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Membrane sweeping at term to promote spontaneous labour and reduce the likelihood of formal labour induction for prolonged pregnancy, in South Asia and the world: a meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 December 2023 and was last updated on 19 December 2023.

INTRODUCTION

Review question / Objective To analyze the effectiveness of membrane sweeping in promoting spontaneous labour and reducing the need for formal labour induction in South Asian and global populations.

Rationale Numerous studies have demonstrated the significant effect of membrane sweeping in promoting spontaneous labour and reducing the need for formal labour induction. However, none clearly explains the relationship between membrane sweep and the POG, parity, timing, and single versus multiple sweeping attempts. [5], [10]. This knowledge gap reduces the effective use of membrane sweeping in clinical practice to get the best results, although some effectiveness is known with most practice variations. The current study was designed to address these grey areas. None of the previous meta-analyses [5], [10] on the effectiveness of membrane sweeping in promoting spontaneous labour and reducing the need for formal labour induction accounted for ethnic differences in the analysis. Labour induction rates vary between subpopulations: 4.4% in Africa and 12.1% in Asia, with notable exceptions in Sri Lanka and India [11]. The gestation period and the incidence of prolonged pregnancy also vary between ethnic groups. The average gestational age at delivery was 39 weeks for Black and Asian women and 40 weeks for white European women [12].

Early fetal maturation increases the incidence of spontaneous onset of labour [12]. Ethnic differences may play a role in managing prolonged pregnancy, changing the principles of obstetric practice and guidelines. The meta-analyses [5], [9] results should therefore applied cautiously to a unique subpopulation. Thus, we aimed to provide

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the best evidence for South Asian populations and to assess the contribution of ethnic differences in interpreting the results. We can easily extrapolate the results to our local (South Asian) population with high accuracy. In addition to its safety profile, the increased use of membrane sweeping instead of formal labour induction in resource-poor areas such as South Asia is a cost-effective measure [5], especially in the context of the 2022-2023 global economic crisis.

Condition being studied Labour induction through mechanical and pharmacological procedures is called formal induction of labour [5]. Formal methods of inducing labour include oxytocin, prostaglandin, and mechanical methods like Foley catheters. Informal and minimally invasive labour induction methods include membrane sweeping, unprotected intercourse, nipple stimulation, and acupuncture [4].

Formal induction methods carry several risks compared to informal conservative methods, including increased cesarean delivery rates, uterine hyper-stimulation, and higher rates of maternal and neonatal infections [4], [6]. Some recommend using informal methods to minimize these adverse effects [4].

Membrane sweeping is more effective in labour induction than nipple stimulation, unprotected intercourse, and acupuncture [6]. Therefore, the current study focuses on the effectiveness of membrane sweeping in minimizing the need for formal labour induction methods.

Membrane sweeping, also known as artificial separation of the membrane (ASM/ ASOM) or membrane stripping, is done by placing the examiner's finger in the cervix and then separating the amnion from the lower uterine segment with a 3600 finger movement. The procedure's success depends on the dilatation of the cervix to accommodate a single digit and the examiner's experience [7]. Various studies suggest subtle changes in the sweeping membrane technique, with some examiners using two fingers in a circular motion or two circumferential motions of the examining finger [5], [8].

Membrane sweeping is a 200-year-old method of inducing labour. Hamilton first described and documented it in 1810 [7]. Membrane sweeping increases the local release of prostaglandin (F2a), cytokines, and phospholipase A2. These hormones promote cervical ripening, potentiating uterine contractions. Thus, the spontaneous contractions of the uterus begin, which triggers the onset of labour [5]. There is no reported increased risk of cesarean section, maternal or neonatal infection, or maternal or neonatal mortality associated with membrane sweeping. Some report considerable maternal discomfort, which must be mentioned in the patient's consent and given due consideration during the procedure [7]. The contraindications to membrane sweeping are the same as for vaginal delivery [7].

METHODS

Search strategy We extracted Title-Abstract files in the formats of .csv, .ris, .bib, and .txt from the following databases to be exported and included in Rayyan.

1. Google Scholar

We conducted an advanced search on 15/06/2023 using the following keywords combined with Boolean expressions. We typed it in the section: 'with all the words' under advanced search. The results showed 8330 articles. Then, we introduced a timeline from 2010-2023 to filter the results. We received 4530 articles as a result.

((Membrane sweep) OR (Membrane strip) OR (Amniotic sweep) OR (Artificial separation of membrane) OR (ASOM)) AND ((Prolong pregnancy) OR (Post-date) OR (Post-maturity) OR (Term pregnancy) OR (Labour induction) OR (Post-term pregnancy)) = 8330 articles

After introducing a timeline, 2010-2023 = 4530 articles

Then we saved the articles to 'My Library.' After that, we used the 'Export all' option to get a CSV file to upload to Rayyan.

