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A Review of the Innovative Clinical Application Research of Warm Needling Therapy

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Abstract: As a model of the combination of "acupuncture, medicine, and moxibustion" in traditional Chinese medicine acupuncture, warm needling therapy synergistically utilizes the mechanical stimulation of acupuncture and the thermal effect of moxibustion. It demonstrates unique advantages in treating diseases such as cold-dampness obstruction and excessive internal cold-deficiency. This article systematically combs the historical context of warm needling therapy, interprets its multi-dimensional mechanism of action in combination with modern medical research, summarizes its current application status in diseases of multiple systems based on clinical data from the past decade, and focuses on discussing the synergistic effects and innovative paths of the combined use of moxa wool packs and Chinese herbal medicine powders. The research shows that the trinity model of "acupuncture-moxibustion-medicine" of warm needling therapy significantly improves the therapeutic effects on chronic pain and cold-deficiency diseases by enhancing efficacy and controlling toxicity. In the future, it is necessary to make in-depth breakthroughs in standardization, intelligence, and mechanism research to provide new ideas for the diagnosis and treatment of integrated traditional Chinese and Western medicine.

1. Historical Tracing: The Construction from Classical Medical Books to the Modern Diagnosis and Treatment System

1.1 Origin and Theoretical Foundation (Pre-Qin Dynasty to Tang and Song Dynasties)

The embryonic form of warm needling therapy can be traced back to the era of Huangdi Neijing, and its core theory revolves around "treating cold with heat" and "applying acupuncture and heat simultaneously". Lingshu Guan Neng records that "where acupuncture is not applicable, moxibustion is appropriate", laying the treatment principle of the synergy of acupuncture, medicine, and moxibustion. Lingshu Shou Yao Gang Rou puts forward that "for treating cold bi (arthralgia) diseases, internal heat should be applied", clearly defining for the first time the indications of warm needling for diseases caused by cold pathogens[1].

In the Han Dynasty, Zhang Zhongjing further standardized the application of warm needling in Treatise on Febrile Diseases. He not only affirmed its effect of "warming the meridians and dispelling cold" (such as treating "the combination of wind and dampness, with painful and vexing joints"), but also warned of the disadvantages of "improper use of fire therapy", emphasizing the importance of

dialectical acupuncture.

In the Tang Dynasty, Sun Simiao elaborated on the "method of warm needling" in Essential Emergency Prescriptions for Emergencies: "First insert the acupuncture needle, and then apply moxibustion", establishing the operation procedure of "applying moxibustion after acupuncture". In the Song Dynasty, Wang Zhizhong proposed in Classic of Acupuncture for Life Preservation that "when the needling obtains qi, retain the needle, and warm it with moxa outside", combining the obtaining of qi by acupuncture with the warming and unblocking effect of moxibustion, and forming the synergistic theory of "acupuncture promoting the effect of moxibustion and moxibustion assisting the power of acupuncture". At this point, the three core elements of warm needling therapy, namely "syndrome differentiation of cold and heat", "acupoint selection", and "operation steps", initially took shape.

1.2 Technical Improvement and Clinical Expansion (Jin and Yuan Dynasties to Ming and Qing Dynasties)

During the Jin and Yuan Dynasties, doctors made breakthroughs in warm needling tools and indications. Dou Hanqing recorded the difference between "fire needle" and warm needling in Zhenjing Zhinan, emphasizing that warm needling "does not make the skin red or hot, but only makes the qi flow", avoiding skin burns. In the Ming Dynasty, Yang Jizhou formally proposed the classic technique of "warming the needle by burning moxa on the needle handle" in Great Compendium of Acupuncture and Moxibustion: "Make moxa with medicine, wrap it around the needle handle, light it for moxibustion, and make the heat enter the acupoint through the needle", introducing traditional Chinese medicine for the first time to improve moxa wool (such as adding Aconitum carmichaeli Debx. and Cinnamomum cassia Presl), pioneering the "medicine-moxa warm needling".

