Saving Babies, Strengthening Care: Cervical Cerclage to Optimize Pregnancy Outcomes in Indian Women with PCOS

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Abstract

Background & context. Polycystic ovary syndrome (PCOS) is common among Indian women and is associated with higher risks of miscarriage, gestational diabetes, hypertensive disorders, and **preterm birth**. India bears the world's largest burden of preterm births, making prevention strategies a public health priority. (PMC, BioMed Central, The Lancet)

Objective. To synthesize global and India-specific evidence on optimizing pregnancy outcomes in women with PCOS, with a focus on **when, for whom, and how** cervical cerclage (history-, ultrasound-, or exam-indicated; transvaginal vs transabdominal) should be integrated into Indian antenatal pathways. (PubMed)

Methods (scoping review). We searched medical databases and gray literature (2020–2025) for peer-reviewed studies, professional guidelines, government documents, credible podcasts/YouTube explainers, and relevant press/industry reports. Inclusion prioritized India-centric data or globally authoritative sources; exclusion removed pre-2000 primary studies unless historically pivotal (e.g., Shirodkar's work). (missionmrcog.com)

Key findings.

- 1. **PCOS elevates obstetric risk:** meta-analyses show increased odds of preterm birth; hyperandrogenic phenotypes and ART/twin gestations further amplify risk. (<u>PMC, MDPI</u>)
- Cerclage is effective in defined subgroups: strongest evidence supports cerclage when a woman with prior spontaneous preterm birth or late miscarriage has a short cervix ≤25 mm in the mid-trimester; universal cerclage or use in twins without dilation is not recommended. (missionmrcog.com, NICE)

- India-specific gaps: variable ultrasound access, sociocultural barriers to transvaginal scanning, uneven ANC quality, and regional PCOS heterogeneity (e.g., high prevalence in Kashmir) complicate equitable implementation. (<u>Nature</u>, <u>Pew Research Center</u>, <u>PubMed</u>)
- Integrated care works: combining risk-based cervical-length surveillance, progesterone (where indicated), judicious cerclage, and GDM screening within national programs (PMSMA/LaQshya) is feasible and impactful; 17-OHPC is no longer advised, while vaginal progesterone remains appropriate for selected patients. (PMSMA, BioMed Central, acog.org)

Conclusions & recommendations. India should embed targeted cervical-length screening (16–24 weeks) for at-risk women with PCOS, ensure referral to preterm-prevention clinics, and standardize cerclage pathways aligned with RCOG/SMFM/NICE guidance—adapted to Indian realities (urban-rural, linguistic, and resource diversity). (missionmrcog.com, publications.smfm.org, NICE)

Keywords: PCOS; preterm birth; cervical cerclage; cervical length; India; antenatal care.

1. Introduction

Global context and definition. PCOS is a chronic, heterogeneous endocrine disorder affecting 6–13% of reproductive-aged women globally (depending on criteria), with metabolic, reproductive, and psychological sequelae across the lifespan. The **International PCOS Guideline (2023)** harmonizes diagnosis and care and highlights pregnancy risks requiring proactive management. (PMC)

India's epidemiology. Indian estimates vary by region and diagnostic criteria. A 2022 systematic review found a pooled prevalence ≈11% using Rotterdam criteria. A 2024 JAMA Network Open analysis emphasizes wide Indian heterogeneity, with Kashmir reporting ~29–35% prevalence in community cohorts. These figures exceed many global estimates and underscore the need for India-specific programs. (PMC, PubMed, JAMA Network)

Preterm birth in India. In 2020, 3.02 million Indian babies were born preterm (≈13% rate)—the highest absolute number worldwide—with South Asia carrying a disproportionate burden. Preventing spontaneous preterm birth (sPTB) is therefore central to India's RMNCH+ A agenda. (The Lancet, PMC)

Why PCOS matters in pregnancy. Meta-analyses (2024) confirm that PCOS increases risks of preterm delivery, GDM, hypertensive disorders, and low birthweight. Hyperandrogenism appears to confer particularly elevated risk; ART and multiple gestation can add further risk. Mechanisms likely include insulin resistance, low-grade inflammation, androgen excess, and

higher rates of obesity—traits especially prevalent in South Asian phenotypes. (<u>PMC</u>, <u>BioMed</u> <u>Central</u>)

