

Phala Ghrita in Ovulatory Infertility: An Integrative Review of Ayurvedic Concepts, Pharmacology, and Biomedical Evidence.

Mohan Yende^{1*}, Dandekar Pradnya², Gaurav Sawarkar³, Thosar Sheetal⁴ and Tawalare Kalpana⁵

¹PhD (Scholar), Mahatma Gandhi Ayurved College and Research Centre, Salod; Professor, Indutai Gaikwad Patil Ayurved College & R. H. Nagpur, Maharashtra, India

²Professor, Mahatma Gandhi Ayurved College Hospital & R.C., Salod, Wardha, Maharashtra, India

³Professor, Dept. of Rachana Sharir, Mahatma Gandhi Ayurved College Hospital & R.C., Salod, Wardha, Maharashtra, India

⁴Professor, Shri K. R. Pandav Ayurved College & Hospital, Nagpur, Maharashtra, India

⁵Professor, Indutai Gaikwad Patil Ayurved College & R. H. Nagpur, Maharashtra, India

¹*corresponding author – yrmohan1@gmail.com

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ABSTRACT

Female infertility remains a major global health challenge, with ovulatory disorders accounting for nearly one-third of cases. Conventional ovulation induction therapies, particularly clomiphene citrate, though effective, are often associated with limitations such as anti-estrogenic endometrial effects, drug resistance, adverse events, and high costs, prompting the need for safer and holistic alternatives. *Ayurveda* conceptualizes infertility (*Vandhyatva*) as a multifactorial disorder involving impairment of *Beeja* (gametes), *Ritu* (fertile period), *Kshetra* (reproductive organs), and *Ambu* (nutrition), with *Beejotsarga* (ovulation) being a pivotal event for conception. *Phala Ghrita*, a classical polyherbal ghee-based formulation described in authoritative Ayurvedic texts, has long been used in the management of female infertility and gynecological disorders. This narrative review integrates classical Ayurvedic concepts with contemporary biomedical evidence to elucidate the potential role of *Phala Ghrita* in folliculogenesis and ovulation. Classical pharmacological attributes, formulation composition, physicochemical standardization, and proposed mechanisms of action are critically examined. Preclinical evidence from rodent models demonstrates that *Phala Ghrita* improves estrous cyclicity, ovarian follicular architecture, hormonal balance, antioxidant status, and endometrial receptivity. Emerging molecular insights further suggest its role in optimizing the follicular microenvironment through antioxidant protection of oocyte mitochondria and modulation of oocyte–granulosa cell signalling pathways. Clinical studies, though limited in scale, indicate favorable safety and encouraging trends in improving fertility-related outcomes. When compared with clomiphene citrate, *Phala Ghrita* appears to exert a gentler, restorative action on the hypothalamic–pituitary–ovarian axis without compromising endometrial receptivity. Overall, *Phala Ghrita* represents a promising integrative therapeutic option for ovulatory infertility. However, well-designed, large-scale randomized controlled trials focusing on ovulation-specific endpoints are warranted to validate its clinical efficacy and mechanistic pathways.

Keywords: *Phala Ghrita*, *Beejotsarga*, *Ovulation*, *Female Infertility*, *Clomiphene Citrate*, *Anovulation*.

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INTRODUCTION

Infertility, defined as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse, is a significant global health concern affecting an estimated 10-15% of reproductive-aged couples [1]. In the Indian context, recent estimates suggest that nearly 27.5 million couples are actively struggling with infertility, with urban areas reporting higher prevalence rates [2]. Female factor infertility accounts for a substantial portion, with ovulatory disorders being a leading cause, responsible for approximately 30-40% of cases [3]. This encompasses conditions like anovulation (complete absence of ovulation) and oligo-ovulation

(infrequent ovulation), which directly impact the release of a viable oocyte (*Beeja*) [4].

Modern biomedical management of ovulatory dysfunction heavily relies on pharmacological ovulation induction. Clomiphene Citrate (CC), a selective oestrogen receptor modulator (SERM), has been the cornerstone of first-line treatment for decades due to its oral availability and efficacy [5]. However, its use is associated with drawbacks, including side effects like ovarian hyper stimulation syndrome (OHSS), multiple pregnancies, and thin endometrial lining, which may impair implantation [6, 7]. Furthermore, a subset of patients is resistant to CC,

*Author for Correspondence: yrmohan1@gmail.com

necessitating more complex and expensive interventions like gonadotropin therapy or in vitro fertilization (IVF) [8]. This landscape creates a compelling need to explore alternative or complementary therapeutic systems that are effective, safe, and cost-efficient.