In the literature of the Ming and Qing Dynasties, the indications of warm needling expanded from single bi (arthralgia) syndrome to the fields of internal medicine and gynecology. For example, Collection of Acupuncture and Moxibustion records that warm needling at Zhongwan (CV12) and Zusanli (ST36) can treat "stomach cold and vomiting", and Compendium of Gynecology applies warm needling at Guanyuan (CV4) and Sanyinjiao (SP6) to treat "dysmenorrhea due to cold coagulation", reflecting the flexibility of "applying moxibustion based on syndrome differentiation and matching medicine according to symptoms". In the Qing Dynasty, Wu Qian summarized the "five elements" of warm needling operation in The Golden Mirror of Medicine: the needle (fine filiform needle), the quality of moxa (aged moxa), the dosage of medicine (the size of a soybean), the moxibustion time (three cones), and temperature control (using ginger slices to prevent scalding), forming a relatively complete technical specification.

1.3 Modern Transformation and International Dissemination (Since the 20th Century)

In the 1950s, warm needling therapy ushered in technological innovation. Lu Shouyan, a famous acupuncture doctor in Shanghai, improved the design of the needle handle and used a hollow spiral structure to fix the moxa wool, solving the problem that the traditional moxa mass was easy to fall off. In the 1980s, the "Bo's Warm Needling Heat Penetration Method" adjusted the acupuncture depth (1.5 - 2 cun) and the amount of moxa wool (a 1.5 cm moxa segment), making the heat sensation conduct along the Bladder Meridian and the Gallbladder Meridian, expanding the thermal effect from the local area to the whole meridian.

Clinical research data show that the annual number of publications related to warm needling in the past decade has increased at a rate of 12% (statistics from the CNKI database). The diseases involved have increased from 12 types in 1980 to the current 47 types, among which musculoskeletal diseases account for 45%, digestive system diseases account for 22%, and gynecological diseases account for

18%. Internationally, Japan has developed "Chinese Herbal Warm Needling Agent" (containing micro-powder moxa wool of ligustrazine) to treat chronic fatigue syndrome. A multi-center study funded by the US National Institutes of Health (NIH) has confirmed that the analgesic effect of warm needling on fibromyalgia is better than that of simple acupuncture (the Visual Analogue Scale (VAS) score decreased by 3.2 vs 2.1, P<0.05), promoting it to enter the complementary medicine system in Europe and the United States[2].

2. Analysis of the Synergistic Effect from the Perspective of Traditional Chinese and Western Medicine

2.1 The Core of Traditional Chinese Medicine Theory: Warming and Unblocking, Tonifying Deficiency, and Dissipating Nodules

2.1.1 Warming and Unblocking the Meridians, Breaking Stasis and Promoting Flow

Nan Jing Twenty-Two Difficulties states: "Blood moistens the body, and qi warms the body". Cold-dampness blockage leads to the stagnation of qi and blood. Warm needling uses the heat of moxa fire to enter the collaterals through the needle body, achieving the effects of "drawing out heat with heat" and "treating blockage with unblocking". Clinical observation shows that the improvement rate of the range of motion of the shoulder joint in patients with periarthritis of the shoulder of the wind-cold-dampness type treated with warm needling reaches 89%, which is 27% higher than that of simple acupuncture. Its mechanism is related to the local blood vessel dilation (the blood flow increases by 210%) and the accelerated dissolution of urate crystals.

2.1.2 Tonifying Yang Qi and Nourishing the Root of Vitality

For the syndrome of deficiency of spleen-yang and kidney-yang, warm needling stimulates "acupoints of vital qi" such as Guanyuan (CV4) and Mingmen (GV4), stimulating the dynamic qi between the kidneys. Research shows that after patients with chronic heart failure (of the heart-kidney yang deficiency type) are treated with warm needling, the 6-minute walking distance increases by 45 meters, the level of N-terminal pro-brain natriuretic peptide (NT-proBNP) decreases by 32%, and the left ventricular ejection fraction (LVEF) increases by 5.2%, indicating its positive intervention in neuro-humoral regulation.

2.1.3 Resolving Phlegm and Dissipating Nodules, Relieving Abscess and Pain

For phlegm-dampness coagulation type disorders (such as mammary gland hyperplasia and thyroid nodules), warm needling combined with moxa containing phlegm-resolving medicine (containing Pinellia ternata (Thunb.) Breit. and Semen Sinapis Albae powder) can increase the local tissue temperature by 2 - 3 °C, promoting the metabolism of phlegm-dampness. Ultrasound examination shows that after 3 months of treatment, the volume of mammary gland nodules decreases by 41%, and the degree of fibrosis decreases by 63%, which is better than that of simple moxibustion (28%, 45%)[3].

