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Comparative Efficacy of Topical *Trailokya Vijaya* Gel Versus 2% Lignocaine Gel for Postoperative Pain Management in Anorectal Surgeries: A Randomized, Open-Label Clinical Trial

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Abstract: ***Background: Postoperative pain following anorectal surgeries is a significant clinical challenge, affecting approximately 50% of patients and impeding recovery. Lignocaine gel 2%, though effective, offers only short-duration analgesia. Trailokya Vijaya Gel, a herbal formulation derived from Cannabis sativa (Bhanga) and Bambusa manna (Tugakshiri), was hypothesized to provide sustained analgesic, anti-inflammatory, and wound-healing benefits via cannabinoid-mediated mechanisms.***
Aim: To evaluate and compare the onset, peak efficacy, and duration of analgesia of Trailokya Vijaya Gel versus 2% Lignocaine Gel in postoperative pain management following anorectal surgeries.
Methods: A randomized, open-label, comparative clinical trial was conducted on 40 patients undergoing anorectal surgeries (haemorrhoidectomy, fistulotomy, fissurectomy, Ksharasutra ligation) at Sanjeevani Ayurveda Hospital, DSRRAU, Jodhpur. Patients were equally allocated to Group A (Lignocaine Gel 2%, n=20) and Group B (Trailokya Vijaya Gel, n=20). Pain intensity was assessed using the Visual Analogue Scale (VAS) at baseline and at 1, 2, 5, 10, 20 minutes and 2, 4, 6, 8, 10 hours post-intervention. Statistical analysis used the Wilcoxon signed-rank test for intra-group and Mann-Whitney U test for inter-group comparisons.
Results: Both interventions significantly reduced postoperative pain from baseline ($p<0.001$). Group B demonstrated a markedly faster onset: 49.18% pain relief at 1 minute versus no change in Group A ($p<0.001$). Peak analgesic efficacy was comparable between groups at 10-20 minutes (Group A: ~73%; Group B: ~70%; $p>0.05$). However, Group B maintained significantly superior pain control throughout the 2-10 hour observation period (Group B: 30.60-60.66% relief versus Group A: 20.25-55.21%; $p<0.05$ to $p<0.001$ at all intervals). No adverse reactions were recorded in either group.
Conclusion: Trailokya Vijaya Gel exhibited faster onset, equivalent peak analgesia, and significantly prolonged duration of pain relief compared to Lignocaine Gel 2%, with an excellent safety profile. It represents a promising herbal-based alternative for postoperative analgesia in anorectal surgery, warranting further large-scale investigation.
Keywords: Postoperative pain; Anorectal surgery; Cannabis sativa; Bambusa manna; Lignocaine; Visual Analogue Scale; Vedanasthapana; Topical analgesia; Trailokya Vijaya Gel

I. INTRODUCTION

Postoperative pain remains one of the most prevalent and distressing sequelae of surgical intervention, affecting an estimated 20-40% of patients globally and up to 50% of those undergoing benign anorectal procedures such as haemorrhoidectomy and fistulotomy.[1]

The anal canal and perianal region are richly supplied by somatic fibres of the pudendal nerve, rendering them exquisitely sensitive to nociceptive stimuli following surgical trauma. Inadequately managed postoperative pain delays mobilisation, prolongs hospitalisation, impairs wound healing, and may precipitate complications including urinary retention, faecal impaction, and wound dehiscence.[2]

Contemporary multimodal analgesic strategies for anorectal surgery incorporate topical local anaesthetics, non-steroidal anti-inflammatory drugs (NSAIDs), and opioid-sparing regimens aligned with Enhanced Recovery After Surgery (ERAS) principles. Lignocaine gel 2%, an amide-class local anaesthetic that reversibly blocks voltage-gated sodium channels in peripheral sensory neurons, is widely employed as a topical agent for its rapid onset and localised effect.[3] However, its relatively short duration of action (30-60 minutes), potential for mucosal irritation, and rare systemic toxicity with repeated application limit its utility as a standalone analgesic in the postoperative period.[4]

