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Comparative Effectiveness of *Trinpanchmula Ghanvati* with *Shveta Parpati* in the Management of *Pittaja Mutrakriccha* (UTI) - Study Protocol for an Open Labelled Randomized Controlled Trial

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Abstract: Background- Ayurvedic literature delineates a comprehensive approach for the management of PittajaMutrakriccha, encompassing the administration of herbo-mineral formulations, adoption of therapeutic yogic interventions, and implementation of appropriate lifestyle modifications. The purpose of this study is to compare the efficacy of TrinpanchmulaGhanvati with Shveta Parpati in the treatment of PittajaMutrakriccha patients. Although plenty of formulations are there, but there is no research work done to proof the efficacy of TrinpanchmulaGhanvati in the management of PittajaMutrakriccha.

Methodsanddesign- In a prospective, open labelled, randomized controlled trial, 60 patients, between 18 and 50 years, diagnosed with Pittaja Mutrakriccha, presenting with cardinal features of PittajaMutrakriccha as described in Ayurvedic texts, two groups will be randomly assigned. In Group one, the patients will receive TrinpanchmulaGhanvati and in Group two, patients will receive Shveta Parpati. Guidelines regarding Pathya-apathya will be given to both the groups. The course of treatment will last for 14 days for both groups. Outcomes will be evaluated on 7th, 14th (During treatment) & 21st& 28th (post-treatment).

Result: The primary outcome will be assessed by checking the grading of the cardinal symptoms of PittajaMutrakriccha mentioned in Ayurvedic texts. Secondary outcome will check for improvement in laboratory investigations and quality of life of the patient.

Conclusion: This trial is first to compares the effectiveness of TrinpanchmulaGhanvati with Shveta Parpati in the patients of PittajaMutrakriccha. TrinpanchmulaGhanvati is envisioned to improve the symptoms of PittajaMutrakriccha, thus proving to be effective in management of patients of PittajaMutrakriccha

Keywords: Controlled trial, TrinpanchmulaGhanvati,Pittaja Mutrakriccha,Shveta Parpati, Randomised Trial.

I. INTRODUCTION

A. Background and rationale

The fundamental components of body are *Dosha*, *Dhatu* and *Mala*. *Dosha* and *Dhatu* balance is essential for a healthy body, and regular and adequate *Mala* excretion is just as vital. Among the trimala, *Mutra* is responsible for *Basti Poorana* and *Kleda Vahanam*. Basti (Urinary Bladder) and Vankshana (Genital area) have been considered as the root/base of MutravahaSrotas and their dysfunction leads to excessive urination or oliguria/dysuria, increased frequency and painful micturition [1]. The commonest symptom of *Mutrakriccha* is "*Dukhenopravrutti*" which means pain and discomfort during micturition [2]. In Ayurveda classics, eight types of *Mutrakriccha* are described, out of which *PittajaMutrakriccha* is the most common among patients [3]. The patient suffers from burning micturation, difficulty in passing urine, straining while passing the urine, urgency for urination, blood-tinged urine and yellowish discoloration [4] . All the symptoms of *PittajaMutrakriccha* are similar to urinary tract infection (UTI), one of the most prevalent diseases affecting people from all age groups including neonate and geriatric age groups. UTI can be complicated and uncomplicated.

Uncomplicated UTI mostly affects healthy individuals with no structural or neurological urinary tract abnormalities, which include cystitis and pyelonephritis. [5] Recurrence of UTI is most common and its burden on society is increasing. Ayurveda has a complete management of *Mutrakricchaand* can reduce the rate of recurrence.

B. Trial design

This will be a prospective, randomized, open labelled, parallel group, double arm study on the diagnosed cases of *PittajaMutrakriccha*. The eligible volunteers who are enrolled will be randomized and allocated to two study arms (intervention group and control group) after obtaining signed informed consent. This study is designed in accordance with standard operating procedures for clinical trials (Declaration of Helsinki) following the ethical standards. The study has been approved by Institutional Ethics Committee of this institute and registered in CTRI [identifier - CTRI/2024/07/070152] prospectively. The trial is currently in the hiring stage. The medication was prepared from G.M.P certified Pharmacy that supplied quality control reports for two different medications.