2.2 Modern Medical Mechanism: Molecular Targets of Multi-system Regulation

2.2.1 Neurobiological Effects

Functional magnetic resonance imaging (fMRI) shows that warm needling stimulation at Zusanli (ST36) can activate the pain inhibition areas of the anterior cingulate gyrus and insula in the brain,

reducing the discharge frequency of C fibers in the spinal dorsal horn by 65%. Electrophysiological detection finds that the peripheral nerve conduction velocity increases by 18% after warm needling, which is related to the enhanced sodium ion influx mediated by the activation of the transient receptor potential vanilloid 1 (TRPV1) channel. This effect can be blocked by 52% by the TRPV1 antagonist (Capsazepine).

2.2.2 Immune and Inflammatory Regulation

In the rheumatoid arthritis model, warm needling with compound medicine-moxa (containing Tripterygium wilfordii Hook. f. powder) can down-regulate the expression of interleukin-17 (IL-17) and interleukin-23 (IL-23) in synovial tissues by 47% - 59%, and at the same time, up-regulate the proportion of regulatory T cells (Treg) to 22.3% (15.8% in the simple warm needling group), exerting an anti-inflammatory effect by inhibiting the differentiation of T helper 17 (Th17) cells. Clinical research confirms that this therapy shortens the morning stiffness time of patients by 2.1 hours and reduces the erythrocyte sedimentation rate (ESR) by 19 mm/h.

2.2.3 Improvement of Metabolism and Microcirculation

Laser Doppler flowmetry shows that the local skin blood flow reaches its peak (3 times the baseline value) within 10 minutes after warm needling and lasts for 40 - 60 minutes, accompanied by an increase in blood oxygen saturation of 12% - 15%. For patients with diabetic peripheral neuropathy, warm needling combined with moxa wool containing Ligusticum chuanxiong Hort. powder can increase the nerve conduction velocity (NCV) by 3.2 m/s, which is related to the vasodilation mediated by nitric oxide (NO) and the repair of endothelial cell function.

3. Current Situation of Clinical Application: Analysis of the Disease Spectrum and Therapeutic Effect Based on Big Data

3.1 Evidence-based Medicine Evidence of Predominant Diseases

3.1.1 Musculoskeletal System Diseases (Accounting for 45%)

Lumbar Intervertebral Disc Herniation (Cold-Dampness Type): A multi-center randomized controlled trial (RCT) (n = 860) shows that the total effective rate of the warm needling combined with traction group is 92.3%, which is 13.7% higher than that of the simple traction group (78.6%). The improvement range of the Japanese Orthopaedic Association (JOA) score is $(15.2\pm3.8 \text{ vs } 9.7\pm2.9, P<0.01)$, and the recurrence rate is reduced by 26% (1-year follow-up).

Knee Osteoarthritis (Cold-Dampness and Blood Stasis Obstruction Type): After 8 weeks of warm needling treatment, the level of matrix metalloproteinase-13 (MMP-13, a cartilage degrading enzyme) in the synovial fluid decreases by 34%, and the type II collagen degradation product (CTX-II) decreases by 29%. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score decreases from 52.3 to 31.6. The therapeutic effect is equivalent to that of intra-articular injection of sodium hyaluronate (P>0.05), but the safety is better (the adverse reaction rate is 1.2% vs 8.7%)[4].

3.1.2 Digestive System Diseases (Accounting for 22%)

Chronic Gastritis (Spleen and Stomach Cold-Deficiency Syndrome): Warm needling at Zhongwan (CV12), Weishu (BL21), and Zusanli (ST36), combined with moxa wool containing Alpinia officinarum Hance powder, after 4 weeks of treatment, the content of prostaglandin E2 (PGE2) in the

gastric mucosa increases by 65%, the blood flow in the gastric antrum increases by 41%, the clinical symptom remission rate is 89%, and the Helicobacter pylori (Hp) eradication rate (combined with quadruple therapy) reaches 91%, which is 17% higher than that of the simple drug group.

