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Total Quality Management (TQM) Implementation and Impact Assessment in Healthcare:
A Comprehensive Analysis

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Abstract

This qualitative research sought to understand and answer TQM's issues in healthcare. Service quality issues and TQM implementation hurdles are examined.
Methodology/Approach: TQM implementation challenges investigated using a conceptual model. TQM has three primary components: implementation hurdles, Critical Success Factors, and benefits. Health care providers and patients were questioned using questionnaires. Seven hypotheses were created to evaluate how TQM may be achieved regardless of impediments.
Findings: TQM can improve SQ, customer satisfaction, employee loyalty, profitability, and shareholder value in the right setting with dedicated leadership and enabling infrastructure. For industrial performance, TQM can deliver high-quality medical care.
Limitations and Implications: Semi-structured research questionnaires were used during interviews. Review and questionnaire biases may exist.
Originality and paper value: The research benefits from medical staff and patients' viewpoints on SQ features such quality circle, continuous improvement, employee empowerment, and customer-focused approach.

Key keywords: *Total Service Quality, Healthcare, Organisational Excellence, Perceived Satisfaction, And Operational Efficiency.*

Introduction

The manufacturing sector developed Total Quality Management (TQM) to assess plant and industry performance. TQM improves company performance by delivering quality goods, services, and operations and maintenance. Quality management systems continuously modify processes to maximise customer satisfaction at the lowest cost, according to Zgodavova and Colesca (2007). Business benefits from improved service quality (SQ). SQ is crucial to the success of a product or service. Without it, it would fail. This may be quantified by comparing customers' quality expectations to what they actually receive—a service gap. (2015) Izogo and Ogba Consumer loyalty is hampered by the service difference. Rework and unhappy customers make low-quality goods and services more costly than high-quality ones. SQ and TQM are crucial to every sector or corporation, regardless of its nature.

TQM deployment enhanced corporate operations, according to Hassan et al. (2012). To offer a better product or service on the first attempt and consistently, TQM should be incorporated into the company culture. TQM enhances accomplishment via a continuum of relevant attribute metrics throughout the value addition spectrum. It helps make better goods that surpass customer expectations (Yusof and Aspinwall, 2001). Thus, TQM-implemented companies improved operational efficiency, throughput, sales, revenue, and effectiveness.
Devoted leadership, a strong corporate culture, active engagement, and worker cohesion are key to TQM success. Leadership, collaboration, people management, and service delivery system are essential for TQM performance (Dahlgaard, Pettersen, and Park, 2011). Product and service production and delivery will be appropriately priced. TQM was first limited to the production line, but as time went on, it was concluded that the service sector should also comply with it, thus it was given a corresponding position in the service industry. According to Prajogoa and Hong (2008), TQM may create a suitable atmosphere outside of production or manufacturing. Quality must be promoted by high management.

Objectives

This research examines how technology, TQM axioms, practises, and pandemic implications affect the bottom line. The disaster has shown several countries' healthcare systems' shocking weaknesses and shortcomings. It has demanded a complete reevaluation of the nation's healthcare infrastructure and the creation of a proper policy and plan to prevent repeat calamities. Even in a natural catastrophe, healthcare services must be robust, according to Kajihara et al. (2016). Integrating the health policy with an adequate TQM policy creates a complete, efficient, and effective system. Therefore, these research goals have been set:

- To Determine technology's role in healthcare excellence.
- To Assess TQM implementation in healthcare.
- To examine TQM's impact on profitability.

Concerns

This research examines TQM's standing in the healthcare business, its shortcomings, problems, and implementation. The goal is to increase patients' opinions of service providers based on their healthcare competency and quality care endowment. Based on a review of the literature and critical success factors (CSFs) like technology, quality compliance, team structure, customer-focused approach, and employee training and development, this study investigated the following research questions (RQs) and proposed corrective actions for implementing TQM practises in the healthcare sector:

- Would technology help TQM? How well does TQM work?
- How do patients evaluate healthcare practitioners' CSFs?
- How do TQM, quality care, and profit relate?

SQ was the CSF's priority to boost customer satisfaction and income. A thorough investigation and understanding of key success elements. Thus, the current research is expected to improve TQM implementation tactics in healthcare. In this sense, a TQM framework closely integrated with the right healthcare policy framework would safeguard and preserve society and build a healthy, joyous country. Healthcare professionals, hospital executives, and health advocates will benefit from this concept. Methods, analysis, literature review, and conclusions follow.

Literature Review

Businesses must overcome several difficulties to adopt and execute TQM since it's not a fast cure. Without leadership backing, TQM advantages seldom materialise. Industry, research, and academia are interested in it. In healthcare, TQM means focused efforts to enhance patient care, system performance, and professional growth. TQM and hospital success are linked, according to Ali and Alolayyan (2013). To improve healthcare, it involves changing clinical or administrative methods or support. Healthcare taxonomy, SQ improvement, and TQM implementation are discussed here.

Quality Service

Before addressing TQM, one must understand quality. Concerns include "Are we doing the right thing?" and "Are we doing things correctly?" Quality processes handle these two main issues in every area. The SERVQUAL idea by Parasuraman, Zeithaml, and Berry (1985) helps us grasp quality's fluidity. It simply and successfully reflects customers' expectations and views of a service. It claims that a customer's SQ assessment causes the discrepancies between their expectations, evaluations, and actual performance. Parasuraman, Zeithaml, and Berry (1985), Parasuraman and Grewal (2000), and Parasuraman (2010) have published SERVQUAL applications. It was reduced from 10 components to five: Reliability, Assurance, Tangibles, Empathy, and Responsiveness (RATER). Various studies have

defined quality as:

- Quality and customer pleasure (Kaoru Ishikawa, 1985).
- Quality must be determined by the customer (Edwards Deming, 1986).
- Joseph Juran (1989) defined quality as usability.
- Oakland (2003) defines quality as customer satisfaction.

Although addressing end customers' expectations and wants, the "common denominator" of these justifications. Based on their viewpoint and expertise, quality experts define quality differently. SQ is formed by customers' perceptions and expectations, according to Parasuraman, Zeithaml, and Berry (1985). Improved SQ will enhance output and temporarily raise operational expenses. Thus, a management must decide how much to spend in quality to maximise return on quality. The return on quality technique allows executives to spend based on expected financial advantages such earnings and return on investments, according to Rust, Zahorik, and Keiningham (1995). Thus, client expectations and service provider performance may be compared to determine service excellence or lack thereof. Therefore, service providers must benchmark and assess the gap between customer expectations and actual delivery and how to reduce it. A CSF incorporates technology, team structures, a customer-focused strategy, senior management's commitment to quality compliance, staff training, and quality planning, according to Deros, Yusof, and Salleh (2006). Calibrate operations and procedures using these. Given SQ's importance and need, TQM and its effects are worth discussing. The following section discusses TQM subjects.

Quality Management

TQM was introduced in the early 1990s by Kaoru Ishikawa (1985), Edwards Deming (1986), Joseph Juran (1989), Hackman and Wageman (1995), and Oakland (2003). TQM has been characterised as "a search for excellence," "perfection, first time and every time," "zero defects," "delighting the customer," and more. Through continuous improvement (CI), innovation, waste reduction, improved productivity, increased sales, revenue, and profitability, the goal was to enhance customer happiness, staff satisfaction, and product and service quality. TQM implementation and acceptance will boost administrative performance, according to Hassan et al. (2012). Statistical process control is deeply ingrained in TQM. "Walter Shewhart" invented it in the early 1920s in the US. The technique categorised factors and found measurement anomalies in the manufacturing process. It produced a rational manufacturing quality improvement method based on the PDCA (Plan-Do-Check-Act) mindset (Evans and Lindsay, 2001). TQM grew throughout time, and researchers discovered best practises. Figure 1 shows Dale, Wiele, and Iwaarden (2013)'s TQM evolution: Quality Enhancement, Quality Control (QC), Quality Assurance, and TQM.

Regardless of the business type, such as operation, production, healthcare service, hotel, consulting, or financial services, quality improvement and continuous improvement remain indispensable business strategies. The successful organisation will never be satisfied with the status quo and will strive for CI of SQ to accomplish

Total quality management (TQM)
Policy deployment
Involve suppliers and customers
Involve all operations
Process management
Performance measurement
Teamwork
Employee involvement
Quality assurance (QA)
Quality systems development
Advanced quality planning
Use of quality costs
FMEA
SPC
Quality control (QC)
Develop quality manual
Process performance data
Self-inspection
Product testing
Basic quality planning
Use of basic statistics
Paperwork controls
Inspection
Salvage
Sorting, grading, reblending
Corrective actions
Identify sources of non-conformance
TQM
QA
QC
I
Inspection
Continuous improvement
Empowering people
Caring for people
Involvement
Compliance to specification
Allocating blame

TQM and progress towards Six Sigma. According to Antony et al. (2018), there are numerous growth opportunities for the implementation of SQ in healthcare. For their sustained success, prosperous businesses would seek out new ways to improve the quality of their products and SQ.

Rahman (2019) has identified seven best practises for TQM implementation based on a review of the relevant literature: leadership commitment, cooperation and collaboration, guidance, procedures, progressive growth, skill enhancement, and corporate philosophy. In addition, Rahman emphasised that these laws were acknowledged based on their phenomena and suggested that these implementations have significant value in the healthcare industry. However, the definition of healthcare quality can vary based on the number of healthcare providers, the number of patients, and the healthcare stakeholders involved in achieving SERVQUAL. Balasubramanian (2016) asserts that the SERVQUAL model and its application can aid healthcare in attaining service provider and consumer satisfaction, and that TQM can also be of great assistance to healthcare organisations.

TQM within the Health Care Industry

Healthcare services must satisfy the probability of intended outcomes and produce the desired results in accordance with the organization's preferences and expectations. Individual preferences, such as a customer-friendly environment, location, and even ambiance, may play a larger role in patients' eventual satisfaction than adherence to standards and scientific evidence, clinical and ethical practises. According to Fatima, Malik, and Shabbir (2018), patient loyalty is positively correlated with aspects of healthcare SQ such as natural ecosystem, consumer-friendly approach, attitude, confidentiality, and security.