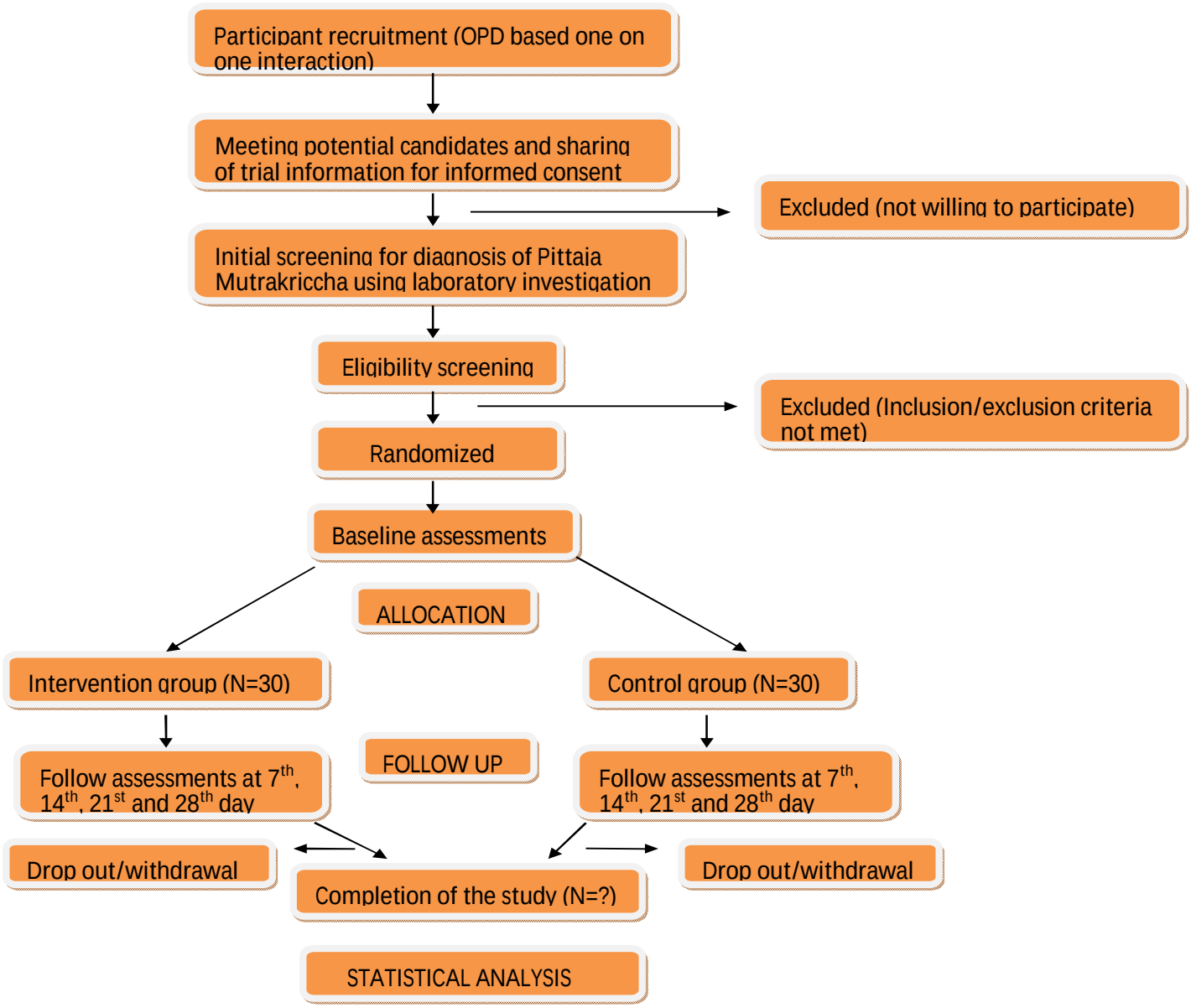

Fig 1: Study flow chart

II. METHODS

A. Intervention

Patients are assigned at randomly to Groups A and B in a 1:1 ratio through a computer generated randomization sequence. Following randomization, patients in Group A, each Patient will be advised for taking *TrinpanchmulaGhanvati*in the dose of 500 mg thrice daily with water for 14 days.

