BMC Pregnancy and Childbirth

SYSTEMATIC REVIEW Open Access

Definitions of failed induction of labor in the literature: a systematic review

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Abstract

Background Induction of labor is a common obstetric intervention with rates up to 25% in developed countries. However, no accepted definition of failed induction of labor exists today. This challenges the comparability between studies investigating induction regimens in terms of efficacy and outcomes, thereby limiting the ability to generate homogenous and valid meta-analyses to inform practice.

Objective The objective of this systematic review was to describe the definitions of failed induction of labor in the reported literature.

Methods A systematic search was conducted in PudMed, EMBASE, and CINAHL. Randomized controlled trials and cohort studies, which explicitly stated a definition of failed induction of labor were included. We extracted the definition from each study and described the components of the definitions.

Results A total of 96 studies were included, yielding 112 distinct definitions, the vast majority of which differed from one another. Significant heterogeneity was observed among these definitions, and twelve unique components were identified within them. The most frequently cited component was the duration of induction, appearing in 65% of the definitions. .

Conclusion The variation in definitions of failed induction of labor used in the literature is vast. To ensure consensus and increase comparability when comparing studies investigating induction of labor, a standard definition is highly needed.

Trial registration Prior to this review a protocol was made and published on PROSPERO with ID number CRD42023405953.

Keywords Labor induction, Failed induction of labor, Systematic review

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Background

Induction of labor (IOL), defined as the process of artificially stimulating the uterus to start labor, is a common obstetric intervention as it is performed in up to 25% of all deliveries in developed countries [1].

The World Health Organization (WHO) recommends that IOL should be performed "only when there is a clear medical indication for it and the expected benefits outweigh its potential harms" [1].

Common indications include post-term pregnancy, hypertensive disorders, and maternal medical complications [1].

When IOL is not successful, it is often labelled as *failed* IOL (FIOL). However, no consensus exists on how to define FIOL [2–4]. In 2024, the American College of Obstetricians and Gynecologists (ACOG) with support from the Society for Maternal-Fetal Medicine (SMFM) published a new clinical practice guideline on first and second stage labor management. In this paper it was stated:" If the maternal and fetal status remain reassuring, cesarean deliveries for FIOL in the latent phase can be avoided by recommending that oxytocin be administered for at least 12–18 h after membrane rupture before deeming the induction to be unsuccessful" [3]. Accordingly, they recommend using FIOL as the terminology in cases when there are no progression in the latent phase [3]. The National Institute for Health and Care Excellence [5] defines unsuccessful IOL as "labor not starting after one cycle of treatment".

FIOL is a frequently reported outcome in research papers [6–12]. The lack of uniform definitions may lead to a heterogenic interpretation of FIOL courses in clinical practice, a heterogenic clinical coding practice, along with difficulties in comparing the efficacy and outcomes between IOL regimes reported in research papers, thereby limiting the ability to perform valid meta-analyses to inform practice.

To work towards a more uniform definition of FIOL and to inform future studies in IOL, we aimed with this systematic review to describe the FIOL definitions reported in the literature.

Methods

Eligibility criteria

Randomized controlled trials (RCT) and cohort studies in pregnant people, written in English, Danish, Norwegian, or Swedish language were included. We had no publication year or geographic restrictions.

Only original, peer-reviewed full-text studies investigating induction regimens, which explicitly stated a definition for FIOL were included. We did not include studies that reported 'successful IOL' without giving a definition for 'unsuccessful IOL' or FIOL.

We excluded studies on IOL (1) after previous cesarean section, (2) due to prelabor rupture of membranes, (3) with breech presentation, (4) in first and second trimester of pregnancy, or (5) with fetal demise.

Information sources and search strategy

On 21st of August 2024, a systematic search was conducted in PubMed, EMBASE, and CINAHL with the search terms ("Labor, Induced") AND ("Treatment Failure") AND ("cohort studies" OR "randomized controlled trial") along with synonyms for each MeSH/Emtree terms (see Appendix A).

Data management and selection process

The selection of studies was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Duplicates were identified and removed automatically using Endnote or removed manually if detected afterwards.

Eligible studies were managed by the reference software, Covidence. Screening of title and abstract for eligibility were performed independently by two authors (EC and LQK), who also performed full-text screening.

Any disagreement, at any stage of the process, was resolved by discussion and, if necessary, consulting a third part (JG).

Data extraction

The following data were manually extracted from the included studies by one author (EC) and when necessary, checked for accuracy by another author (LQK): Author, country of conduct, year of publication, research objective(s), study design, sample size, inclusion criteria, exclusion criteria, induction method(s), definition(s) of FIOL including individual components of the definitions.