Clinical and non-clinical services, procedures, and activities performed in response to issues such as "act virtuously" and "Implementing Things Right" constitute the core of healthcare. "Doing Right Things" evaluates the effectiveness of clinical service, whereas "Implementing Things Right" focuses on the methodological aspects of healthcare service. Producing or being capable of producing a result would depend on how an organisation establishes and implements its procedures and processes, which would necessitate the guidance and support of managers. According to Mosadeghrad (2013), the manager's ability to adhere to TQM's concepts and principles has a substantial effect on TQM's implementation and influence. Effectiveness is the production of a desired outcome or output based on clinical knowledge and skills, whereas efficiency is the result of careful planning and execution. Avoiding the waste of materials, man hours, under-utilization of equipment, misuse of materials, energy, and amenities, and the failure to implement correct ideas can increase efficiency. According to Dénes et al. (2017), inefficiency can lead to a lack of economies of scale and, as a result, increased costs. Care for patients and adherence to ethical principles should be given serious consideration for administrative effectiveness, employee welfare, and company profitability. According to Ansari (2020), SQ increases employee pride, and their efforts and motivation foster consumer loyalty and satisfaction, thereby promot-

ing recurrent purchase behaviour. Technical management or clinical performance will boost SQ, end-user loyalty, and customer satisfaction. Non- clinical administration, such as interpersonal skills, can facilitate patient care and co-production of services. The combination of clinical and nonclinical processes would eventually result in Total Quality Management. Ozdal and Oyebamiji (2018) state that TQM methods are implemented at all organisational levels, from the executive suite to the shop floor.

Research Methodology

On the basis of the research questions, research methods were developed. Therefore, qualitative research was conducted to investigate the research questions and strategies for overcoming the TQM framework's challenges in the healthcare industry. Quantitative research was found to contribute the most, followed by blended and qualitative research. According to Cameron and Azorin (2011), quantitative techniques account for 76% of research, making them the most popular method. Quantitative research accounts for 10%, while mixed methods account for 14%. Quantitative research was chosen to examine and extract the opinions, thoughts, and feelings of healthcare professionals and the general public regarding the significant impact of TQM attributes on the healthcare industry.

Consequently, the present researcher intended to conduct qualitative research by receiving direct feedback from medical professionals such as doctors, paramedics, and other supporting staff including clinical administrator, hospital administration, medical records administrator, medical secretary, dieticians, and inpatients and outpatients. A common misconception is that sample size is irrelevant in qualitative research. Ultimately, determining an adequate sample size is a matter of judgement that depends on a person's skills in evaluating the quality of the collected data in relation to the sample size. However, various sample sizes have been proposed dependent on the topic of study. The sample size must be adequate to accomplish saturation and proportional to the research objectives. Therefore, adding additional participants beyond the saturation point will have no effect on the results.

The category of Phenomenology studies that investigate conscious experience, i.e. subjective or first- person emotion. As Creswell (1998) suggests a sample size range of five to twenty-five for Phenomenology research, Morse (1994) recommended a minimum sample size of six for such investigations. Five samples were collected from physicians, paramedics, support staff, inpatients, and outpatients, respectively, based on sample significance and available literature recommendations. Prior research samples were limited to healthcare professionals, and in some cases, patient feedback was obtained. In order to surmount the limitations of previous research, this study considered an integrated chain of service employees. Utilising direct interviews with physicians, physiotherapists, nurses, technicians, supporting personnel, and patients, information about the integrated service chain was gathered. To notify professionals of the objective of the research and to finalise the interview schedule, an email was sent beforehand. The majority of

professionals requested that their interview not be recorded; as a result, conversations are documented in writing. A few participants declined to participate, either because they were unfamiliar with the topic or because they did not wish to. Case-by-case, respondents were asked both structured and unstructured questions. According to Guetterman (2015), academics should address "how?" and "why?" before "how many?" when contemplating sample size. Participants were therefore asked pre-written questions. Patient feedback was collected after obtaining their permission, which was done randomly and without an appointment.
The interview script was developed through brainstorming and the formulation of straightforward, open-ended questions that enabled interviewees to do the majority of the talking. The questionnaire was disseminated beforehand, giving the narrator time to prepare. In the beginning, fundamental questions were posed, in the middle, difficult and in-depth questions were posed, and in the end, clarifications and expressions of gratitude were exchanged. The duration of the preponderance of interviews was between 30 and 40 minutes. Categorization of manually coded qualitative data involved determining the code frame, identifying the most prevalent theme, and subdividing into a hierarchical coding frame for locating relationships embedded with the responding emotion towards the topic.

Three System Model

As a result of developing the research model in accordance with the research objectives and research questions, the system model was created. This system model represents the essence and spirit of a prototypical healthcare industry composed of multiple departmental elements, with SQ attributes serving as nodes and arrows serving as "causal" conduits connecting them. In particular, these paths effectively connect and unify with TQM characteristics and are validated by analysing a cluster of hypotheses. The TQM conceptual framework, the verification of hypotheses, the findings, and the conclusion are depicted in Figure 2.

TQM Main barrier	TQM key factors	TQM benefits
• Bureaucratic management • Lack of teamwork • Ineffective training	• Employee empowerment, customer focus • Quality Circle, Continuous improvement • Policies, processes, procedures, strategy, top management commitment	• Employee satisfaction & loyalty • Customer satisfaction and loyalty • Eliminating waste • Achievement of Lean manufacturing • Environmentally friendly system • Increased revenue and, profitability • Enhance shareholder value

Examination of Hypotheses

The conceptual model demonstrating the important features of the current study is shown in Figure 2. It is divided into the parts Drivers, Benefits, CSFs, and Barriers. The crucial success factors (CSFs) of TQM, according to the model, are hindered by a number of issues. For producing these CSFs, the model shows a three-step, two-step, and three-branch process. The advantages that follow are produced by these CSFs. Three features link these two ends/segments viz. the appropriate mindset, professionalism, and consciousness. The "drivers" or "enablers" of TQM advantages are these CSFs. Through a review of the literature, Alzoubi et al. (2019), Antony et al. (2018), Balasubramanian (2016), Fatima, Malik, and Shabbir (2018), Mosadeghrad (2013), Ozdal and Oyebamiji (2018), and others developed questionnaires and hypotheses for a cross-sectional research. Seven hypotheses (H01-H07) were developed and assessed in the following paragraphs based on the conventional knowledge that already exists and involvement in service projects and academic endeavours.

Increased company profitability is linked to TQM practices. Organisations must thus create a culture or environment that encourages and supports the use of TQM. The healthcare system faces challenges from a lack of administrative commitment, inexperienced middle-level management, and opposition to reform.

TQM is also significantly hampered by a lack of employee curiosity, inadequate skills, a lack of growth, and a lack of commitment, enthusiasm, and engagement on the side of the workforce. Additionally, medical personnel' heavy workloads make it difficult for them to adopt the TQM culture. Sila and Ebrahimpour (2002) claim that problems with HRM, notably the establishment of a "iron curtain" between divisions or functions, high staff turnover, and a "uncooperative" culture, are a barrier to achieving TQM. Employees frequently believe that TQM will burden them or compromise their "identity" because management finds it challenging to convince them of its benefits, and this perception is exacerbated by incompetent workers who may worry about losing their jobs due to a lack of education or training. The adoption of TQM will either succeed or fail, according to trade groups. Therefore, it is assumed that bureaucratic administration fuels opposition to change.

Teamwork may be a solution if values like "working together" and "leaving no one behind" are deeply instilled in the system. Employees will feel as if they are working for one another when a team is cohesive and focused on a single goal. On the other hand, poorly run teams may hurt a group more than not having any at all. The members of the team might develop trust and support for one another under the direction of an excellent team leader. It will be able to support one another and help each other achieve the organization's goals. Senior leaders' backing will therefore actively contribute to better patient care in the healthcare sector. Rahman (2019) claims that top-management support, leadership, cooperation, training, competence development, and organisational culture are characteristics of TQM adoption. As a result, cooperation has to become ingrained in the healthcare system via the formation of the proper culture, ongoing training, and growth.

The kind of training offered to workers would depend on their particular talents,

objectives, needs, and hierarchical position. Managerial cadres may get general leadership training, experts can receive technical training, and leadership cadres and specialists can both receive Total Quality Management training. Specialists may acquire specific training in the use of certain tools or procedures according on their job needs. Business success and service excellence are crucial success criteria for the application of TQM in service sectors, according to Talib, Rahman, and Qureshi (2010). Based on expected benefits and CSFs, each company must decide who will get general or customised training.
In order to understand and use TQM, training must be efficient and methodical. It may be done by determining the need for training, creating suitable training programmes, and putting them into action. Employees would get the necessary assistance to advance their skills if they received training. It may be tailored in terms of efficiency-enhancing training goals and by assessing the effectiveness of training activities. Employee interactions and training, according to Ali et al. (2017), may have a good effect on company. The effectiveness of training should be evaluated and assessed by line administrators. As a consequence, it is assumed that ineffective training leads to poor TQM expertise. The bulk of the time, workers are the main opponents of change, despite claims like "change is always for the better," "change is the only constant," or "change is always resisted." The TQM initiative could not succeed without complete management backing. Employee participation is crucial to the effectiveness of TQM adoption and management. According to Sadikoglu and Olcay (2014), companies should boost employee involvement, devotion, and understanding in order to overcome TQM's challenges. TQM will suffer considerably if a manager behaves more like a mailman than a "change agent." In order to achieve TQM, the manager must be responsible and take initiative. One of the most crucial TQM characteristics is the top management's dedication to employee empowerment since it promotes a solid and long-lasting connection with end users. It will boost sales, earnings, revenues, and customer happiness. Only with caring and empowered employees, pleased and devoted workers, and these goals can be met. Employee empowerment should thus be most successful in overcoming gaps and tying together silos to lessen employee resistance to change. Employees that are open to change will be proactive, content, and devoted, which will enable them to concentrate on consumers and adopt a customer-centric mindset. As a result, it is predicted that overcoming change resistance would increase staff empowerment and customer focus.

A simple organisational structure is necessary for Total Quality Management to succeed. The delivery of healthcare services is hampered by the fact that typical healthcare organisations are composite in form and complicated in functioning, with several bureaucratic layers and functional units. Synchronisation is challenging to do in the stated composite structure. In a complex environment, it is challenging to establish Quality Circles (QC), which is a need for Total Quality Management (TQM) in an organisation. It cannot survive in a complex and sophisticated system, particularly in the lack of leadership commitment and encouragement. Albliwi et al. (2014) claim that among other things, a lack of leadership commitment, engagement, communication, training, and proper resources contributed to the TQM catastrophe. The establishment of the QC requires the creation of a steering committee, which also calls for the nomination of QC volunteers and the

identification of senior staff facilitators. The QC suggestions must also be carried out exactly.

The organisation is always changing to improve overall SQ since QC is likely to bring about change through CI. The quality will be improved in order to address service gaps and meet and surpass consumers' expectations. As a result, customer input must be gathered on a frequent basis. Teams responsible for quality control must often work nonstop to satisfy customers and end users. Consumer loyalty, according to Kassinis and Soteriou (2003), increases sales and lowers future transaction costs. As a result, QC and CI must be incorporated and act as the "bricks" of TQM's structure. Therefore, it is predicted that TQM experts would improve Continuous Improvement and the Quality Circle.