2. Science Direct

We conducted an advanced search on 15/06/2023 using the following keywords combined with Boolean expressions. However, Science Direct allows a maximum of eight Boolean expressions only. Therefore, we modified the search terms and Boolean expressions used for other databases, excluding ASOM and Term pregnancy. Under advanced search, we typed the following search terms combined with Boolean expressions in the section: 'Find articles with these terms.' The results showed 7009 articles. Then, we introduced a timeline from 2010-2023 to filter the results. We received 3704 articles as a result.

((Membrane sweep) OR (Membrane strip) OR (Amniotic sweep) OR (Artificial separation of membrane)) AND ((Prolong pregnancy) OR (Postdate) OR (Post-maturity) OR (Labour induction) OR (Post-term pregnancy)) = 7009 articles

After introducing a timeline, 2010-2023 = 3704 articles

Then, we downloaded a hundred titles/abstracts at a time as RIS files and uploaded them into Rayyan. 3. Cochrane Library

We conducted an advanced search on 15/06/2023. We typed each search term under 'search manager' in the Cochrane database. We have

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reported results for each search term separately. Then, we combined the first five search terms with the Boolean expression OR, resulting in 114 articles. We also combined search terms from seven to twelve using the same Boolean expression, resulting in 15670 articles. Finally, we combined results six and thirteen using the Boolean expression AND, resulting in 39 articles. After that, we filtered articles, introducing two search limits, Trials, and a timeline (2010-2023), vielding 34 articles as the final result. ID Search & Hits #1 Membrane sweep 43 #2 Membrane strip 41 #3 Amniotic sweep 4 #4 Artificial separation of membrane 24 #5 ASOM 10 #6 #1 OR #2 OR #3 OR #4 OR #5 114 #7 Prolong pregnancy 386 #8 Post-date 51 #9 Post-maturity 20 #10 Term pregnancy 12288 #11 Labour induction 4595 #12 Post-term pregnancy 203 #13 #7 OR #8 OR #9 OR # 10 OR #11 OR #12 15670 #14 #6 AND #13 39 Search limit: Trials 37 Search limit: Trials and Timeline, 2010-2023 34 4. PubMed We conducted an advanced search on 15/06/2023. The results showed 167 articles. Then, we introduced three filters: Full-text articles.

The results showed 167 articles. Then, we introduced three filters: Full-text articles, Randomized controlled trials, and a timeline (2010-2023). We received six articles as final results.

((Membrane sweep[Title/Abstract]) OR (Membrane strip[Title/Abstract]) OR (Amniotic sweep[Title/ Abstract]) OR (Artificial separation of membrane[Title/Abstract]) OR (ASOM[Title/ Abstract])) AND ((Prolong pregnancy[Title/ Abstract]) OR (Post-date[Title/Abstract]) OR (Postmaturity[Title/Abstract]) OR (Term pregnancy[Title/ Abstract]) OR (Labour induction[Title/Abstract]) OR (Post-term pregnancy[Title/Abstract])) = 167 articles

Filters: Full-text articles = 131 articles

Filters: Full-text articles and Randomized controlled trials = 16 articles

Filters: Full-text articles, Randomized controlled trials, and Timeline, 2010-2023 = 6 articles

5. Manual search

We also conducted a manual search. Our selection criteria were the most cited, most recent five metaanalyses in the same databases, searched using the same search strings. We searched 4530 articles from Google Scholar, and the same articles were searched for RCTs. We searched 3704 articles from Science Direct, and the same articles were searched for RCTs. We searched 39 articles from the Cochrane database, the same articles received in the search for RCTs, but without applying any search limit. We searched 131 articles from PubMed, the same articles received in the search for RCTs. However, we applied only one filter: Full-text articles in this search. Altogether, we searched 8404 articles for meta-analyses.

After applying the predefined criteria, we selected two meta-analyses for manual search. The first meta-analysis had 44 articles, while the second had seven articles. Thus, we searched 51 articles using our manual search strategy.

1) Avdiyovski H, Haith-cooper M, and Scally A, "Membrane sweeping at term to promote spontaneous labour and reduce the likelihood of a formal induction of labour for postmaturity : a systematic review and meta-analysis," J. Obstet. Gynaecol. (Lahore)., vol. 0, no. 0, pp. 1–9, 2018. Manual search = 44 studies

2) Finucane EM, Murphy DJ, Biesty LM et al., "Membrane sweeping for induction of labour," Cochrane Database Syst. Rev., vol. 2020, no. 2, 2020.

Manual search = 7 studies.