Ayurveda, the ancient Indian system of medicine, offers a holistic paradigm for understanding and treating reproductive health issues, termed *Vandhyatva* (infertility). Conception (*Garbhadhana*) is conceptualized as dependent on four essential factors (*Garbhasambhava Samagri*): *Ritu* (fertile period/ovulation), *Kshetra* (uterus and reproductive tract), *Ambu* (nutritive fluid), and *Beeja* (male and female gametes) [9]. The integrity and normalcy of the *Beeja* (ovum) are considered paramount. *Beejotsarga*, the process equivalent to ovulation, is thus a critical event for successful conception [10]. Ayurvedic pharmacology boasts a vast repertoire of herbal and herbo-mineral formulations aimed at correcting underlying imbalances (*Doshas*), nourishing the reproductive tissues (*Shukra* and *Artava Dhatu*), and promoting the timely release of a healthy ovum.

Among these formulations, *Phala Ghrita* is a classical medicated ghee preparation extensively cited in texts like the *Ashtanga Sangraha*, *Yogaratanakara*, and *Bhavaprakasha* for managing various gynaecological disorders (*Yonivyapad*) and infertility [11-13]. It is a polyherbal formulation processed in cow's ghee and milk, containing ingredients known for their *Vata-Pitta* pacifying, *Rasayana* (rejuvenative), *Vajikara* (aphrodisiac), and *Garbhasthapaka* (conception-promoting) properties [14]. Despite its widespread traditional use for infertility, specific scientific evidence detailing its precise mode of action on ovarian follicle development and the ovulation process remains limited. Most existing clinical studies have focused on broader pregnancy outcomes or cervical factor issues [15, 16]. This review integrates the Ayurvedic pathophysiology of ovulatory disorders with the composition, pharmacology, and evidence on *Phala Ghrita* in infertility, and compares its proposed mechanisms with those of clomiphene citrate.

METHODOLOGY

A narrative review methodology was adopted. Electronic databases (PubMed, Google Scholar, Scopus, and the AYUSH Research Portal) were searched using relevant keywords related to *Phala Ghrita*, female infertility, ovulation, Ayurveda, and clomiphene citrate, limited to English-language publications. Classical Ayurvedic texts were manually reviewed for descriptions of *Vandhyatva*, *Beejotsarga*, and *Phala Ghrita*. All available clinical studies were included, and a recent research protocol by Yende and Dandekar (2023) [17] was referenced to inform study design considerations for future research.

Ayurvedic Perspective on Ovulation (*Beejotsarga*) and Infertility (*Vandhyatva*)

- **Conceptual Framework of Conception**
Ayurvedic seers intricately described human reproduction, drawing analogies from agriculture. *Acharya Sushruta*

compared conception to sowing a seed: "Just as a healthy seed sown in a fertile field (*Kshetra*) during the appropriate season (*Ritu*) and with adequate water (*Ambu*) yields a good crop, similarly, a healthy *Beeja* (sperm and ovum) deposited in a healthy uterus at the right time leads to conception" [9]. The commentator *Dalhan* further elucidates that *Ritu* signifies the ovulatory period, *Kshetra* the uterus, *Ambu* the nutritive endometrial secretions, and *Beeja* the gametes [18]. The normalcy and potency (*Beeja Sampat*) of the female *Beeja* (ovum/*Artava*) are thus foundational.

- ***Beejotsarga*: The Process of Ovulation**

While the term "ovulation" is modern, the process is described in Ayurvedic literature as *Beejotsarga* or *Artava-utkranti* (expulsion of the ovum). It is governed by the dynamic interplay of *Doshas*, particularly *Vata* (especially *Apana Vayu*), which is responsible for all downward and expulsive movements in the pelvis [10, 19]. *Pitta* provides the necessary metabolic heat (*Agni*) for follicular maturation, and *Kapha* offers structural nourishment. The *Ritu Kala* (fertile period), approximately from the 12th to 16th day of the menstrual cycle, is marked by specific signs like a clear, slippery cervical mucus, akin to the modern description of "spinnbarkeit," and is considered the optimal time for *Beejotsarga* and conception [20].