Cervical insufficiency and cerclage. Cervical insufficiency (CI) refers to painless cervical dilation leading to second-trimester loss or early preterm birth. Cerclage—a suture to reinforce the cervix—dates back to 1955, when Dr. V.N. Shirodkar (Mumbai) described the eponymous technique; the McDonald modification followed in 1957. Cerclage remains a cornerstone prevention strategy for defined high-risk groups. (PMC, Obstetrics & Gynecology)

"In women with a singleton pregnancy and a history of second-trimester loss or preterm birth, **cerclage is beneficial when mid-trimester cervical length ≤ 25 mm**." — RCOG Green-top 75 (2022) (<u>missionmrcoq.com</u>)

Indian sociocultural context. India's antenatal landscape shows progress and gaps: ≥1 ANC visit is >90%, four-plus visits ~59%, and ultrasound in ~78% of pregnancies nationwide (with urban-rural and wealth-education gradients). Acceptance of transvaginal ultrasound (TVUS)—essential for accurate cervical-length (CL) measurement—can be limited by modesty, privacy, and local norms, necessitating sensitive counseling, female sonographers where possible, and multilingual materials. (PMC, Pew Research Center, Nature)

Problem statement. Despite high PCOS prevalence and India's preterm-birth burden, cerclage is under-used in the right women and over-used in the wrong settings. System-level barriers (variable CL screening, uneven access to high-quality TVUS, late booking) and PCOS-specific risks are not consistently addressed in public or private care. The goal is to operationalize guideline-concordant pathways suited to Indian realities, focusing on who should be screened, when to offer cerclage, and how to integrate with progesterone and GDM protocols. (PMSMA, BioMed Central)

Scope & limitations. This article centers on **singleton pregnancies** in Indian women with PCOS, the group with the most robust evidence base for CL-guided cerclage algorithms. Twins and higher-order gestations are addressed only where evidence intersects with PCOS care. We synthesize evidence through August 2025, privileging guideline-grade summaries, India-specific data, and high-quality meta-analyses; heterogeneity of PCOS definitions and limited Indian RCTs on cerclage remain constraining factors. (missionmrcog.com)

2. Methodology

Research design & approach. We conducted a structured scoping review of clinical guidelines, systematic reviews/meta-analyses, Indian epidemiology and policy documents, and practice resources (professional magazines, press releases, and credible educational podcasts/YouTube) from 2020–2025, plus historically pivotal items (e.g., Shirodkar). (PMC)

Database & web search strategy. Searches combined terms for *PCOS*, *preterm birth*, *cervical insufficiency*, *cervical length*, *cerclage*, *India*, *FOGSI*, *ICMR*, *MoHFW*, *PMSMA*, and *LaQshya*. We queried PubMed, Cochrane, BJOG/Wiley, JAMA Network, PLOS, AJOG/AJOG-MFM, and official portals of RCOG, SMFM, ACOG, NICE, WHO, FOGSI, MoHFW/NHM, and UNICEF; gray literature included FICCI/KPMG reports and selected media that summarized peer-reviewed findings. (PubMed, publications.smfm.org, NICE, UNICEF DATA, National Health Mission)

Inclusion criteria. (i) Guidelines and consensus statements (RCOG Green-top 75; SMFM Consult #70 (2024); NICE NG25; ACOG progestogen advisory (2023)), (ii) meta-analyses/systematic reviews on PCOS and pregnancy outcomes, cerclage effectiveness, pessary vs cerclage, (iii) Indian policy (PMSMA, LaQshya) and NFHS-5 indicators, (iv) India-specific PCOS/ANC/preterm epidemiology, (v) educational podcasts/webinars (SMFM, MRCOG tutorials) and professional newsletters (FOGSI) aligned with primary sources. (missionmrcog.com, AJOG, NICE, acog.org, PMSMA)

Exclusion criteria. Non-peer-reviewed blogs; single-center case series without relevance to Indian practice; pre-2000 primary literature (except historical background). (PMC)

Data extraction & synthesis. We abstracted: (1) **risk estimates** (e.g., OR for preterm birth in PCOS), (2) **cerclage indications** and technique/timing recommendations, (3) **national program elements** (screening, referral), and (4) **implementation barriers** (access, culture, language). Findings were organized under biological/technical evidence, sociocultural challenges, system response, and innovative solutions. (PMC, missionmrcog.com)

Timeline & scope. Most sources were 2020–2025 to reflect current policy and evidence (e.g., SMFM 2024 CL guidance; ACOG 2023 progestogen update; 2023–2025 analyses of PCOS pregnancy risks). India-specific data included NFHS-5 (2019–21), PMSMA/LaQshya documents, ICMR PCOS Task Force outputs, and FOGSI practice points (2024–2025). (AJOG, acog.org, PMSMA, National Health Mission, PMC)

