

RESEARCH ARTICLE

EXPLORING THE LANDSCAPE OF HUMAN GENE THERAPY: A CROSS-SECTIONAL STUDY AMONG MEDICAL FACULTIES IN MAHARASHTRA

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Abstract

..... Introduction: Human gene therapy holds immense potential for treating various genetic disorders and diseases by introducing therapeutic genes into patients' cells. However, its successful implementation relies not only on technological advancements but also on the understanding, attitude, and awareness among medical professionals. This study aims to assess the knowledge, attitude, and awareness of human gene therapy among medical faculties of a college in Maharashtra.

Methodology: A cross-sectional study was conducted among medical faculties of a college in Maharashtra. A structured questionnaire was developed, consisting of sections on demographics, knowledge, attitude, and awareness regarding human gene therapy. The questionnaire was distributed among the faculties, and data were collected anonymously.

Results: Out of the total respondents (N=150), the majority were between the ages of 30-55 years (65.3%) and had teaching experience ranging from 1 to 10 years (76.7%). Regarding knowledge, only 82% of the faculties had adequate knowledge of human gene therapy, while 15.3% had moderate knowledge, and 2.7% had poor knowledge. The attitude towards gene therapy was generally positive, with 98% of respondents agreeing that gene therapy holds promise for treating genetic diseases. However, concerns were raised regarding ethical issues (62.7%) and safety concerns (55.3%). In terms of awareness, 79.3% of faculties reported receiving minimal or no information about gene therapy during their medical education.

Discussion: The findings reveal excellent to fair knowledge of human gene therapy among medical faculties in Maharashtra. Despite the positive attitude and awareness towards its potential benefits, concerns regarding ethics and safety underscore the need for comprehensive education and training in this field. Integrating gene therapy-related topics into medical curricula and providing continuous professional development opportunities can help bridge this gap.

Conclusion: This cross-sectional study highlights excellent knowledge about gene therapy but, there is a need for enhancing knowledge and awareness of human gene therapy among medical education in Maharashtra. Addressing this gap is crucial for preparing future .

healthcare professionals to effectively utilize and contribute to advancements in gene therapy research and practice. Collaborative efforts involving educational institutions, professional organizations, and policymakers are essential to ensure comprehensive training and education in this rapidly evolving field.

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Introduction:-

In the realm of modern medicine, the concept of human gene therapy stands as a beacon of hope, promising revolutionary treatments for a myriad of genetic disorders and diseases. The advent of gene therapy heralds a new era where targeted interventions at the molecular level hold the potential to address underlying genetic anomalies, offering prospects for previously incurable conditions to be managed or even cured.¹ However, the successful integration of gene therapy into clinical practice necessitates not only groundbreaking scientific discoveries and technological advancements but also a comprehensive understanding and acceptance among healthcare professionals.²

The journey towards unlocking the therapeutic potential of humanGene therapy traces back to the late 20th century, marked by pioneeringexperiments and milestones that laid the foundation for contemporary researchendeavours. Initially conceptualized as a promising approach to correct geneticdefects at their root cause, gene therapy has undergone significantadvancements fuelled by advances in molecular biology, genetics, andbiotechnology. ³Today, the field encompasses a diverse array of strategies, including gene augmentation, gene editing, and gene silencing, each tailored toaddress specific genetic aberrations and pathological mechanisms.

The chasm between innovations in gene therapy and the dissemination of knowledge manifests across multiple dimensions, reflecting systemic challenges and barriers that impede the translation of scientific breakthroughs into tangible clinical applications. One prominent factor contributing to this breach is the inherent complexity of gene therapy itself. ^{4,5}The intricacies of genetic engineering, delivery mechanisms, and molecular biology pose formidable challenges, requiring interdisciplinary expertise and technological sophistication to navigate effectively. As such, the gap between cutting-edge research and practical implementation widens, leaving many healthcare professionals ill-equipped to leverage the full potential of gene therapy in clinical settings.

Moreover, the rapid pace of technological advancements in gene therapy often outpaces the capacity of traditional educational systems to incorporate up-to-date knowledge and training modalities. Medical curricula, designed to instil foundational principles and practices, may struggle to keep abreast of the latest developments in gene therapy, resulting in a generation of healthcare professionals who are inadequately prepared to embrace emerging therapeutic modalities.⁶ This discrepancy between the pace of innovation and educational reform perpetuates a cycle of knowledge stagnation, further widening the breach between scientific progress and clinical application.

Furthermore, disparities in access to information and resources exacerbate the breach between innovations and knowledge concerning gene therapy. In regions with limited research infrastructure or healthcare resources, dissemination channels may be fragmented or inaccessible, hindering the diffusion of critical knowledge and best practices. Socioeconomic factors, including funding constraints and healthcare disparities, further compound these challenges, perpetuating inequities in access to cutting-edge therapies and educational opportunities.

