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RESEARCH ARTICLE

A CROSS SECTIONAL STUDY TO ASSESS THE KNOWLEDGE, ATTITUDE AND AWARENESS OF HUMAN GENE THERAPY IN MEDICAL AND PARAMEDICAL STUDENTS OF A MEDICAL COLLEGE IN MAHARASHTRA

Dr. Deepali Vaishnav[1], Dr. Manjusha Hivre[2] and Dr. Shrirang Holkar[2]

1. Professor, Department of Biochemistry, MGM Medical College, Aurangabad.
2. Assistant Professor, Department of Biochemistry, MGM Medical College, Aurangabad.

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Abstract

Background: Gene therapy is an emerging technology characterized by uncertainty in scientific knowledge with regard to benefits and risks. The development of a routinely used gene therapy to successfully fight against severe diseases is still under process.

Aim: This study was conducted to assess the knowledge, attitude and awareness regarding gene therapy among Undergraduate and postgraduate students.

Material and methods: A cross sectional questionnaire based study was carried out among postgraduate andundergraduate medical and allied students of the medical college for a period of six months regarding knowledge, attitude and awareness about gene therapy.

Results: This study included 300 participants. Data from this study revealed a high level of awareness and knowledge of gene therapy and a positive attitude among the undergraduate and postgraduate students.

Conclusion: Our results showed excellent knowledge about gene therapy among the medical and para medical students.

Introduction:-

The term “gene therapy” in itself is self-explanatory. Gene therapy is defined in different ways, but this definition is a simple way of explaining the term to all types of fraternities. So we define “gene therapy” as the insertion, alteration, or removal of genes within individual cells and biological tissues to treat a disease. Gene therapy is one of the zones of supreme ethical concern in modern genetics. Despite its extremely novel nature, there has been a boundlesspact of commercial and public awareness in gene therapy because it is seen as having such great potential asremedy for disease.[1]

Human gene therapy seeks to alter or influence the expression of a gene or to modify the biological wealth of living cells for therapeutic practice. Products that facilitate their effects by transcription or translation of transported genetic material, or by precisely altering host (human) genetic sequences, are well thought-out gene therapies. Gene therapy products are varied and include genetically modified viruses (viral vectors), genetically modified microorganisms (e.g., bacteria, fungi), genome-edited/editing products, and ex vivo genetically modified human cells.[2]

Corresponding Author:-Dr.Shrirang Holkar
Address**:**-Assistant Professor, Department of Biochemistry, MGM Medical College,

Gene therapies may diverge from conservative drugs in that vector and transgene expression may endure for the life span of the subject. The technology is still in its premature stages. Currently gene therapy, the replacement of an abnormal gene with a normal gene, is still in experimental stage. There have been more than 1000 trials in the past few decades. During that time there have been many optimistic results, but also serious setbacks. A lot of progress has been made in developing methods to introduce and express genes using viral and other vectors.Many questions concerning possible inadvertent (adverse) effects remain open and unanswered.[3]There are a number of safety issues associated with gene therapy, however, which are unique to this area.

Gene therapy continues to be of interest, mostly to develop treatments for single gene disorders.Gene therapy is an evolving technology characterized by ambiguity in scientific knowledge with regard to benefits and hazards. The development of a routinely used gene therapy to successfully fight against severe diseases takes longer than it had been expected, and the fight will continue till a stage is reached which will achieve excellence in treating a disorder in its fullest form. That excellence will be a miracle in the field of genetics and human medicine.[4,5]

There is a gigantic breach between the innovations and knowledge concerning gene therapy in new generations. Hence, a clear and translucent risk communiqué is needed to reach an acceptable understanding of any innovation and of conceivable non-intended side effects so that a considerable foundation for informed and responsible decision making can be shaped. Also, not many published studies are available on the current statusof the knowledge and attitudes towards gene therapy among students of medical college in Maharashtra. Consequently, a cross-sectional survey ofmedical and non-medical undergraduates and postgraduate students aimed tounderstand their knowledge, attitudes, and concerns related togene therapy in a medical college in Maharashtra.