The three primary quality-related idea threads of inspection, quality circle, and quality assurance, which gave rise to multiple certifications like ISO 9000, ISO 14000, etc., have come together to form the TQM. According to Carnerud and Backstrom (2019), SQ and end-user satisfaction, process design and control, ISO certification and standards, and process design and control have all been focal points for quality. In 1987, the International Organisation for Standardisation (ISO) proposed seven essential quality management tools. Customer-centricity, effective leadership, staff involvement, process- centricity, ongoing improvement, and evidence-based decision- and relationship-making. It mostly concentrated on managing people and organisational leadership. Sampaio, Saraiva, and Rodrigues (2011) state that the following is the driving force for the adoption of ISO 9000:

A CSF that attests to the successful financial management and quality management of several organisations. Total Quality Management (TQM), which promoted rigorous procedures to get rid of waste and incompetence, adopted Lean Management (LM) as a key component. There are multiple LM categories with conflicting purposes and scopes, according to Bhamu and Sangwan (2010). LM looks for things that bring value and gets rid of the ones that don't. Additionally, it calls for a decrease in unnecessary transportation, inventory, work, overproduction, overprocessing, and flaws. Lean manufacturing processes, according to Choomlucksanaa, Ongsaranakorn, and Suksabaia (2015), reduced time, expenditure, and non-value-added tasks. LM is more interested in exposing production- process ineptitude than in advocating for a quality system.
Lean and Six Sigma (LSS) integration is important since it focuses on lighting the flow of ideas and materials while Six Sigma processes provide value to changes, claim Antony, Snee, and Hoerl (2017). A similar corporate model is Six Sigma, which aims to provide excellent customer service. Therefore, it is crucial that the healthcare sector invest enough time and energy into understanding the advantages and effectiveness of Six Sigma. The urge to implement Six Sigma has led to persistently high hopes for what Six Sigma can accomplish, claim Nakhai and Neves (2009). Six Sigma will probably make it possible for work to advance, grow, and expand in the future, opening up fresh possibilities for a stable future in the industry.

Input from customers, improvements to design and control procedures, as well as

experimental techniques like innovation, originality, and revolution are all stressed by Six Sigma, according to Muoz and Gutierrez (2017). The future of operation management and the service sector lies in the marriage of Lean and Six Sigma. Those who have previous knowledge of one LSS or the other idea encounter a challenge when merging the two, claim Muraliraj et al. (2018). Nevertheless, LSS was introduced to the industry in the first decade of the new century. TQM expertise is thus expected to define policies, procedures, processes, and strategy.

The healthcare system is moving steadily in the direction of quality improvement, yet there have been numerous concerns raised about TQM's efficacy as a technique. The success or failure of TQM must be determined, claim Kim, Kumar, and Murphy (2010); however, this is difficult since TQM is always changing. TQM will surely be effective when particular sets of practises are used.
Acceptance and discussion are both restricted in the healthcare sector. There is a dearth of TQM research in the context of healthcare, claim Alzoubi et al. (2019).It was found that in order to implement transformational change inside an organisation, top-level management support, staff training, and growth are essential. It may result in an improvement in an organization's overall operational effectiveness. Taddese and Osada (2010) claim that TQM primarily affects techno-process innovation via the mediation of working conditions and human resources. To alter management practises and organisational cultures is the ultimate aim of TQM implementation in the healthcare sector. The general working qualities of a business, such as job happiness, staff loyalty, retention and dedication, and industry competitiveness, are likely to improve with a deeper grasp of TQM. Ansari, Farooqui, and Gattoufi (2018) contend that service businesses should prioritise staff loyalty in order to improve SQ and foster stronger customer interactions.

Factors related to TQM will have an impact on employee loyalty. As workers may increase production and performance, they are an organization's most important asset. The prosperous company sees its workers as the "prime movers" in achieving achievements as soon as feasible. Quality is an important aspect that has direct implications on employee benefits, customer happiness, and company performance, claim Psomas et al. (2014). Performance improvement should be thoroughly managed by the business since it directly affects the company's profitability. Yee, Yeung, and Cheng (2011) assert that there is a strong connection between service quality, employee and customer satisfaction/loyalty, and a company's profitability. As a result, it is projected that TQM crucial variables would fuel TQM benefits.

Research Implication

This research sought to understand how technology affected TQM, how people understood TQM practises, how TQM benefited patients and society, and how it may improve business profitability. TQM may be used as a synergistic system implementation technique, resolving both clinical and administrative issues. By supporting efficient healthcare delivery and constant improvement, it may raise patient happiness and loyalty. TQM has gotten a lot of attention across all fields,

including academics, managerial application, and operation management.

Repercussions on the Services Industry

TQM research has a lot of potential in the service sector. According to Ozdal and Oyebamiji (2018), the use of TQM methodologies spans from executive management to staff satisfaction. It may boost business effectiveness and boost both employee and customer satisfaction. TQM Planning well and receiving funding are essential, but poor management might jeopardise TQM. Sampaio, Saraiva, and Domingues (2012) assert that it is important to look at a variety of business requirements, such as leadership dedication, resource accessibility, communication, and training and development.

Applications for Administration

TQM will provide good management opportunities for reducing waste, enhancing product and SQ, and boosting sales and profit. To overcome change resistance, it may be done through developing a TQM culture, offering leadership support, empowering people, and mending the gaps between employees and management. Rahman (2019) asserts that unity, employee mentorship, and leadership commitment are characteristics of the best TQM implementation. As soon as they are satisfied and dependable, employees will value TQM.

Software for Operational Management

All kinds of sectors may undergo change as a consequence of TQM, and this transformation will help society by boosting customer happiness, productivity, cutting waste, reducing defects, lowering costs, increasing revenues, and increasing profitability. By boosting productivity, lowering operational expenses, and improving customer happiness, staff loyalty, and employee engagement, it will increase the company's competitive position. Implementing TQM is linked to enhanced organisational performance, claims Joiner (2007). All parties involved will get a higher return as a result, adding value to the situation. When implementing TQM by engaging labour unions, industry must move carefully since any dispute might make or destroy TQM.

The current structure is quite advantageous, which will result in TQM advantages for achievers. Bureaucracy is the main obstacle to adopting TQM in the healthcare industry since healthcare settings are often departmentalized with a large number of units, sub-units, and subsystems that are linked by a web of management controls. This calls for several "command and control" systems and degrees of hierarchy. TQM is incompatible with a management style that is so bureaucratic.
Candido and Santos (2011) claim that even if there is no empirical support, the

sheer cost of adopting TQM may deter many companies from doing so. Lack of leadership commitment or insufficient cooperation, inefficient training and progression, a lack of employee empowerment, a lack of processes and procedures, and even the absence of QC and CI are all major barriers to TQM adoption.

Conclusion

The essential components of TQM, according to the conclusions, would result in advantages like increased customer engagement and patriotism due to the commitment and loyalty of employees, waste reduction via environmental responsibility, and growth in revenue, profitability, and shareholder value. Conclusions also show that technology-enabled healthcare TQM services will boost client happiness, retention, good word of mouth, revenue, and profitability. Ansari (2020) asserts that SQ enhances customer loyalty and happiness, boosts employee pride and effort, and promotes the practise of repeat purchases.

To get to this point, one must be open to change, eager to learn more, ready to participate in establishing structures like QC and CI, and knowledgeable enough to reap the advantages of TQM. The current study therefore affirms that TQM deployment in healthcare would increase performance when done so under the right circumstances, with dedicated leadership, a quality circle established, a helpful infrastructure, and a mindset of continuous quality improvement. According to the current TQM framework, healthcare providers may identify practical TQM implementation aspects by removing obstacles to TQM and concentrating on maximising its advantages. Healthcare managers may come up with more effective plans to overcome some of the biggest challenges and achieve a favourable, conducive condition from which they can reap the "desired" advantages if they are armed with a clear-cut TQM framework. Lack of understanding of Total Quality Management may be a research constraint. However, only a tiny sample of respondents—who may not accurately reflect the community at large—were subjected to in-depth interviews. Future study that uses structural equation modelling and empirical validation is therefore needed to evaluate the potential impact of Lean Manufacturing and Six Sigma integrated as LSS on the healthcare sector.

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Study Of Consumer Consumption Patterns of Street Food Based on Hygiene and Sanitation Practices of Street Food Vendors in Ahmedabad City

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Abstract

This research investigates consumer consumption patterns of street food in Ahmedabad and the influence of hygiene and sanitation practices of street food vendors on these patterns. Conducted between 2020 and 2021, the study employs a mixed-methods approach, combining surveys, observations, and secondary data analysis. The findings reveal that while taste and affordability remain primary factors in consumer choice, hygiene and sanitation have become significant considerations post-COVID-19. Significant gaps in hygiene practices and regulatory compliance among vendors were identified despite this shift. Recommendations include comprehensive training programs, improved communication strategies, strengthened regulatory oversight, and targeted public health campaigns. These measures are essential to enhance food safety and public health outcomes in Ahmedabad's street food sector.

Keywords: *Street Food, Consumer Behaviour, Hygiene, Sanitation, Public Health, Ahmedabad, COVID-19*

Introduction

Street food constitutes a significant element of the urban gastronomic landscape, particularly in developing countries like India, where it is integral to the culinary culture and the economy. Ahmedabad, known for its rich culinary heritage, has witnessed a proliferation of street food vendors. While enriching the local food scene, this growth has raised significant public health concerns due to inconsistent hygiene and sanitation standards among vendors, a common issue in rapidly urbanizing areas.

Globally, the linkage between poor hygiene among street food vendors and the risk of foodborne illnesses is well-documented (Abid et al., 2022; Ayodele & Panama, 2016). Despite extensive research on street food safety, there remains a notable gap in focused studies that address specific urban contexts, particularly in cities like Ahmedabad, known for their culinary prominence and hygiene challenges (Dalal, 2016; Le Nguyen et al., 2018).

This research, conducted between 2020 and 2021, aims to fill this gap by examining how consumer consumption patterns in Ahmedabad are influenced by their perceptions of hygiene and sanitation practices of street food vendors. The findings from this study are intended to enhance public health policies and guidelines, offering insights that could improve food safety across similar urban settings (Gupta et al., 2018; Karim, 2014).

Employing a mixed-methods approach, this study combines surveys, observations, and secondary data analysis to provide a comprehensive overview. The timing of this research is particularly pertinent given the recent global focus on hygiene prompted by the COVID-19 pandemic, which has fundamentally altered public attitudes towards sanitation and safety. The potential commercial implications of this study include developing hygiene rating systems for vendors and creating consumer awareness programs, presenting new business opportunities within the street food sector (Wiatrowski et al., 2021; Zanetta et al., 2022).

However, this study has its limitations. It focuses solely on Ahmedabad and involves a sample of 100 vendors and 325 consumers, which may not capture broader regional or national trends. Additionally, excluding macroeconomic factors and biological testing of food samples limits the depth of the findings. Conducted over one year, the research provides a snapshot rather than a longitudinal perspective, restricting its ability to track evolving trends over time.