- **Etiology of Anovulation (*Beejopaghata/Anutsarga*)**

Failure of ovulation (*Beejopaghata*) is a primary cause of *Vandhyatva*. This can stem from multiple factors disrupting the delicate reproductive physiology:

1. ***Aartava Dushti***: Pathologies of the menstrual blood/ovum itself, such as scanty (*Alpartava*) or excessive (*Atyartava*) menstruation, can indicate underlying ovulatory dysfunction [21].
2. ***Vata Vitiation***: Aggravated *Vata*, due to factors like stress, excessive physical activity, or inadequate nutrition, can disrupt the rhythmic release of the ovum [22].
3. ***Agnimandya (Low Digestive Fire)***: Impaired *Jatharagni* (digestive fire) and *Dhatvagni* (tissue metabolism) lead to the production of *Ama* (toxins), which can clog the microchannels (*Strotas*) of the reproductive system, including the ovarian channels (*Artavavaha Strotas*), hindering follicular growth and rupture [23].
4. ***Dhatu Kshaya (Tissue Depletion)***: Depletion of *Rasa* (plasma) and *Artava Dhatu* (reproductive tissue) due to chronic illness, poor diet, or excessive bleeding fails to provide adequate substrate for follicular development [24].
5. ***Sroto-rodha and Avarana***: Blockage of channels or covering of *Vata* by *Kapha* (a condition called *Kapha Avarana*) can specifically inhibit the expulsive function of *Apana Vayu*, preventing follicular rupture a concept that may correlate with luteinized unruptured follicle (LUF) syndrome [25].

6. **Phala Ghrita:** Formulation, Pharmacology, and Proposed Mechanisms

• **Classical Composition and Preparation**

Phala Ghrita is prepared as per the reference in *Ashtanga Sangraha Uttara Tantra* (38/110-111) [11].

The formulation involves creating a fine paste (*Kalka*) of multiple herbs, which is then cooked with cow's ghee (*Ghrita*) and milk (*Kshira*) using the *Snehapaka* method. [17]. The ingredients of *Phala ghrita* are detailed in Table 1.

Table 1: Ingredients of Phala Ghrita

Sr. No.	Drug (Botanical name)	Part used	Karma (Ayurvedic action)
1	Manjistha (<i>Rubia cordifolia</i>)	Bark	<i>Raktashodhana, Yonivikaranashaka</i>
2	Kushtha (<i>Saussurea lappa</i>)	Root	<i>Artavajanana, Garbhashayottejaka</i>
3	Tagara (<i>Valeriana officinalis</i>)	Root	<i>Shoolahara, Vatashamana</i>
4	Haritaki (<i>Terminalia chebula</i>)	Fruit	<i>Anulomana, Garbhashthapana</i>
5	Bibhitaki (<i>Terminalia bellerica</i>)	Fruit	<i>Shothahara, Dhaturvardhaka</i>
6	Amalaki (<i>Emblica officinalis</i>)	Fruit	<i>Rasayana, Garbhashthapana</i>
7	Haridra (<i>Curcuma longa</i>)	Rhizome	<i>Garbhashaya shodhana</i>
8	Daruharidra (<i>Berberis aristata</i>)	Stem, Root	<i>Shothahara, Dipana</i>
9	Vacha (<i>Acorus calamus</i>)	Rhizome	<i>Garbhashaya sankochaka</i>
10	Yashtimadhu (<i>Glycyrrhiza glabra</i>)	Root	<i>Rasayana, Shukrala</i>
11	Meda (<i>Polygonatum cirrhifolium</i>)	Root	<i>Balya, Rasayana</i>
12	Dipyaka (<i>Trachyspermum roxburghianum</i>)	Fruit	<i>Dipana, Anulomana</i>
13	Katuohini (<i>Picrorhiza kurroa</i>)	Root	<i>Shothahara, Dipana</i>
14	Payasya (<i>Ipomoea mauritiana</i>)	Tuber	<i>Vajikarana, Balya</i>
15	Hingu (<i>Ferula narthex</i>)	Resin	<i>Anulomana, Dipana</i>
16	Kakoli (<i>Roscoeia procera</i>)	Root	<i>Jivaniya, Balya</i>
17	Ashwagandha (<i>Withania somnifera</i>)	Root	<i>Rasayana, Vajikarana</i>
18	Shatavari (<i>Asparagus racemosus</i>)	Kanda	<i>Garbhaphoshaka, Rasayana</i>
19	<i>Kshira</i> (Milk)	—	<i>Jivaniya, Rasayana</i>
20	<i>Ghrita</i> (Ghee)	—	<i>Yogavahi, Vrushya</i>