Material and Methods:-

Study design and sample size:-

A cross sectional questionnaire based study was carried out among 300 students of MGM Medical College in Department of Biochemistry Aurangabad for a period of six months. Ethical clearance was obtained from the Institutional Ethics Committee. Inclusion criteria included subjects who were willing to participate in the study and then a written consent was obtained from them.A sample size of 300 included 100 MBBS students, 50 Allied health science students, 30 Physiotherapy students, 50 Nursing students, 40 Pharmacy students and 30 postgraduate/ superspecialty students; and questionnaire was designed in such a way that the procedure should not take more than 10 minutes per participant.

Study Quessionaire:-

The questionnaire was prepared in English language based on anextensive literature review of previously published reviews and studies, the survey was refined from validated questionnairesthat were previously used to address our objectives. A structured questionnaire with a set of 20 questions was designed to evaluate the knowledge, attitude and awareness among participants regarding human gene therapy. The questionnaire was pre tested amongst 10 teaching faculty members to confirm its validity and reliability and to avoid uncertainty. Following the pretest, some modifications 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 self-estimated level of knowledge (n = 4).

A five point Likert scale was used for scoring.

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 each statement 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 assessment is shown in **Table. 2**.

Statistical Analysis:-

After collection, the Descriptive analysis of the Data was performed to get the frequency of responses using SPSS version 20. Normally distributed variables were compared using the student t-test, and non-normally distributed variables were compared using the Mann-Whitney test. Homogeneity of variances was checked using Levene's test

before the t-test. Continuous data were described as mean and standard deviation, and categorical variables as frequencies and percentages.

Independent sample t-test was used to assess the difference between undergraduate and postgraduate scores for knowledge, attitude and awareness. Chi Square test was used to assess the significance of the responses and a P value <0.05 was considered statistically significant. Correlation between knowledge and attitude scores was assessed using the Spearman correlation.