Ayurvedic surgical science (*Shalya Tantra*) conceptualises postoperative pain (*Shastranipatajata Vedana*) as primarily *Vata-dosha*-mediated and advocates *Vedanasthapana* (analgesic), *Shothahara* (anti-inflammatory), and *Vrana-ropaka* (wound-healing) interventions. The classical text *Rasatarangini* describes *Trailokya Vijaya Vati*, a preparation combining *Bhanga Ghan Satva* (*Cannabis sativa* L.) and *Vanshlochan* (*Bambusa arundinacea manna*), indicated for pain, haemorrhoids, and pro-convulsive states.[5] *Bhanga* contains cannabinoids including cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), which exert peripheral analgesic effects via CB1/CB2 receptor activation, inhibit prostaglandin synthesis through COX-2 suppression, and reduce smooth muscle hypertonicity - mechanisms directly relevant to postoperative anorectal pain.[6] *Tugakshiri* (*Bambusa manna*), employed as the pharmacologically equivalent substitute (*Pratinidhi Dravya*) for the scarce *Vanshlochan*, is rich in silica, polysaccharides, flavonoids (orientin, vitexin), and phenolic compounds that confer demulcent, anti-inflammatory, and epithelial regenerative properties.[7]

Despite this pharmacological rationale, no randomised comparative clinical trial has evaluated topical *Cannabis-Bambusa* gel formulations against standard anaesthetic gels in the postoperative anorectal context. The present study was therefore designed to address this evidence gap by comparing the onset, peak efficacy, and duration of analgesia of a novel *Trailokya Vijaya* Gel with standard 2% Lignocaine Gel in patients undergoing anorectal surgeries.

II. MATERIALS AND METHODS

A. *Study Design and Setting*

A prospective, randomized, open-label, interventional, comparative clinical study was conducted at the *Shalya Tantra* Outpatient and Inpatient Department, Sanjeevani Ayurveda Hospital, DSRRAU, Jodhpur, Rajasthan, India. Institutional Ethics Committee approval was obtained (letter no. DSRRAU/PGIA/IEC/22-23-631), and the trial was registered with the Clinical Trials Registry of India (CTRI/2024/06/068891).

B. *Sample Size and Randomisation*

A total of 40 patients fulfilling predefined inclusion criteria were enrolled and randomly allocated to two parallel groups of 20 patients each using simple randomisation. Group A (Control) received topical 2% Lignocaine Gel, and Group B (Trial) received topical *Trailokya Vijaya* Gel. All 40 patients completed the study with zero dropout.

C. *Inclusion and Exclusion Criteria*

Patients aged 20-99 years of either sex, diagnosed with *Arsha* (haemorrhoids), *Bhagandara* (fistula-in-ano), or *Parikartika* (fissure-in-ano), undergoing anorectal surgery under local anaesthesia and willing to provide informed consent were included. Exclusion criteria comprised severe systemic illness (diabetes mellitus, hypertension, cardiac, renal or hepatic disease), known hypersensitivity to lignocaine or herbal constituents, concurrent analgesic or immunosuppressive medication, pregnancy or lactation, active postoperative complications, unexplained severe preoperative pain, chronic alcohol dependence, and positive serology for HIV, HBsAg, or VDRL.

D. *Interventions*

Group A received commercially sourced 2% Lignocaine Hydrochloride topical gel (Carbopol base). Group B received *Trailokya Vijaya* Gel, prepared in the Department of *Rasashastra* and *Bhaishajya Kalpana*, DSRRAU, using authenticated plant materials. Bhanga (Cannabis sativa L.) dried leaves were Soxhlet-extracted with a 1:1 hydroalcoholic solvent (ethanol:distilled water) at a 1:10 solute-to-solvent ratio.

Tugakshiri (synthetic *Bambusa manna*) crystals were dissolved in freshly boiled distilled water. Both extracts were combined in a 6:3 ratio (*Bhanga:Tugakshiri*) and gelled with Carbopol 940, glycerine, propylene glycol, and triethanolamine (pH adjustment), incorporating 2-phenoxyethanol as preservative. The final product was a translucent greenish-brown gel. Both gels were applied locally to the operated anorectal site (approximately 2-3 g per application) immediately postoperatively and re-applied at dressing change if required. Rescue analgesia (Inj. Diclofenac sodium 75 mg) was administered when VAS score exceeded 6.