Patients in Group B will be advised to take *Shveta Parpati* in the dose of 500mg twice daily with water for 14 days. Contents of *TrinpanchmulaGhanvati*and *Shveta Parpati* are listed below:

Table no: 1 - Contents of *TrinpanchmulaGhanvati*[6]

Sr no	Drug name	Botanical name	Quantity	Parts used
1	Kush	DesmostachyaBipinata	1 Part	Root
2	Kash	Saccharum Spontaneum	1 Part	Root
3	Shara	Saccharum Muja	1 Part	Root
4	Ikshu	Saccharum Officinarum	1 Part	Root
5	Darbha	Imperata Cylindrical	1 Part	Root

Table no: 2 - Contents of Shveta Parpati[7]

Sr no	Drug name	Chemical Compound Name	Quantity
1	Kalmi Shora/ Suryakshara	Potassium Nitrate	16 parts
2	Sphatika	Potash Alum	2 parts
3	Navsadar	Ammonium Chloride	1 part

B. Eligibility

1) Inclusion Criteria: Patients of either gender with the age group of 18-50 years presented with cardinal features of *PittajaMutrakriccha* as described in Ayurvedic texts or patient with laboratory investigation showing Pus cells/RBCs/Epithelial cells in urine sample above normal range is randomly selected, who are willing and able to participate in the study and provide written informed consent.

2) Exclusion Criteria: Patient below 18 years and above 50 years of age; Patients suffering from- Diabetes Mellitus, Kidney stone, Benign Prostate Hyperplasia, Cancer, Renal failure, Pyelonephritis, Nephrotic or Nephritic Syndrome, STDs, Sepsis, Tuberculosis, Cardiac disorders, Alcohol and other drug abusers, history of trauma, pregnant and lactating women and having TLC count >12,000/µL.

C. Screening, Consent

Apparently healthy volunteers (18-50 years) with already diagnosed and freshly diagnosed with *PittajaMutrakriccha* will be included in the study. The research scholar will collect written informed consent from each participant prior to screening. The patient information sheet will be given to the participant containing details of the study in English/Hindi language whichever will be best suited and the patient will be instructed to go through it to discuss any query. The patient will be given sufficient time to take voluntary participation in the study. When the patient will be fully satisfied with the various aspects of the study, he/she will be asked to sign the consent form. Participant will be screened extensively for eligibility and upon determining eligibility they will be enrolled in the study following randomization procedure. Then the participants will be followed up at their predetermined time points till the completion of study period.

D. Participant Timeline

The trial consist of 14 with a follow up on every 7th day. Participant will visit scholar 2 times during the trial and 2 times after the completion of trial. A telephonic reminder will be given to patients regarding their follow up. The research scholar will contact the participants for monitoring the symptoms and trial drug related side effects. On follow up both subjective and objective parameters will be monitered on { 7th, 14th (During treatment), 21st& 28th (post-treatment) } (Table no 2).

Table no 2:Assessment Criteria

Subjective Criteria

1) Peeta Mutrata (Yellow color urine)

Normal color (pale)	0
Mild yellow	1
Yellow	2
Dark Yellow	3

2) Muhurmuhur mutra pravrutti (Frequency of urination)

Less than 5 times	0
5-8 Times	1
9-12 Times	2
More than 12 times	3

3) Daha (Burning sensation)

Absent	0
Mild-Occasional	1
Moderate burning with every voiding	2
Severe burning with every voiding	3

4) Ruja (Pain during urination)

Absent	0
Mild	1
Moderate	2
Severe	3

LABORATORY INVESTIGATIONS

S. No	Parameters	Day 0	Day 14th
1	HB	□	□
2	TLC	□	□
3	DLC	□	□
4	Urine Routine	□	□
	Color	□	□
	pH	□	□
	Specific Gravity	□	□
	Urine Sugar	□	□

	Urine Albumin	□	□
5	Urine RBC (Saraktamutrata)	□	□
6	Urine Pus cells	□	□
7	Urine WBC	□	□
8	Urine Culture	□	

Withdrawal criteria: The patient with major ailment which needs the new line of treatment and having any Adverse Drug Reaction (ADR) will be withdrawn from the study. Also the patient not willing to participate further or want to terminate will be also withdrawn.

III. METHODS - ASSIGNMENT OF INTERVENTIONS

A. Randomization and allocation

The sequence generation will be done with the help of computer generated random numbers with an allocation ratio 1:1. A predetermined computer generated randomization chart will be developed.

B. Allocation concealment and blinding

The document of randomization will not be disclosed to ensure concealment. The trial interventions will be seal packed properly in air tight container and will be given to patient according to randomization schedule. Both the intervention and trial drug will be known to participant and the research scholar. No blinding or masking should be applied.