Discrepancies or uncertainties in the extracted data were resolved by discussion and when necessary, by consulting a third part (JG).

Risk of bias and quality assessment in individual studies

As our outcomes were of descriptive nature and not depending on the validity of the methods or results of the studies, we did not perform a risk of bias assessment nor a quality assessment of the included studies.

Data synthesis

Components used in the different definitions of FIOL were grouped in exploratory categories and presented as counts and percentages per number of included studies.

Results

Study selection

A total of 1,320 studies were identified by the search. After excluding 1,224 studies (440 duplicates and 784 ineligible studies), a total of 96 studies were included in the study (Fig. 1).

Study characteristics

In a total of 96 included studies, there were 50 RCTs and 46 cohort studies published between 1984 and 2024 and with a total of 1,425,727 pregnant people (Appendix B).

The studies originated from 32 different countries, with the United States being the most common country of origin, contributing 16 studies.

Sixty-six studies evaluated dinoprostone (vaginal tablet or insert, or intracervical gel), whereas the number of other medicaments/methods were as follows: Misoprostol oral/oral titrated, sublingual, vaginal, or cervical (n=59), oxytocin (n=38), Foley balloon or double balloon catheter (n=27), amniotomy (n=15), placebo (n=5), adjunctive sweeping of membranes followed by dinoprostone vaginal insert (n=1), isosorbide mononitrate (n=1), laminaria (n=1), or mifepristone (n=1).

The included studies had gestational ages ranging between 24 and 43 weeks, of which 61/96 studies (64%) only included pregnancies with a GA $\geq$ 37 weeks. Forty-eight studies (50%) had Bishop score as part of the inclusion criteria. See Appendix B for an overview of the study characteristics.

Definitions of failed induction of labor

From the 96 studies, we extracted 112 definitions of FIOL (Appendix B). Some of the definitions from different studies were almost identical, i.e. had only minor variations in wording. These included four studies from Korea [11, 13–15], four studies from Israel [7, 16–18], three from Germany [19–21], and two from the United states [22, 23] along with another two from the United States [24, 25]. The studies from each country/group were authored one or more of the same researchers.

Nine out of 96 studies (9%) reported more than one definition of FIOL, ranging from two to four different definitions [7, 16–18, 26–30].

The most frequent component included in the FIOL definition was a time aspect (65%). The proportions of other components used in the definitions were as follows: cervical change or dilation (44%), failure to go into active labor (27%), contractions or uterine activity (21%), rupture of membranes (15%), number of doses of misoprostol (n=12) or dinoprostone (n=4) (14%), Bishop score (14%), "did not go into labor" (13%), cesarean section (12%), no vaginal delivery (6%), fetal asphyxia or fetal distress (6%), and/or inability to perform amniotomy (6%). Table 1 gives an overview of the components and their individual frequency.

We chose to register both "cesarean section" and "no vaginal delivery" as components to precisely clarify how various studies define FIOL.

While numerous studies reported that a cesarean section was performed following a diagnosis of FIOL (i.e. a