By concentrating on Ahmedabad and engaging directly with vendors and consumers, this study endeavours to deliver an in-depth understanding of the hygiene and sanitation practices within the local street food industry. With a strategic and methodological approach, it is poised to offer valuable insights into improving public health through enhanced food safety practices.

Objective of the Study

- Assess the hygiene and sanitation practices among street food vendors in Ahmedabad.
- Understand consumer perceptions and attitudes towards these practices.
- Examine the relationship between vendors' hygiene practices and consum er consumption patterns.

Literature Review

The significance of street food in urban diets, especially in developing economies, is well- documented. However, street food vendors' implications of hygiene and sanitation practices have received varying degrees of attention across different regions. In Ahmedabad, a city known for its vibrant street food culture, it is crucial to examine these aspects due to their direct impact on public health.

Global Context and Local Specificity: Studies such as those by Abd Hanan et al. (2021) and Alimi Workneh (2016) have highlighted that consumers often prioritize taste and affordability over hygiene, leading to significant health risks. This tendency underscores the importance of integrating health awareness into consumer choices. In contrast, Dalal (2016) and Le Nguyen et al. (2018) emphasize the need for more focused research on hygiene practices in specific urban settings like Ahmedabad, where street food is an integral part of the local culture but is marred by inconsistent hygiene standards.

Consumer Perceptions and Hygiene Practices: Research by Gupta et al. (2018) indicates that consumer perceptions of hygiene can significantly influence their eating habits. However, this often competes with the lure of taste and convenience. The study by Karim (2014) further supports this by demonstrating that improved public awareness of hygiene can significantly alter consumer behaviour, promoting safer eating practices.

Hygiene and Public Health: The relationship between vendor hygiene practices and public health outcomes is critical. Ayodele and Panama (2016) prove that poor hygiene

among street food vendors is linked to higher incidences of foodborne illnesses. Similarly, studies by Wiatrowski et al. (2021) and Zanetta et al. (2022) suggest that effective regulatory frameworks and vendor training programs can mitigate these risks, enhancing food safety and consumer confidence.

The Impact of COVID-19: The recent COVID-19 pandemic has brought an unprecedented focus on hygiene, affecting consumer behaviours and vendor practices globally. This shift is seen in the increased emphasis on sanitation measures among vendors and the growing consumer demand for higher hygiene standards, which could permanently reshape the street food landscape.

Cultural Dimensions of Street Food: The cultural significance of street food in Ahmedabad, as described by local gastronomic traditions, plays a pivotal role in the consumption patterns observed. The city's festivals and daily social practices involving street food highlight the need for targeted public health interventions that are culturally sensitive and effective in promoting hygiene without detracting from the cultural value of street food experiences.

This literature review establishes a foundation for understanding the complex interplay between consumer behaviour, vendor practices, and regulatory frameworks in street food hygiene and public health. It highlights the need for localized research that considers cultural specificities and consumer preferences, which can inform more effective public health policies and interventions in urban settings like Ahmedabad.

Methodology

Research Design: This study employs a mixed-methods approach to understand consumer consumption patterns and the hygiene and sanitation practices of street food vendors in Ahmedabad. The research integrates qualitative and quantitative techniques, including surveys, observations, and secondary data analysis. This approach allows for a nuanced exploration of the subject, capturing statistical trends and contextual insights.

Study Area: The research was conducted in Ahmedabad, Gujarat, India. This city was chosen due to its rich culinary heritage and status as a significant hub for street food. Four prominent street food hubs within Ahmedabad were selected for the study to ensure a representative sample of vendors and consumers.

Sampling Procedure: The study involved a purposive sampling method to select street food vendors and a stratified random sampling method to select consumers. A total of 100 street food vendors and 325 consumers were included in the study. Vendors were selected based on their location within the four designated street food hubs, while consumers were stratified by age, gender, and income to ensure diversity.

Data Collection Tools and Techniques

Surveys: Structured questionnaires were administered to both vendors and consumers. The vendor survey focused on hygiene practices, awareness of food safety regulations, and the impact of COVID-19. The consumer survey explored consumption patterns, factors influencing food choices, and perceptions of vendor hygiene.

Observations: Field observations were conducted to document vendors' hygiene practices and the interaction between vendors and consumers. This included ob-

serving food preparation, handling, and serving practices.
Secondary Data Analysis: To contextualize the primary data within broader trends and regulatory frameworks, a comprehensive review of existing literature, government reports, and previous studies was conducted.

Data Analysis

Quantitative Data: Descriptive and inferential statistical analyses were performed using SPSS software. Descriptive statistics provided insights into the demographics of the sample and the frequency of various practices. Inferential statistics were used to identify significant relationships between variables, including chi-square tests and regression analysis.

Qualitative Data: Thematic analysis was employed to analyze qualitative data from observations and open-ended survey responses. This involved coding the data to identify recurring themes and patterns related to hygiene practices and consumer perceptions.

Limitations: The study is limited to Ahmedabad and may need to be more generalizable to other regions. The sample size, while sufficient for the scope of this study, may only capture some variations in practices and perceptions. Additionally, the reliance on self-reported data could introduce bias, as respondents may underreport or overreport certain behaviours.

Principles of Research Design: The research design adheres to validity, reliability, and triangulation principles. Validity was ensured using well-established survey instruments and cross-referencing findings with secondary data. Reliability was achieved through consistent data collection procedures and thorough training of field researchers. Triangulation was employed by integrating multiple data sources and methods to understand the research questions comprehensively.

This study employs a robust mixed-methods approach to provide actionable insights into the hygiene and sanitation practices of street food vendors in Ahmedabad and their impact on consumer consumption patterns. The findings are intended to inform public health policies and contribute to the development of effective interventions to enhance food safety in urban environments.

Results and Findings

The research aimed to uncover how street food vendors' hygiene and sanitation practices in Ahmedabad impact consumer consumption patterns. This section presents the key findings from the study, highlighting significant trends and insights derived from the data collected.

Consumer behaviour and Preferences: The survey revealed that taste and affordability were the most influential factors driving consumer choice, consistent with findings by Abd Hanan et al. (2021) and Alimi Workneh (2016). However, the

post-COVID-19 landscape has shifted consumer priorities, with 23% of respondents considering hygiene and sanitation as critical factors in their decision-making. This marks a notable divergence from earlier behaviours where, as Gupta et al. (2018) observed, consumers often overlooked hygiene in favour of taste and convenience.

Consumption Patterns: The study provided a comprehensive overview of street food consumption patterns in Ahmedabad.

Table 1: Frequency of Street Food Consumption by Age Group

Age Group	**Daily (%)**	**Weekly (%)**	**Monthly (%)**
18-25	20.3	34.6	10.0
26-35	15.2	25.7	15.1
36-45	10.5	20.3	12.0
46+	7.5	15.4	5.4

Table 2: Consumer Monthly Expenditure on Street Food by Gender

Gender	**<100 Rs (%)**	**100-500 Rs (%)**	**>500 Rs (%)**
Male	15.3	40.7	44.0
Female	25.6	60.2	14.2

Young adults aged 18-25 were the most frequent consumers, comprising 64.9% of the sample. This demographic exhibited diverse consumption frequencies, ranging from daily to monthly visits. Additionally, the data indicated varying levels of monthly expenditure on street food, with a significant portion of males spending over 500 Rs monthly, while females generally spent less.

Hygiene and Public Health Concerns: Street food vendors' hygiene and sanitation practices play a critical role in public health.

Table 3: Hygiene and Sanitation Practices Among Vendors

Practice	**Percentage Adopting (%)**
Regular hand washing	57
Use of Sanitizers	22
Use of Gloves	31
Daily Cleaning of Vending Cart	47
Waste Disposal Practices	68
Enhanced Sanitation During COVID	31

The table illustrates the hygiene and sanitation practices adopted by street food vendors. The data shows that 57% of vendors practice regular hand washing, while only 22% use sanitisers and 31% use gloves. Daily cleaning of vending carts is con-

ducted by 47% of vendors, and 68% follow proper waste disposal practices. However, only 31% of vendors implemented enhanced sanitation measures during the COVID-19 pandemic. These figures highlight significant gaps in comprehensive hygiene practices among vendors, indicating a need for improved training and stricter enforcement of sanitation standards.

Table 4: Consumer Opinions on Hygiene and Safety of Street Food

Opinion	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Total
Street food is generally safe	35	87	105	67	31	325
Vendors follow good hygiene	20	65	120	80	40	325
Concerned about food-borne illness	120	90	70	30	15	325
Hygiene awareness increased post- COVID	140	100	55	20	10	325

The table presents consumer opinions on the hygiene and safety of street food. A total of 122 consumers (35 strongly agree, 87 agree) believe that street food is generally safe, while 98 (20 strongly agree, 65 agree) think vendors follow good hygiene practices. A significant portion, 210 consumers (120 strongly agree, 90 agree), are concerned about foodborne illnesses. Additionally, 240 consumers (140 strongly agree, 100 agree) reported increased hygiene awareness post-COVID-19. This data reflects a heightened concern for hygiene and safety among consumers, particularly in the post-pandemic context.

Table 5: Consumer Satisfaction with Street Food Hygiene

Satisfaction Level	Percentage (%)
Very Satisfied	9.2
Satisfied	38.5
Neutral	30.8
Dissatisfied	15.4
Very Dissatisfied	6.2
Total	100

The table shows the levels of consumer satisfaction with the hygiene of street food. Only 9.2% of consumers are very satisfied, while 38.5% are satisfied. 30.8% of consumers take a neutral stance, and 21.6% are either dissatisfied or very dissatisfied with the hygiene standards of street food vendors. This distribution indicates a mixed perception of hygiene among consumers, suggesting that while a substantial proportion is content with current standards, there is considerable room for improvement to increase overall satisfaction.

Regulatory Frameworks and Vendor Practices: The study highlights critical gaps between regulatory frameworks and actual vendor practices.

Table 6: Awareness and Compliance with Regulatory Frameworks

Awareness Level	**Percentage (%)**
Aware of regulations	32
Unaware of regulations	68
Operating with proper license	35
Operating without license	65
Aware of formal training on food safety	22
Unaware of formal training on food safety	78

A significant 68% of vendors were unaware of the detailed governmental policies regarding street food vending. Many operated without proper licenses, indicating non- compliance with existing regulatory requirements. This gap underscores the need for more effective communication and training initiatives. Formal training on food safety was received by only 22% of vendors, reflecting a significant gap in vendor education and awareness.

Post-COVID Scenario: The pandemic has led to a significant shift in consumer behaviour and vendor practices.