3. Discussion

A) Biological & technical factors: what the evidence says

PCOS and heightened obstetric risk. Contemporary meta-analyses confirm that PCOS increases odds of preterm birth(pooled OR ~1.3), GDM, and hypertensive disorders; risk may be higher in hyperandrogenic phenotypes. Elevated BMI, insulin resistance, and inflammation likely mediate risk—and are particularly pronounced in South Asian women. (MDPI, PMC, Oxford Academic)

Cervical biology in PCOS. While cervical insufficiency is not universal in PCOS, small studies suggest **higher androgens correlate with greater cervical shortening** across the second trimester, possibly expediting preterm remodeling. Metformin does **not** lengthen the cervix per se, though it may modestly reduce late miscarriage/preterm birth as a composite in pooled analyses. (Oxford Academic, The Lancet)

Cervical cerclage: indications and magnitude of benefit.

- **History-indicated** (typically at 11–14 weeks): consider for women with ≥3 **prior** second-trimester losses/preterm births, per RCOG Green-top 75. (missionmrcog.com)
- Ultrasound-indicated: for women with prior sPTB/late loss and CL ≤ 25 mm at 16–24 weeks; benefit is larger when CL < 15 mm. (missionmrcog.com)
- **Exam-indicated (rescue)**: in painless dilation with exposed membranes up to ~24–27 weeks, emergency cerclage **delays birth ~34 days** and can halve birth <34 weeks vs expectant care in suitable cases, though neonatal benefit depends on context and expertise. (<u>missionmrcog.com</u>)

Who should not receive cerclage? Major guidelines discourage routine cerclage in singletons with incidentally short cervix and no prior sPTB, and in twins without dilation; evidence favors vaginal progesterone for some short-cervix scenarios instead. (missionmrcog.com, NICE)

Technique & timing. Evidence comparing **Shirodkar vs McDonald** suggests the Shirodkar may reduce early preterm birth in some cohorts; however, surgical expertise and placement **as high as practical** are key, and overall comparative data are mixed and low-quality. **Transabdominal cerclage (TAC)** is reserved for failed/contraindicated transvaginal cases (often pre-pregnancy or early pregnancy in specialized centers). (PubMed, Obstetrics & Gynecology)

Adjuncts & comparators.

Progesterone: After FDA withdrawal of 17-OHPC (Makena), ACOG/SMFM endorse vaginal progesterone for selected short-cervix scenarios; it can be offered in addition to cerclage when both are indicated. (acog.org)

• Cervical pessary: High-quality RCTs (TOPS) show no benefit in singletons with CL ≤ 20 mm and higher perinatal mortality, cautioning against routine use. (PubMed)

Where PCOS intersects. Because women with PCOS are more likely to (a) conceive with higher BMI and insulin resistance, (b) need ovulation induction/ART (raising twin risk), and (c) show greater CL shortening with high androgens, they are over-represented among those who benefit from risk-based CL surveillance and timely cerclage. The key is phenotype-informed triage rather than blanket cerclage. (PMC, Oxford Academic)

Preterm-birth prevention bundle for PCOS in India (technical core).

- Early booking + baseline risk assessment (prior sPTB/late loss, cervical surgery, uterine anomalies).
- Transvaginal CL screening 16–24 weeks for those at risk; threshold ≤ 25 mm triggers action; <15 mm indicates stronger cerclage benefit.
- Choose the right tool: progesterone alone (short cervix, no prior sPTB), cerclage (prior sPTB + short cervix or rescue), or combined, per shared decision-making. (missionmrcoq.com, NICE)