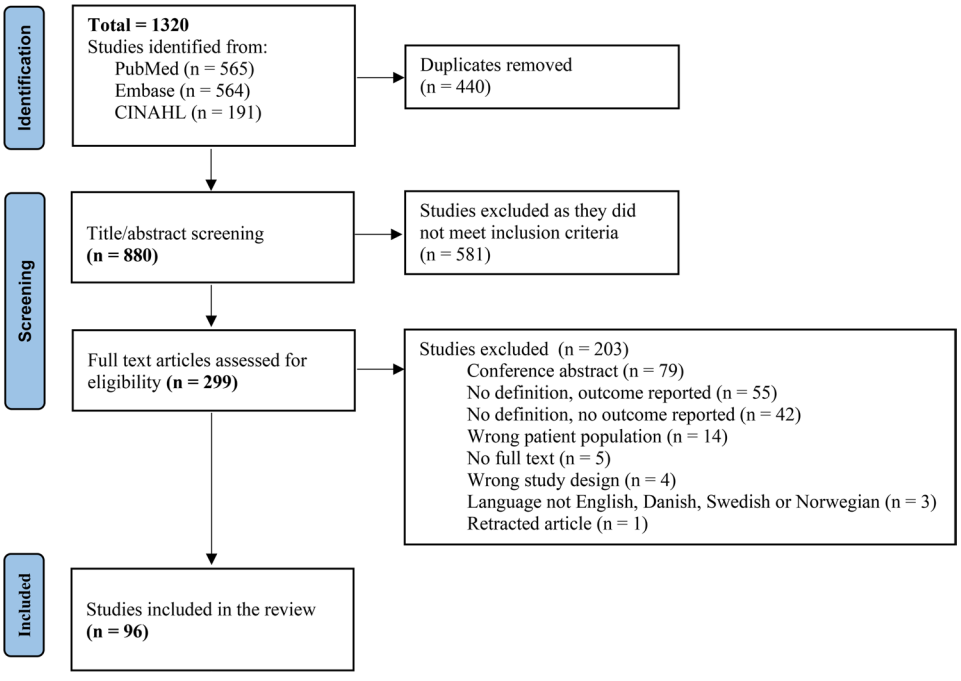

Fig. 1 Flowchart. PRISMA 2020 Flow Diagram. Selection of the studies included in the review

Table 1 Components included in definitions of failed induction of labor

Components included in definitions	*N*	%
Time aspect	73	65
Cervical change or dilation	49	44
Failure to go into active labor	30	27
Contractions or uterine activity	23	21
Rupture of membranes/amniotomy	17	15
Number of doses	16	14
Bishop score	16	14
Did not go into labor	15	13
Cesarean section	13	12
No vaginal delivery	7	6
Fetal asphyxia or fetal distress	7	6
Inability to perform amniotomy	7	6

Number of components in definitions and number per total number of definitions (112)

Table 2 Number of components included per definition

Number of components included per definition (*N*=112)	*N*	%
One component	22	20
Two components	41	37
Three components	31	28
Four components	14	12
Five components	4	3

clinical outcome), cesarean section was only included as a component when it was part of the definitional criteria for FIOL, for example: "Cesarean section was considered as unsuccessful induction of labor."

We also registered both "rupture of membranes" and "inability to perform amniotomy" as components, as the former refers to definitions requiring membrane rupture before being able to diagnose FIOL, while the latter refers to definitions including the inability to perform amniotomy.

The number of different components used in the definitions ranged from one to five components in each study. An overview of these can be seen in Table 2.

Interestingly, 55/299 (18%) studies during full text screening did not include a definition of FIOL even though it was one of their outcomes (Fig. 1).

Below is a description of all referenced components included in the FIOL definitions.

Time aspect

In 73 definitions including a time component, numerous variations were observed ranging from not being in active phase of labor six hours after initiation of induction with oxytocin infusion [31] till defining FIOL in cases where birth did not occur within five days with use of either prostaglandin or oxytocin [32]. The most often used time component was a duration of 24 h from start of IOL in the definition of FIOL.

Cervical change or dilation

In 49 definitions including cervical change or dilation as a component, 29/49 definitions (59%) included a quantitative evaluation of cervical dilation (between two and six cm), while the remaining definitions included less quantitative statements like an unchanged cervix, no cervical dilation or ripening, unripe or unfavorable cervix, failure of sufficient ripening, lack of cervical ripening, or no advance in cervical dilation for two hours, respectively.

Failure to go into active labor

In 30 definitions including failure to enter active labor as component, 14/30 (47%) definitions gave criteria for entering active labor such as degree of cervical dilation (ranging from three to six cm) [7, 13–15, 18, 24, 25, 33–38], cervical effacement [36, 37], or "uterine contractions causing progressive cervical dilation and effacement" [28].

Contractions or uterine activity

In 23 definitions including contractions or uterine activity as components, two studies specified the time interval between contractions (every two to three minutes) [39, 40], two studies the number of contractions (three to five) every 10 minutes [41, 42], and one definition included "persistent uterine activity of 200 Montevideo units" [43]. The remaining 18 definitions used the words "regular", "intense", "ideal" or "adequate" to describe contractions or uterine activity.

Rupture of membranes/amniotomy

In 17 definitions, spontaneous rupture of membranes or amniotomy was mandatory before FIOL could be diagnosed.

Number of doses

In 16 definitions including any number of medication doses for IOL as component, the number of doses ranged from two to 10. One study did not quantify the number of doses given, but simply stated that FIOL could be diagnosed in case of failure of sufficient ripening of the cervix, following the use of "repeated doses of prostaglandin" [44].

Bishop score

In 16 definitions with Bishop score as part of the definition, 12/16 studies (75%) had an exact quantification of the Bishop score, with cutoffs ranging from a score below four to a score below eight [7, 8, 16–18, 30, 45–49]. The remaining four definitions included an "unchanged Bishop score" as one of their criteria for diagnosing FIOL [50–53].

Did not go into labor

In 15 definitions of FIOL, there was a component of not going into labor. How the woman was in labor was not clarified in any of these definitions except in one study, where labor involved "regular contractions with continued cervical changes" [54].