E. Outcome Assessment

The primary outcome measure was postoperative pain intensity assessed using the internationally validated 10-point Visual Analogue Scale (VAS; 0 = no pain, 10 = worst imaginable pain). Assessments were recorded at: baseline (0 min, pre-intervention); onset phase (1, 2, 5 minutes post-application); peak analgesic phase (10, 20 minutes); and duration phase (2, 4, 6, 8, 10 hours). The mean difference (MD) and percentage pain relief at each time point were calculated relative to baseline. Safety was monitored by recording any adverse drug reactions throughout the observation period.

F. Statistical Analysis

Data were analysed using GraphPad InStat 3 software. Continuous variables are expressed as Mean ± Standard Deviation (SD). Intra-group differences (pre- vs. post-treatment) were assessed using the Wilcoxon matched-pairs signed-rank test. Inter-group comparisons at each time point were performed using the Mann-Whitney U test. A p-value <0.05 was considered statistically significant and $p<0.01$ highly significant.

III. RESULTS

A. Demographic and Baseline Characteristics

The study population comprised predominantly young adult males: 47.5% were aged 20-30 years and 85% were male. Most patients (67.5%) followed a vegetarian diet. Constipation was present in 50% of patients, and hard stool consistency in 45%, reflecting common predisposing factors for anorectal disease. Vata-Pitta constitutional type (Prakriti) predominated (45%). Baseline VAS scores were comparable between groups (Group A: 8.15 ± 1.04; Group B: 9.15 ± 0.75; $p>0.05$), confirming homogeneity at enrolment.

Characteristic	Group A (Lignocaine, n=20)	Group B (Trailokya Vijaya, n=20)	Total (n=40)
Age 20-30 years	7 (35%)	12 (60%)	19 (47.5%)
Male sex	16 (80%)	18 (90%)	34 (85%)
Vegetarian diet	15 (75%)	12 (60%)	27 (67.5%)
Constipated bowel	9 (45%)	11 (55%)	20 (50%)
Vata-Pitta Prakriti	10 (50%)	8 (40%)	18 (45%)
Baseline VAS (Mean ± SD)	8.15 ± 1.04	9.15 ± 0.75	—

Table 1: Baseline demographic and clinical characteristics of study participants

B. Intra-Group Analysis

Group A (Lignocaine Gel 2%): No change in VAS score was recorded at 1 minute (MD = 0), consistent with the pharmacokinetic latency of sodium-channel blockade. From 2 minutes onward, a statistically highly significant reduction in pain was observed (MD = 4.15; 50.92% relief; $p<0.001$). Peak analgesia was achieved at 10-20 minutes (~73% relief). Pain scores progressively increased from 2 hours onward, with residual relief of 55.21% at 2 hours declining to 20.25% at 10 hours; all time points remained statistically significant versus baseline ($p<0.001$).

Group B (Trailokya Vijaya Gel): A remarkable 49.18% reduction in VAS score was recorded as early as 1 minute post-application (MD = 4.50; p<0.001). The analgesic effect progressed through 2 minutes (52.46%) and 5 minutes (56.28%), reaching peak efficacy of 69.40-71.04% at 10-20 minutes (p<0.001). Pain control remained superior during the duration phase: 60.66% at 2 hours, declining to 30.60% at 10 hours, with all time points highly significant versus baseline (p<0.001).

Time Point	Group A Mean (MD%)	Group B Mean (MD%)	p-value (Inter-group)	Significance
Baseline (0 min)	8.15 (—)	9.15 (—)	—	NS
1 min	8.15 (0%)	4.65 (49.18%)	<0.001	H.S.
2 min	4.00 (50.92%)	4.35 (52.46%)	0.011	S.
5 min	3.80 (53.37%)	4.00 (56.28%)	0.007	S.
10 min	2.20 (73.01%)	2.80 (69.40%)	0.147	N.S.
20 min	2.15 (73.62%)	2.65 (71.04%)	0.154	N.S.
2 hr	3.65 (55.21%)	3.60 (60.66%)	0.004	S.
4 hr	4.65 (42.94%)	4.15 (54.64%)	<0.001	H.S.
6 hr	5.80 (28.83%)	4.90 (46.45%)	<0.001	H.S.
8 hr	5.95 (26.99%)	5.70 (37.70%)	0.001	S.
10 hr	6.50 (20.25%)	6.35 (30.60%)	0.002	S.

