was compared between both groups. The total amount of radiation exposure was around 0.5 mSv per study.

Quality of life

Quality of life assessment was done using WHOQOL-BREF at baseline and at 3 months postoperatively. DAUGS 20 was used postoperatively at 3 months.

Results

A total of 51 patients with biopsy proven distal gastric carcinoma were evaluated between November 2012 and December 2013. Out of these, 21 patients were excluded due to various reasons. The 30 patients included in this study underwent either a Roux-en-Y gastrojejunostomy [n = 16 (53.3%)] or a Billroth II gastrojejunostomy [n = 14 (46.7%)]. Curative gastrectomy was possible in 20 patients. Palliative gastrectomy was done in in 4 patients and gastrojejunostomy to bypass the unresectable gastric cancer was done in 6 patients (Fig. 1).

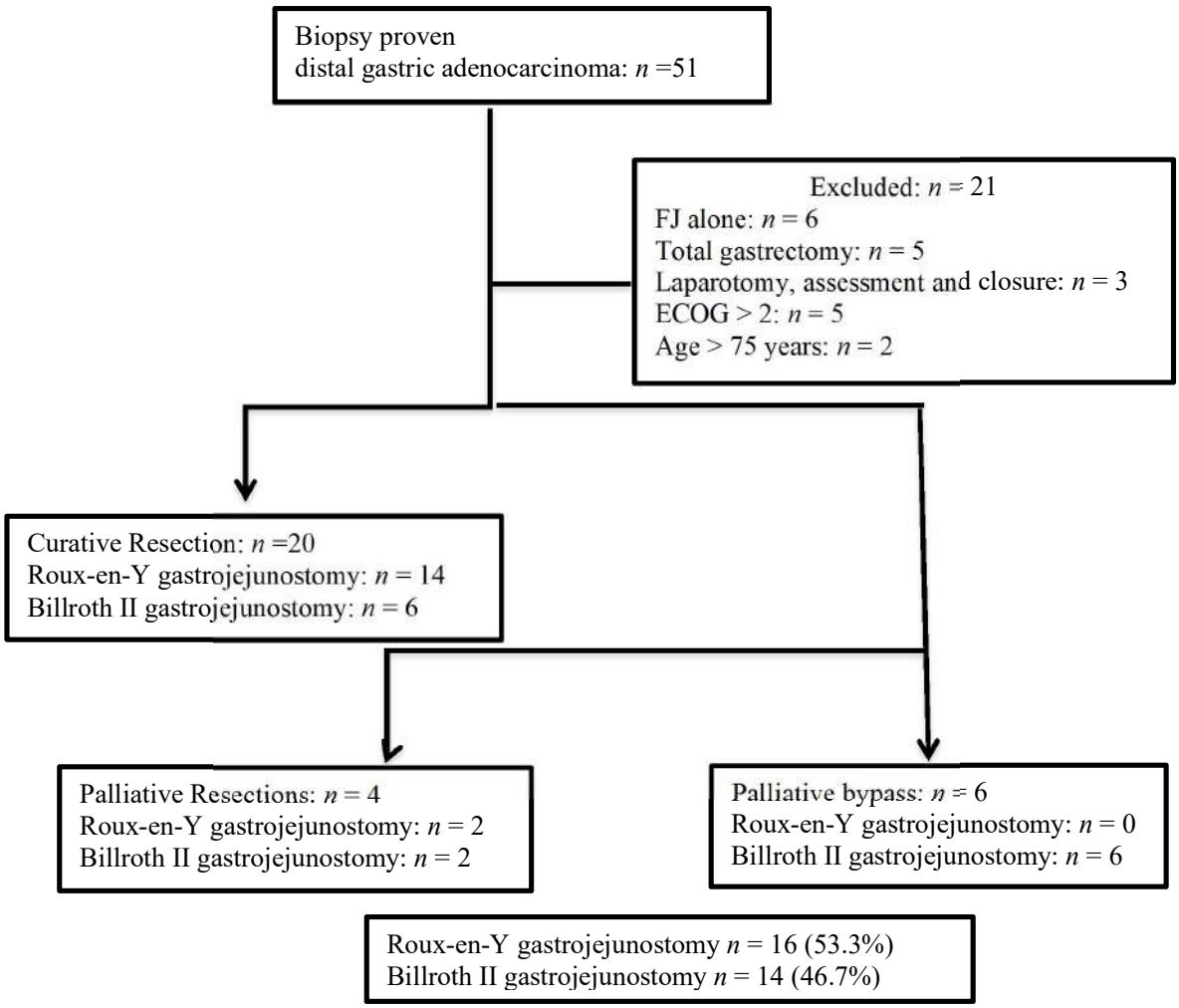

Fig. 1. Flow chart showing study allocation

Patient Characteristics (Table 1)

Table 1. Characteristics of the patients

Characteristics	**Overall n = 30**	**Roux-en-Y n = 16**	**Billroth II n = 14**	**p-value**
Age (years):				
Mean	55±12	54.9±12.8	55.6±11.6	
Median	54	51	56.5	0.8
Range	26-72	26-72	31-70	
Sex (%):				
Male	21 (70)	10 (62.5)	11 (78.6)	
Female	9 (30)	6 (37.5)	3 (21.4)	0.4
GI bleed (%)	13 (43.3)	7 (43.8)	6 (42.9)	1.0
Gastric outlet obstruction (%)	20 (66.7)	8 (50)	12 (85.7)	0.05
Pain (%)	18 (60)	11 (68.8)	7 (50)	0.4
Anorexia (%)	25 (83.3)	12 (75)	13 (92.9)	0.3
Weight loss (%)	26 (86.7)	12 (75)	14 (100)	0.1
Blood transfusion (%)	10 (33.3)	5 (31.3)	5 (35.7)	1.0
Mean BMI (kg/m^2)	18.5±3.0	19±3.5	17±2.3	0.3

Serum albumin (g/dl)	3.5±0.7	3.6±0.8	3.3±0.7	0.3
ECOG: 1 2	 14 16	 11 5	 3 11	 0.01
Stage (%): IB IIA IIB IIIA IIIB IIIC IV	 1 (3.3) 1 (3.3) 5 (16.7) 2 (6.7) 6 (20) 6 (20) 9 (30)	 1 (6.3) 1 (6.3) 4 (25) 1 (6.3) 3 (18.8) 4 (25) 2 (12.5)	 0 0 1 (7.1) 1 (7.1) 3 (21.4) 2 (14.3) 7 (50)	 0.3
Peritoneal metastases (%)	7 (23.3)	1 (6.2)	6 (42.8)	0.02
Ascites (%)	8 (26.7)	2 (12.5)	6 (42.8)	0.07
Liver metastases (%)	5 (16.7)	1 (6.2)	4 (28.5)	0.12
Locally advanced (%)	9 (30)	2 (12.5)	7 (50)	0.04

Surgery and postoperative nutritional parameters (Table 2)

Out of the 30 patients who were subjected to gastric surgery, feeding jejunostomy was added in 17 patients (56.6%). Roux-en-Y reconstruction was done more commonly after curative resections than after palliative resections with a statistically significant difference (p = 0.001). After subtotal gastrectomy, reconstruction with Roux-en-Y anastomosis was done in 16 patients and with Billroth II gastrojejunostomy in 8 patients, which again was a statistically significant finding (p = 0.05). Postoperatively, the mean duration of nasogastric tube drainage was 3±0.8 days in patients with Roux-en-Y gastrojejunostomy and was 4.5±2 days in the Billroth II group, which was statistically significant (p=0.02). Resuming regular oral diet was significantly earlier in the Roux-en-Y group than the Billroth II group (6.2±2.2 days *vs*. 8.8±3.9 days; p = 0.03).

Table 2. Surgery and postoperative nutritional parameters

Parameter	**Roux-en-Y n=16**	**Billroth II n=14**	**p-value**
Surgery (%): Curative Palliative	 14 (87.5) 2 (12.5)	 6 (42.8) 8 (57.2)	 0.01
Surgery (%): Resection Bypass	 16 (100) 0	 8 (57.1) 6 (42.9)	 0.05
Mean nasogastric tube drainage (days)	3±0.8	4.5±2	0.02
Mean onset of regular oral diet (days)	6.2±2.2	8.8±3.9	0.03

Follow up (Table 3)

At follow up 3 months after surgery, 24 patients survived. The mean follow up was similar between both the groups (p = 0.2). Clinical features such as reflux, dumping and early satiety were similar in both the groups (p = 0.2). The mean DAUGS20 score, mean change in body weight, the increase or decrease in mean serum albumin levels, the mean percentage of calorie intake and Visick grading were similar in both the groups. The T1/2 of gastric emptying time was also similar among both the groups.

Table 3. Follow up parameters at 3 months after surgery

Variable	Roux-en-Y	Billroth II	p-value
Mean follow up (months)	8±4.4	5.9±4.8	0.2
Symptoms (%): Asymptomatic Reflux symptoms Dumping Early satiety	 8 (57.1) 1 (7.1) 0 5 (35.5)	 6 (60) 1 (10) 2 (20) 1 (10)	0.2
Mean DAUGS20 score	19±3.4	22.5±3.8	0.5
Weight change (kg): Mean±SD Range	 0.7±5.9 -8 to 12	 -2.1±5.8 -10 to 9	0.1
Albumin difference (g/dl): Mean±SD Range	 0.22±0.7 -0.9 to 1.2	 0.14±1 -1.5 to 1.8	0.7
Mean Kcal intake (%)	80.5±27.4	76.2±28	0.9
Visick grade: 1 2 3 4	 8 5 0 3	 2 6 1 5	0.17
Gastric emptying time T1/2 (min): Mean±SD Range	 46.2±13.9 14 to 201	 27.7±3.3 11 to 41	0.29

Quality of life (Table 4)

The quality of life (QOL) was analysed between both the groups. All the domains in the preoperative period were similar. In the postoperative period, physical domain (p = 0.01) was significantly better in the Roux-en-Y group but the other domains (psychological, social and environmental) were similar in both the groups.

Table 4. Mean Scores of the WHOQOL-BREF assessment

Domains	Preoperative QOL			Postoperative QOL 3 months after surgery		
	Roux-en-Y	Billroth II	p-value	Roux-en-Y	Billroth II	p-value
Physical	7.8±3.4	7.6±2.9	0.8	10.2±1.4	8.2±2.5	0.01
Psychological	8.3±3.1	8.5±3.6	0.8	9.1±3	9.8±3	0.5
Social	9.7±3.6	10.2±3.0	0.6	10.4±2.7	10.3±3.3	0.4
Environmental	8.9±3.4	8±2.5	0.4	9.6±2.3	8.9±2.7	0.4

Discussion

There was a male predominance of the disease in our study; the male to female ratio was 2.3:1. Global cancer statistics shows that gastric cancer is one to two times more common among men [3,9].