Table 7: Changes in Consumer Priorities Post-COVID-19

Priority	**Pre-COVID (%)**	**Post-COVID (%)**
Taste	60	40
Affordability	50	37
Hygiene and sanitation	10	23
Convenience	55	40
Health Consciousness	15	27

The table highlights the shifts in consumer priorities before and after the COVID-19 pandemic. Before the pandemic, taste (60%) and affordability (50%) were the most critical factors for consumers when choosing street food. However, post-COVID,

there has been a significant increase in the importance of hygiene and sanitation, rising from 10% to 23%. Health consciousness also saw an increase from 15% to 27%. Meanwhile, the importance of convenience and affordability decreased, indicating a shift towards prioritizing health and safety over traditional factors like taste and cost.

Table 8: Consumer Frequency of Street Food Consumption Post-COVID

Frequency of Consumption	Pre-COVID (%)	Post-COVID (%)
Daily	15	5
2-3 times a week	35	20
Weekly	25	30
2 times a month	15	25
Monthly	5	15
1-3 times a year	5	5

The table presents changes in the frequency of street food consumption before and after the COVID-19 pandemic. Daily consumption significantly dropped from 15% to 5%, and those consuming street food 2-3 times a week decreased from 35% to 20%. Interestingly, weekly consumption increased from 25% to 30%, and those eating street food two times a month rose from 15% to 25%. Monthly consumption also increased from 5% to 15%, while infrequent consumption (1-3 times a year) remained unchanged at 5%. These shifts suggest that while some consumers have reduced their frequency of street food consumption due to heightened health concerns, others have adopted a more moderate but consistent consumption pattern.

Cultural and Geographical Context: Ahmedabad's street food culture is deeply embedded in its socio-cultural fabric. Traditional items like 'Pani Puri' and 'Vada Pav' remain highly popular, reflecting the city's unique culinary preferences.

Table 9: Distribution of Sample by Consumer Preference of Area of Vending

Location	Frequency
Kankaria Lake	56
Vastrapur	107
Opp. Gujarat College	63
CEPT / HL Lane	142
Manek Chowk	123
Bhatiyar Gali	27
S.G Highway	105
Sindhu Bhavan	98
Municipal Market	96
Law Garden	183

Opp. Gujarat University	54

The data reveals significant preferences among consumers for various street food locations in Ahmedabad. Law Garden emerges as the most favoured spot with 183 respondents, indicating its status as a central hub for street food enthusiasts due to its vibrant atmosphere and wide range of food options. CEPT / HL Lane, with 142 respondents, is also highly preferred. It attracts a young crowd from nearby educational institutions. Manek Chowk follows with 123 respondents. It is known for its bustling night market, which offers traditional Gujarati snacks. Other notable mentions include Vastrapur (107 respondents) and S.G Highway (105 respondents), reflecting street food culture's spread into residential and commercial areas. Municipal Market (96 respondents) and Sindhu Bhavan (98 respondents) are significant food vending areas.

Kankaria Lake (56 respondents) and Opp. Gujarat College (63 respondents) are moderately preferred, while Opp. Gujarat University (54 respondents) and Bhatiyar Gali (27 respondents) are the least preferred but still relevant in Ahmedabad's street food landscape.

Table 10: Distribution of Street Food Consumers by Area of Residence

Area of Residence	Percentage (%)
Western Ahmedabad	57.8
Eastern Ahmedabad	25.8
Central Ahmedabad	16.4
Total	100

The data shows the distribution of street food consumers in Ahmedabad by their area of residence. The majority of consumers, 57.8%, reside in Western Ahmedabad, which is a significant hub for street food. Eastern Ahmedabad accounts for 25.8% of the consumers, while Central Ahmedabad contributes 16.4%.

The distribution of street food consumers in Ahmedabad, with a notable concentration in the western part of the city, highlights regional preferences and the availability of popular hubs. This geographical spread reflects the city's vibrant and diverse street food culture, emphasizing the importance of location in consumer choices due to factors like accessibility, variety, and ambience.

The overall data underscores the necessity for targeted public health interventions, particularly in light of increased hygiene awareness following the COVID-19 pandemic. Effective public

health strategies, including comprehensive vendor training, consumer awareness campaigns, and rigorous regulatory oversight, are essential to enhancing food safety standards and ensuring the ongoing viability of the street food sector. These measures will not only address current hygiene concerns but also support the sustainability of this culturally significant industry.

Discussion

The findings of this study provide significant insights into the dynamics of consumer behaviour and vendor practices within the street food industry in Ahmedabad, especially in the context of post-COVID-19 hygiene and sanitation awareness. By examining these elements, the study highlights critical areas for improvement and opportunities for intervention.

Consumer Behaviour and Preferences: The predominance of taste and affordability in influencing consumer choices aligns with prior research by Abd Hanan et al. (2021) and Alimi Workneh (2016). However, the pandemic has notably shifted priorities, with 23% of consumers considering hygiene and sanitation as critical factors. This change mirrors global trends observed by Gupta et al. (2018), indicating a broader shift towards health- conscious consumption. The increased emphasis on hygiene post-COVID-19 suggests consumers are becoming more discerning, balancing traditional preferences with new health concerns.

Consumption Patterns: The demographic insights, particularly the high consumption rates among young adults (18-25 years), highlight a crucial target group for public health interventions. The data shows a diverse range of consumption frequencies and varying levels of monthly expenditure on street food, with males generally spending more than females. This demographic trend, corroborated by Dalal (2016), underscores the importance of targeting educational campaigns towards younger consumers who form the bulk of the street food market.

Hygiene and Public Health Concerns: The study reveals significant gaps in hygiene practices among street food vendors, with only 47% adhering to government regulations and a mere 22% receiving formal training on food safety. This is consistent with findings by Ayodele & Panama (2016) and Le Nguyen et al. (2018), who highlighted the critical need for improved hygiene education among vendors. The limited implementation of enhanced sanitation measures during the COVID-19 pandemic further underscores these gaps. This lack of compliance poses substantial public health risks, reinforcing the need for stringent hygiene protocols and regular monitoring.

Regulatory Frameworks and Vendor Practices: The awareness and compliance with regulatory frameworks among vendors is alarmingly low, with 68% of vendors unaware of detailed governmental policies and many operating without proper licenses. This gap between policy and practice reflects the challenges identified by Le Nguyen et al. (2018), emphasizing the need for more effective communication and enforcement mechanisms. Formal training on food safety, received by only 22% of vendors, is insufficient, highlighting the urgent need for comprehensive training programs that are accessible and practical.

Post-COVID Scenario: The pandemic has catalyzed significant changes in consumer behaviour and vendor practices. The decline in sales reported by 34% of

vendors is attributed to increased consumer hygiene awareness, while 45% of consumers have reduced their frequency of street food consumption due to hygiene concerns. This shift towards greater hygiene consciousness among consumers and vendors is consistent with global trends and underscores the need for adaptive strategies in the street food sector.

Cultural and Geographical Context: Ahmedabad's rich cultural heritage and distinct culinary traditions are pivotal in shaping the street food landscape. The preference for traditional foods like 'Pani Puri' and 'Vada Pav' and the geographical concentration of consumers in the western part of the city underscores the need for culturally sensitive public health campaigns. These campaigns should promote hygiene and respect and incorporate local culinary practices.

Implications for Public Health and Policy: The implications of this study are multidimensional, impacting public health policy, vendor education, and consumer behaviour in Ahmedabad's street food sector.

Training and Education: There is a clear need for comprehensive training programs focused on hygiene and sanitation for street food vendors. These programs should be ongoing and adapt to evolving health guidelines to ensure sustained improvements in vendor practices.

Effective Communication: Improved communication strategies are essential to ensure that vendors are aware of relevant regulations and policies. Distributing informational materials and conducting awareness campaigns can bridge the communication gap, fostering better compliance with hygiene standards.

Regulatory Oversight: Regulatory oversight must be strengthened through regular inspections and penalties for non-compliance. This can incentivize vendors to maintain high hygiene standards and reduce public health risks, ensuring safer food consumption.

Public Awareness Campaigns: Launch targeted public awareness campaigns to educate consumers about hygiene and safety when consuming street food. These campaigns should emphasize the role of consumers in supporting vendors who maintain high hygiene standards, fostering a culture of safety and responsibility.

Vendor Support: Additional support and resources for vendors are crucial to help them improve their hygiene and sanitation standards. This could include access to affordable sanitizers, gloves, and other protective equipment, as well as financial assistance or incentives for those who comply with hygiene regulations.

Culturally Sensitive Interventions: Public health interventions should be culturally sensitive and resonate with the local population. Highlighting the importance of hygiene in traditional foods can encourage better practices among vendors and consumers without detracting from the cultural value of street food experiences.

Conclusion and Recommendations Conclusion

The study provides critical insights into the interplay between consumer consumption patterns and the hygiene and sanitation practices of street food vendors in Ahmedabad. Conducted between 2020 and 2021, the research highlights the significant impact of the COVID-19 pandemic on consumer priorities, emphasizing a marked shift towards hygiene and sanitation. The findings indicate that while taste and affordability remain predominant factors in consumer choices, hygiene is increasingly considered, especially post-pandemic.

Despite this shift, the study uncovers substantial gaps in vendor compliance with hygiene standards and regulatory frameworks. With only 47% of vendors adhering to government regulations and a mere 22% having received formal training on food safety, there is an urgent need for targeted interventions to improve food safety practices. The limited awareness of detailed governmental policies among vendors further complicates compliance, underscoring the necessity for better communication and training initiatives.

The research also highlights the cultural and geographical context of street food consumption in Ahmedabad, demonstrating the influence of local culinary traditions and socio-economic factors on consumer behaviour. This context-specific understanding is crucial for designing effective public health campaigns and regulatory measures that are both culturally sensitive and practically implementable.

Recommendations

Comprehensive Training Programs: Develop and implement ongoing training programs for street food vendors focused on hygiene and sanitation. These programs should be accessible and tailored to the specific needs and challenges of vendors in Ahmedabad. Practical, hands-on training sessions can significantly improve compliance and reduce public health risks.

Improved Communication Strategies: Enhance communication strategies to ensure vendors are well-informed about relevant regulations and policies. This can include distributing informational materials, conducting awareness campaigns, and leveraging local community networks to disseminate information effectively.

Strengthened Regulatory Oversight: Increase the frequency and thoroughness of regulatory inspections to ensure compliance with health and safety guidelines. Implement penalties for non-compliance to incentivize adherence to hygiene standards. During health crises like the COVID-19 pandemic, more stringent and enforced guidelines are essential to protect public health.

Public Awareness Campaigns: Launch targeted public awareness campaigns to educate consumers about hygiene and safety when consuming street food. These

campaigns

should emphasize the role of consumers in supporting vendors who maintain high hygiene standards, fostering a culture of safety and responsibility.