Result:-

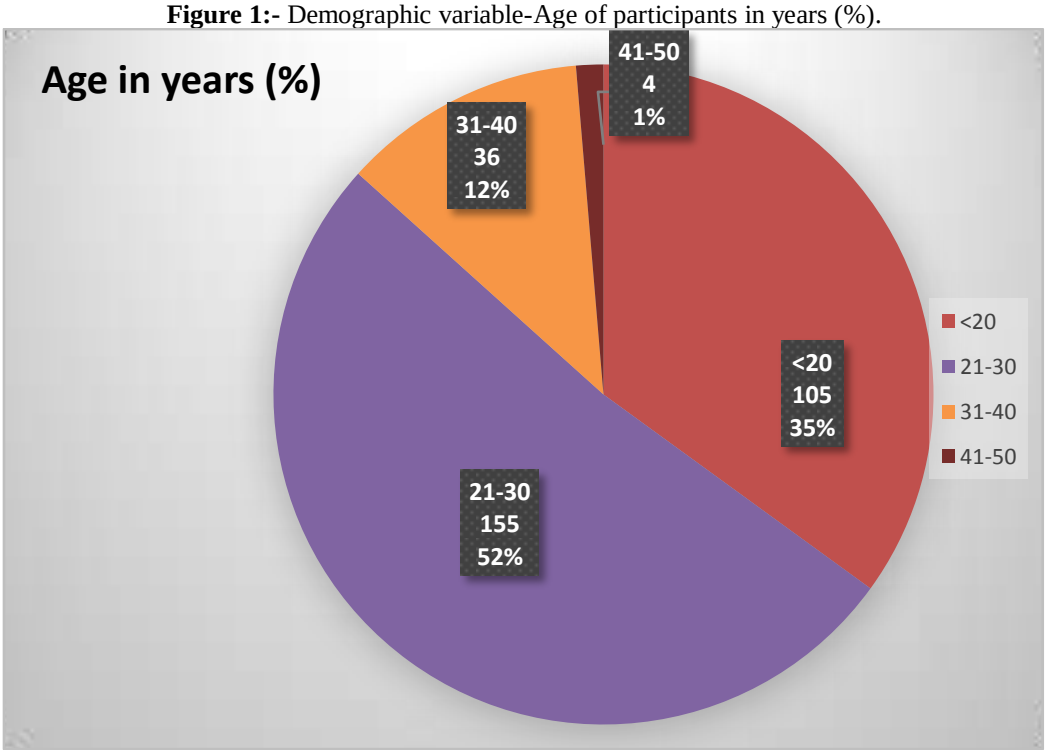
Socio-Demographic Variables:-

The following observations were made by the data analyzed for demographic and professional variables. A total of 300 students participated in the study. Majority of the participants were in the age group 21-30 years (51.7%). 98.7% of the participants were less than 40 years which comprises of the younger generation as demonstrated in **Figure 1**. The male-to-female ratio of the students participated was approximately 1:1, with 158 males and 142 females. Descriptive statistics of the participants i.e categorical data was presented as number and percentage as shown in **Table1**.

Table 1:- Socio-demographic variables of participants.

Sr No.	Demographic Variable	Category	Number (%)
1	Age (years)	≤20-50	300 (100)
2	Gender	Male	158 (52.7)
		Female	142 (47.3)
3	Qualification/Education	MBBS	100(33.3)
		BPTh	30 (10)
		BSc Nursing	42 (14)
		Post Basic Nursing	08 (2.7)
		BSc AHS	50(16.7)
		MSc Medical	05 (1.7)
		B. Pharm	40 (13.3)
		MD/MS/Diploma/DNB	20 (6.6)
		DM/Mch/Ph.D	05 (1.7)

Figure 1:- Demographic variable-Age of participants in years (%).



Assessment of Knowledge of Gene Therapy:-

In the second section of the survey, we explored student's knowledge about gene therapy. Calculating the correct response for the questionnaire, a score of around 29 was considered as having excellent knowledge regarding the study.

The mean knowledge scores of all undergraduate and postgraduate students were 32.55± 3.48 and 27.39± 2.27 respectively. There was a significant statistically difference in knowledge between undergraduate and postgraduate students (P = <0.0001). Amongst the postgraduates, no significant difference between MD group and DM group was noted in regards to the mean score (29.46± 2.07, 28.33± 1.22) using independent sample t-test (p = 0.57). However, a significant difference in mean score was found between MBBS students (30.21± 2.97) and paramedical students (35.21± 2.53) (p = 0.04) in the undergraduates.

According to the individual question analysis regarding knowledge of human gene therapy, 97% participants were aware of the term 'Gene Therapy'. In addition, 71% of the participants thought that gene therapy was designed to introduce genetic material into cells. However, more than half (n = 219; 73.0%) of the participants were aware that the therapy may have ethical issues involved. Moreover, 69% participants were ready to consider gene therapy as a boon to mankind. (**Table 2**)

Table 2:- Information regarding knowledge of human gene therapy among the participants in percentage (according to likert scale) (n=300).