We staged the tumor by using CT scan alone, though recent studies have also used laparoscopy for staging. Most of our patients presented with gastric outlet obstruction and GI bleed, and palliative resection or bypass was warranted in most of them. Curative distal gastrectomy was possible in 20 out of 30 patients (66.6%). Billroth II procedure was done more frequently than the Roux-en-Y anastomosis in our study patients with poorer performance status and unresectable lesion (bypass only), as the Billroth II procedure required a single anastomosis and was quicker. In a study by Burke et al. [10], the risk of finding peritoneal metastases at the time of laparotomy was 25–37% after an otherwise, unremarkable CT scan, which was similar to our study (23%).

The requirement for nasogastric tube drainage was significantly more in patients with Billroth II reconstruction ($p = 0.02$) and onset of oral diet was significantly earlier in the Roux-en-Y group ($p = 0.03$). While comparing Billroth I anastomosis and Roux-en-Y reconstruction, some studies from Japan have shown that the Roux-en-Y group had significantly prolonged delayed gastric emptying and time to resume oral intake (5,11), while other studies have shown that Roux-en-Y had better results [12]. In another randomized controlled study between Billroth II and Roux-en-Y reconstruction done for peptic ulcer disease, gastric atony was similar between both the groups [4].

In the present study at the end of 3 months, 23 patients survived and were available for evaluation. The patients in the Roux-en-Y group had a mean of 0.7±5.9 kg gain in body weight, and patients in the Billroth II group had a mean of -2.1±5.8 kg change in the body weight when compared to the pre-operative body weight. Patients who had undergone curative resection had gained weight. Patients who had palliative surgery and who developed adjuvant therapy-related side-effects had weight loss. In a retrospective comparative study in patients with carcinoma of stomach by Fukuhara et al. [5], 34% of patients with Roux-en-Y reconstruction and 41% of patients with Billroth II reconstruction had weight loss at 3 months postoperatively ($p>0.05$). Postoperative weight gain was also non-significant between the Roux-en-Y and Billroth II groups in peptic ulcer disease in the study by Csendes et al. [4].

On analysis of nutritional parameters at 3 months postoperatively, the Roux-en-Y group had better mean serum albumin levels and mean dietary calorie intake values than the Billroth II group, but these were not statistically significant ($p = 0.7,0.9$ respectively). Similar results were also seen in study by Imamura et al [13], done in gastric cancer patients where the average intake volume was compared with the preoperative value and was not significant between both the groups ($p>0.05$). In patients operated for peptic ulcer disease, Visick grading was significantly better in the Roux-en-Y group than the Billroth II group in the study by Csendes et al. [4]. In our study, Visick grading was similar in both the groups.

In western countries gastric emptying time was measured using chicken liver or low-fat, liquid egg white sandwich meal (14). As many of our patients are vegetarians and the dietary habits are different from the western countries, we used steamed rice cake (Idli) with 15-20 mCi of Tc99m sulphur colloid which has been previously standardized in our hospital. Though the emptying half time (T½) was prolonged in Roux-en-Y group, it was not statistically significant between both groups ($p=0.2$). Cohen AM et al., in their study found that the incidence of delayed gastric emptying after gastrectomy had been up to 20% [15].

We used WHOQOL-BREF in our study as it is validated in an Indian population and is available in Hindi. The baseline values of all the domains were similar in both groups. At follow up 3 months after surgery, the physical domain was significantly better after Roux-en-Y reconstruction ($p = 0.01$). This may be because of the fact that two-thirds of our patients had either gastric outlet obstruction or gastrointestinal bleed. In some of the studies comparing Billroth I and Roux-en-Y reconstruction, there was no significant difference [16]. A nonrandomized retrospective comparison of Billroth I, Billroth II, and Roux-en-Y reconstruction 3 years after partial gastrectomy showed that Roux-en-Y resulted in a better QOL [17]. The Dysfunction After Upper Gastrointestinal Surgery - DAUGS 20 score, based on 7 factors, combined symptoms of gastroesophageal reflux, deglutition

difficulty, limitation of physical activity, diarrhea, dumping, transfer dysfunction and hypoglycaemic symptoms. Even though the score was better in Roux-en-Y reconstruction, it was not statistically significant (p=0.5). In the study by Nakamura et al., which compared Billroth I and Roux-en-Y reconstruction, there was no significant difference [16].

Conclusion

Following subtotal gastrectomy for distal gastric cancer, the reconstructive procedure of choice is debatable. Even though the Roux-en-Y gastrojejunostomy was proven to be superior in peptic ulcer disease, the results are mixed in carcinoma stomach. In this prospective study comparing Roux-en-Y gastrojejunostomy and Billroth II gastrojejunostomy after subtotal gastrectomy for distal gastric cancer, despite the limitations, the short-term results like removal of nasogastric tube drain and initiation of enteral nutrition favoured Roux-en-Y gastrojejunostomy. However, at the end of the third month, except for improvement in the physical parameters of quality of life, the other quality of life parameters and nutritional parameters were similar in both the groups.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Role of Neuromonitoring in the Spinal Separation of Pyopagus Twins

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Abstract

Introduction and Aim: Separating the spinal cord while separating spine sharing conjoined twins may have long-lasting implications for the survivors. We aim to study the role of neurophysiological monitoring in delineating the spinal anatomy as an important component to pre-operative planning and twin separation, thereby improving neurological outcome.

Case Report: Study involves two pairs of pyopagus conjoined twins with a shared spine. The twins were subjected to neurophysiological monitoring under general anesthesia to identify the neuronal supply and cross-innervation of various organs including lower limbs and anal sphincters with respective brain. Pre-operatively, the spinal cord was seen to be joined terminally with varying degree in both set of twins. Neurophysiological monitoring done preoperatively on the first set of twins revealed cross innervation from twin B to twin A, although twin A had its independent complete innervation. The sphincter was predominantly controlled by twin A. In the second set of twins, there was no cross innervation, both twins had equal control of sphincter hence the sphincter allocation was done using other general and anatomical factors. Neurophysiological monitoring was also utilized intraoperatively to divide the cord in its functional midline instead of anatomical midline thereby preserving neural outflow and function. Post-operatively, both set of twins retained motor and sensory supply to lower limbs and mobilize both limbs well, aided with physiotherapy.

Conclusion: Better functional outcomes are possible with the use of neurophysiological monitoring during the workup and management of spine-sharing conjoined twins.

Keywords: Neurophysiological monitoring, pyopagus, conjoined, twins

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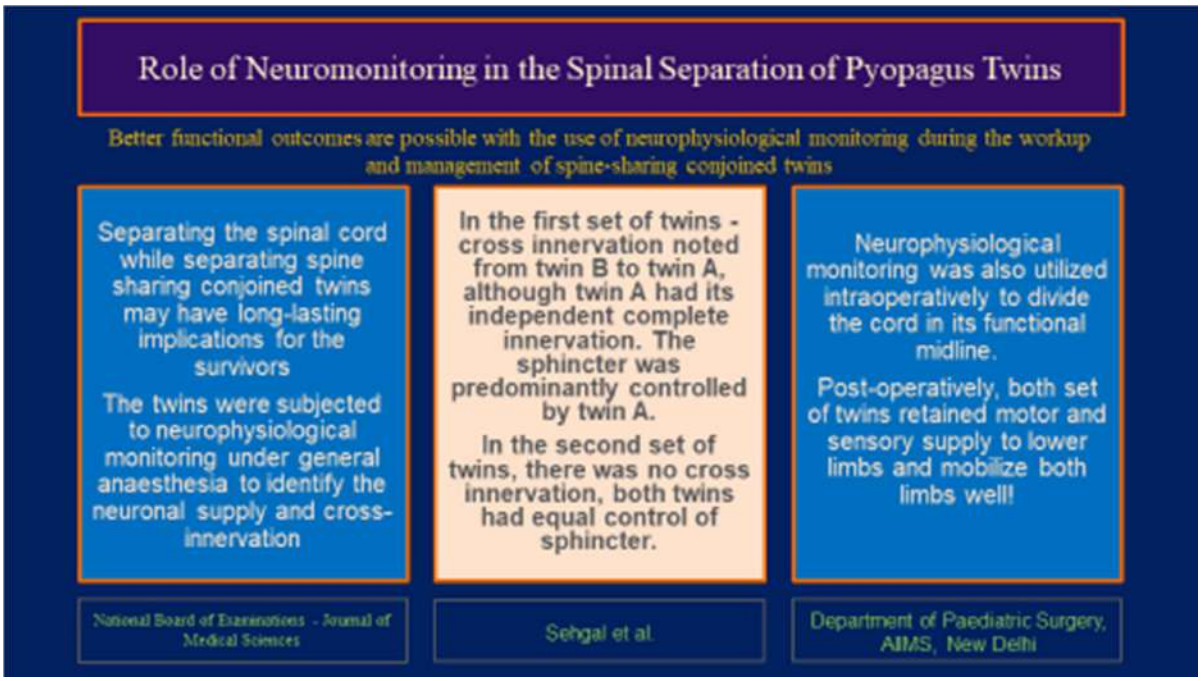
Graphical Abstract



Introduction

Insults at different stages of embryogenesis may lead to varying types of twinning. Caudal duplication syndrome: more evidence for theory of caudal twinning [1,2,3]. Pyopagus twins, a rare variant of conjoined twins, are notable for their union at the sacrum and perineum. They may have spinal and spinal cord abnormalities with variable fusion of their spinal cord [4]. The shared organs can generally be separated and reconstructed, which leads to a good outcome in these cases. The challenge in separation of these twins lies in the separation of the shared spines, which have to be divided in a way to preserve the neural innervation to each twin.

Intraoperative neurophysiological monitoring (IONM) assesses the functions of the neural tissue during the procedure, to limit neurological insult while handling tissues. Although routinely used in neurosurgical cases, only limited case reports have utilized this technique in the separation of spinal separation in conjoined twins. Motor evoked potentials are generated on transcranial stimulation at different levels in the brain and are transported by the pyramidal tract. They monitor the motor pathway and can be recorded at the spinal cord level or the muscle [5]. Electromyography monitors the integrity of the nerves during surgery. Electrical potential is produced on depolarization of a motor nerve which is then monitored using subdermal or intramuscular electrodes placed in the affected muscle [6].

Intraoperative neurophysiological monitoring has occasionally been used in the separation of these twins, to improve functional outcomes and prevent neurological deficits [7]. We present our experience of utilization of neurophysiological monitoring for the separation of two pairs of pyopagus conjoined twins.

Case History

Two pairs of antenatally detected conjoined twin girls were presented to our hospital. They were joined from the lower back, facing partially away from each other, sharing their lower back and had a common perineum. They were noted to have one common anal opening and 2 separate urethra and vagina openings. A detailed evaluation was necessary to understand the anomalous intraspinal anatomy Spina bifida occulta: radiographic and operative correlation [8] were carried out for both the pairs of the twins. Both pairs underwent computed tomography (CT), magnetic resonance imaging (MRI) and gastrointestinal studies for better understanding of their anatomy. To avoid confusion, the first set of twins were referred to as Twin A and B and second set as Twins 1 and 2, respectively.