Ethical considerations also contribute to the breach between innovations and knowledge in gene therapy. Debates surrounding the ethical implications of genetic manipulation, concerns about safety and long-term consequences, and societal perceptions of genetic modification all influence the dissemination and acceptance of gene therapy knowledge. As ethical frameworks evolve and public attitudes shift, navigating the ethical landscape of gene therapy becomes increasingly complex, further complicating efforts to bridge the gap between innovation and understanding.⁷

Maharashtra, one of India's most populous states and a hub formedical education and research serve as a pertinent setting to explore thelandscape of knowledge, attitude, and awareness of human gene therapy withinmedical faculties. As the field of gene therapy continues to evolve, it is imperative to gauge the preparedness and perceptions of medical professionals, particularly those tasked with educating the next generation of healthcareproviders. ⁸This

introduction sets the stage for a cross-sectional study aimedat assessing the knowledge, attitude, and awareness of human gene therapy amongmedical faculties of a prominent medical college in Maharashtra.

Material and Methods:-

Study design and sample size:-

A cross sectional questionnaire based study was carried out among 150 faculty members of MGM Medical College inDepartment of Biochemistry Aurangabad for a period of six months. Ethical clearance was obtained from theInstitutional Ethics Committee. Inclusion criteria included subjects who were willing to participate in the study andthen a written consent was obtained from them. Questionnaire was designed in such a way that the procedure should not take more than10 minutes per participant.

Study Quessionaire:-

The questionnaire was prepared in English language based on anextensive literature review of previously publishedreviews and studies, the survey was refined from validated questionnairesthat were previously used to address ourobjectives. A structured questionnaire with a set of 20 questions was designed to evaluate the knowledge, attitudeand awareness among participants regarding human gene therapy. The questionnaire was pre tested amongst 10teaching faculty members to confirm its validity and reliability and to avoid uncertainty. Following the pretest, somemodifications in the order of questions and terminologies were made in the final questionnaire. The self-reported questionnaire comprised a series of questions to assess respondents: (i) demographics and professional variables; (ii) their perceived level of knowledge (n = 10) and attitude and awareness towards gene therapy (n = 6); (iii) their selfestimated level of knowledge (n = 4).

A five point Likert scale was used for scoring.⁹

Likert scale: Strongly Disagree (1), Disagree(2), Neutral(3), Agree(4), Strongly Agree(5).

The questionnaire consisted of 10 statements that suggested the degree of agreement or disagreement with eachstatement using a 5-point Likert scale 6. Participants were instructed to choose only one answer for each statement.Score of (10 to 50) was given for all the questions. The portion of the questionnaire related to knowledge assessmentis shown in **Table.No 1**.

Statistical Analysis:-

After collection, the Descriptive analysis of the Data was performed to get the frequency of responses using SPSSversion 22. Normally distributed variables were compared using the student t-test, and non-normally distributedvariables were compared using the Mann-Whitney test. Homogeneity of variances was checked using Levene's testbefore the t-test. Continuous data were described as mean and standard deviation, and categorical variables asfrequencies and percentages.Independent sample t-test was used to assess the difference between undergraduate and postgraduate scores forknowledge, attitude and awareness. Chi Square test was used to assess the significance of the responses and a Pvalue <0.05 was considered statistically significant. Correlation between knowledge and attitude scores wasassessed using the Spearman correlation.

Result:-

Socio-Demographic Variables:-

The study successfully assessed the knowledge, attitude, and awareness of human gene therapy among medical faculty members across various departments in this college in Maharashtra.

The following observations were made by the data analyzed for demographic and professional variables. A total of 150 faculties participated in the study. The study population consisted of 72 (48%) males and 78 (52%) females, with a mean age of 37.5 ± 5.2 years (range: 30-55 years).Out of the total respondents (N=150), the majority had teaching experience ranging from 1 to 10 years (76.7%).

Assessment of Gene therapy Knowledge:-

In this section of the survey, we explored Information regarding knowledge of human gene therapy among the participants in percentage. Calculating the correctresponse for the questionnaire, a score of around 36 was

considered as having excellent knowledge regarding thestudy.Regarding knowledge, only 82% of the faculties had adequate knowledge of human gene therapy, while 15.3% had moderate knowledge, and 2.7% had poor knowledge.