Table 2: Comparative VAS scores and pain relief (%) in Group A vs. Group B. MD% = Mean Difference percentage; H.S. = Highly Significant; S. = Significant; N.S. = Not Significant

C. Inter-Group Comparison

Onset phase (1-5 min): Group B demonstrated markedly superior early analgesia. The inter-group difference was most pronounced at 1 minute (Group A: 0% relief vs. Group B: 49.18%; p<0.001) and remained statistically significant at 2 and 5 minutes (p=0.011 and p=0.007, respectively).

Peak phase (10-20 min): Both groups achieved comparable maximal pain relief (~73% vs. ~70%), with no statistically significant inter-group difference (p=0.147 and p=0.154), indicating equivalent peak analgesic potency.

Duration phase (2-10 hr): Group B maintained consistently superior pain control at all time points from 2 hours onward (p<0.05 to p<0.001). At 6 hours, Group B retained 46.45% relief versus 28.83% in Group A; at 10 hours, 30.60% versus 20.25%, respectively. No adverse drug reactions were recorded in either group throughout the observation period.

IV. DISCUSSION

This randomised comparative trial demonstrates that *Trailokya Vijaya* Gel offers clinically and statistically significant advantages over standard 2% Lignocaine Gel in three key domains: markedly faster onset of analgesia, equivalent peak pain relief, and substantially prolonged duration of analgesic action. These findings are discussed below in the context of pharmacological mechanisms and relevant literature.

A. Faster Onset of Analgesia

The most striking inter-group difference was observed at 1 minute, where Group B achieved approximately 50% pain reduction while Group A showed no change. This aligns with the known pharmacokinetics of lignocaine, which requires 2-5 minutes to penetrate mucosal tissues and achieve adequate sodium-channel blockade.[3] In contrast, the hydroalcoholic extract of *Cannabis sativa* in *Trailokya Vijaya* Gel contains cannabinoid-rich fractions (chromatographic RF ~0.23) that interact rapidly with peripheral

CB1 and CB2 receptors at cutaneous and mucosal nerve endings, suppressing the release of nociceptive neurotransmitters such as substance P and glutamate.[8] The high lipophilicity of cannabinoids facilitates rapid membrane permeation, explaining the virtually immediate analgesic onset. Ethanol as the extraction solvent and propylene glycol as a penetration enhancer in the gel formulation further accelerate transmucosal cannabinoid absorption.

Comparable rapid-onset effects have been documented with topical cannabidiol formulations in preclinical wound pain models. Hammell et al. demonstrated that transdermal CBD markedly attenuated joint swelling and spontaneous pain behaviours in arthritic rats, with measurable tissue concentrations within minutes of application.[9] While direct clinical comparators for anorectal topical cannabinoid gels are absent in current literature - itself reflecting the research gap addressed by the present study - analogies can be drawn with studies on topical anaesthetic combinations. Linares-Gil et al. (2018) reported that lidocaine plus diclofenac topical gel provided significantly better early pain control in benign anorectal surgery compared to lidocaine alone, suggesting that anti-inflammatory adjuncts accelerate functional analgesia onset,[10] consistent with our observations.

B. Equivalent Peak Analgesic Efficacy

Both formulations achieved their maximal analgesic effect between 10 and 20 minutes post-application, with approximately 70-73% pain relief and no statistically significant inter-group difference. This indicates that *Trailokya Vijaya* Gel is not inferior to the established gold-standard topical anaesthetic at peak effect. The cannabinoid-flavonoid synergy evident in the phytochemical profile of *Bhanga* extract (flavonoids at RF 0.05-0.15; cannabinoids at RF 0.23) likely replicates the dual peripheral and central sensitisation blockade achieved by lignocaine's sodium-channel mechanism. Bhanga cannabinoids reduce smooth muscle hypertonicity at the internal anal sphincter via CB-receptor-mediated modulation of neuromuscular excitability - a mechanism particularly relevant in post-sphincterotomy pain where sphincter spasm is a primary driver of nociception.[6]

The Ayurvedic pharmacological framework corroborates these findings: *Bhanga* is classified as *Vedanashamaka* (analgesic), *Shoolahara* (anti-spasmodic), and *Vata-Kaphahara* in the *Doshic* paradigm. *Vata dosha* governs all sensory and pain transmission in Ayurvedic physiology, and its vitiation following surgical trauma *(Shastrakrita Vedana*) is considered the fundamental pain mediator. Classical *Nighantus* universally affirm *Trailokya Vijaya's* potency in *Shoolanashana* (pain elimination), consistent with the clinical evidence generated here.