Sr. No.	Questions regarding Knowledge	SD n(%)	D n(%)	N n(%)	A n(%)	SA n(%)	p- value
1	I have heard the term Gene Therapy-yes	0	2 (0.7)	0	7 (2.3)	291 (97)	<0.01
2	Gene therapy is designed to introduce genetic material into cells	24 (8)	9 (3)	0	54 (18)	213 (71)	0.001
3	A gene that is inserted directly into a cell usually does not function.	130 (43.3)	115 (38.4)	5 (1.7)	40 (13.3)	10 (3.3)	<0.001
4	A vector is a different type of gene.	117 (39)	84 (28)	21 (7)	63 (21)	15 (5)	<0.01
5	The vector can be injected or given intravenously (by IV) directly into a specific tissue in the body, where it is taken up by individual cells.	63 (21)	12 (4)	6 (2)	72 (24)	147 (49)	0.003
6	Gene therapy is safe.	174 (58)	93 (31)	3 (1)	30 (10)	0	0.000
7	There are ethical issues involved in gene therapy.	6 (2)	15 (5)	18 (6)	42 (14)	219 (73)	0.001
8	Germ-line gene therapy is transfer of a section of DNA to cells that produce eggs or sperm.	69 (23)	18 (6)	20 (6.7)	10 (3.3)	183 (61)	0.001
9	Genetic disorders can be cured by gene therapy.	204 (68)	69 (23)	9 (3)	6 (2)	12 (4)	0.002
10	Gene Therapy is a boon to mankind.	30 (10)	27 (9)	3 (1)	33 (11)	207 (69)	0.000

Likert scale:

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

Additionally, 59.2% of the undergraduates, compared to 94.7% of the postgraduates, were strongly agreeing the statement, that they have heard the term "Gene Therapy". The other three questions which were strongly agreed by all the students is shown in **Table 3**. Similarly, 52.7% of the participating undergraduates and 94.7% of the postgraduates were in total disagreement for gene therapy being considered as safe. **(Table 4)**

Table 3:- Comparison of the score (%) of undergraduate and postgraduate students for information regarding knowledge of human gene therapy for strongly agreeing with the question.

Sr. No.	Questions regarding Knowledge	Undergraduate (262)	Postgraduate (38)	Total (300)	P value
1.	I have heard the term Gene Therapy- yes	155 (59.2)	36 (94.7)	291 (97)	0.217
2	Gene therapy is designed to introduce genetic material into cells	189 (72.1)	30 (78.9)	213 (71)	0.336
7	There are ethical issues involved in gene therapy.	189 (72.1)	30 (78.9)	219 (73)	0.336
10	Gene Therapy is a boon to mankind.	175 (66.8)	32 (84.2)	207 (69)	0.295

Table 4:- Comparison of the score (%) of undergraduate and postgraduate students for information regarding knowledge of human gene therapy for strongly disagreeing with the question.

	Questions regarding Knowledge	Undergraduate (262)	Postgraduate (38)	Total (300)	P value
6	Gene therapy is safe.	138 (52.7)	36 (94.7)	174 (58)	0.176
9	Genetic disorders can be cured by gene therapy.	180 (68.7)	24 (63.2)	204 (68)	0.382

Self-Assessed Knowledge of Gene Therapy:-

Table 5 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 on various answers. Majority of the respondents (n = 249; 83%) were aware of the meaning of gene therapy. On hearing the term gene therapy, maximum participants (n=264; 88%) thought of genetic disorders. Information regarding question 13 and 14 is demonstrated in **Figure 2** and **Figure 3** respectively.

Table 5:- Questions on self assessed knowledge about 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

Figure 2:- Response of students in percentage (undergraduates and postgraduates) for question no 13 (Source Of Information Regarding Gene Therapy).