B) Sociocultural challenges specific to India

- Diversity & disparities. India's regional, linguistic, and socioeconomic diversity shapes antenatal pathways. NFHS-5 reveals improved coverage, yet quality remains uneven; ultrasound use is high overall but shows large wealth- and education-related gaps (absolute inequality ~30 percentage points). Rural women often present later, and female providers are not uniformly available—barriers that particularly affect acceptance of TVUS. (PMC, Nature)
- 2. Cultural sensitivity with TVUS and cerclage counseling. Concerns about modesty, fear of pain, and myths surrounding "stitches in the womb" can deter uptake. Best practices include: privacy-assured spaces, chaperones, female sonographers, vernacular counseling materials (Hindi, Bengali, Tamil, Telugu, Marathi, Kannada, Malayalam, Gujarati, Punjabi, Assamese, Odia, Urdu), and inclusion of family decision-makers when the woman prefers. Evidence from LMIC reviews identifies training and equipment as major ultrasound barriers. (SpringerOpen)
- PCOS stigma and mental health. Indian women report stigma around infertility and body hair/weight, delayed diagnosis, and inconsistent counseling—factors that can delay antenatal engagement and risk-based screening. Integrating mental-health support and peer groups (including online) can improve adherence to surveillance and follow-up. (PMC)
- 4. **Regional heterogeneity in PCOS.** Kashmir's extraordinarily high PCOS prevalence highlights the need for **state-tailored protocols** (e.g., lower threshold for CL screening and earlier referral). Urban centers may see higher ART use and twin pregnancies; rural belts face access gaps. **Lean PCOS** phenotypes in South Asia also warrant attention:

insulin resistance and adverse outcomes can occur **despite lower BMI**. (<u>PubMed</u>, <u>Oxford Academic</u>)

C) Current system response in India—and the gaps

What's in place.

- PMSMA (monthly specialist ANC) and LaQshya (labor-room quality improvement) provide national scaffolding for standardized antenatal and intrapartum care; GDM screening is now national policy (DIPSI-based). These initiatives are critical for embedding risk-based CL screening and referral pathways. (PMSMA, National Health Mission)
- FOGSI has issued focused practice points for PCOS (lifestyle, obesity, infertility) and has begun publishing preterm-labour algorithms that reference CL < 25 mm thresholds and discussion of cerclage and progesterone—a pivot toward guideline-concordant prevention. (FOGSI)

What's missing.

- Standardized CL screening: No national requirement to perform TVUS CL for at-risk singletons (16–24 weeks). Many programs specify "ultrasound" but not how to measure cervix or what to do when short. (National Health Mission)
- Clinical pathways for high-risk PCOS: PCOS is not consistently coded as a risk flag
 for targeted CL surveillance within public platforms, despite meta-analytic evidence of
 risk. (PMC)
- Workforce and equipment: Gaps in trained sonographers, female providers, and maintenance of TVUS probes in rural/tribal areas limit coverage; quality audits seldom include CL measurement fidelity. (<u>SpringerOpen</u>)
- Coverage and affordability: While many states reimburse cerclage in public facilities, transabdominal cerclage (TAC) requires referral to tertiary centers and may not be uniformly covered; package catalogs are complex and opaque to patients. (<u>National Health Authority</u>)

D) Innovative solutions & best practices (India-ready)

1) Make CL screening simple & scalable.

- Who: women with PCOS plus any of: prior sPTB/late miscarriage, prior second-trimester painless dilation, cervical surgery, or suspected uterine anomaly; ART conceptions and multifetal pregnancies warrant specialist review, though routine cerclage in twins is not recommended. (missionmrcog.com)
- When/how: TVUS CL at 16–24 weeks, measured per standard technique (empty bladder; endocervical canal seen; three measurements; shortest used). ≤25 mm triggers algorithm. (publications.smfm.org)

Algorithm (singleton):

- Prior sPTB/late loss + CL ≤ 25 mm → Cerclage (stronger effect if <15 mm);
 discuss adding vaginal progesterone. (missionmrcog.com)
- No prior sPTB, CL ≤ 25 mm → Vaginal progesterone, not routine cerclage; re-scan in 1–2 weeks. (<u>publications.smfm.org</u>)
- Rescue scenario (painless dilation with membranes) → Emergency cerclage by experienced team after counseling; consider amnioreduction/tocolysis per unit protocol. (missionmrcog.com)

2) PCOS-specific pregnancy optimization.

- Preconception: align with 2023 PCOS Guideline and FOGSI practice points—weight management, physical activity, letrozole-led ovulation induction, and metabolic risk control. (PMC, FOGSI)
- In pregnancy: universal GDM screening (DIPSI) and tight glycemic control; vaginal progesterone when indicated for short cervix; avoid routine pessary in singletons; consider metformin continuation selectively (evidence suggests reduced late miscarriage/preterm in pooled analyses, but not consistent across trials). (National Health Mission, PubMed, The Lancet)

3) Cultural & linguistic tailoring.

- Introduce "cervical support stitch" as a plain-language term in counseling leaflets translated into major Indian languages; emphasize that stitches are temporary (vaginal cerclage removed at 36–37 weeks) and meant to prevent early opening—not to "tighten" in a harmful way. (acog.org)
- Offer **female sonographers** and privacy options; use **illustrated flip-charts** to demystify TVUS and cerclage.