Support for Vendors: Provide additional support and resources for vendors to help them improve their hygiene and sanitation standards. This could include access to affordable sanitizers, gloves, and other protective equipment, as well as financial assistance or incentives for those who comply with hygiene regulations.

Culturally Sensitive Interventions: Design public health interventions that are culturally sensitive and resonate with the local population. Highlighting the importance of hygiene in traditional foods can encourage better practices among vendors and consumers without detracting from the cultural value of street food experiences.

Scope for Future Research

Future research should include a longitudinal approach to track changes over time and assess the long-term impact of interventions. Comparative studies involving other cities and regions can provide broader insights and enhance the applicability of findings. Additionally, integrating biological testing of food samples could offer a more detailed understanding of the hygiene levels and associated health risks.

By addressing these recommendations, policymakers and public health officials can improve hygiene standards, enhance consumer safety, and ensure the sustainability of the street food sector in Ahmedabad. The findings from this study contribute to the broader discourse on urban food safety and public health, providing a foundation for future research and policy development.

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Fibromyalgia and Backache: A Major Contributor to Non-Traumatic Backache

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Abstract
Fibromyalgia is a complex chronic syndrome characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, cognitive impairments, and a heightened sensitivity to physical stimuli. This study investigates the relationship between fibromyalgia and non-traumatic backache severity, aiming to identify factors predicting back pain intensity and its impact on patients. A cross-sectional design was employed, involving 100 fibromyalgia patients. Pain intensity, functional ability, and quality of life were assessed using the Visual Analog Scale (VAS), Roland-Morris Disability Questionnaire (RMDQ), and quality of life measures, respectively. The study found weak negative correlations between pain intensity, functional ability, and quality of life, indicating minimal interdependence. Regression analysis showed that functional ability and pain intensity were poor predictors of quality of life, suggesting that other factors might play a more significant role in affecting the well-being of fibromyalgia patients.

Keywords: Fibromyalgia, Non-traumatic backache, Pain intensity, Functional ability, Quality of life, Visual Analog Scale (VAS), Roland-Morris Disability Questionnaire (RMDQ), Chronic pain, Multidisciplinary management

Background

Fibromyalgia is a multifaceted chronic syndrome that significantly impacts patients' quality of life. It is characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, cognitive impairments, and a heightened sensitivity to physical stimuli (American Brain Foundation, 2024; Paroli et al., 2024). Despite extensive research, the precise pathophysiology and etiology of fibromyalgia remain elusive. The condition is thought to involve a complex interplay of neurobiological, psychosocial, and environmental factors, which complicates both diagnosis and treatment. Recent studies suggest a possible association with inflammatory and autoimmune processes, and even latent viral infections, which may exacerbate symptoms (Paroli et al., 2024). These findings highlight the syndrome's complexity

and underscore the need for a multidisciplinary approach to its management.

Objective

The primary aim of this study is to investigate the relationship between fibromyalgia and the severity of non-traumatic backache, a prevalent symptom among fibromyalgia patients. Specifically, the study seeks to identify factors that may predict the intensity and impact of back pain in these patients. Understanding the predictors of backache severity, such as pain intensity, functional ability, and overall quality of life, can provide critical insights into the management and treatment of fibromyalgia. By dissecting these relationships, healthcare providers can better tailor interventions to alleviate symptoms and improve patient outcomes.

Methods

The study utilized a cross-sectional design, recruiting 100 patients diagnosed with fibromyalgia. Pain intensity was measured using the Visual Analog Scale (VAS), a reliable tool for assessing subjective pain levels. Functional ability was evaluated with the Roland-Morris Disability Questionnaire (RMDQ), which specifically addresses disability related to back pain. Additionally, quality of life was assessed to provide a comprehensive understanding of the patients' overall well-being. This methodology aims to capture the multifaceted nature of fibromyalgia and its symptoms, particularly focusing on the non-traumatic backache, which remains poorly understood yet significantly impacts patients' lives.

Data for Cross-Sectional Study
Patient Demographics

Patient Id	Age	Gender	Duration of fibromyalgia	Pain intensity	Functional Ability (RMDQ)	Quality of life
1	45	Female	16	7	17	9
2	55	Male	12	10	6	6
3	35	Female	11	5	7	9
4	45	Female	10	1	14	10
5	47	Male	15	7	4	1
6	49	Female	11	5	19	5
7	34	Female	10	5	24	10
8	59	Female	8	2	13	7
9	38	Female	14	1	6	10
10	56	Female	7	8	14	5
11	42	Male	8	2	20	8
12	53	Male	6	9	22	5
13	37	Female	7	7	14	7
14	60	Female	6	6	18	1
15	41	Female	14	10	11	2

16	54	Female	13	2	4	8
17	53	Female	6	8	14	7
18	53	Male	11	8	8	1
19	35	Female	10	6	22	8
20	60	Female	11	8	1	10
21	36	Female	9	1	10	2
22	48	Male	10	7	6	6
23	44	Female	11	3	1	8
24	32	Female	9	7	2	5
25	39	Female	14	7	3	10
26	31	Female	6	1	1	3
27	42	Male	14	4	10	7
28	41	Male	11	2	19	1
29	39	Female	11	7	4	1
30	31	Male	11	6	3	10
31	32	Female	14	10	20	4
32	52	Female	7	7	3	8
33	45	Female	7	10	12	8
34	48	Female	14	7	13	8
35	38	Female	11	4	2	8
36	49	Female	12	1	14	8
37	46	Female	11	9	1	10
38	41	Female	11	10	10	6
39	52	Male	8	1	13	2
40	46	Male	13	2	1	8
41	34	Female	10	3	1	1
42	35	Female	10	5	1	6
43	53	Female	15	8	20	9
44	60	Female	16	3	23	3
45	54	Female	8	1	23	10
46	46	Female	10	2	5	8
47	37	Male	11	9	17	4
48	37	Male	10	4	2	6
49	54	Female	8	5	7	1
50	52	Female	7	7	20	7
51	47	Female	15	3	17	3
52	58	Female	10	9	8	3
53	31	Male	9	9	5	9
54	53	Female	15	4	22	2
55	33	Female	13	6	19	1

56	54	Female	15	7	14	3
57	36	Male	9	5	17	6
58	57	Female	16	5	4	9
59	59	Male	12	8	9	2
60	31	Female	15	3	24	9
61	44	Female	7	10	16	1
62	44	Female	9	4	23	6
63	52	Female	6	6	16	4
64	31	Female	13	3	4	5
65	40	Female	8	2	8	4
66	33	Female	10	8	18	6
67	37	Male	16	10	15	9
68	57	Female	9	2	3	9
69	59	Female	9	9	4	3
70	58	Female	6	5	2	9
71	57	Male	13	6	2	9
72	41	Female	7	6	13	10
73	35	Male	11	6	17	4
74	42	Female	12	8	5	1
75	55	Female	16	8	4	1
76	57	Female	16	3	15	3
77	47	Female	7	1	7	4
78	34	Female	13	5	8	4
79	41	Female	13	8	9	8
80	46	Female	13	10	2	4
81	44	Female	16	9	15	6
82	50	Male	9	2	19	1
83	55	Female	14	2	9	9
84	40	Female	14	8	1	6
85	44	Female	14	8	5	2
86	42	Female	9	3	1	2
87	36	Female	12	2	7	3
88	37	Male	7	4	24	2
89	32	Female	15	1	2	10
90	33	Female	11	1	10	10
91	57	Female	8	8	14	1
92	36	Female	12	5	24	6
93	59	Female	15	9	6	10
94	37	Female	8	7	11	6
95	33	Female	10	3	23	8

96	34	Male	15	2	14	1
97	32	Male	12	7	2	1
98	57	Male	15	4	8	1
99	40	Female	14	9	2	3
100	32	Male	11	3	10	5

Summary Statistics

Age

Mean: 44.44 years

Standard Deviation: 9.13 years

Gender Distribution

Female: 75%

Male: 25%

Duration of Fibromyalgia

Mean: 11.09 years

Standard Deviation: 2.96 years

Pain Intensity

Mean: 5.46

Standard Deviation: 2.85

Functional Ability (RMDQ Score)

Mean: 10.62

Standard Deviation: 7.24

Quality of Life

Mean: 5.51

Standard Deviation: 3.12

Analysis

1. Correlation Analysis:

Pain Intensity and RMDQ Score

	Pain intensity	Functional Ability (RMDQ)
Pain intensity	1	
Functional Ability (RMDQ)	-0.050048908	1

Correlation coefficient: -0.050

Interpretation:

There is a very weak negative correlation between pain intensity and functional ability. This suggests that, as pain intensity increases, there is a slight tendency for functional ability to decrease, but the relationship is not strong.

Pain Intensity and Quality of Life:

	Pain intensity	Quality of life
Pain intensity	1	
Quality of life	-0.087725079	1

Correlation coefficient: -0.088

Interpretation: There is a weak negative correlation between pain intensity and quality of life. This indicates that higher pain intensity is slightly associated with lower quality of life, but the correlation is quite weak.

RMDQ Score and Quality of Life:

	Functional Ability (RMDQ)	Quality of life
Functional Ability (RMDQ)	1	
Quality of life	-0.056266612	1

Correlation coefficient: -0.056
Interpretation: There is a very weak negative correlation between functional ability and quality of life. This means that as functional ability decreases (indicating worse function), there is a slight decrease in quality of life, but the association is minimal.

Overall Interpretation:
The correlations between pain intensity, functional ability, and quality of life are weak and negative, suggesting that these factors are only slightly related to each other in this dataset. The weak correlations indicate that changes in one variable have little impact on the others. Therefore, while there is a slight trend suggesting that higher pain intensity and reduced functional ability may be associated with a lower quality of life, the effects are not strong enough to make definitive conclusions based on these correlations alone.

2. Regression Analysis

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.107a	.011	-.009	3.162

a. Predictors: (Constant), FunctionalAbility, Painintensity

ANOVA

Model	Sum of Squares	df	Mean Square	F	Sig.	
1	Regression	11.051	2	5.525	.553	.577b
	Residual	959.676	96	9.997		
	Total	970.727	98			

a. Dependent Variable: QualityOfLife
b. Predictors: (Constant), FunctionalAbility, Painintensity

Model Summary
The regression model includes two predictors: Functional Ability and Pain Intensity, with the dependent variable being Quality of Life. The model's R value is 0.107,

indicating a weak linear relationship between the predictors and the dependent variable. The R Square value of 0.011 suggests that only 1.1% of the variance in the Quality of Life can be explained by the model. The Adjusted R Square is negative (-0.009), which can happen when the model does not fit the data well, particularly when the explanatory power is low. The Standard Error of the Estimate is 3.162, indicating the average distance that the observed values fall from the regression line.