Cesarean section

In 13 definitions, a cesarean section was part of the FIOL definition, i.e. " Cesarean section was considered as unsuccessful induction of labor" [55].

No vaginal delivery

In seven definitions, FIOL was diagnosed if the woman did not give birth vaginally. In five of these [19–21, 32, 56], vaginal birth had to occur within a certain interval, ranging from 48 hours [56] to five days [32] from the start of IOL, and in the remaining two studies IOL failed if a cesarean section was required due to a failed vaginal delivery [57, 58].

Fetal asphyxia or fetal distress

Seven definitions included the component of fetal asphyxia or distress [7, 16–18, 59, 60], while in one, the definition of FIOL included the absence of fetal distress together with the person not being in active labor [31]. Four of the definitions using this component were almost identical and written by the same author [7, 16–18].

Inability to perform amniotomy

Seven definitions included a component of not being able to perform an amniotomy [29, 61–65].

Discussion

This systematic review aimed to describe the definitions of FIOL across RCTs and cohort studies.

We found 112 definitions of FIOL in 96 studies, each incorporating different combinations of time variables, cervical effacement, mode of delivery, or other process- or labor-related factors. Notably, the most used component in these definitions was the time aspect which was part of 65% of the definitions, highlighting the critical role the duration of IOL plays in evaluating labor inductions. Overall, our findings point to a significant heterogeneity in how FIOL is defined in the literature, both in terms of the components included in the definitions and the threshold criteria set by different studies within each of the components.

Comparison with existing literature

The variation in FIOL definitions found in our review is consistent with prior studies on the subject [2, 66]. A review evaluated the literature for studies where failed IOL was the primary or secondary outcome [2]. Failed IOL was defined according to the authors as not entering the active phase of labor after 24 h of prostaglandin ± 12 h of oxytocin infusion. There were seven studies identified in the review, since most definitions used in published studies used more definitive outcomes like mode of delivery as their definition [2].

Another review examined the definitions of FIOL [66] in eight RCTs of which all definitions were different from one another. Five of eight (63%) definitions included failure to reach the active phase of labor or active dilation. Cervical change or dilation were included in four of eight definitions (50%) which is comparable to our findings. Like in our data, contractions or uterine activity were included in two of eight (25%) definitions. In this review, the authors proposed a far more detailed definition of FIOL, namely "The inability to achieve a cervical dilatation of four cm and 90% effacement, or at least five cm (regardless of effacement) after a minimum of 12 to 18 h of membrane rupture and oxytocin administration (with a goal of 250MU or five contractions/10 min)" [66]. Similar to the previous review, the definition was not based on mode of delivery.

The most frequently used component in the definitions explored in our systematic review was the time aspect. This is a component that may be easy adaptable to a clinical setting. In a clinical practice guideline published by ACOG and SMFM in 2024 it is stated that the latent phase should be up to 24 h or longer and that oxytocin should be administered 12 to 18 h after membrane rupture, before the diagnosis of a FIOL is made [3]. The scientific foundation for this guidance is a comprehensive literature search for primary literature in Cochrane Library, Cochrane Collaboration Registry of Controlled Trials, EMBASE, PubMed, and MEDLINE [3].

Defining FIOL as the inability to deliver vaginally carries inherent challenges, since vaginal delivery depends on several factors during labor such as cephalo-pelvic disproportion or fetal distress, which are factors that are not necessarily related to the induction process. Consequently, the inability to achieve active labor would be a more reasonable definition of FIOL. However, this calls for a standardization in determining and defining the start of labor and the duration of the latent phase [67].

An observational study (N=397) evaluated the association between length of the latent phase in IOL among nulliparous pregnant people and the chance of vaginal delivery [68]. They found that in pregnant people who were still in the latent phase after 12 h, there was a 59% chance of vaginal delivery. After 18 h in the latent phase, there was a 32% chance of vaginal delivery. In the same study postpartum hemorrhage and chorioamnionitis increased with increasing length of the latent phase, and the authors recommended considering the latent phase duration of up to 18 h before diagnosing FIOL [68].

In another observational study (*N*=10,677) there was more than 40% of nulliparous people with a latent phase ≥18 h who delivered vaginally, and most people (96%) reached the active phase within 15 hours [4]. Postpartum hemorrhage, chorioamnionitis and blood transfusions increased with increasing length of the latent phase, however there was no exact duration, of which the complications markedly increased. The authors suggested that the latent phase should last at least 15 h after the rupture of membranes and initiation of oxytocin before considering a cesarean section for FIOL [4].