C. Prolonged Duration of Analgesia

The most clinically significant finding of this study is the sustained analgesic effect of *Trailokya Vijaya* Gel over a 10-hour observation period, maintaining statistically superior pain control versus Lignocaine Gel from 2 hours onward. Lignocaine's limited duration reflects its rapid hepatic metabolism (half-life approximately 1.5-2 hours) and redistribution from the application site. By contrast, the herbal gel matrix - incorporating polysaccharide and silica-rich fractions from *Bambusa manna* (RF 0.28-0.31) - appears to create a bioadhesive depot on the anorectal mucosa enabling sustained release of active cannabinoid and flavonoid constituents. This mechanistic hypothesis is supported by the known mucoadhesive properties of plant polysaccharides such as arabinogalactans present in bamboo manna, which prolong residence time of co-formulated actives at mucosal surfaces.[7]

The anti-inflammatory contribution of *Tugakshiri* cannot be discounted in sustaining analgesia. Its bioactive compounds - orientin, vitexin, and tricin glucosides - have demonstrated COX-2 inhibitory and prostaglandin-suppressing activities in experimental models.[7] Since postoperative pain is partly maintained by peripheral sensitisation driven by ongoing prostaglandin E2 release at the wound site, sustained suppression of this inflammatory cascade by *Tugakshiri* components logically extends the analgesic window beyond the duration achievable by local anaesthetic sodium-channel blockade alone. From the Ayurvedic perspective, *Tugakshiri's Sheeta virya* (cooling potency) and *Shothahara* action reduce the Pitta-mediated inflammatory component of postoperative pain, while its *Snigdha* and *Madhura Rasa* properties soothe and lubricate the sensitive anorectal tissues, reducing frictional nociception.

These results are broadly consistent with previous Ayurvedic clinical studies that reported enhanced and sustained postoperative pain control with herbal formulations: Nirwal (2018) demonstrated that *Avagahan Sweda* and *Matra Vasti* provided prolonged relief in post-haemorrhoidectomy pain versus controls,[11] and Gupta (2018) showed *Yashtimadhu*-based preparations superior to standard care for fistula-in-ano postoperative pain over extended observation periods.[12]

D. Safety Profile

The absence of adverse drug reactions in either group across the observation period is noteworthy. Topical cannabinoid formulations with low systemic absorption present minimal psychoactive risk, consistent with the findings of Hammell et al.[9] and the established safety profile of CBD-dominant Cannabis extracts in topical applications.

Cannabis sativa derivatives for topical/research formulations with low-THC content are legally permissible for clinical use under the NDPS Act 1985 in India under authorised supervision. Lignocaine's established local safety profile in mucosal applications was confirmed by the absence of allergic or systemic reactions in Group A, consistent with published data.[10]

E. Limitations and Future Directions

This study has several limitations that should be acknowledged. The open-label design introduces potential observer bias, as blinding was not feasible given the visible difference between formulations. The sample size of 40 patients, while adequate for preliminary comparison, limits generalisability; a powered double-blind multicentre trial is warranted. The absence of pharmacokinetic data (e.g., plasma cannabinoid levels) precludes direct mechanistic confirmation of the sustained-release hypothesis. Long-term follow-up beyond 10 hours was not assessed, leaving questions regarding wound healing outcomes and recurrence of pain unaddressed. Future studies should incorporate objective wound healing parameters, quality-of-life instruments, and histological assessment of tissue repair.

V. CONCLUSION

Trailokya Vijaya Gel, formulated from standardised *Bhanga* (*Cannabis sativa)* and *Tugakshiri (Bambusa manna)* extracts, demonstrated statistically significant advantages over 2% Lignocaine Gel in postoperative pain management following anorectal surgeries. It exhibited a markedly faster onset of analgesia (within 1 minute), comparable peak analgesic efficacy at 10-20 minutes, and significantly prolonged pain control sustained throughout a 10-hour observation period, with an excellent safety profile and no adverse reactions. These findings provide clinical validation for the Ayurvedic concept of *Vedanasthapana* and support the integration of this evidence-based herbal formulation into multimodal postoperative analgesia protocols for anorectal surgery. The study supports the alternate hypothesis that a significant difference exists between the two formulations, favouring *Trailokya Vijaya* Gel. Larger randomised controlled trials with blinded assessment, pharmacokinetic analysis, and extended follow-up are recommended to consolidate these findings and facilitate clinical adoption.