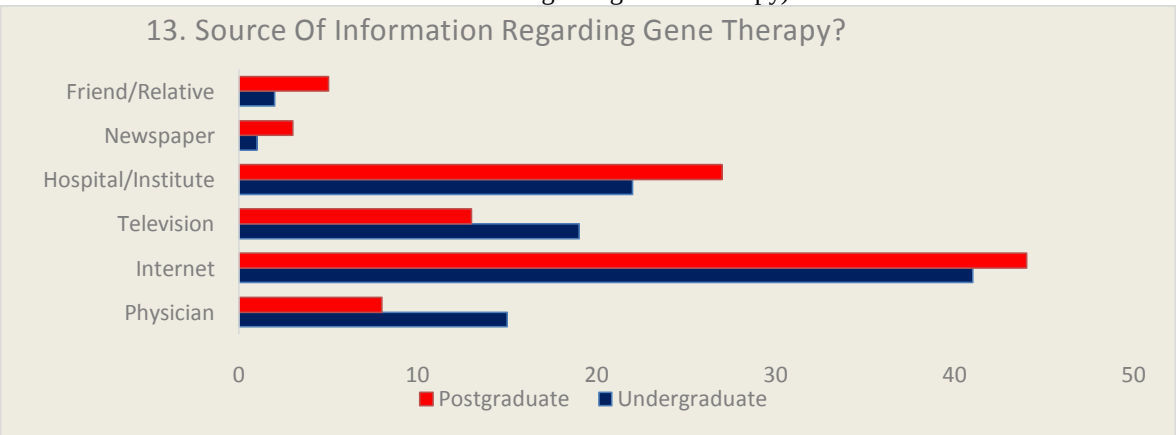
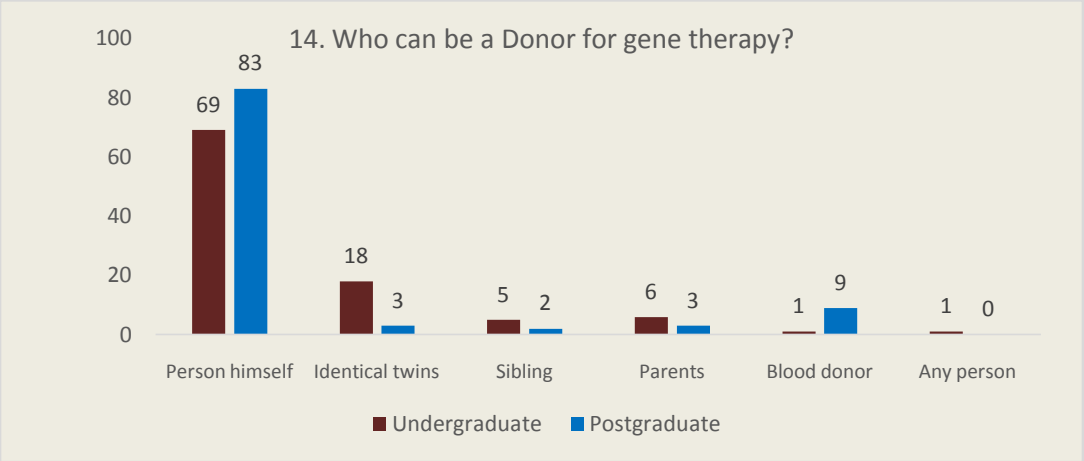


Figure 3:- Response of undergraduate and postgraduate students (%) for question 14 (Who can be a Donor for gene therapy).



Participants Attitudes and Awareness towards Gene Therapy:
Respondents' attitudes and awareness toward gene therapy are reported in **Table 6**. Majority of the respondents (94.7%) were of the belief that gene therapy will soon become a useful treatment strategy. Attitude and awareness score was found to be statistically significant among the students. Participants were well aware regarding first gene therapy patient and potential benefits and harms. More than half (62%) of the participant students were concerned about the safety of patients.

Table 6:- Information regarding attitude and awareness regarding human gene therapy among the participants in percentage (n=300).

Sr. No.	Questions regarding Attitude and Awareness	Yes	No	Neutral	P value
15.	Gene therapy will soon become a useful treatment strategy in near future.	284 (94.7)	10 (3.3)	6 (2)	0.556
16.	Gene therapy uses sections of DNA to treat or prevent disease.	178 (59.3)	60 (20)	62 (20.7)	0.020
17.	I am aware that a four-year old girl became the first gene therapy patient at the NIH Clinical Center.	161 (53.7)	31 (10.3)	108 (36)	0.01
18.	I am aware of potential benefits and harms of gene therapy.	108 (36)	114 (38)	78 (26)	0.00
19.	It is possible to cure adults with debilitating diseases using gene therapy	60 (20)	159 (53)	81 (27)	0.00
20.	Are you concerned in regards to safety of patients about the use of gene therapy?	186 (62)	60 (20)	54 (18)	0.043

Relationship Between Socio-Demographic Factors and Gene Therapy Knowledge:
Linear regression analysis for factors affecting knowledge score such as age, gender and education was plotted. High knowledge score was associated with younger age (p=0.02), MS/MD/DM/Mch and Ph.D. degree holders (p=0.01). However, there was a positive correlation between knowledge and attitude (rho 0.3, $P < 0.0001$).