In both the pairs of twins the spinal cords were said to be fused as per the images. In the first pair, CT scan revealed spina bifida of L3 to L5 vertebra and fusion of the sacral vertebrae (S2 - S5) with common coccygeal vertebrae. Magnetic resonance imaging of lower spine revealed two separate conus medullaris with a common fused filum terminale. The Twin B was also found to have a right old MCA infarct. Both twins had moved their lower limbs, with a power of 4/5 in both limbs of Twin A and power of 3/5 in limbs of twin B as per the Medical Research Council, UK, Manual Muscle Testing scale. However, both had limb wasting, along with neuroorthopaedic deformities, noted to be more in twin B.

In the second pair of twins, multiple lumbar vertebral defects in both twins were noted on the CT imaging with fused lower sacral (S3-S5) vertebra, with open posterior elements. Magnetic resonance imaging revealed that the conus was low lying and fused at L5 level. There was a syrinx in the cord, which increased in size over a year to reach the conus. As a result there was a a neural tissue of length 1.3 mm separating the fused conus with terminal syrinx and dysplastic neural tissue. Hyperintensity was seen in the bilateral deep white matter in the occipital lobe of Twin B due to suspected metabolic insult. Both twins had moved their lower limbs, with a power of 4/5 in all limbs, as per the Medical Research Council, UK, Manual Muscle Testing scale. However, these twins also had limb wasting, along with neuroorthopaedic deformities, noted to be more in twin 1.

There was also a dilemma of the control of the common anal sphincter, which had to be given to either one of the twins during separation or divided in a way that each twin retained control of the sphincter to prevent future fecal incontinence. Hence, a multidisciplinary team was formed with the inclusion of neurophysiologists to aid in the separation.

Technique of Neurophysiological Monitoring

The first pair of twins then underwent pre separation neurophysiological monitoring using the NIM-ECLIPSE® NS System (Medtronics, USA) under general anaesthesia, avoiding muscle relaxants during the stimulation Time. Sterile, paired subdermal stainless steel needle electrodes were placed using sterile technique in the limb muscles and around the EAS after the patients were prepped. Muscle motor evoked potentials (m-MEP) recordings were attempted using fast charge transcranial stimulation at a frequency of 275Hz and voltage of 100-1000V.

On transcranial stimulation of twin A followed by twin B motor cortex and recording of m-MEPs from lower body muscles (Bilateral Rectus Femoris, Tibialis Anterior, Extensor Halluces Longus, Abductor Halluces) of both twins, we found that there was no cross over of nerve fibers from twin A to twin B in lumbar and upper sacral region (S1) and twin A had her independent neural supply, but there was a cross over of nerve fibres (L4, L5, S1) from twin B to twin A (Fig. 1). Muscles in the right lower limb of twin B did not elicit m-MEPs even at high voltages and seem to

have poorly developed motor supply. On transcranial stimulation of twin A followed by twin B motor cortex and recording of m-MEPs from, bilateral abductor halluces (AH) of both the twins and anal sphincters (AS) (S1,S2,S3,S4), we found cross-over of sacral fibres from twin B to twin A. Twin B's motor cortex seems to have adequate motor control of right side of only the anal sphincter and its right AH has poor motor supply and no m-MEPs were recorded from it despite the high degree of stimulation. Twin A however, had a good control of the entire anal sphincter (Fig. 2). In view of these findings, we decided that the anal sphincter would be given to twin A to improve her fecal continence. Intra-operative nerve root mapping was also done to identify and separate the nerve fibres during the spinal separation. Triggered electromyography (EMG) was utilised for nerve root mapping, using a single pulse of duration 500 µs and frequency of 1 Hz. Biphasic stimulation was performed with bipolar stimulator probe and cathodal stimulation with monopolar stimulator probe.

Following principles of laminectomy & intra-spinal dissection, we opened the dura, & identified a closely apposed U-shaped spinal cord configuration [9], with nerves fanning out inferiorly. Nerve roots from L4-S3 were identified on the basis of responses obtained from Abductor hallucis, Extensor Hallucis Longus, Tibialis anterior, Rectus femoris and Anal sphincter (Fig. 3). Few nerve roots were identified which evoked triggered EMGs from both twins (twin B showed greater amplitude than twin A). In such cases, neural fibres going to twin A were divided, as twin A has its own intact nerve innervation for all muscles apart from this accessory cross innervation from twin B. All the sacral nerve roots that triggered EMG response from anal sphincter were spared to ensure intact anal sphincteric function. This led us to carefully divide the cord in its functional midline than the instinctive anatomical midline.

Figure 1. Findings of transcranial stimulation of twin A followed by twin B motor cortex showing no cross-over of nerve fibers from twin A to twin B and a cross-over of nerve fibres (L4, L5, S1) from twin B to twin A

Figure 2. Findings of transcranial stimulation of twin A followed by twin B motor cortex showing complete control of anal sphincter by twin A and partial control by twin B.2.

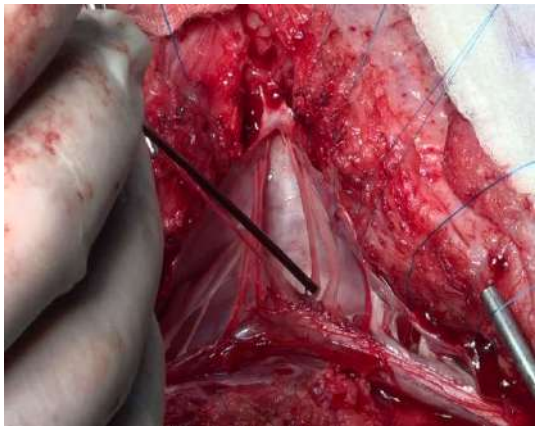


Figure 3. Direct stimulation of nerve roots using co-axial electrode.

We also evaluated the m-MEP, before and after the separation surgery. Transcranial stimulation was performed on twin A followed by twin B's motor cortex and recording of MEPs from muscles (Bilateral Brachioradialis, Adductor Longus, Rectus Femoris, Tibialis Anterior, Extensor Hallucis Longus, Abductor Hallucis, Anal Sphincter) of both twins. On first stimulating twin A, m-MEPs were obtained at 500 V, and no responses were recorded from twin B. These responses remained intact after sacral bone separation. The m-MEPs were obtained at 400 V from twin B on stimulation, with reduced response from right side lower limb muscles, not showing any response even at 1000 V, except for left Abductor Hallucis. Cross responses were recorded from twin A in lower limb muscles. After sacral bone separation, responses from twin B remained intact but the cross responses from twin A disappeared. The result from this study also helped us to prognosticate the parents with regard to the future outcome and also has a potential medicolegal implication.

In the second pair of twins, we proceeded directly to the separation surgery. Prior to the procedure, after induction, the children were subjected to neurophysiological monitoring to identify inter twin neural communication and control of the anal sphincter. We found both twins to have an equal control of the sphincter and no neuronal cross over. Hence we proceeded to divide the spinal cord in the functional

midline as identified with monopolar and bipolar triggered EMG electrodes. The anal sphincter was given to Twin 1 as she was neurologically better. Post-separation, the m-MEPs were noted to be intact in both twins.

Outcomes

Both pair of twins were moving their limbs in the immediate post-operative period. Once the wound related issues subsided, both pairs were mobilised. In the first set of twins, both stand with support and Twin A walks with support as well. Among the second set of twins, Twin 1 is able to walk without support for short distances and Twin 2 walks with support. All received extensive physiotherapy in the post-operative period and with the help of special shoes and walkers, they were discharged home in a mobile condition.

Among the first set of twins, twin B required a stoma as she did not receive the sphincter. Twin A has adequate bowel control with requirement of bowel management for constipation, but no soiling. Among the second set of twins, both are on bowel management. Twin 2 has had severe constipation and occasional soiling at follow up.

Discussion

The goal of spinal separation in pyopagus twins is to have two neurological intact children. With the complex anatomy and anatomical anomalies often identified in these twins, it is imperative to use technology which helps us attain this goal. The advantage of neuromonitoring during the intra-operative period of spinal separation allows the separation with minimal neurological damage. Since we are conclusively able to identify the source of the neural tissue encountered, we can thereby divide it in the correct cleavage plane.

The role of intraoperative neuromonitoring has been debated in case reports of pyopagus twin separation. According to some authors, if there is no neurological difference between the twins, IONM would have little role in changing their management as there is no option other than sectioning the cord as equally as possible [5,6,10,11]. Others also omit IONM in cases where either twin is not expected to survive or is not stable enough to withstand a prolonged general anesthesia time [4].

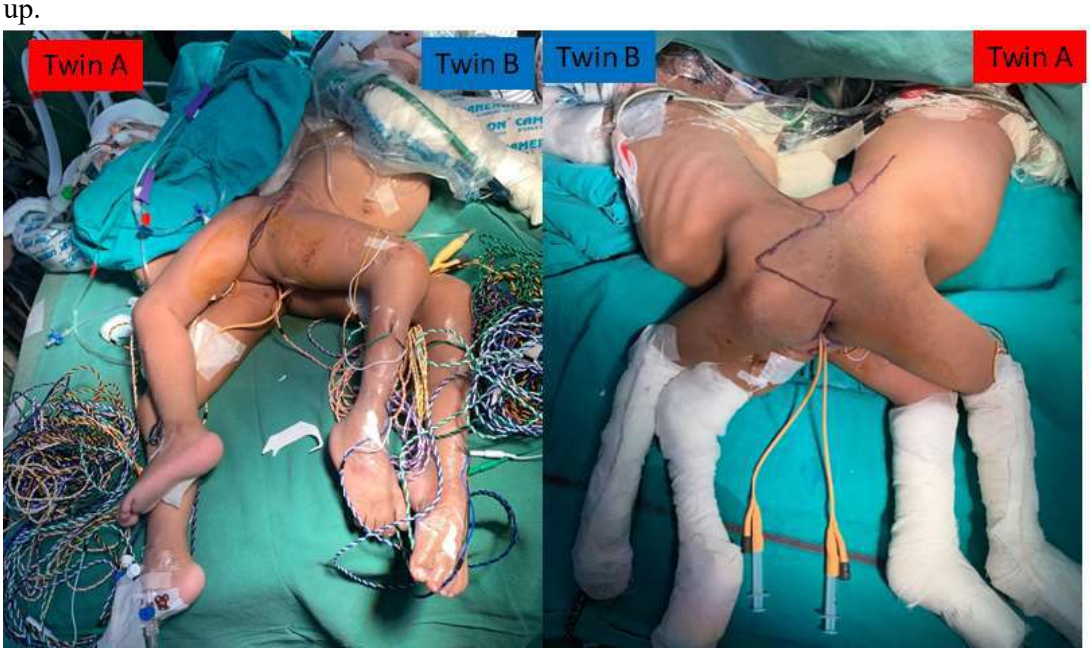


Figure 4. Placement and arrangement of needle electrodes in the lower limb muscles of twins 1 and 2

However, with this approach, some minor neurological deficits have also been reported by Fieggen et al. [7]. Utilization of this technique however, has led to improved outcomes as reported by some authors, especially in cases with a fused U shaped spinal cord, where sectioning the cord at the apex is challenging as the cleavage plane may not be in the anatomical midline. Fieggen et al. have also reported patient specific evidence in separating the anal sphincter complex utilizing IONM [7].