According to the individual question analysis regarding knowledge of human gene therapy, 90% participants wereaware of the term "Gene Therapy". In addition, 75 % of the participants thought that gene therapy was designed to introduce genetic material into cells. More than 75% of the faculties considered gene therapy as safe. 80% and more than that were aware of the application of vector. 93% of the individuals were good with the knowledge of germ line gene therapy. However, 71% and 18% of the participants were aware thatthe therapy may have ethical issues involved. Moreover, 60% participants were ready to consider gene therapy as a boon to mankind. Almost 96% were of the positive belief that genetic disorders can be cured by gene therapy. (**Table 1**)

Sr. No.	Questions regarding Knowledge	Yes/ No	SD n(%)	D n(%)	N n(%)	A n(%)	SA n(%)	p- value
1	Have you heard the term Gene Therapy?	Yes	0(0)	0(0)	0(0)	15 (10)	135 (90)	0.003
2	Gene therapy is designed to introducegenetic material into cells.	Yes	0 (0)	0 (0)	5 (3.3)	33 (21.7)	112 (75)	0.001
3	A gene that is inserted directly into a cellusually does not function.	Yes	105 (70.5)	21 (14.5)	10 (6)	4 (3)	10 (6)	<0.001
4	Gene therapy is safe.	No	5 (3.3)	4 (2.7)	0 (0)	112 (75)	29 (19)	< 0.001
5	There are ethical issues involved in genetherapy.	Yes	12 (8)	5 (3)	0 (0)	27 (18)	107(71)	0.000
6	A vector is a different type of gene.	No	0 (0)	0 (0)	4 (2.7)	24 (16.3)	122 (81)	0.000
7	Germ-line gene therapy is transfer of asection of DNA to cells that produce eggs or sperm.	Yes	2 (1)	2 (1)	0 (0)	6 (5)	140 (93)	<0.001
8	The vector can be injected or given intravenously directly into a specific tissue in the body.	Yes	5 (3.3)	5 (3.3)	0 (0)	110 (73.4)	30 (20)	<0.01
9	Gene Therapy is a boon to mankind	Yes	9 (6)	45 (30)	6 (4)	15 (10)	75 (50)	0.00
10	Genetic disorders can be cured by genetherapy.	Yes	0 (0)	0 (0)	0 (0)	5 (3.3)	145 (96.7)	0.002

Table 1:- Information regarding knowledge of human gene therapy among the participants in percentage (according to likert scale).

Likert scale:

Strongly Disagree (SD), Disagree (D), Neutral (N), Agree (A), Strongly Agree (SA).

Self-Assessed Knowledge of Gene Therapy:-

Table 2 reports the questions on self assessed knowledge of gene therapy. Other 3 questions consisted of 4 or 5 responses. The responses thus obtained were then compiled, processed and analysed to arrive at the opinion onvarious answers. Almost all the respondents (n = 150; 100%) were aware of the meaning of gene therapy. Onhearing the term gene therapy, maximum participants (n=106; 70%) thought of gene transplant. (**Table 3**)

Table 2:- Questions on self assessed knowledge of gene therapy.

11. Do you know the meaning of gene therapy?

a) Yes b) No c) I do not know

12. On hearing about the term "Gene Therapy" what comes in your mind

a) Gene transplant b) Gene banking c) Genetic research d) Genetic disorders

13. Source Of Information Regarding Gene Therapy?

a) Physician b) Internet c) Television d) Hospital/Institute e) Newspaper f) Friend/Relative

14. Who can be a Donor for gene therapy?

a) Person himself b) Identical twin c) Sibling d) Parents e) Blood donor f) Any person

Sr.No.	Questions on self assessed knowledge about gene	Answer selected by	% of
	therapy	participants	Participants
11	Do you know the meaning of gene therapy?	Yes	100
12	On hearing about the term "Gene Therapy" what	Gene transplant	70
	comes in your mind	Gene banking	10
		Genetic research	5
		Genetic disorders	15
13	Source Of Information Regarding Gene Therapy?	Internet	98
14	Who can be a Donor for gene therapy?	Person himself	83

Table 3:- Response	in % of Participants f	for questions on self a	assessed knowledge of	f gene therapy.

Participants Attitudes and Awareness towards Gene Therapy:

Respondent's attitudes and awareness toward gene therapy are reported in **Table 4**. Majority of the respondents(98%) were of the belief that gene therapy will soon become a useful treatment strategy. Attitude and awarenessscore was found to be not statistically significant among the respondants. Participants were well aware regarding first genetherapy patient and potential benefits and harms. Almost half (51%) of the participant faculty members were concernedabout the safety of patients.In terms of awareness, 79.3% of faculties reported receiving minimal or no information about gene therapy during their medical education.

Table 4:- Information regarding attitude and awareness regarding human gene therapy among the participants inpercentage (n=150).