Participant or population Low-risk women with a single fetus in cephalic presentation at Term (37-42 weeks) pregnancy with gestation confirmed by certain LMP or first-trimester scan.

Intervention Membrane sweeping.

Comparator No intervention/sham or vaginal examination.

Study designs to be included Randomized controlled trials.

Eligibility criteria Inclusion criteria: Study design of randomized controlled (RCT) trial • RCTs published in English from January 2010 to May 2023• Availability of full-text articles• Low-risk women with a single fetus in cephalic presentation• Term (37-42 weeks) pregnancy with gestation confirmed by certain LMP or first-trimester scan• Having essential data to calculate relative risk (RR) and 95% confidence interval (CI)• Studies comparing membrane sweep to no intervention/ sham or vaginal examination Exclusion criteria:• Women with a previous cesarean delivery• Contraindications for vaginal birth• Review articles, case reports, documents, or observational studies.

Information sources 1. Google Scholar; 2. PubMed; 3. Science Direct; 4. Cochrane Library; 5. Manual search.

Main outcome(s) Analyzing the effectiveness of membrane sweeping in promoting spontaneous labour and reducing the need for formal labour induction in South Asian and global populations.

Additional outcome(s) Analyzing the effectiveness of membrane sweeping in promoting spontaneous labour and reducing the need for formal labour induction in South Asian and global populations in relation to POG, Parity and number and frequency of membrane sweeping.

Data management Study selection was conducted in two rounds using a semi-automated tool, Rayyan [13]. In the first round, records were screened for title and abstract by two authors, one as the reviewer (JS) and the other as a collaborator (JM), using a blind approach. Duplicated and ineligible titles and abstracts were removed in the first round. The reviewer resolved the conflicts. In the second round, full-text screening followed a similar blind approach, with conflicts resolved by the reviewer.

When necessary, the authors were contacted for further information. Study selection was reported using the PRISMA 2020 flow diagram for updated systematic reviews [14].

Quality assessment / Risk of bias analysis The Cochrane risk-of-bias tool for randomized control trials (RoB 2) was used to assess the quality of each RCT in seven domains: random sequence generation, allocation concealment, performance bias, detection bias, attrition bias, reporting bias, and other biases [15]. We investigated publication bias using funnel plots, where a deviation from the funnel-shaped distribution indicated the publication bias.

Strategy of data synthesis Review Manager (RevMan) 5.4 version was used for statistical analysis. Dichotomous data were analyzed using the Mantel-Haenszel statistical method. The random effect was used as the analysis model. The risk ratio with a 95% confidence interval was the effect measure. The I2 statistic was used to identify systematic variability between studies. A p-value 50% indicated significant heterogeneity. We had several multi-arm RCTs. When the multi-arm distinction was irrelevant to the research question, we chose the method of "combing groups" [16].

Subgroup analysis The analysis was conducted in two parts: primary and secondary. In the primary analysis, we assessed the effectiveness of membrane sweeping in promoting spontaneous labour onset and reducing formal labour induction. In the secondary analysis, we examined the impact of factors such as frequency and number of membrane sweepings, parity and gestational age on the effectiveness of membrane sweeping. The primary and secondary analysis included two subgroups: South Asia and the rest of the world.

Sensitivity analysis It is not possible to conduct sensitivity analyses in RevMan by omitting individual diagnostic studies.

Language restriction RCTs published in English from January 2010 to May 2023.

Country(ies) involved Sri Lanka.

Keywords Membrane sweeping; spontaneous labour; formal induction; South Asia; rest of the world; Meta-analysis; prolonged pregnancy; artificial separation of membranes (ASM).

Dissemination plans The study will be published in a peer reviewed, indexed journal.

Contributions of each author

Author 1 - DMCS Jayasundara - • Substantial contributions to the conception and design of the study.

• Active involvement in planning the research methodology and data collection.

• Played a key role in conducting data analysis and interpretation.

• Drafted the initial version of the manuscript and revised it critically for intellectual content..

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Author 2 - IA Jayawardane - • Contributed significantly to the conception and design of the study.

• Participated in planning and organizing the data collection process.

Assisted in data analysis and interpretation.

• Reviewed and critically revised the manuscript for important intellectual content.

• Gave final approval for the version to be published.

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Author 3 - HMBH Denuwara - • Actively participated in the research design and methodology.

• Conducted data collection and contributed to data analysis.

• Played a role in drafting and revising the manuscript.

• Provided critical input to enhance the intellectual content of the manuscript.

• Gave final approval for the version to be published.

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Author 4 - TDKM Jayasingha - • Made substantial contributions to the study's conception and design.

• Was directly involved in data collection and analysis.

• Collaborated in drafting the manuscript and revising it critically.

• Ensured the manuscript met high intellectual standards.

• Gave final approval for the version to be published.

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