In our study, although we could have done without IONM for spine separation in the second set of twins, in the first set, given the anatomy and challenges in separating a fused spinal cord in way that precludes neural deficits in either twin, led us to utilize this technique. However, IONM is not replaceable in situations where the sphincter control has to be decided among two neurological intact twins. The additional information obtained in the first set of twins that the entire sphincter was controlled by Twin A helped us plan the final anal sphincter allocation to her and prepare Twin B for a stoma.

Limitations of this technique are that it can be used only in places where the equipment is available and there is availability of a neurophysiologist to interpret the results. The placement of electrodes and adequately preparing the twins in OT is however a time-consuming task. It took us an additional 30 mins to prepare the set-up and place the subcutaneous electrodes in the children, fix them with sterile adhesive dressings and wrap them in a way it does not entangle during the process of the separation (Fig. 4). Close communication between teams is also essential as this procedure must be performed without a muscle relaxant, hence if the technique is planned to be used, it must be communicated to the anesthetist to provide only a short acting muscle relaxant during induction [11].

Conclusion

IONM is a valuable tool which should be utilized while separating spine sharing conjoined twins. Apart from aiding in diving the spinal cord in the functional midline, it also helps to allocate the anal sphincter to the more appropriate twin. With the help of a multidisciplinary approach, successful separation and good neurological outcomes are attainable, utilizing technology to our advantage.

Conflicts of interest

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

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ORIGINAL ARTICLE

A Comparative Study between Infusion of Dexmedetomidine and Infusion of Magnesium Sulfate on Haemodynamic Changes in Laparoscopic Surgeries Under General Anaesthesia – A Prospective, Randomized, Double-Blind Study

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Abstract
Background: The study was undertaken to compare between infusion of Dexmedetomidine and infusion of Magnesium sulfate on haemodynamic changes in laparoscopic surgeries under general anaesthesia – a prospective, randomized, double-blind study
Materials and Methods: 80 patients of ASA grade I and II of both sexes undergoing elective surgery in SPS Hospitals, Ludhiana. They were randomly divided into two groups of forty each. Group M received Magnesium Sulfate 30mg/kg in 100ml NS over 10 mins as loading dose followed by 10mg/kg/h in NS to make 50ml and given as infusion. Group D received Dexmedetomidine 1mcg/kg in 100ml NS over 10mins as loading dose followed by 0.2mcg/kg/h in NS to make 50ml and given as infusion. Haemodynamic parameters were noted every 5 mins starting from the time when patient was shifted to operating room to initial 30 mins of pneumoperitoneum and thereafter every 10 mins till the time of deflation. **Results:** Attenuation of haemodynamic response during pneumoperitoneum was better with Dexmedetomidine group. More number of patients were comfortable with sedation score 2 or 3 (Modified Ramsay Sedation Score) while using Dexmedetomidine group for the first 30 mins than Magnesium Sulfate. No significant adverse effects were noted in both groups.
Conclusion: Dexmedetomidine infusion even at a dose of 0.2mcg/kg/h provides a better attenuation of haemodynamic changes during pneumoperitoneum than Magnesium Sulfate in Laparoscopic surgeries. Dexmedetomidine also provides a better sedation score in terms of benefits versus side effects in patients.

Keywords: Dexmedetomidine, Magnesium sulfate, haemodynamic response, laparoscopic surgeries, pneumoperitoneum.

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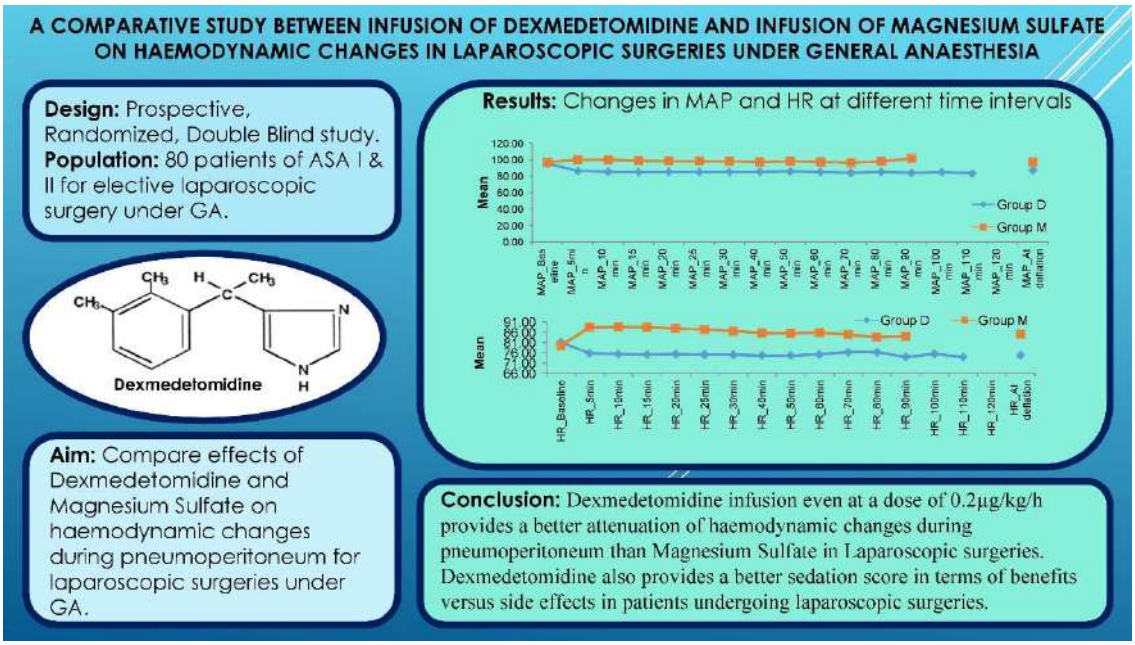
Graphical Abstract



Introduction

Laparoscopic surgeries are one of the most commonly performed surgeries these days. The use of laparoscopy has revolutionized the surgical field with many advantages. There is a reduction of postoperative pain, less postoperative surgical and pulmonary complications, early recovery and reduced hospital stay [1]. The scope of laparoscopic surgeries extends to various gastrointestinal, gynaecological (e.g., diagnostic laparoscopy, ectopic pregnancy), urological (e.g. nephrectomy, prostatectomy) and vascular procedures.

Major step of laparoscopic surgery is pneumoperitoneum creation. Use of carbondioxide for pneumoperitoneum and rise in intra-abdominal pressure (IAP) have various systemic effects [2]. Cardiovascular: This depends on the IAP. At lower IAP of less than 15 mmHg, there is an increase in cardiac output and blood pressure due to augmentation of venous return. However, at higher IAP of more than 15 mmHg, due to the reduction of venous return (compression of inferior venacava), cardiac output and blood pressure fall (Figs. 1 and 2). Changes in respiratory system include increase in airway pressures, decrease in lung volume leading to basal atelectasis and intrapulmonary shunting. Intracranial pressure can increase because of hypercapnia, increased IAP and trendelenberg position, which can be lethal to those with decreased intracranial compliance (Fig. 3).

Adverse effects of pneumoperitoneum might be potentiated by trendelenberg or reverse trendelenberg position. Trendelenberg position will lead to decrease in venous return and reduction in MAP. Pneumoperitoneum will activate of neurohormonal stress response [1] and renin angiotensin aldosterone system [3]. Pressures of more than 15 mmHg are related to vital pathophysiologic effects. The circulatory and ventilatory changes are often appreciated after 5 min of the onset of insufflation of gas, however they reverse over a period of 2 h [4].

Different classes of drugs have been used to reduce haemodynamic changes associated with laparoscopic surgery with variable response. Clonidine an α_2-adrenergic agonist has been studied widely [5,6]. Using α_2-adrenergic agonist can decrease anaesthetic and analgesic requirements, provide better haemodynamic stability without impairment of myocardial or renal blood flow and attenuate neurohumoral "stress response" of major

surgery [7]. These may reduce circulating catecholamine level during surgery. All these properties make Dexmedetomidine an ideal agent for premedication. Magnesium use as a therapeutic agent for conditions like preeclampsia, eclampsia, and torsades de pointes arrhythmias [8].

There are only limited clinical studies which compared effects of Dexmedetomidine and Magnesium Sulfate as premedication followed by infusion in perioperative haemodynamic stability and postoperative sedation. Our study aims in comparing the effect of Magnesium Sulfate and Dexmedetomidine in attenuating haemodynamic responses during pneumoperitoneum in laparoscopic abdominal surgeries.

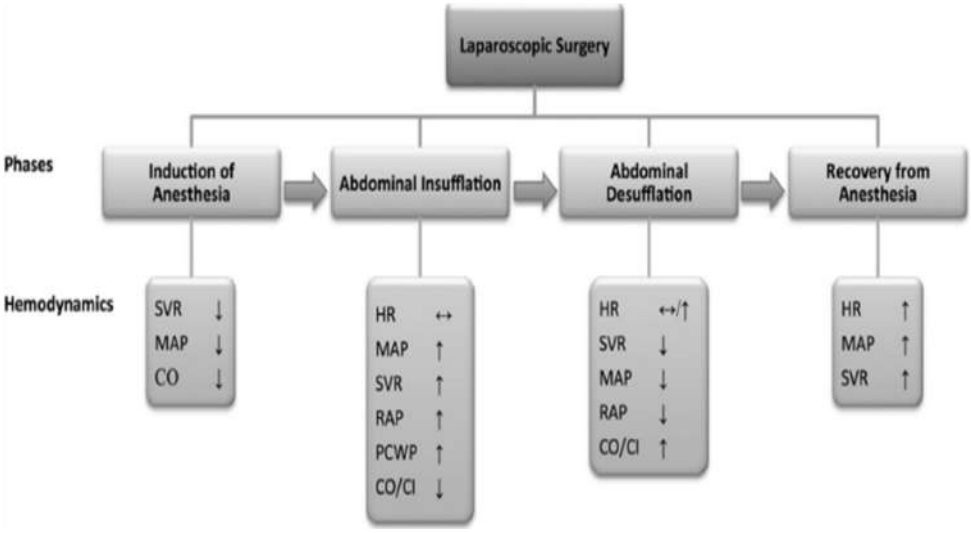


Figure 1: Haemodynamic changes at different phases of laparoscopic surgery [9]