Discussion:-

Gene therapy is an emerging technology characterized by uncertainty in scientific knowledge with regard to benefits and risks.[7] Gene therapy is understood as the capacity for gene improvement by means of the correction of altered (mutated) genes or site-specific modifications that have therapeutic treatment as target. It present exhilarating opportunities, but also pose major challenges.[8,9] The current study investigated the level of knowledge, attitude and awareness regarding gene therapy among undergraduate and postgraduate students of medical and paramedical fraternity.

In our study, majority of the participants were of younger generation. Most studies found that younger participants were more accepting of gene therapy, possibly due to an increase in concern by older individuals and reduced exposure to the development and use of these modern technologies.[10]

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. This is in contrast to a study conducted in Malaysia in which they found that most respondents had poor to fair knowledge, and nearly half had no genomics education[11].

It is also novel in that it is one of the few cases where large-scale debate of the ethical considerations has taken place well before the technologies concerned have become available on anything but a very experimental level. Although debate about other issues in genetics, such as screening and counseling, has taken place, this has occurred either after technologies have been developed or at the same time.[12] Gene therapy is one of the first chances to allow ethical debate to shape and contribute to a technology from the very first stages of its development. Moreover, several countries had launched gene therapy educational programs to both healthcare professionals and patients [13]. Our students were well aware of the ethical issues both in favor of and against its development and use regarding gene therapy.

The active substance in gene therapy medicinal products consists of a recombinant nucleic acid used in human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Although not all gene therapy medicinal products involve the use of cells, in the case of ex vivo gene therapy, cells play an essential role. [14]Majority of the participants in our study disagreed for gene therapy being safe and effective for genetic disorders.

The FDA regulates human gene therapy products as biological products. The field of gene therapy holds great promise for treating a wide array of illnesses, from genetically inherited diseases such as cystic fibrosis or hemophilia to heart disease, acquired immune deficiency syndrome, graft versus host disease, and cancer. The use of gene therapy in the areas of wound healing, tissue repair, and tissue engineering is also being investigated. Participants were also concerned about the safety.[15] Banet and Ayuso; 2003[16] commented, "From an academic point of view, we consider it is important to provide students with a basic conceptual framework for understanding the location, transmission and expression of hereditary information and the basic mechanisms involved in the evolution of living beings.[17] Such knowledge would also help students to understand the biological significance of certain phenomena such as cell division, germ line cell, cell cycle, gene therapy etc.Hence education regarding gene therapy is must for evolving the technology and its utilization.

Over the years definitely knowledge has increased. This seems to be fairly good percentage and also draws attention to the fact that youths are concerned with knowledge regarding gene therapy. Data from this study revealed a high level of awareness and knowledge and a positive attitude towards gene therapy. It is high time that the message needs to be passed for the benefit of population. A concerted effort of creating awareness can take this message forward. It is time to develop programs to update the awareness related to gene therapy. In few decades, we may see a day when genetic disorders are tackled effectively and efficiently with gene replacement. Government should also make certain amendments for all the families having a history of genetic disorder.

Conclusion:-

The results of the present study concluded that majority of the medical students were aware of gene therapy in disease and health. The awareness regarding gene therapy was generally fair among the paramedical students. Gene therapy research and application should be a part of curriculum of medical and paramedical education. Most of the students supported that it can be a boon to mankind.

Limitation:-

The sample size was smaller for this study, hence a study with larger sample size is needed for the assessing the awareness, attitude and knowledge among the students, not only medical but non medical also. 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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