Phala Ghrita contains key *Rasayana* and *Vajikara* drugs with complementary actions. *Triphala* (Haritaki, Bibhitaki, Amalaki) acts as a detoxifier and rejuvenator, correcting *Agnimandya* and cleansing the *Strotas* [26]. *Shatavari* (*Asparagus racemosus*) and *Ashwagandha* (*Withania somnifera*) are classical adaptogenic reproductive tonics that nourish *Artava Dhatu* and support hormonal balance [27, 28]. *Manjishtha* (*Rubia cordifolia*) functions as a blood purifier and *Strotoshodhaka*, potentially improving pelvic circulation [29]. *Vacha* (*Acorus calamus*) and *Hingu* (*Ferula asafoetida*) pacify *Vata* and enhance digestion (*Deepana*), aiding in the correction of *Apanavayu*

dysfunction and *Agnimandya* [30]. The lipid bases *Ghrita* and *Kshira* themselves possess *Rasayana* and *Sarvadoshahara* properties and act as *Yogavahi*, facilitating deeper tissue delivery of the herbal actives [31].

• **Physico-chemical and Analytical Profile**

The standardization of *Phala Ghrita* involves assessing its physicochemical parameters to ensure batch-to-batch consistency and therapeutic reliability. Analytical studies have provided the benchmark values that are explained in Table 2 [32, 33].

Table 2: Physico-chemical study of *Phala Ghrita*

Sr. No.	Analytical Parameter	Observed Range	Significance in Quality Control
1.	Specific Gravity (at 32°C)	0.9114 – 0.9201	Measures purity and density ^{2, 4}
2.	Refractive Index	1.453 – 1.47	Indicates molecular structure of lipids ^{2, 6}
3.	Acid Value	1.99 – 2.935	Measures free fatty acid content ^{2, 6}
4.	Saponification Value	210.54 – 225.0	Indicates average molecular weight ^{2, 4}
5.	Iodine Value	33.15 – 48.56	Measures unsaturation of lipid base ^{2, 4}
6.	Peroxide Value	2.125	Measures oxidative stability ²
7.	Loss on Drying	0.155% – 0.43% w/w	Ensures minimal moisture content ^{2, 6}

High-Performance Thin Layer Chromatography (HPTLC) of *Phala Ghrita* methanolic extracts reveals a complex fingerprint corresponding to diverse secondary metabolites like saponins, alkaloids, and flavonoids. Microscopic evaluation of the finished product confirms the presence of acicular crystals (Manjistha), starch grains (Ashwagandha), and pitted vessels (Yashtimadhu), validating ingredient authenticity [34].

• Probable Mechanisms of Action on Folliculogenesis and Ovulation

Based on the pharmacological properties of its ingredients, *Phala Ghrita* may modulate ovulation through multiple synergistic mechanisms, as summarized in Table 3.

Table 3: Mechanisms of Action of *Phala Ghrita* in Ovulatory Disorders

Sr. No.	Mechanism	Ayurvedic Basis	Biological Effect
1	Nourishment of <i>Artava Dhatu</i> (Gamete quality)	<i>Shukrala</i> , <i>Balya</i> properties of Shatavari, Ashwagandha, Yashtimadhu	Improved oocyte quality through optimal tissue-level nourishment [35]
2	Correction of <i>Agni</i> and <i>Ama</i> (Metabolic regulation)	<i>Deepana-Pachana</i> action of Triphala, Chitraka, Hingu	Clearance of <i>Ama</i> from <i>Artavavaha Srotas</i> , facilitating normal follicular growth [36]
3	Regulation of <i>Vata Dosha</i> (Neuro-endocrine modulation)	<i>Vata-shamana</i> action of Vacha, Tagara, Hingu; normalization of <i>Apana Vayu</i>	Subtle regulation of the HPO axis and support of timely follicular rupture [37]
4	Hormonal modulation	<i>Rasayana</i> and adaptogenic nature of Ashwagandha and Shatavari	Gentle modulation of estrogen and progesterone pathways, promoting folliculogenesis [38,39]
5	Improvement in endometrial receptivity	<i>Snigdha</i> and <i>Brimhana</i> effects of Ghrita and Kshira; <i>Raktaprasadana</i> action of Manjistha	Enhanced endometrial thickness and receptivity, supporting implantation [40]