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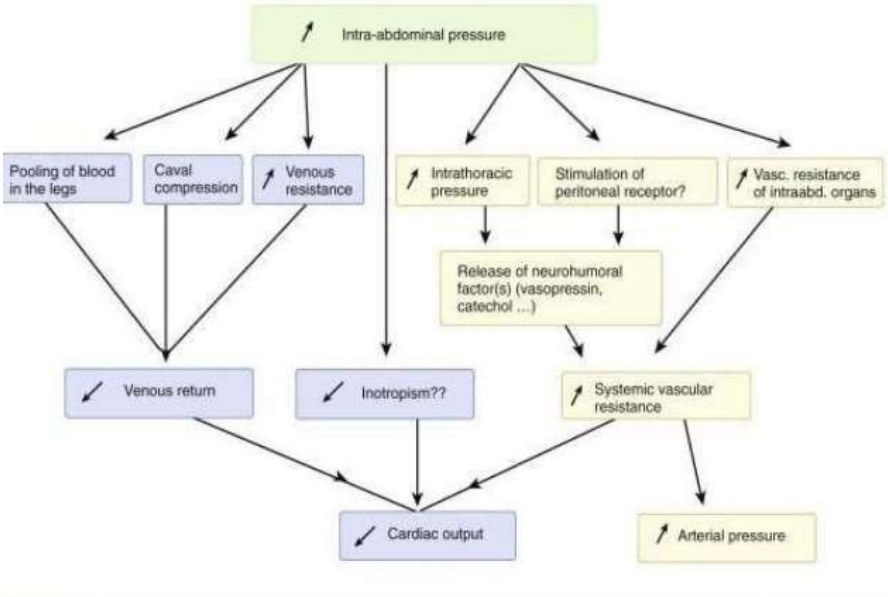

Figure 2: Schematic representation of different mechanism leading to reduced cardiac output [10]

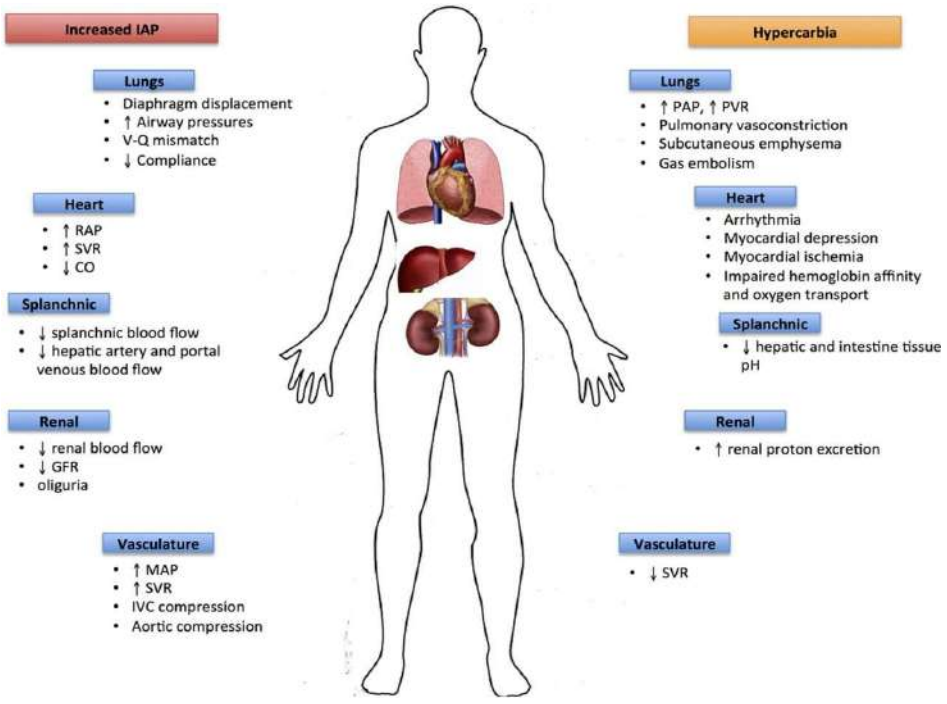

Figure 3: Two components of laparoscopic surgery [11,12]

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Pathophysiology of the Pneumoperitoneum

Methods

This study was conducted after the approval by the ethical committee of Satguru Partap Singh Hospitals, Ludhiana after signing of the informed consent by the patient. The datas were collected by the observer (myself) using the study proforma. It was collected and analysed from June 2019 to April 2021 at Satguru Partap Singh Hospital as per methodology.

Study population: 80 adult patients in two groups of 40 each, ASA I & II of either sex undergoing elective laparoscopic surgery under GA.

Study design: It was a Prospective, Randomized, Double Blind study.

Inclusion criteria:

Patients between the age of 18-65 years of either sex with ASA Grade I or II undergoing elective laparoscopic surgery under general anaesthesia.

Exclusion criteria:

Morbid obesity (BMI>40 kg/m2)**,** Intubation attempts more than two**,** Duration of pneumoperitoneum more than 120min, substance abuser, known allergy or hypersensitivity to study medicines, Pregnant and lactating mothers, Emergency surgeries**,** Patients who are on Calcium Channel Blockers as they interact with magnesium.

Eligible patients were explained regarding scope, nature of the study and about the study related risks in their own vernacular language. Informed and written consent were taken. They were given freedom of withdrawing at any stage from the study. Patients were divided into two groups. Randomization was done by a plan generator from www.randomization.com. The appropriate numbered envelope was opened and drug was prepared according to the card inside indicating patient group D and M.

Group D: Patients received Dexmedetomidine loading dose of 1µg/kg in 100ml NS over 10min followed by 0.2µg/kg/h in NS to make 50ml and given as infusion.

Group M: Patients received Magnesium Sulfate 30mg/kg in 100ml NS over 10 min as loading dose followed by 10mg/kg/h in NS to make 50ml and given as infusion.

A complete history of present and past illness was taken; general, physical examination and systemic examinations were conducted. Routine investigations were done along with ECG. Consents were obtained. All patients were premedicated with Tab. Zolpidem 10 mg orally at night before the surgery and Tab. Pantoprazole 40mg at 6:00 AM on the day of surgery.

Patients were kept fasting for 6 h for solids although clear fluids were allowed 2 h prior to the surgery. Preoperatively Patient's consent and PAC were checked. Pulse oximetry, non-invasive blood pressure and electrocardiography were started and baseline vital parameters like heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and arterial O_2 saturation (SpO_2) were recorded in all patients. In operating room iv cannulation done. Group M was given Magnesium Sulfate loading dose of 30mg/kg in 100 ml NS over 10 min followed by infusion at a rate of 10mg/kg/h in 50 ml NS. Group D was given Dexmedetomidine loading dose of 1µg/kg in 100ml NS over 10 min followed by infusion at a rate of 0.2µg/kg/h in 50 ml NS. Haemodynamic parameters were noted every 5 min starting from the time when patient was shifted to operating room to initial 30 min of pneumoperitoneum and thereafter every 10 min till the time of deflation.

Injection fentanyll 2 µg/kg iv was given, after preoxygenation with 100% O2 patient was induced with IV propofol (Dose was titrated by assessing the loss of eyelash reflex and verbal response). Tracheal intubation was done after giving rocuronium 0.8 mg/kg iv and confirmed by bilateral chest auscultation and $EtCo_2$ monitoring. Anaesthesia was maintained with sevoflurane (MAC-1), N_2O, O_2 (50:50). During CO_2 insufflation in to the peritoneum the intra-abdominal pressure was maintained between 12-14mmhg throughout laparoscopic procedure.

The patient was ventilated to keep end-tidal CO_2 between 35 and 45mmhg. Injection paracetamol 1gm was infused to all patients of both groups in the study. Vitals (HR, SBP, DBP, MAP) were recorded. Controlled ventilation with targeted $EtCO_2$ level 35-45 mmHg. Episodes of bradycardia (heart rate < 60/min) was treated with one dose of atropine 0.6 mg and for those who were not responding, the drug infusion was stopped and excluded the case from study. Hypotension (mean arterial pressure lower than 20% of baseline) incidents were treated with ephedrine 6 milligram incremental boluses. Hypertension (MAP>110) was managed by increasing sevoflurane up to a MAC value of 1.5 and for those who were not responding nitroglycerine infusion was started at a rate of 2.5-5 µg/min and excluded patient from study. The drug infusion in question was stopped as soon as pneumoperitoneum is deflated.

The time of inflation and deflation of pneumoperitoneum, total duration of surgery was noted. Ondansetron 4mg slow iv was given towards the end of surgery. Port sites were infiltrated with 0.2% ropivacaine 5ml at each site. Neostigmine and glycopyrrolate used to reverse neuromuscular blockade after surgery. Patients were then transferred to recovery room. All observations were made by anaesthetist unaware of the nature of drugs administered. After the procedure level of sedation was assessed in the recovery room by the observer (myself) every 30 min for two h using Ramsay Sedation Scale.

Results

All the relevant data was collected. Data were described in terms of range, mean ±standard deviation (±SD), median, frequencies (number of cases) as appropriate. Comparisons of quantitative variables between the study groups was done using student t-test and for independent samples for parametric and non - parametric data respectively. For comparing categorical data, chi-square test

(X2) test was performed and the exact test was used when the expected frequency is less than 5. A probability value (p-value) less than 0.05 was considered statistically significant. All statistical calculations were done using Statistical Package or Social Sciences (SPSS version 17) statistical programme for Microsoft window (Table 1).

A. Demographic Data

Table 1: Demographic Details off Both Group with Baseline Characteristics

		GROUP D		GROUP M		*p-value*
		MEAN	**SD**	**MEAN**	**SD**	
AGE(years)		39.58	12.41	41.58	9.37	*0.292*
WEIGHT(kg)		73.23	11.38	73.98	8.5	*0.768*
GENDER	MALE	12		8		*0.302*
	FEMALE	28		32		
ASA	1	25		29		*0.34*
	2	15		11		
DURATION OF SURGERY(min)		76.38	22.33	74.98	16.14	*0.743*
SPO2(%)		98.05	0.81	98.05	0.78	*0.992*
ETCO2(mmhg)		38.63	2.62	38.55	2.97	*0.779*

B. Haemodynamic Changes During Surgery

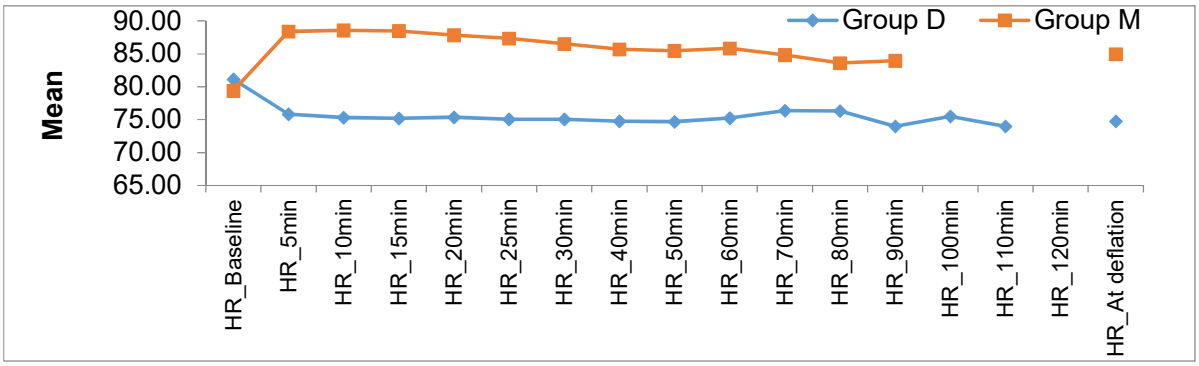

Figure 4: Distribution of Patients According to Heart Rate

Figure 4 shows the mean baseline HR and the mean HR at different time intervals from baseline. The mean baseline heart rate in group D was 81.15±7.91 bpm and the mean heart rate in group M was 79.43±6.66 bpm (*p = 0.605*). HR difference in group D and group M from 5 min to 70 min were found to be significant. There was better attenuation of HR in group D. At 80 min in group D was 76.36 ± 5.10 and the mean heart rate at 80 min interval in group M was 83.64±12.42 and the difference in heart rate were statistically analysed to be insignificant (*p = 0.122*). At 90 min in group D was 74.00±3.16 and the mean heart rate at 90 min interval in group M was 84.00±10.03 and the difference in heart rate were statistically analysed to be insignificant (*p= 0.110*).