Irritable Bowel Syndrome (Diarrhea Type): Warm needling at Shenque (CV8), Tianshu (ST25), and Dachangshu (BL25), combined with moxa wool containing Atractylodes lancea (Thunb.) DC. powder, can prolong the intestinal transit time by 23%, reduce the water content in the feces by 38%, increase the abundance of short-chain fatty acid (SCFA)-producing bacteria (such as Roseburia) in the intestinal flora by 55%, and increase the level of interleukin-10 (IL-10), an anti-inflammatory factor, by 42%.

3.1.3 Gynecological Diseases (Accounting for 18%)

Primary Dysmenorrhea (Cold Coagulation and Blood Stasis Type): Warm needling at Sanyinjiao (SP6), Guanyuan (CV4), and Zigong (EX-CA1) acupoints, adding moxa wool containing Angelica sinensis (Oliv.) Diels and Ligusticum chuanxiong Hort. powder, after 3 treatment cycles, the VAS score decreases from 7.8 ± 1.3 to 3.2 ± 0.9 , the serum prostaglandin F2 α (a pain-causing factor) decreases by 49%, and the resistance index (RI) of the spiral artery of the endometrium decreases from 0.85 ± 0.11 to 0.62 ± 0.08 . The therapeutic effect lasts for 6 months after the drug is stopped.

Chronic Pelvic Inflammatory Disease (Cold-Dampness and Blood Stasis Obstruction Type): The total effective rate of the warm needling combined with traditional Chinese medicine enema treatment group is 93.4%, which is 13.2% higher than that of the simple traditional Chinese medicine group (80.2%). After treatment, the levels of C-reactive protein (CRP) and interleukin-6 (IL-6) decrease by 58% and 47% respectively, the absorption time of pelvic effusion is shortened by 12 days, and the patency rate of the fallopian tube is increased by 21%[2].

3.2 Operation Specifications and Safety Data

Currently, warm needling operations follow the Specifications for the Technical Operation of Traditional Chinese Medicine Acupuncture Warm Needling Acupuncture (2020 edition), and the core parameters are as follows[1]:

Needle: A 0.30×40 mm stainless steel filiform needle (the roundness of the needle tip ≤ 0.05 mm), and the needle handle is wound with a moxa wool segment (diameter 0.8cm, length 1.5cm, and the proportion of traditional Chinese medicine powder $\leq 30\%$).

Temperature Control: Keep a distance of 2 - 3cm from the skin, with the degree that the patient feels "deep thermal sensation". The single treatment lasts for 20 - 25 minutes, each course of treatment consists of 10 times, with an interval of 2 - 3 days.

Contraindications: It is prohibited for those with a body temperature $> 37.5 \, \text{C}$, abnormal blood coagulation function (PT>18s), and skin ulcers. It should be used with caution for those with yin deficiency syndrome (red tongue with little coating).

In terms of safety, a retrospective analysis of 50,000 cases from 23 third-class grade-A hospitals across the country shows that the incidence rate of adverse events is 0.92%. Among them, mild scalds (blisters \leq 5mm) account for 78%, dizziness and nausea (syncope during acupuncture) account for 15%. There are no reports of infections, nerve damage, or fire accidents. By using heat-insulating silicone pads (which can reduce the skin surface temperature by 15% - 20%), the scald rate can be reduced to below 0.3%.

4. Synergistic Innovation of Moxa Wool Packs and Chinese Herbal Medicine Powders: From Empirical Medication to Precise Compatibility

4.1 The Three-Fold Effect Model of the Synergy of "Acupuncture-Moxibustion-Medicine"

Traditional moxa wool (containing artemisinin and eucalyptol) and Chinese herbal medicine powders (active ingredients) form a composite effect under the action of heat (Table 1):

Acupuncture Moxibustion Action Level Chinese Medicine |Synergistic Mechanism Effect| Effect Mechanical Thermal-Mechanical Infrared Powder Particles Physical Level Radiation Stimulation Coupling Release of Neuropeptides Active Multi-target Regulation Local Biochemical (Substance P Ingredients (such (Anti-inflammatory, Vasodilation and Level (SP), Calcitonin as Volatile Oils, Analgesic, Permeation Gene-Related Alkaloids) Immunomodulatory) Peptide (CGRP)) Targeting of Meridian Zang-Fu Organs Conduction Integration of the Hypothalamic (Guided by System Level (Connection of Neuro-Endocrine-Immune Thermoregulation Medicinal the Twelve Network Meridian Meridians)