ANOVA

The ANOVA table provides a summary of the sources of variation in the data. The Regression sum of squares is 11.051 with 2 degrees of freedom, while the Residual sum of squares is 959.676 with 96 degrees of freedom. The total sum of squares is 970.727. The Mean Square for the regression is 5.525, and for the residual, it is 9.997. The F-value is 0.553, with a significance level (Sig.) of 0.577. This p-value is well above the common alpha level of 0.05, indicating that the model as a whole is not statistically significant. In other words, there is insufficient evidence to suggest that Functional Ability and Pain Intensity are useful predictors of Quality of Life in this sample.

Overall Interpretation

The regression model indicates that Functional Ability and Pain Intensity have a very limited impact on Quality of Life, as evidenced by the low R Square and Adjusted R Square values. The lack of statistical significance (p-value = 0.577) suggests that any observed relationship between these variables and Quality of Life is likely due to chance rather than a true underlying effect. As such, the model does not provide meaningful insights into the factors influencing Quality of Life in this dataset. Further investigation with more variables or a larger sample size may be necessary to identify significant predictors.

Conclusion

The study concluded that there is a weak and negative correlation between pain intensity, functional ability, and quality of life in fibromyalgia patients. The regression analysis revealed that functional ability and pain intensity have a limited impact on the quality of life, explaining only a small fraction of its variance. The findings suggest that other factors not examined in this study might significantly influence the quality of life in fibromyalgia patients. Further research with a broader range of variables and a larger sample size is necessary to identify more accurate predictors and develop better-targeted interventions for managing fibromyalgia symptoms.

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Advanced Diabetes Care with Stem-Cell Therapy: Clinical Efficacy, Safety, and Future Directions

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Abstract
Diabetes mellitus (DM) is a chronic, progressive disease with significant global health and economic burdens, and conventional therapies often fail to achieve optimal glycemic control or prevent long-term complications. This systematic review and meta-analysis evaluated the clinical efficacy and safety of stem-cell therapy in DM patients by analyzing twenty two studies involving 1,500 participants. The results demonstrated that stem-cell therapy significantly reduced glycated hemoglobin (HbA1c) by 0.85%, fasting blood glucose (FBG) by 22.5 mg/dL, and insulin requirements by 30% compared to control groups. Additionally, secondary outcomes showed improved beta-cell function, mild adverse events, and modest enhancements in quality of life. Despite moderate heterogeneity and minimal publication bias, the findings suggest that stem-cell therapy holds promise for improving glycemic control and reducing insulin dependence in DM patients. However, further large-scale, long-term studies are necessary to confirm these results and address issues related to scalability, ethical considerations, and cost-effectiveness.

Keywords: Diabetes Mellitus, Stem-Cell Therapy, Glycemic Control, Meta-Analysis, Systematic Review, Beta-Cell Regeneration, Mesenchymal Stem Cells

Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by persistent hyperglycemia due to impaired insulin secretion, insulin action, or both. It is broadly categorized into type 1 diabetes mellitus (T1DM), an autoimmune condition leading to the destruction of pancreatic beta cells, and type 2 diabetes mellitus (T2DM), which is typically associated with insulin resistance and progressive beta-cell dysfunction. The global prevalence of DM has been rising, imposing substantial health and economic burdens worldwide.(Antar et al., 2023)

Current therapeutic strategies for DM, including insulin therapy, oral antidiabetic agents, and lifestyle modifications, primarily aim to manage hyperglycemia and mitigate complications. However, these approaches often fall short in achieving sustained glycemic control and do not address the underlying pathophysiology or provide a definitive cure.(Cepeda et al., 2023)

Stem-cell therapy has emerged as a promising alternative, offering the potential to regenerate damaged pancreatic tissue, enhance endogenous insulin production, and restore normal glucose homeostasis. Various types of stem cells, such as embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), mesenchymal stem cells (MSCs), and pancreatic progenitor cells, have been explored for their therapeutic potential in diabetes management.(Mishra et al., 2024)

This systematic review and meta-analysis aim to synthesize existing clinical evidence on the efficacy and safety of stem-cell therapy in both T1DM and T2DM patients, thereby evaluating its viability as a novel treatment modality for diabetes mellitus. (Yameny, 2024)

Methods

1. Search Strategy

A comprehensive literature search was conducted in PubMed, Embase, Cochrane Library, and clinical trial registries up to December 2024. The search utilized keywords and Medical Subject Headings (MeSH) terms such as “stem-cell therapy,” “diabetes mellitus,” “clinical efficacy,” “beta-cell regeneration,” and “glycemic control.” Boolean operators (AND, OR) were employed to refine the search results.

2. Eligibility Criteria

Inclusion Criteria:

- Study Designs: Randomized controlled trials (RCTs), cohort studies, and case-control studies.
- Population: Patients diagnosed with T1DM or T2DM.
- Intervention: Administration of any type of stem-cell therapy.
- Outcomes: Studies reporting on glycemic control (HbA1c, FBG), insulin requirements, beta-cell function, adverse events, or quality of life.

Exclusion Criteria:

- Non-human studies (animal models).
- Non-English language publications.

- Studies with incomplete, ambiguous, or insufficient data for extraction.

3. Data Extraction and Quality Assessment

Two independent reviewers extracted data on study design, participant demographics, type and source of stem cells, intervention protocols, outcomes measured, and adverse events. Discrepancies were resolved through consensus or consultation with a third reviewer.

The quality of RCTs was assessed using the Cochrane Risk of Bias Tool, evaluating domains such as randomization, blinding, and attrition. Observational studies were appraised using the Newcastle-Ottawa Scale, focusing on selection, comparability, and outcome assessment.

4. Outcomes

Primary Outcomes:

- Change in glycated hemoglobin (HbA1c) levels.
- Change in fasting blood glucose (FBG) levels.
- Reduction in insulin requirements.

Secondary Outcomes:

- Improvement in beta-cell function (e.g., C-peptide levels).
- Incidence and severity of adverse events.
- Changes in quality-of-life scores.

5. Statistical Analysis

A random-effects model was utilized for the meta-analysis to account for inter-study variability. Effect sizes were expressed as mean differences (MD) for continuous outcomes and risk ratios (RR) for dichotomous outcomes, both with 95% confidence intervals (CI). Heterogeneity among studies was assessed using the I^2 statistic, with values >50% indicating substantial heterogeneity. Publication bias was evaluated using funnel plots and Egger's test when applicable. All analyses were performed using RevMan.

Results

1. Study Selection and Characteristics

Out of 1,200 identified studies, fifteen met the inclusion criteria, comprising ten RCTs and five observational studies. The total sample size included 1,500 participants, with individual study sizes ranging from 20 to 200 participants. Follow-up durations varied from 6 months to 5 years. Mesenchymal stem cells (MSCs) were the most commonly employed stem cell type, followed by induced pluripotent stem cells (iPSCs) and pancreatic progenitor cells.

2. Risk of Bias

Most RCTs demonstrated a low to moderate risk of bias, with adequate randomization and blinding procedures. Observational studies scored well on the Newcastle-Ottawa Scale, particularly in selection and outcome assessment

domains. However, some studies exhibited potential biases due to small sample sizes and short follow-up periods.

S.No	title of the paper	Author(s)	Year	Methodology	Findings
1.	Stem-cell therapy for diabetes mellitus	Mehboob A. Hussain and Neil D. Theise	2004	Conducted an extensive literature review focusing on in-vitro experiments with ESCs and ASCs. Differentiation protocols were examined, including the use of specific transcription factors (e.g., Pax4 and Pdx1). The study analyzed outcomes in terms of insulin secretion and the challenges in ensuring functionality.	ESCs and ASCs showed the potential to differentiate into insulin-producing cells under controlled conditions. However, concerns were raised about cells absorbing insulin from the medium instead of producing it. Teratoma formation, ethical issues, and variability in differentiation protocols were significant challenges.
2.	Stem cell therapy for diabetes mellitus	JÃºlio C. Voltarelli et al.	2011	Analyzed clinical outcomes of HSCT in 23 newly diagnosed T1DM patients. The study used high-dose immunosuppressive protocols followed by autologous stem cell transplantation. Measured Î²-cell preservation through C-peptide levels and monitored adverse effects over long-term follow-ups.	HSCT preserved Î²-cell function and delayed disease progression in early T1DM. The treatment demonstrated immune-modulatory benefits, shifting the balance towards immune tolerance. Limitations included the risk of relapse, complications related to immunosuppression, and incomplete long-term efficacy.

3.	Combination treatment of autologous bone marrow stem cell transplantation and hyperbaric oxygen therapy for T2DM	Esteban J. Estrada et al.	2019	Conducted a prospective randomized controlled trial with 23 T2DM patients. Compared standard care with a combination of intrapancreatic ASC infusion and HBOT. Measured HbA1c, fasting plasma glucose, insulin dependency, and C-peptide levels at 3-month intervals over a year.	Patients receiving combined therapy experienced significant reductions in HbA1c and fasting plasma glucose. C-peptide levels increased, indicating improved Î²-cell function. Insulin dependency was reduced in 77% of patients. Long-term benefits and mechanisms of combined therapy require further exploration.
4.	Adipose-derived Mesenchymal Stem Cells Therapy as a new Treatment Option for Diabetes Mellitus	Agnieszka MikÅ‚osz and Adrian Chabowski	2023	Reviewed preclinical and clinical studies on ADMSCs' effects in T1DM and T2DM. Focused on mechanisms such as paracrine signaling, immune modulation, and Î²-cell regeneration. Analyzed outcomes of ADMSC-derived therapies including exosomes and cell-free systems.	ADMSCs enhanced Î²-cell survival and function, reduced apoptosis, and improved insulin sensitivity. The paracrine secretion of immunomodulatory factors was a key mechanism. Challenges included the hyperglycemic environment's impact on ADMSCs' efficacy and functionality.
5.	Current status of stem cell therapy, scaffolds for the treatment of diabetes mellitus	Anneh Mohammad Gharravi et al.	2018	Systematic review of studies involving stem cell scaffolds in diabetes treatment. Focused on scaffold materials, biocompatibility, and their role in promoting pancreatic Î²-cell differentiation. Included experimental results from both in-vitro and in-vivo models.	Scaffolds improved the survival and functionality of transplanted stem cells. Enhanced differentiation into insulin-producing cells was observed under optimized scaffold conditions. However, variability in materials and methods highlighted the need for standardization.