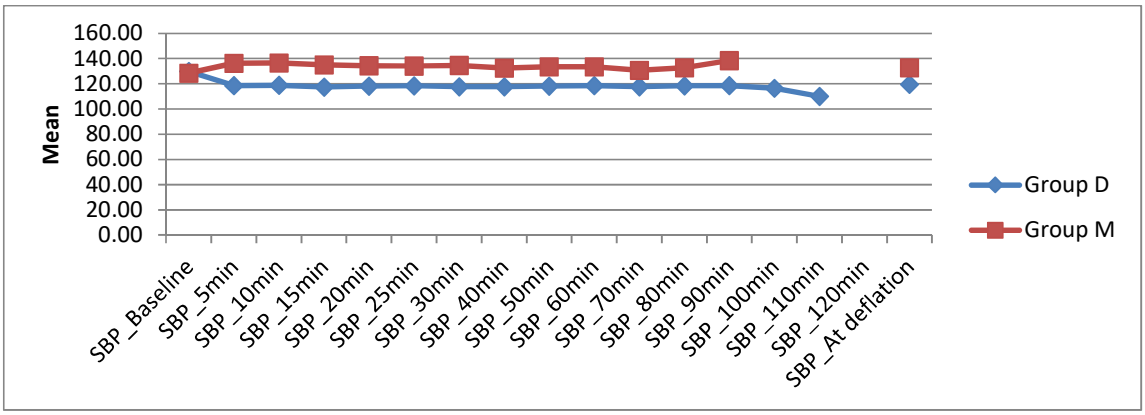

Figure 5: Distribution of Groups According to Systolic Blood Pressure (SBP)

Figure 5 describes the mean SBP at different time intervals from baseline. At baseline mean SBP in group D was 129.85±12.05 and the mean SBP in group M was 128.50±11.77. The mean SBP was compared among study groups and was insignificant (*p= 0.773*). From 5 min to 90 min interval, the difference of SBP in group D and group M were found to be significant. Better control of SBP was in group D.

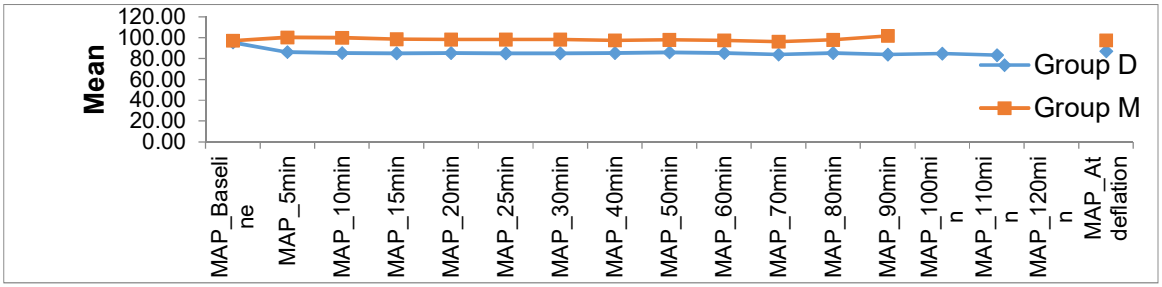

Figure 6: Distribution of Groups According to Mean Arterial Pressure

Figure 6 depicts the mean arterial blood pressure at different time intervals. The mean of mean arterial pressure in the group D was 95.42±8.31 and the mean of mean arterial pressure in group M was 97.12±6.88. The means were compared in the two groups and it was found to be statistically insignificant (*p = 0.437*). The means were compared in the two study groups and it was found to be statistically significant from 5 min to 90 min (*p= 0.014*).

Secondary Findings

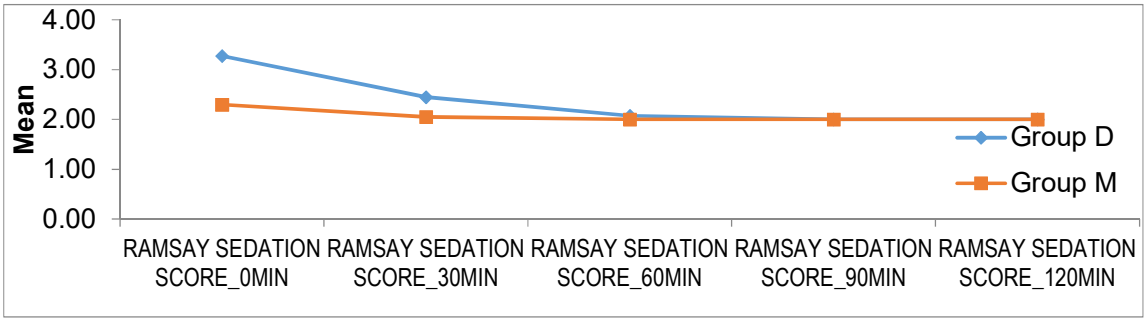

Figure 7: Distribution of Groups According to Ramsay Sedation Score

Figure 7 shows the mean Ramsay Sedation score at different intervals. The mean Ramsay Sedation score at immediate postoperative period in the group D was 3.28±0.60 and in group M was 2.30±0.52 difference was statistically significant (*p= 0.0001*). At 30 min, the mean of group D was 2.45±0.50 and in group M was 2.05±0.22. Statistical analysis was done to reveal that there was significant difference between two groups (*p = 0.0001*). From 60 min onwards differences were insignificant.

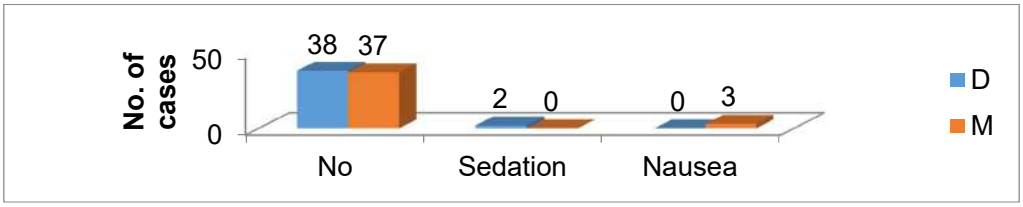

Figure 8: Distribution of Groups According to Side Effects Observed

Figure 8 shows the side effects observed postoperative period in the group D and group M. In group D, 2 (5 %) were having sedation and others having no side effects, while in group M 3 (7.5%) were having nausea and others having no side effects.

Discussion

Pneumoperitoneum creation by inflating CO_2 is the key element of all laparoscopic surgeries. The search for an ideal agent was started from 1970 to attenuate the haemodynamic responses during laparoscopic surgeries. The study was conducted as per the methodology described.

The baseline H.R was comparable in both groups. HR was found to be lower in Dexmedetomidine group than the other group (*p= 0.605*). This may be due to bolus dose of Dexmedetomidine before administrating maintenance dose as infusion. The difference at baseline and till 5 min was insignificant may be because of other agents used for induction. HR was significantly lower in Dexmedetomidine after 10, 20, 30, and up to 40 min of pneumoperitoneum than Magnesium Sulfate.

Zarif et al [13] in his study used Dexmedetomidine with a loading dose of 1µg/kg followed by infusion at 0.4µg/kg/h and Magnesium Sulfate at a loading dose of 2g followed by infusion at 15µg/kg/min, their results show that in Magnesium Sulfate group, both SBP and DBP increased abruptly after pneumoperitoneum and sustained high throughout procedure when compared to Dexmedetomidine group where it was better attenuated. These findings were comparable with our study even with infusion dose of Dexmedetomidine at 0.2µg/kg/h.

The comparison of baseline systolic blood pressure among two groups in our study revealed that there is no statistically significant difference (*p =0.773*). Then after starting and up to 60 min of pneumoperitoneum both SBP and DBP were significantly lower with Dexmedetomidine than with Magnesium Sulfate (*p = 0.0001*). Hence MAP was significantly lower with Dexmedetomidine than with Magnesium Sulfate. There was no significant difference among the groups at baseline mean blood pressure. These findings were comparable with Kalra et al. [14] study in which they compared clonidine and Magnesium Sulfate for attenuation of haemodynamic responses to pneumoperitoneum. They have found that Clonidine is better in blunting haemodynamic response than Magnesium Sulfate when used 15 min before pneumoperitoneum.

Dexmedetomidine acts by decreasing of sympathetic outflow from the locus ceruleus. As a result, norepinephrine levels will decrease and thereby decrease in MAP and HR.

Analgesic property is mediated mainly through the dorsal horn of spinal cord.

Jee et al. found that Magnesium Sulfate bolus of 50 mg/kg before pneumoperitoneum increased serum magnesium concentrations to 2-4 mmols/l, which is enough to inhibit catecholamine release in vitro [15]. Release of vasopressin can also cause change in haemodynamics during pneumoperitoneum. Vasodilatory effects of Magnesium Sulfate can counter effects of vasopressin which is released by compression abdominal capacitance vessels by pneumoperitoneum. Precise mechanism by which magnesium reduces vasopressin concentration need to be studied further. ***Jee et al.*** [14] in their study gave Magnesium Sulfate 50 mg/kg immediately before pneumoperitoneum for patients undergoing laparoscopic and observed that Magnesium Sulfate before pneumoperitoneum attenuates arterial pressure increases during laparoscopic cholecystectomy. This attenuation is apparently related to reductions in the release of catecholamine, vasopressin, or both.

Bryskin and Weldon [15] during laparoscopic resection of phaeochromocytoma used a combination of Dexmedetomidine and Magnesium Sulfate for haemodynamic control found to have haemodynamic stability, which favors the efficacy of both drugs. Ismail et al. [16] observed similar effects of when compared Magnesium Sulfate, Dexmedetomidine, and lignocaine on the haemodynamic responses in patients undergoing laparoscopic cholecystectomy. The HR and MAP changes were found to be greater in both the lignocaine and control groups than the Dexmedetomidine and Magnesium Sulfate groups after drug administration, after induction, after intubation, throughout pneumoperitoneum at 10 min intervals and in the postoperative period after 10 min with highly significant difference.