Table 1: Model of the Synergy of "Acupuncture-Moxibustion-Medicine"

4.2 Formulation Principles and Efficacy Verification of Compound Medicine-Moxa

4.2.1 Core Formula for Cold Syndrome: Basic Formula for Warming Yang and Unblocking the Meridians

Tropism)

Composition: Artemisia argyi (60%) + Aconitum carmichaeli Debx. (15%) + Zingiber officinale Roscoe (10%) + Cinnamomum cassia Presl (15%)

Efficacy: Warming the kidney and aiding yang, suitable for bi (arthralgia) syndrome of yang deficiency type and chronic heart failure.

Experimental Data: In the model of inflammation induced by injecting carrageenan into the plantar of rats, after the combustion of this compound moxa wool, the content of prostaglandin E2 (PGE2) in the local tissue decreased by 39%, and the level of β -endorphin increased by 55%. The onset time of analgesia was 15 minutes earlier than that of pure moxa, and the duration was extended by 40 minutes.

4.2.2 Core Formula for Blood Stasis Syndrome: Basic Formula for Promoting Blood Circulation and Removing Blood Stasis

Composition: Artemisia argyi (50%) + Ligusticum chuanxiong Hort. (20%) + Carthamus tinctorius L. (15%) + Olibanum (15%).

Efficacy: Promoting blood circulation and unblocking the collaterals, suitable for dysmenorrhea of qi stagnation and blood stasis type and postoperative adhesion of the lumbar vertebra.

Clinical Verification: In a group comparison of 60 dysmenorrhea patients, after treatment, the blood flow velocity (PSV) of the uterine artery in the compound group increased by 32 cm/s, and

thromboxane B2 (TXB2) decreased by 41%. Compared with the simple warm needling group, the pain relief time was shortened by 2.3 hours, and the usage rate of painkillers was reduced by 65%.

4.2.3 Core Formula for Dampness Syndrome: Basic Formula for Removing Dampness and Invigorating the Spleen

Composition: Artemisia argyi (55%) + Atractylodes lancea (Thunb.) DC. (20%) + Poria cocos (Schw.) Wolf (15%) + Agastache rugosa (Fisch. et Mey.) O. Kuntze (10%).

Efficacy: Awakening the spleen and resolving dampness, suitable for diarrhea of cold-dampness stagnating in the spleen type and obesity.

Mechanism Research: Experiments on the mouse model of spleen deficiency showed that this compound could increase the expression of the intestinal tight junction protein ZO-1 by 72%, inhibit the increase in intestinal mucosal permeability induced by tumor necrosis factor- α (TNF- α) (the transepithelial electrical resistance increased by 58%), and at the same time, up-regulate the expression of the gene related to fatty acid oxidation (PPAR α) by 2.3 times.

4.3 Quality Control and Safety Evaluation

4.3.1 Optimization of the Particle Size of Chinese Herbal Medicine Powder

Scanning electron microscopy shows that the Chinese herbal medicine powder with a particle size of 50-100µm is the most evenly distributed in the moxa wool, and the volatilization rate is stable during combustion (the peak concentration appears within 10-15 minutes). It is recommended to use the air jet milling technology to control the particle size.

4.3.2 Database of Compatibility Contraindications

Based on the Pharmacopoeia of the People's Republic of China and the Handbook of Compatibility Contraindications of Acupuncture and Chinese Medicine, an intelligent retrieval system containing 238 pairs of contraindication combinations (such as Aconitum carmichaeli Debx. and Pinellia ternata (Thunb.) Breit., Glycyrrhiza uralensis Fisch. and Daphne genkwa Sieb. et Zucc.) is established to avoid the superposition of toxic components.

4.3.3 Transdermal Toxicity Experiment

Using the Franz diffusion cell method, determine the transdermal amount of toxic components such as aconitine and strychnine in the compound medicine-moxa, set a safety threshold (such as aconitine $\leq 0.5 \mu \text{g/cm}^2 \cdot \text{h}$), and guide the clinical medication dosage (the addition amount of Aconitum carmichaeli Debx. powder $\leq 10\%$).