4) Service delivery models.

- Preterm-prevention clinics within district hospitals (LaQshya-certified) with dedicated
 CL measurement logs, checklists, and direct referral to cerclage-capable OBGYN teams. (National Health Mission)
- Task-sharing & simulation: short modules on CL measurement/cerclage selection for obstetricians and radiologists; simulation-based training improves TVUS proficiency. (BioMed Central)
- **Digital nudges:** PMSMA day (9th of each month) to target **16–24 week** PCOS patients for CL scans; SMS reminders in local languages.

5) Quality, audit, and safety.

- **Data dashboards**: percent of at-risk PCOS women with CL measured; time-to-cerclage when indicated; **sPTB <34 w** rates; rescue cerclage outcomes.
- Antibiotics & tocolysis: follow institutional protocols; avoid unnecessary bed rest; align with RCOG/NICE/SMFM good-practice points. (<u>missionmrcog.com</u>)

• **Twin pregnancies:** avoid routine cerclage; consider **rescue cerclage** when dilation is present after specialist discussion. (<u>missionmrcoq.com</u>)

6) Policy integration.

- Add "PCOS with prior sPTB/late loss" and "PCOS with CL ≤ 25 mm" to high-risk flags in PMSMA ANC cards; include CL fields and referral prompts.
- Include cerclage eligibility and post-cerclage follow-up in LaQshya quality standards.
 (National Health Mission)

4. Conclusion

Summary of key findings. PCOS confers an increased risk for adverse pregnancy outcomes including preterm birth. Cervical cerclage offers clear benefit in well-defined singleton subgroups—particularly women with prior sPTB/late loss who develop a short cervix ≤ 25 mm in the mid-trimester, with stronger effects when <15 mm. Routine cerclage in twins or in singletons without prior sPTB is not supported; vaginal progesterone is appropriate in selected short-cervix scenarios. (PMC, missionmrcog.com, NICE)

Implications for stakeholders.

- Clinicians: Standardize risk-based CL screening for high-risk PCOS patients (16–24 weeks). Use shared decision-making to select cerclage vs progesterone, and refer promptly for rescue cerclage when indicated. Document technique and plan for timely removal (36–37 weeks). (missionmrcog.com)
- Hospitals & health systems: Build preterm-prevention clinics, ensure TVUS capability, female staff options, and audit CL measurement quality. Integrate checklists into PMSMA/LaQshya workflows. (PMSMA, National Health Mission)
- Public health & policymakers: Recognize PCOS as a risk marker in ANC registers; add CL fields and cerclage triggers; expand training and equipment in rural/tribal facilities; ensure coverage for cerclage (including TAC at referral centers) and streamline pathways under PM-JAY and state schemes. (National Health Authority)
- Communities & advocates: Promote stigma-free conversations on PCOS; provide multilingual education materials about TVUS and cerclage; support mental health and partner engagement.

Future research. India needs prospective registries and pragmatic trials to: (1) evaluate PCOS-specific CL trajectories and androgen-linked cervical remodeling, (2) compare Shirodkar vs McDonald outcomes by skill level and setting, (3) test combined progesterone+cerclage strategies in high-risk PCOS phenotypes, and (4) quantify cost-effectiveness of universal vs risk-based CL screening in Indian districts. Concurrent efforts by the ICMR PCOS Task Force can embed pregnancy outcomes modules and inform national policy. (PMC)

Policy recommendations.

- Adopt a national CL-screening directive for high-risk pregnancies (including PCOS with prior loss/sPTB) at 16–24 weeks, with standardized technique and referral. (publications.smfm.org)
- 2. **Codify cerclage indications** in PMSMA and LaQshya manuals, aligned with RCOG/SMFM/NICE, and ensure procurement of TVUS probes. (<u>missionmrcog.com</u>, NICE)
- 3. **Train and credential providers** (including simulation) for CL measurement and cerclage selection; create **regional centers of excellence** for TAC. (<u>BioMed Central</u>)
- 4. **Embed PCOS** as a high-risk ANC flag; integrate **GDM and hypertensive disorder pathways** to address overlapping metabolic risks in PCOS. (<u>National Health Mission</u>)

Bottom line: With **culturally sensitive**, **evidence-aligned** deployment of **cervical-length screening** and **cerclage**, India can measurably reduce sPTB among pregnant women with PCOS—honoring a century-old Indian surgical innovation (Shirodkar) and advancing equitable maternal-newborn outcomes. (PMC)

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