We also observed that in patient who received an infusion of Dexmedetomidine induction dose of propofol was less. However an objective criteria need to ascertain this. Reversible bradycardia and hypotension were recorded in the Dexmedetomidine group in our study. Very few of them required nitroglycerine infusion who developed hypertensive response. Among thirty patients two of them had sedation in Dexmedetomidine group while in Magnesium Sulfate group three of them showed only nausea as side effect. But none of the patient in our study had sedation score > 4, so none of the patient requires any type of airway or ventilator support. These findings are correlating with the study done by Kumar et al. [17] in 2014 on comparative study of effects of Dexmedetomidine and clonidine premedication in perioperative haemodynamic stability and postoperative analgesia in laparoscopic cholecystectomy. Clonidine group received 2 µg/kg of diluted in normal saline, given slow intravenous infusion over 10 min. Dexmedetomidine group received 1 µg/kg of diluted in normal saline, given slow intravenous infusion over 10 min. The studies with higher infusion rates had more incidences of adverse effects like hypotension and bradycardia.[33] In our study, we used Dexmedetomidine in an infusion rate of 0.2 µg/kg/h during laparoscopic surgeries and did not observe significant incidence of hypotension or bradycardia. Dexmedetomidine causes sedation but it does not cause delay in the recovery time as shown in the study.

In our study Dexmedetomidine group showed significant difference in sedation score for the first 30min when compared with Magnesium Sulfate group similar findings were noted by Hall et al. [18]. According to study done by Salman et al. [19]. Dexmedetomidine has comparable effects to remifentanil and may be an alternative to remifentanil in ambulatory anaesthesia.

Our study had some limitations. We had to exclude cases where duration of surgery more than 120 mins, IAP was restricted to 14 mmhg and since we chose different laparoscopic surgeries, positioning during surgeries, likely to alter the haemodynamics, which was not taken into account.

Conclusion

We did a prospective, randomized, double-blind study to compare the effect of

infusion of Dexmedetomidine and Magnesium Sulfate on haemodynamic changes in laparoscopic surgeries under general anaesthesia. The following conclusions were made, Dexmedetomidine infusion even at a dose of 0.2µg/kg/h provides a better attenuation of haemodynamic changes during pneumoperitoneum than Magnesium Sulfate in Laparoscopic surgeries. Dexmedetomidine also provides a better sedation score in terms of benefits versus side effects in patients undergoing laparoscopic surgeries.

Conflicts of interest

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

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PERSPECTIVE ARTICLE

Metaversopsy - A Perspective

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'Metaverse' is a big buzz word in the world of technological advancement nowadays. Interestingly, there are lot many definitions for this term from being just a hypothetical iteration of internet in science fiction to being an absolutely true virtually interacting medium. However, one of the most acceptable definitions from my point of view would be, "A massively scaled and interoperable network of real time rendered 3D virtual worlds that can be experienced synchronously and persistently by an effectively unlimited number of users with an individual sense of presence, and with continuity of data, such as identity, history, entitlements, objects, communications, and payments [1]."

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The next important question that pops up in one's mind is, *'why should a forensic pathologist be aware of the advances in the field of computer science/tech'?* The straightforward answer would be whether we like it or not, technology is always on the go to disrupt every single branch of medicine either purposefully or forcefully. Moreover, it is not nonsensical to accuse molecular biologists and computer science geeks about their extremely heightened enthusiasm in encroaching on to every other domain in the universe to just ensure their relevance. On top of that, if we look at the current climate of medical research in the aftermath of COVID 19 pandemic, there is an additional renewed interest in molecular medicine, imageology and digital health.

Although metaverse can purportedly revitalize health sector to a great extent, the most simplified understanding of what metaverse does when we look at it from a broader prospect is-

- Primarily, connected health and Internet of Medical Things (IoMT) in their Zenith. It is an increased and immersive telepresence of health care providers generating an easy access to outpatient services coupled with advent of extremely reliable wearables to acquire vital data remotely. Indeed, to make this a reality there needs to be a convergence of artificial intelligence, virtual reality (VR), extended reality (XR) and augmented reality (AR) in synchrony with the blockchain technology that ensures data protection.
- Secondly, the digital twinning. It is the creation of a virtual model of the real-life counterpart in the metaverse for research purpose. Lucidly said, it is bioinformatics performing at its Everest peak! There are several such dry lab techniques in scientific research. E.g., Quantitative Structure Activity Relationships (QSAR) mathematical models to predict measures of toxicity using molecular descriptors in toxicology. This is also referred to as something called augmented regulatory science. Several such approaches of research are a part of dry lab in drug design and development from a long time. We can assume that this digital twinning is more or less the same in a magnificent magnitude like the science of precision medicine.

It has been claimed by several researchers that a Metaverse of medical Technology and Artificial Intelligence (MeTAI) ecosystem can facilitate research and performance of AI based medical practice especially in the field of radiology and its allied specialities [2]

I shall not dole out deep in to the explainability of AI and deep learning paradigms being employed for usage in metaverse. Neither I wish to bring in the bioethics or legal issues entangled with the use of metaverse in health at this juncture. These legal and ethical considerations all together constitute a recalcitrant challenge better kept open for the reader to comprehend.

Of late, we as practicing crime pathologists can't deny the presence of a lot of published data in the field of digital pathology in general and virtual autopsy (virtopsy) in particular, despite the hard fact that these things can only complement and never substitute the traditional autopsy. As we are aware, the virtopsy model encompasses the use of certain technologies like 3D body surface imaging methods, multidetector and multi-slice computed tomography (CT), magnetic resonance imaging (MRI), data merging of surface and radiological data, high-resolution micro-CT and micro-MRI (MR microscopy), magnetic resonance spectroscopy (time-of-death determinations), image-guided percutaneous biopsy, post-mortem angiography and synthetic body model development [3]

Virtopsy came into existence during the first decade of the 21st century and since then has been used across the globe in several jurisdictions. It has also been successfully applied to solve many medico-legal questions till date. Prof. Dr. Michael Thali and his team at the institute of forensic medicine, university of Zurich, Switzerland is one of the most active research groups in this arena.

Metaversopsy can be defined as a technologically aided autopsy procedure that converges multiple existing human imaging modalities, robotics and artificial intelligence to enhance the scientific perceptibility of the forensic pathologist on real time basis. There is an unusually high degree of interoperability of technologies reduced in space and time, thereby turning it out to be a perfect *virobot* master slave system and even more than that!

It isn't all new approach, but when we develop an algorithmic approach with due standardisation and validation like it was done in the case of virtopsy, Metaversopsy can be an altogether next generation tool in the arsenal for forensic autopsy. If we consider that the average time to conduct a traditional autopsy is somewhere between 3-6 hours, the existing virtopsy method can aid us in reducing it to 1-2 hours. If Metaversopsy comes into existence one can achieve impeccable speed of performing an autopsy in span of minutes.

If we dissect the idea further, Metaversopsy is a no scalpel/ non-destructive or minimally invasive imageology and 3D reconstruction-based autopsy procedure like virtopsy except for the fact that there are elements of machine intelligence/learning, robotics and convergence of image/ intervention technologies being used in real time. The data which gets processed through machine intelligence/learning and deep learning networks may be presented on a virtual interactive interface to the pathologist. The pathologist also may be able to delve deeper into the levels of body with the virtual tools available for him with his choicest views and magnifications using his VR/AR/XR headset and command the robotic system for any interventions on the corpse. Apart from this, the technology can also apparently be upgraded further for providing suggestions as to causative factors of trauma and differential diagnosis in connection with morbid anatomy findings in the corpses (Figures 1 and 2).

The concept of corpse twinning, i.e., creating a virtual counterpart of the deceased will give us a meaningful scope to investigate the possible mechanisms of infliction of violence in majority of the cases. This is absolutely an improvement of what is being practiced today because we aren't using the exact replica of a person/milieu in simulations as of now. Sometimes, *phantoms* can be printed using 3D printing technologies which may eventually replace dummies in simulation experiments. Personally, I wish for this kind of a virtual media solution to make medical illustration easier in the courts of law for people from different backgrounds.

Corpse twinning is like the digital twin of the patient for the purpose of risk assessment and precision therapeutics. This approach will augment existing simulation methods in investigating cases of ballistic injuries, injuries due to missiles, fire accidents, fall from height, bomb blasts and mass disasters. Nevertheless, developing case specific algorithms and standardization of corpse twinning demands a lot of dry lab work before it can be started on a real time basis. But, if Chat GPT can happen, corpse twinning will also be a reality for sure.

The seamless virtual connectivity expected from metaverse helps us to work in teams from across the globe in real time. A trans-continental autopsy wouldn't be that far into the future with metaverse in the horizon. Obviously, when more human brains are at work, we have better results. I always believe that the two most important byproducts of technology making inroads in forensic pathology is democratization of knowledge and increased transparency in the actions of so-much hyped forensic expert's work!

Illustration - Firearm injuries case:

When the corpse passes through the Metaversopsy suite, a corpse twin is created in the virtual world by integrating multimodal surface and radiological imaging along with 3D Photogrammetry. AI based technologies depict the track of the wound, detail of the distorted projectile, its virtually reengineered pure form and creates a simulation of launch of the projectile and subsequently furnishes type, range and direction of fire in real time basis. Machine learning and deep learning algorithms help in this process using neural networking model. There is always a scope for error and pathologist need not always subscribe to the suggestions of the bot-metaverse system. She can use her brains to negate the *Metaversopsy* suggestions and this will subsequently work through deep learning neural networks for the AI becoming smarter in future. This data can also be shared among professionals for case discussion and presented to the ballistic expert for furthering his study in confirming the class and individual characteristics of the weapon. The Robot system aids the pathologist in image guided tissue/sample collection for ancillary investigations or further analysis (Figs. 1 and 2).