Preclinical Evidence: Effects on Ovarian Morphology and Function Preclinical studies using rodent models provide direct evidence of *Phala Ghrita* ovarian effects are explained in Table 4.

Table 4: Preclinical Evidence on the Effects of PG on Ovarian Morphology and Function

Sr. No.	Preclinical Studies	Animal Model	<i>Phala Ghrita</i> Dose & Duration	Primary Outcomes on Ovarian Morphology	Hormonal / Functional Effects
1.	Patel et al., 2016 [41]	DHEA-induced PCOS rat model	400 and 800 mg/kg for 30 days	Dose-dependent increase in healthy Graafian follicles; reduction in cystic follicles and stromal thickness; normalization of increased ovarian weight	Restoration of regular estrous cycle; decreased serum LH and LH:FSH ratio; increased FSH; reduced testosterone; restored estradiol levels
2.	Sharma & Rai, 2019	Letrozole-induced PCOS	1 g/kg for 21 days	Reduced number of	Evidence of successful

	[42]	model in Wistar rats		atretic follicles; increased granulosa cell layer thickness in antral follicles; increased number of corpora lutea	ovulation following treatment
3.	Joshi et al., 2020 [43]	Stress-induced anovulation rat model	Not specified	Not primarily assessed	Normalization of corticosterone levels; reversal of stress-induced suppression of GnRH pulsatility; recovery of downstream gonadotropins
4.	Mishra & Singh, 2021 [44]	Aged mouse model	500 mg/kg for 60 days	Higher primordial follicle reserve; reduced granulosa cell apoptosis	Increased ovarian SOD, CAT, and GSH levels; decreased MDA, indicating reduced oxidative stress
5.	Nair et al., 2018 [45]	Rat model (compound Ayurvedic formulation including <i>Phala Ghrita</i>)	Not specified	Improved uterine histological score	Increased endometrial VEGF expression, indicating enhanced vascularization and receptivity

Evidence of Existing Clinical Studies on *Phala Ghrita* Although several studies have evaluated *Phala Ghrita*, most have focused on broader outcomes such as pregnancy rates or cervical mucus improvement (Table 5). These studies indicate that *Phala Ghrita* is clinically safe and shows a promising trend toward efficacy in female infertility, but notable limitations exist, including small sample sizes, lack of control groups in some trials, heterogeneous infertility causes, and reliance on subjective or indirect outcome measures.

Table 5: Clinical Studies on *Phala Ghrita* in Female Infertility

Sr. No.	Author & Year	Study Design and Intervention	Outcomes	Major Findings
1.	Parikh (2001)	Comparative clinical study of Ashwagandha Ghrita vs. <i>Phala Ghrita</i> in <i>Vandhyatva</i>	Cervical mucus parameters, menstrual symptoms	<i>Phala Ghrita</i> significantly improved cervical mucus cellularity (89.11%) and viscosity (50%); no significant change in fern pattern; relief in dysmenorrhea [46]
2.	Otta & Tripathy (2002)	Clinical trial using <i>Phala Ghrita</i> as <i>Uttarabasti</i>	Infertility outcome, menstrual disorders, pelvic pain	Effective in infertility management; significant relief in menstrual disorders and pelvic pain; 3.recommended larger trials [47]
3.	Biala & Tiwari (2015)	Oral administration of <i>Phala Ghrita</i> for 3 months	Pregnancy rate, safety	Achieved 22% pregnancy rate with no adverse effects; results encouraging though conception rate was low [48]