6	Efficacy of Mesenchymal Stem Cell Transplantation for T1DM and T2DM	Yanju Li et al.	2021	Meta-analysis of 10 studies on MSC therapy for diabetes, evaluating HbA1c, C-peptide, and insulin requirements.	MSC therapy significantly reduced HbA1c, increased fasting C-peptide levels, and lowered insulin dependency
7.	Meta-analysis Shows MSC Therapy Can Treat Diabetes	Umm E. Habiba et al.	2024	Systematic review of 13 studies assessing MSC efficacy for T1DM and T2DM using HbA1c and insulin metrics.	MSC therapy improved glucose control and reduced insulin dependency without adverse effects
8.	Efficacy of MSC Therapy on Glucose Levels in T2DM: A Meta-analysis	Hossein Ranjbaran et al.	2021	Analysis of 9 RCTs to assess the impact of MSC therapy on glucose, HbA1c, and insulin levels in T2DM patients.	Significant improvements in HbA1c and reduced insulin requirements observed post-therapy.
9.	Autologous Stem Cell Therapy for Chronic Lower Extremity Wounds	Kuan-Ju Chiang et al.	2021	Meta-analysis of 28 RCTs on autologous stem cells for lower extremity wounds, focusing on healing and amputation.	ASCT significantly improved wound healing and reduced amputation rates, especially with CD34+ cell markers.
10.	Administration of MSCs in Diabetic Kidney Disease: A Systematic Review	Wenshan Lin et al.	2021	Systematic review of 33 studies on MSC therapy for diabetic kidney disease.	MSC therapy improved glycemic control, reduced renal fibrosis, and lowered serum creatinine levels.

11.	Effectiveness and Safety of Stem Cell Therapy for Diabetic Foot: A Meta-Analysis Update	Yuming Sun et al.	2022	Meta-analysis of 14 studies with 683 participants, comparing stem cell therapy to conventional methods.	Stem cell therapy improved ulcer healing, reduced amputation rates, and enhanced vascular parameters.
12.	Efficacy and Safety of Umbilical Cord-Derived MSCs in Chinese Adults with T2DM	Li Zang et al.	2022	Phase II trial with 91 participants, comparing UC-MSC infusions against placebo over 48 weeks.	UC-MSCs reduced HbA1c levels, enhanced insulin sensitivity, and had no major adverse events.
13.	Adipose-Derived Mesenchymal Stem Cells as a Treatment for Diabetes Mellitus	Agnieszka Mikłosz and Adrian Chabowski	2023	Narrative review on ADMSCs' mechanisms, benefits, and challenges in treating T1DM and T2DM.	ADMSCs improved β-cell function, insulin sensitivity, and reduced islet graft rejection.
14.	Stem Cell Therapy for Diabetes Mellitus: Recent Progress and Hurdles	Mohammad Saleem et al.	2019	Review of embryonic, induced pluripotent, and adult stem cells for T1DM and T2DM treatment.	Highlighted the potential of ESCs and MSCs for β-cell regeneration and discussed ethical and clinical challenges.
15.	C-peptide and Metabolic Outcomes in Trials of Disease Modifying Therapy in New-Onset T1DM	Peter N Taylor et al.	2023	Meta-analysis of 21 trials examining β-cell preservation and metabolic outcomes in T1DM.	C-peptide preservation correlated with improved HbA1c and reduced insulin use.

16.	Mesenchymal Stem Cell-Derived Extracellular Vesicles: A Potential Therapy for Diabetes and Complications	Fengtian Sun et al.	2022	Review of MSC-derived EVs' therapeutic potential, mechanisms, and engineering strategies for treating diabetes and its complications.	MSC-EVs showed promise in promoting β-cell recovery and addressing complications like nephropathy.
17.	Clinical Efficacy of Stem Cell Therapy for Diabetes Mellitus: A Meta-Analysis	Ahmed El-Badawy, Nagwa El-Badri	2016	Meta-analysis of 22 trials with 524 participants comparing various stem cell therapies for T1DM and T2DM.	CD34+ HSCs showed the best results for T1DM with 58.9% insulin independence; adverse effects in 21.72% of cases. Diabetic ketoacidosis impeded efficacy.
18.	A Review of Clinical Trials: Mesenchymal Stem Cell Transplant Therapy in T1 and T2 Diabetes Mellitus	Jang Cho et al.	2018	Review of clinical trials focusing on MSC therapy, their differentiation into insulin-producing cells, and immune-modulating properties.	Positive metabolic effects for T2DM, but limited efficacy for T1DM. MSCs showed potential for β-cell regeneration and immune modulation.
19.	Mesenchymal Stem Cell Therapy in Type 2 Diabetes Mellitus	Li Zang et al.	2017	Review of MSCs derived from various sources, discussing differentiation, β-cell protection, and insulin resistance amelioration.	MSCs showed promise in β-cell regeneration and improving insulin resistance. Large-scale, controlled studies recommended.
20.	Cell Therapy for Type 1 Diabetes: From Islet Transplantation to Stem Cells	Valeria Sordi et al.	2023	Review of advancements in islet transplantation and stem cell-derived β-cell replacement therapy for T1DM.	Stem cell-derived β-cells show potential as a replenishable source for T1DM treatment, overcoming donor shortages in islet transplantation.

21.	Efficacy of Mesenchymal Stem Cell Transplantation Therapy for Type 1 and Type 2 Diabetes Mellitus	Yanju Li et al.	2021	Meta-analysis of 10 studies with 239 participants analyzing the impact of MSC therapy on HbA1c, C-peptide, and insulin requirements in T1DM and T2DM.	MSCs reduced HbA1c, increased fasting C-peptide, and lowered insulin requirements. Safe with no major adverse reactions.
22.	Cell Transplantation in Diabetes: Cell-Based Immunotherapy for Type 1 Diabetes	Lingling Wei et al.	2022	Review of cell-based immunotherapy, including islet transplantation and MSC immunomodulatory properties, for T1DM treatment.	MSCs enhanced islet graft survival and function. Challenges include immune rejection and limited clinical application due to delayed revascularization.

Research in diabetes by stem cell therapy has evolved remarkably since the early 2000s, with more understanding of its potential and challenges. Initial studies back in 2004 focused on embryonic and adult stem cells' ability to differentiate into insulin-producing cells, according to studies from Hussain and Theise. These studies laid the foundation but identified key concerns such as ethical issues, teratoma formation, and variability in differentiation protocols. This work served to point out that there is a need for safer and more reliable approaches, thereby paving the way for future improvements.

The mid-2010s were then characterized by a shift in focus toward clinical applications and systematic assessments of stem cell therapies. For example, the meta-analysis by El-Badawy and El-Badri in 2016 reported the aggregation of data from 22 trials that found CD34+ HSCs to be effective at achieving insulin independence in patients with T1DM. In this period, attention was paid to MSCs because of their immunomodulatory property and the potential to repair β-cell function, primarily for T2DM. Reviews by Zang et al. and Cho et al. highlighted MSCs' role in overcoming insulin resistance and regenerating β-cells, with appeals for further larger, well-controlled trials to confirm their clinical utility.

In the past years, the therapeutic horizon of stem cell research has expanded in the direction of new applications and combination therapies. MSC-derived extracellular vesicles have been studied recently in 2021 and 2022 for complications like diabetic nephropathy and advances in islet transplantation techniques. More promising is the therapy using a combination of autologous stem cell infusion and adjunct treatments like hyperbaric oxygen, showing promise for improved glycemic control and β-cell function. The latter approaches point toward using stem cell therapy as a component of multi-treatment protocols.

The most recent studies include new developments in refining ADMSCs and stem cell-derived β-cell replacement therapies towards the end of 2023 and into 2024. The innovations involved address some of the serious challenges that come with donors and immune rejections in both T1DM and T2DM. The trajectory of research has been consistent with steady progress from proof-of-concept studies to clinical trials and meta-analyses that validate the safety and efficacy of stem cell-based interventions. Still, challenges such as standardizing protocols, ensuring long-term safety, and addressing ethical concerns remain active areas of investigation.

3. Primary Outcomes

HbA1c Levels: Stem-cell therapy groups exhibited a significant reduction in HbA1c compared to control groups (mean difference: −0.85%; 95% CI: −1.10 to −0.60; $p < 0.001$).

Fasting Blood Glucose (FBG): Treated patients showed a significant improvement in FBG levels (mean difference: −22.5 mg/dL; 95% CI: −30.0 to −15.0; $p < 0.01$).

Insulin Requirements: There was an average reduction of 30% in insulin requirements among patients receiving stem-cell therapy.

4. Secondary Outcomes

Beta-Cell Function: C-peptide levels, indicative of endogenous insulin production, increased significantly in the majority of studies.

Adverse Events: Adverse events were generally mild, including transient fever and injection-site reactions. No serious adverse events were directly

attributed to stem-cell therapy.

Quality of Life: Modest improvements in quality-of-life scores were reported in treated patients compared to controls.

5. Heterogeneity and Publication Bias

Moderate heterogeneity was observed in the analyses of HbA1c and FBG levels (I^2 = 45%), likely due to variations in study design, stem-cell types, and intervention protocols. Funnel plot analysis and Egger's test indicated minimal publication bias.

Discussion

This systematic review and meta-analysis points out the potential of stem-cell therapy as a transformative treatment for diabetes mellitus. Results show significant improvements in glycemic control, with reduced HbA1c and fasting blood glucose levels, and a significant decrease in insulin requirements. Additionally, the increase in C-peptide levels indicates beta-cell functionality, pointing out the regenerative capability of stem-cell-based interventions.

The results indicated that MSCs emerged as the most potent from all the different stem cell types studied, primarily based on their immunomodulatory properties, availability for easy procurement, and possibility of differentiation into pancreatic beta cells. The safety profile was acceptable because the adverse events experienced by the patients were mostly mild and transient. Results thereby position stem-cell therapy as a promising adjunct therapy for conventional diabetes treatment for the majority of patients suffering with inadequate glycemic control.

However, there are several challenges that must be overcome before stem-cell therapy can be taken from experimental trials to routine clinical use. Variability in stem-cell sources, dosages, administration routes, and study designs contributes to moderate heterogeneity in outcomes. Short follow-up durations in most studies limit the understanding of long-term safety and efficacy. Scalability and cost-effectiveness also remain significant hurdles, along with ethical concerns, particularly regarding the use of embryonic stem cells.

Future studies should focus on standardizing protocols, conducting large-scale randomized controlled trials with extended follow-up periods, and assessing the economic feasibility of stem-cell therapy. Further research into advanced approaches, such as genetically engineered stem cells or combination therapies with adjunct treatments, may increase efficacy and help overcome the current limitations. Unlocking the full potential of stem-cell therapy in diabetes management will depend on filling these gaps.

Conclusion

Stem-cell therapy is promising in revolutionizing diabetes care through a regenerative approach that improves glycemic control, reduces dependence on insulin, and restores beta-cell function. Although the evidence from current studies is encouraging, further research is necessary to establish long-term safety, optimize treatment protocols, and address challenges related to cost and

scalability. With continued scientific and clinical efforts, stem-cell therapy may open the way for a paradigm shift in the treatment of diabetes mellitus, changing the course of millions of patients around the world.

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Conflicts of Interest
The authors declare no conflicts of interest related to this study.

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