IV. METHODS – DATA COLLECTION, MANAGEMENT AND ANALYSIS

A. Data collection and management

The primary source of data will be through symptoms of the assessment criteria, which will be measured during the visits. The data will be collected by the research scholar himself to procure a reliable data. The collected data will be recorded in the case record form (CRF). Consent forms and CRFs will be stored in the concerned department of this institute. Confidentiality of the patients would be maintained during the entire trial.

B. Statistical analysis

The subjective and objective parameters will be analyzed. The 30 patents in every group will be studied. Unpaired t-test will be applied on the collected data to achieve p value. Detailed statistical plan will be developed before data analysis using SPSS and MS Excel.

V. DISCUSSION

In this trial, the efficacy of *TrinpanchmulaGhanvati* with *Shveta Parpati*in the treatment of *PittajaMutrakriccha* is compared. In classics eight types of *mutrakriccha* has been described among which *PittajaMutrakriccha* holds significant clinical importance. The characteristic features of *PittajaMutrakriccha* include *Shoolayukta* (painful micturition), *Raktayukta/peetayukta* (presence of blood or yellowish discoloration of urine), *dahayukta*(Burning sensation during urination) and *Muhurmuhur Mutra Pravritti* (frequent micturition) can be correlated to UTI in modern sciences [8]. Urinary tract infections are second in frequency after respiratory tract infections. [9] UTI are potentially a serious condition and may lead to the development of serious chronic pyelonephritis and chronic renal failure. With the introduction of effective antibiotics problem has been solved to some extent but the use of antibiotics has limitations like side effects, chances of reinfection and relapse even after long-term therapy. UTI reduces the quality of life of the patients. Recurrent UTI have a detrimental effect on social interactions, self-esteem, and ability to work, although social function may be significantly more impaired than physical function.

Keeping in view of the above limitations this study has been chosen to fill this gap of providing a safe and effective line of treatment as Ayurveda provides multiple formulations for this. As in *PittajaMutrakrichha* vitiation of *Pitta* and *Vata Dosha*. *Pitta* spreads in to general circulation with the help of *Vyana Vayu* or *Rasa*. Then aggravated *Pachaka Pitta* and *Samana Vayu* leads to *agnimandyta*. As a result, *Kleda*is formed in excess.

Dushita Kleda in turn affects the quantity of *Mutra* and disturbs the concentration of urine. Vitiated *Pitta* results in *Haridra Mutra*. Vitiated Pitta along with *Pratiloma Gati* of *Apana Vayu* obstructs the urinary pathway resulting in burning type of pain during micturition. The *Laxanas* like *Daha Peeta* and *Raktavarna Mutra Pravrutti* or*Haridra Varna* indicative of *Pitta Prakopa*. It indicates increased concentration of urine. *Sarakta Mutra* indicates hematuria. While *Osha, Chosa, Daha* is the *NantamajaVikaras* of *Pitta*. So, it can be inferred that, pain is burning type in *PittajaMutrakriccha*. In Pittaja*MutrakrichhaTrinpanchmulaghanvati* is used.*Trinpanchmulaghanvati* contains the drugs *Kusha, Kasa, Sara, Darbha,* and *Ikshu.* All the drugs are having *Madhura* and *Kashaya* rasa except *Ikshu* which having only *Madhura rasa*, all are having *Shita virya, Madhura vipaka, Laghu* and *Snigdha guna* and all are having *Prabhav Mutrakricchahara* and mitigate *Pitta* and *Vata* and acts as *Mutrala* or Diuretic. Also does *Mutravirechana* and *Bastishodhan*a by their properties by breaking the pathogenesis of disease [10,11,12,13]. *Shveta Parpati* contains *Suryakshara, sphatika*and*navsadar*. [14]*Suryakshara* is having *Katu, Lavana rasa* and *Ushna Virya* with *Mutra Shodhaka, Daha* Shamana and Mutrala (Diuretic) properties[15] .*Suryakshara* and *Sphatika* are *Ksharas*, and hence they have the karma of *Shodhana* and *Ropana*. *Sphatika* with its *Madhura Vipak*a alleviates Pitta. *Suryakshara* being *Tikshna* and *Ushna* could act on *Kapha* and *Vata*. [16] By the Alkalizing properties *Shveta Parpati* mitigates the pathogenesis of *Mutrakriccha* through neutralize the acidic pH of urine.Hence, the drug plays an important role in the treatment of *PittajaMutrakriccha* and is selected for the study. So here an effort is made to see whether *Trinpanchmulaghanvati* or *Shveta Parpati* is more effective in the management of *PittajaMutrakriccha*

VI. DECLARATIONS

1) Ethics approval and Consent to Participate: The Ethics Committee of Shri Krishna Ayush University, Kurukshetra, accepted the study (SKAU/Acad/2024/10809).