However, if the definition of FIOL were based on their suggestions, a considerable number of people (i.e. 32% [68] vs. >40% [4]) would give birth vaginally, even though they were diagnosed with FIOL. Similarly, in some studies continuing the induction process after a diagnosis of FIOL results in vaginal delivery in some people, even though they were diagnosed with FIOL [2]. One study defines FIOL as:" Cases where amniotomy was not possible after 24 hours of DVI insertion." However, it is noteworthy that these same cases were subsequently managed with an additional attempt at cervical ripening, either using a dinoprostone vaginal tablet or mechanical methods such as a balloon catheter [61].

Challenges in defining FIOL

One of the significant challenges identified in this review is the inconsistency in the components included in the FIOL definitions. For instance, while many studies considered the time aspect of induction, there was considerable variation in the threshold for determining whether the time elapsed was considered a failure.

The inclusion of cesarean section as a diagnostic criterion for FIOL in 12% of the definitions is another point of concern. Defining FIOL as the occurrence of a cesarean section without accounting for the underlying causes, reflects to a large extend labor management in the individual delivery site and include unmeasurable factors like the person's choice to have a cesarean section or the caretakers' subjective evaluation of the chance of vaginal birth during the process of IOL. Also, in people with obstetric indications for IOL like preeclampsia, performing a cesarean section could indicate progression of her obstetric condition that indicates expedited birth.

Besides this huge inconsistency in the definitions of FIOL another important issue is the fact that 55/299 (18%) studies during full text screening did not even define FIOL even though it was one of their outcomes.

Therefore, our findings do not only reveal a huge variation in how studies define FIOL but also a concerning degree of non-reporting, which further contributes to ambiguity in the field.

Strengths and limitations

To our knowledge this is the first systematic review investigating definitions of FIOL. The literature search and screening process adhered to rigorous methods, we followed a publicly available protocol, and we included a considerable number of studies (96).

However, there are limitations to consider. The primary focus of this review was on definitions of FIOL, and as such, we did not explore the association between FIOL definitions and labor outcomes such as the rates of FIOL or cesarean section in the individual studies. We included only RCTs and cohort studies, and since RCTs often aim to compare two different induction regimes, their choice of FIOL may reflect a more academic and less clinical and patient-focused perspective [28, 29, 56, 61, 69]. However, given the huge variation seen in this review, even within studies investigating the same medication for IOL, one may hypothesize that the observed variation can be generalized to most studies. Another limitation of our study is the lack of a risk of bias assessment. The possible heterogeneity in the methodological rigor in the included studies, in particular the retrospective cohort designs, may be a limitation to our study.

Implications for future research and clinical practice

Awareness must be raised that the term FIOL is used interchangeably and with much variation in included components and their level of detail in published research.

While a uniform definition of FIOL may be challenging to establish, given the multiple factors influencing labor progression, a consensus on the key components of FIOL would be an essential first step. For instance, adopting a definition based on the failure to achieve active labor, with a standardized duration of the latent phase (e.g. 24 h) before diagnosing FIOL, could provide more consistency across studies and clinical settings.

Suggestions for achieving consensus could include the use of Delphi panels or expert working groups convened by major professional organizations (e.g., WHO, ACOG). In addition, pilot testing any proposed consensus definition(s) would be essential before widespread implementation.

In addition, future research should consider the specific context in which FIOL is being defined, whether in experimental studies comparing induction methods or in clinical practice, where outcomes such as maternal wish for a vaginal birth should be stressed in the decision to diagnose FIOL.

Conclusion

The number of definitions of FIOL (112) in research studies outweighs the number of published studies (96) and, although there are components used more frequently than others, the variation in definitions is vast.

While universal consensus may be difficult due to the complexity of labor physiology and institutional variability, adopting a minimum set of shared diagnostic criteria, can help standardize the FIOL definition across studies and clinical practice.

Abbreviations

IOL	Induction of labor
FIOL	Failed induction of labor
ACOG	American College of Obstetricians and Gynecologists
SMFM	Society for Maternal-Fetal Medicine
RCT	Randomized controlled trials
EC	Emma Louise Eisland-Schmidt Christiansen (corresponding author)
LQK	Lise Qvirin Krogh
JG	Julie Glavind

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12884-025-08550-8.

Supplementary Material 1.

Acknowledgements

Not applicable.

Authors' contributions

EC and LQK screened title and abstract together with full text screening. EC and LQK extracted data from the studies. JG was consulted in cases of any disagreements. EC was a major contributor in writing the manuscript, and LQK and JG substantively revised it. All authors read and approved the final manuscript. All authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

Funding

The dissemination of results from this study was funded by the Novo Nordic Foundation (Grant number NNF19OC0057545).

Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 29 September 2025 / Accepted: 1 December 2025
Published online: 06 December 2025

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