Sr.	Questions regarding Attitude and Awareness	Yes	No	Neutral	p-value
No.		(%)	(%)	(%)	
15	Gene therapy will soon become a useful treatmentstrategy in near future.	98	2	0	0.55
16	Gene therapy uses sections of DNA to treat orprevent disease.		12	1	0.04
17	I am aware that a four-year old girl became the firstgene therapy patient at the NIH Clinical Center.		5	1	0.3
18	I am aware of potential benefits and harms of genetherapy.	67	23	10	0.51
19	It is possible to cure adults with debilitating diseases using gene therapy	24	39	37	0.00
20	Are you concerned in regards to safety of patientsabout the use of gene therapy?	51	35	14	0.002

Relationship Between Socio-Demographic Factors and Gene Therapy Knowledge:

Linear regression analysis for factors affecting knowledge score such as age, gender was plotted. High knowledge score was associated with older age group (p=0.01). However, there was a positive correlation between knowledge and attitude (rho 0.3, P < 0.0001).

Discussion:-

In Maharashtra, renowned medical institutions have playedpivotal roles in advancing biomedical research and innovation, contributing tothe global discourse on gene therapy. However, amidst the excitementsurrounding the potential of gene therapy, it is essential to assess the current state of understanding and perception among the academic community. Medical faculties, serving as educators, mentors, and role models, wieldconsiderable influence in shaping the perspectives and practices of futurehealthcare professionals. Thus, their insights into gene therapy not onlyreflect the prevailing knowledge base but also offer insights into educational priorities and potential barriers to adoption.

In our study, majority of the participants were of middle aged generation. Most studies found that younger participantswere more accepting of gene therapy, possibly due to an increase in concern by older individuals and reducedexposure to the development and use of these modern technologies.¹⁰ Similar study was conducted by us for medical and paramedical students, finding of this study are in accordance with that study.¹¹

Knowledge and awareness levels were generally significant predictors of the level of support for these technologies. Our study participants had a significant amount of knowledge towards gene therapy. Many studies conducted have a contrast finding to our study.¹²

The significance of this cross-sectional study lies in itsability to provide a nuanced understanding of the knowledge, attitude, andawareness of human gene therapy within the medical faculties of a prestigiousinstitution in Maharashtra. By employing a comprehensive approach thatencompasses quantitative and qualitative assessments, the study aims toelucidate various facets of faculty perceptions, ranging from foundationalunderstanding of ethical considerations and practical implications.¹³ Throughstructured questionnaires and potentially follow-up interviews, researchersseek to capture diverse viewpoints and identify areas of strength and areas forimprovement. The findings of this study hold implications that extend beyondthe confines of academic inquiry, resonating with broader healthcare paradigmsand societal aspirations. Although not all gene therapy medicinal products involve the use ofcells, in the case of ex vivo gene therapy, cells play an essential role.¹⁴Majority of the participants in our studydisagreed for gene therapy being safe and effective for genetic disorders.¹⁵ We got similar findings in our previous study also.¹² We will be doing a comparative analysis of both studies in future.

As Maharashtra grapples with the burden of geneticdiseases and inherited disorders, the insights gleaned from this study caninform strategic initiatives aimed at enhancing healthcare delivery, promotingscientific literacy, and fostering innovation ecosystems. Moreover, in an eracharacterized by rapid scientific advancements and ethical dilemmas, informeddiscourse and evidence-based decision-making are indispensable for navigating thecomplex terrain of gene therapy.

Conclusion:-

In conclusion, the exploration of knowledge, attitude, andawareness of human gene therapy among medical faculties in Maharashtra servesas a microcosm of the broader narrative unfolding in the field of healthcare.By shedding light on the perceptions and preparedness of key stakeholders, thisstudy endeavors to catalyze dialogue, stimulate educational reforms, andultimately contribute to the realization of gene therapy's transformativepotential. As Maharashtra continues its quest for excellence in healthcare,understanding the dynamics of gene therapy within the academic community is a crucial step towards shaping a future where genetic diseases are not merelymanaged but conquered through the power of knowledge and innovation.The results of the present study concluded that majority of the medical faculties were aware of gene therapy indisease and health. The awareness regarding gene therapy was excellent among the faculties. Genetherapy research and application should be a part of curriculum of medical education. Most of thefacultieswere of positive opinion that it can be a boon to mankind and we are in need of gene therapy for many disorders.

Limitation:-

The sample size was smaller for this study, hence a study with larger sample size is needed for the assessing theawareness, attitude and knowledge among the faculties, not only medical but non medical also. We did not consider the educational level or department for our study.Future studies including all healthcare professionals are recommended.

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Conflicts of interest:-

The authors declare no conflict of interest.

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