VI. ACKNOWLEDGEMENTS

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Conflict Of Interest

The authors declare no conflict of interest. The study received no external funding.

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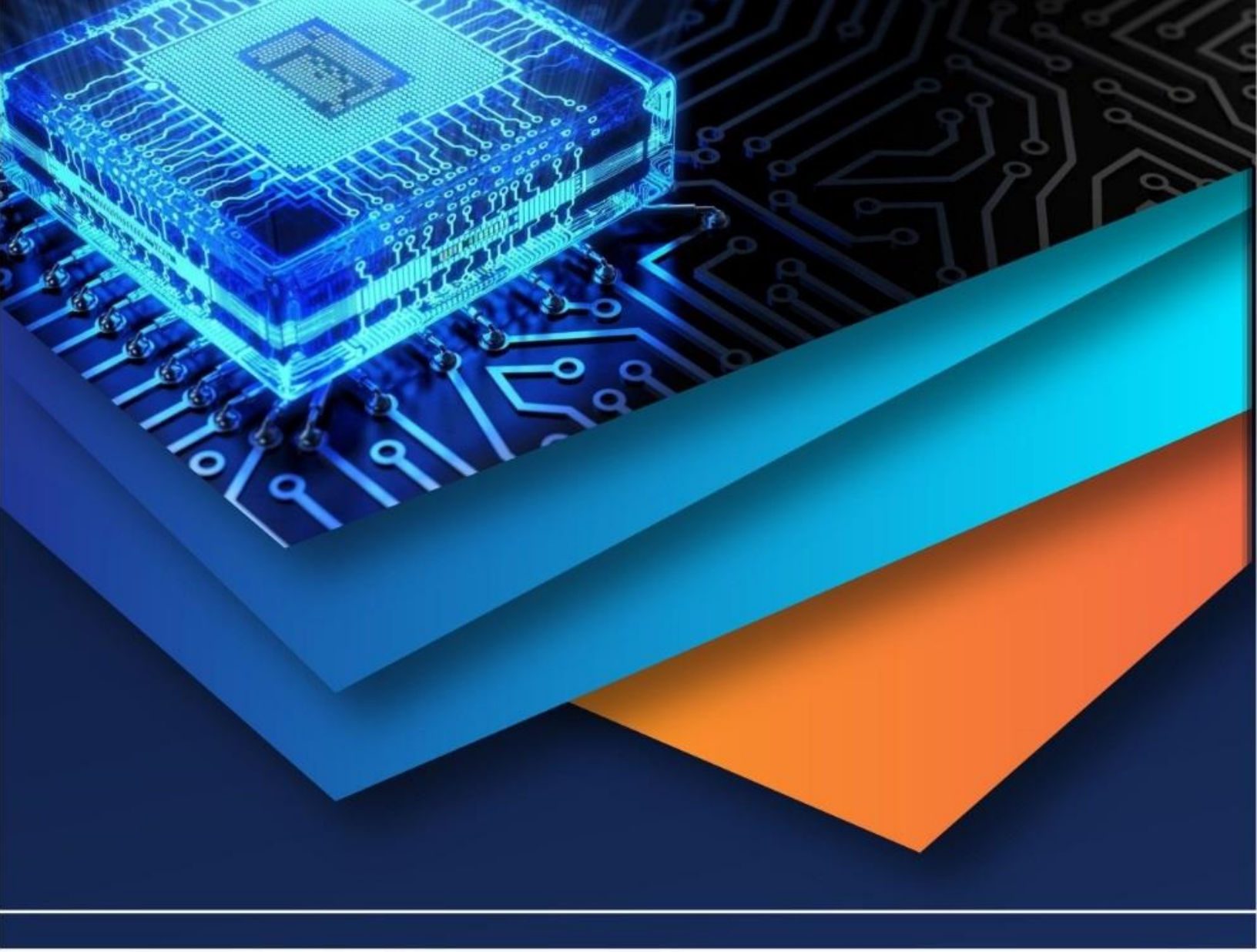

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