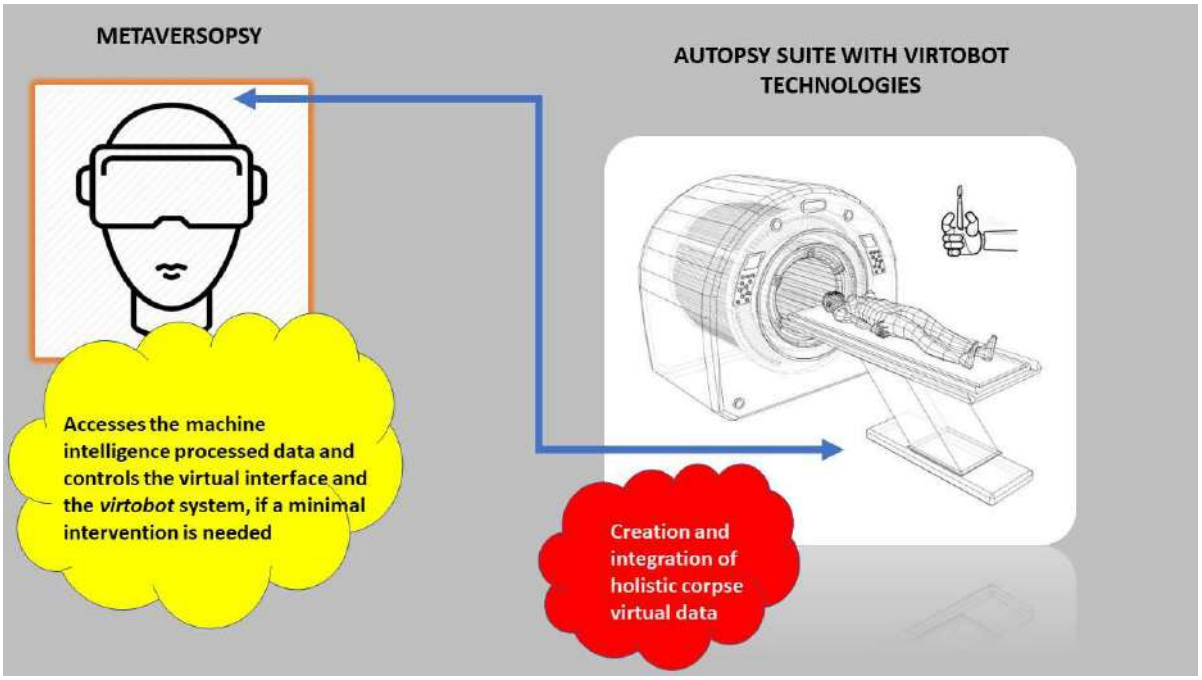

Figure 1: The autopsy surgeon works on a virtual interface integrated with a robotic system to carry-out additional interventions like obtaining samples for ancillary investigations.

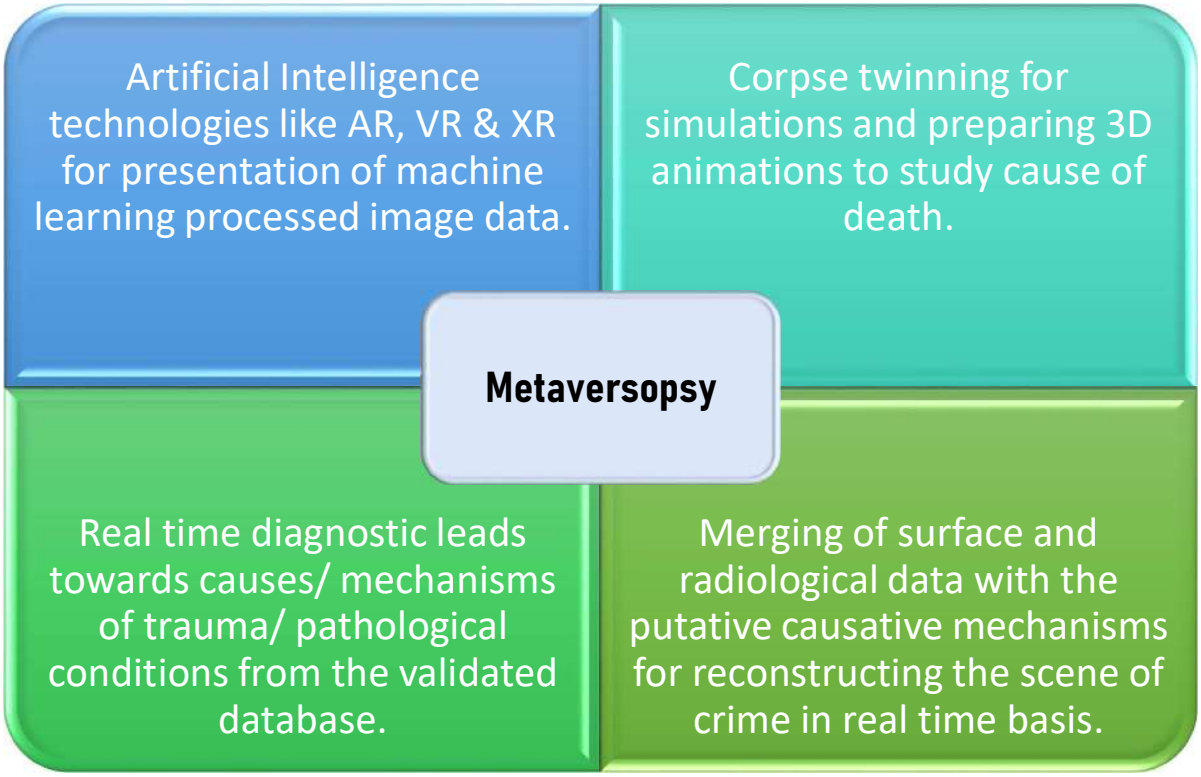

Figure 2: Convergence of Artificial Intelligence, Robotics, and Medical Imaging Technologies in Forensic Pathology – Metaversopsy.

Collection, storage, processing, further processing and transfer of sensitive personal data requires a strict compliance of General Data Protection Regulation (GDPR) and its respective recitals. The cardinal principles of data privacy and security are enshrined in the article 5.1-2 of the GDPR. These include lawfulness, fairness & transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity & confidentiality; and accountability [4]. Needless to say, storage and reproduction of the data of the deceased person for scientific reporting and archiving necessitates a tamper-proof privacy framework. A strict Data Impact Assessment (DIA) is essential in this scenario to anticipate any future data privacy issues before implementing the programme. A complete and comprehensive regulatory mechanism for data protection in compliance with GDPR is quintessential. Nevertheless, handling and transfer of such extremely sensitive data is a huge matter of privacy concern in medico-legal issues especially in cases of violent sexual crime on women and children.

The high volume of processed as well as raw data that is generated during *Metaversopsy* requires a proper anonymisation before being employed for educational and research purposes. The legal issue of ownership of data currency of the deceased person and all matters incidental thereto needs to be thoroughly thought out before venturing further. The rights of the deceased 'data subject' is altogether a novel concept in privacy law which requires a detailed study. Hopefully, the blockchain technology addresses some of these challenges. Blockchain technology can ensure privacy through the use of techniques such as Zero-Knowledge proofs and homomorphic encryption. Zero-knowledge proofs allow for the verification of information without revealing the actual data, while homomorphic encryption allows for computations to be performed without the need to decrypt it first [5].

If the Metaversopsy clears the simple test of science, it would be just a matter of time to rope in all stakeholders of criminal justice system into the confidence bracket of technology-based solutions in autopsy practice. Nonetheless, it's a long way to go wherein we are supposed to go for hybrid practice for at least a few years to generate more data to pass the standardisation test.

There are several people who buy water for the idea of metaverse, and we also do have equally good number of critics who are hyper-sceptical about the feasibility of such a large-scale financial project. These references can be accessed for instance [6,7].

Unfortunately, most of the research in medicine is not being aimed at the unmet needs of patients or propositions made by clinicians. Although this is a personal opinion, I feel like there are three major industries subterraneanly dictating medical research. They are firstly the *IT industry*, secondly the *central dogma group of molecular biologists* and finally the *imageology physicists*. All the three groups share a commonality of delusion of *pan-panacea!*

The only perfect rationale for image-tech based solutions in autopsy practice from my perspective is, we can use it in situations like COVID 19 pandemic. It is no exaggeration that the entire modern medicine took its birth in autopsy theatres where corpses were dissected, and disease pathology was studied. Autopsy pathology still remains the gold standard in understanding emerging and re-emerging novel pathological basis of disease. Hence, where traditional autopsy is risky and takes huge time, technologies like the Metaversopsy on a grand scale can provide some quick and reliable solutions in times of crisis. The quantum leap in Metaversopsy technology will take its own time to crystallize but will definitely get established in practice.

In our country, the virtopsy project was launched at the AIIMS, Delhi recently with support from ICMR. The research team under the stewardship of Prof. Dr. Adarsh Kumar opined that although this concept emerged a couple of decades back, it did not pick up quick acceptance in the forensic field comparted to techniques like the DNA analysis which have become so ubiquitous. It is also an undeniable fact that the costs involved in software, hardware of image-based methods will delay the implementation in our country [8]. It is also worth to mention that AI based methods were

also employed in India to estimate time since death which is one of the primary objectives of a medico legal autopsy [9].

The National Convention on Medicine and Law 2018 organised by Institute of Medicine and Law, Mumbai, compiled several issues pertaining to the need and legality of virtopsy in India. It was also mentioned during the conclave that cost won't be a hindrance in the long run because we can make our tailor-made software with the help the giant IT ecosystem in the county. Moreover, in a country like India, the economies of scale will help in cost cutting. The same principles augur well for *Metaversopsy.* There is nothing in Indian law that bars imageology in autopsy practice. The evidentiary value of such reports would fall under the ambit of Sec 3(2), Sec 45 and Sec 62 of Indian Evidence Act (IEA). It is also important to mention that all the relevant provisions of Information Technology Act 2000 Shall apply to these image-based methods because high fidelity cybersecurity is essential when virtopsy is being extended to the metaverse. On the other hand, this shall also open vistas of tampering of digital evidence and crimes related thereto which is beyond the scope of present discussion [10]. One also needs to bear in mind that, although image-based technologies can increase objectivity in arguments they are also limited by certain biases and element of subjectivity in medico-legal practice.

The major risk of excessively relying on technology is sometimes it can land us in more problems than it was intended to solve. The principles laid down by WHO in the vision document on ethics and governance of AI in health and the recommendations of UNESCO on ethics of artificial intelligence are worth reviewing to open the debate of risks and benefits in using metaverse to solve medico-legal issues [11,12].

The ultimate advantage for the forensic pathologist with advancements of this sort would be saving a lot of time in framing opinions, especially when there is a huge workload in a high-volume centre or when there is an acute increase of workload due to mass disasters. There is no doubt adoption of this technology increases presentability and probative value of evidence in the courts of law. The purported benefits for the other stakeholders like the relatives of the deceased would be a minimally invasive autopsy and more comprehensive understanding about cause of death. There is an obvious increased ease of solving crime for the different agencies which are part of criminal justice system.

It would be a smack of myopia if I don't put a word on the feasibility of the project. The hardware, software involved in the project along with the wearables like immersive VR/AR/XR headsets are hugely expensive at this point of time. The training of forensic pathologists and other ancillary staff towards adopting such technology and managing the huge dataset takes considerable amount of time. The cost effectiveness and risk benefit analysis of this project needs to be carried out in a more scientific way by future researchers.

In conclusion, with my understanding on the subject, I can assure that we aren't discussing science fiction, and everything makes sense in view of the steep pacing technology research blended with increased paradoxical curiosity to find a solution for everything in AI. It is good sometimes! Metaversopsy can also become a VR game in Zuckerberg's Metaverse! Who knows!

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