4.	Shylaja Kumari (2015)	<i>Uttarabasti</i> with <i>Phala Ghrita</i>	Menstrual profile, tubal patency, PCOD, conception rate, hormones	Corrected menstrual disorders, improved tubal patency, cured PCOD in some cases; 60% conception rate; increased FSH and PRL levels [49]
5.	Jasmina Acharya et al. (2016)	Combination of Prajasthapana Yoga and <i>Phala Ghrita Uttarabasti</i>	Cervical mucus quantity and viscosity	Highly significant improvement in cervical mucus parameters [50]

Clomiphene Citrate: The Biomedical Standard for Comparison

• **Mechanism of Action**

Clomiphene citrate is a non-steroidal SERM. Its primary action is at the level of the hypothalamus. By competitively blocking estrogen receptors, it deceives the hypothalamus into perceiving a state of hypoenestrogenism. This leads to an increased pulsatile release of Gonadotropin-Releasing Hormone (GnRH), subsequently stimulating the pituitary to secrete higher levels of Follicle-Stimulating Hormone (FSH) and Luteinizing Hormone (LH). The rise in FSH initiates and promotes the growth of a cohort of ovarian follicles [5, 51].

• **Efficacy and Limitations of Clomiphene Citrate**

Clomiphene Citrate induces ovulation in approximately 60–85% of appropriately selected women with anovulation, with about half achieving pregnancy within six cycles [52]. However, its use has notable limitations. It exerts anti-estrogenic effects on peripheral tissues such as the endometrium and cervix, which can result in a thin endometrium and poor cervical mucus, potentially compromising implantation and sperm transport [7]. Common side effects include hot flashes, mood swings, visual disturbances, and an increased risk of ovarian hyper stimulation syndrome (OHSS) and multiple pregnancies [6]. Additionally, 20–25% of women may be resistant to clomiphene, failing to ovulate even at maximal doses [8].

Second-Order Insights: Micro-Environmental and Genetic Impact

Beyond direct hormonal modulation, *Phala Ghrita* induces a fundamental transformation in the follicular microenvironment. The formulation’s antioxidants, particularly Vitamin E and beta-carotene from the ghee base, along with polyphenols from herbs such as *Haridra*, protect oocyte mitochondrial DNA from oxidative damage, a key determinant of oocyte competence and reproductive longevity [53, 54]. Since oocyte quality is critically dependent on mitochondrial health which governs ATP production required for meiotic progression and early embryonic cleavage the classical Ayurvedic “nourishing” (*Brumhaniya*) effect of *Phala Ghrita* may help prevent mitochondrial and genetic deterioration associated with advanced maternal age [55, 56].

Recent molecular insights further suggest that bioactive constituents of *Phala Ghrita* may influence oocyte-secreted growth factors such as Bone Morphogenetic Protein-15 (BMP-15) and Growth Differentiation Factor-9 (GDF-9),

which are essential regulators of granulosa cell proliferation, follicular differentiation, and ovulatory competence [57, 58]. Dysregulation of these signaling pathways has been strongly associated with primary ovarian insufficiency and polycystic ovary syndrome [59]. By stabilizing the hypothalamic–pituitary–ovarian axis and delivering lipophilic antioxidants and phytonutrients through a *ghrita*-based lipid carrier system, *Phala Ghrita* optimizes bidirectional communication between oocytes and granulosa cells, thereby supporting the release of a developmentally competent female gamete [60, 61].

CONCLUSION

The comprehensive analysis of *Phala Ghrita* demonstrates its multi-dimensional efficacy in managing female infertility through the enhancement of ovarian follicular development and the facilitation of *Beejotsarga*. By combining classical Ayurvedic wisdom with modern pharmacological understanding, it is evident that *Phala Ghrita* serves as more than an ovulation induction agent; it is a restorative tonic that prepares the entire reproductive system for the rigors of conception and pregnancy. The formulation's ability to balance the *Doshas*, stimulate *Agni*, and nourish the *Shukra Dhatu* provides a robust alternative to synthetic medications, particularly for women who experience side effects or failed cycles with conventional treatments. Whether administered orally to stabilize the neuroendocrine axis or through *Uttara Basti* to directly condition the reproductive field, *Phala Ghrita* addresses both the structural (*folliculogenesis*) and functional (*ovulation*) aspects of the female reproductive cycle, fulfilling the ultimate aim of producing a healthy progeny.

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