5. Future Research Directions and Industrialization Paths

5.1 Basic Research

Revealing the Scientific Essence of the Interaction of "Heat-Medicine-Acupoint":

Thermodynamic Modeling: Combine infrared thermal imaging and liquid chromatography-tandem mass spectrometry (LC-MS/MS) to construct a three-dimensional dynamic model of "moxa wool combustion-volatilization of Chinese herbal medicine-skin penetration", and analyze the release rules of effective components at different temperatures (40-60 °C) (such as volatile oils at 15-30 °C and alkaloids at 35-45 °C).

Epigenetic Regulation: Study the effects of the warm needling compound on DNA methylation (such as the promoter region of hypoxia-inducible factor- 1α (HIF- 1α)) and histone modification (demethylation of H3K27me3), and explain the molecular mechanism of its "warming yang and transforming qi" at the gene expression level.

5.2 Technological Innovation

Research and Development of Intelligent and Standardized Equipment:

Temperature-Controlled Electronic Warm Needling Instrument: Integrate a semiconductor heating module (accuracy $\pm 0.5 \, \text{C}$), a pressure sensor (real-time feedback of the needling sensation), and a slow-release patch of Chinese herbal medicine to achieve "precise temperature control (38-45 $\, \text{C}$) + directional drug delivery (nano drug-loading membrane)", solving the problems of smoke pollution and uneven temperature caused by the combustion of traditional moxa wool.

Pre-prepared Compound Medicine-Moxa Sticks: Produce standardized medicine-moxa (such as for dysmenorrhea type and stomach cold type) in accordance with the Specifications for Compound Preparations of Warm Needling Acupuncture, use aluminum foil for independent packaging (validity period of 24 months), and attach a QR code to trace the source of Chinese herbal medicine and the basis for compatibility, promoting the popularization of primary medical care.

5.3 Clinical Transformation

Constructing a New Diagnosis and Treatment System of Integrated Traditional Chinese and Western Medicine:

Joint Tackling of Major Diseases: For refractory diseases such as knee osteoarthritis (KOA) and chronic fatigue syndrome (CFS), carry out research on reducing toxicity and enhancing efficacy of "warm needling compound + biological agents". For example, verify whether warm needling can reduce the injection frequency of sodium hyaluronate in KOA (from once a week to once every two weeks).

Appropriate Technologies for Community Healthcare: Develop a "smart warm needling device for home use" (equipped with a safety locking function), combined with remote guidance via APP (acupoint positioning, treatment course management), provide home rehabilitation programs for neck, shoulder, waist and leg pain and cold-deficiency gastrointestinal diseases, and reduce the consumption of medical resources.

5.4 International Development

From Standard Output to Cultural Identity[5]:

Formulation of ISO Standards: Promote the inclusion of the "Operation Specifications of Warm Needling Therapy" and the "Quality Standards of Compound Medicine-Moxa" into ISO/TC 249, and jointly compile the Clinical Application Guidelines of Warm Needling with the World Health Organization (WHO), clarifying indications (such as chronic pain with a Numerical Rating Scale (NRS) pain score \geq 4 points) and contraindications (such as platelets < 50×10 9 /L).

Visual Popular Science Communication: Use virtual reality (VR) technology to display the process of "warm needling heat flow following the meridians", and demonstrate the microscopic mechanism of the synergy of "acupuncture-moxibustion-medicine" in killing Helicobacter pylori and dissolving urate crystals through 3D animation, reducing cross-cultural understanding barriers and promoting the promotion and application in countries along the Belt and Road.

6. Conclusion

After thousands of years of practical testing, the concept of "simultaneous treatment with acupuncture, medicine, and moxibustion" of warm needling therapy conforms to the trend of modern medicine's precise treatment and multi-target intervention. The synergistic innovation of moxa wool and Chinese herbal medicine not only breaks through the curative effect boundary of traditional acupuncture but also constructs a three-dimensional treatment system of "physical stimulation-thermal effect-pharmacological action". In the future, relying on technologies such as big data and artificial intelligence, it is necessary to solve problems such as insufficient standardization and vague mechanism interpretation, and promote this characteristic therapy of traditional Chinese medicine from empirical medicine to evidence-based medicine, contributing a "Chinese solution" to the prevention and treatment of global chronic diseases.

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