2) Financial Implications: The financial allotment shall be given by Shri Krishna Ayush University for the study will be utilized and will be completed within the financial limit provided by the institute.

3) Followed Guidelines: The common guidelines for clinical trials, known as the Declaration of Helsinki, are being followed in the conduct of this trial.

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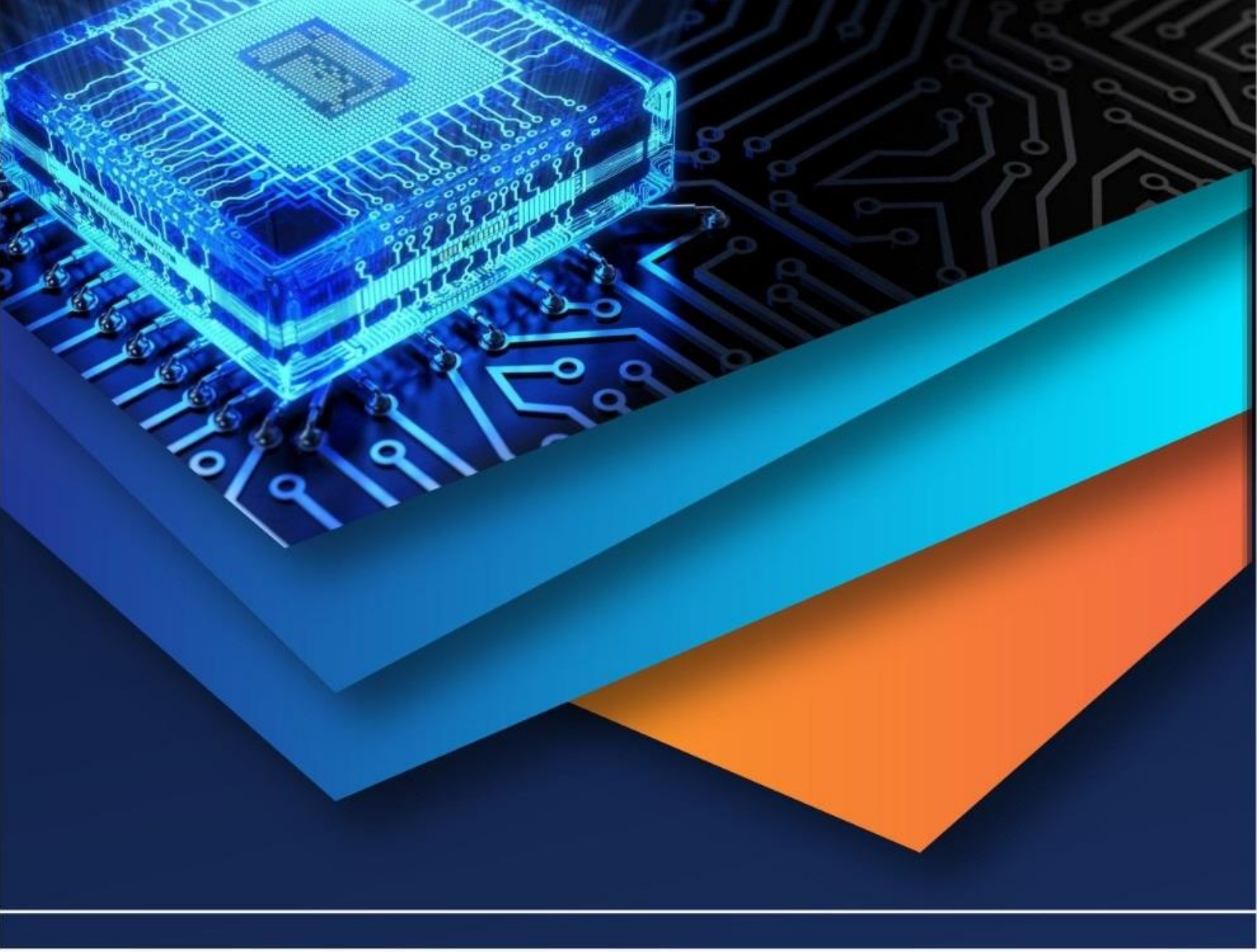

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