

RESEARCH ARTICLE

What Is the Safest Population-Level Caesarean Delivery Rate? A National Cohort Study Using Natural Variation

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ABSTRACT

Objective: Ten to fifteen per cent has been proposed for many decades as the optimal level of caesarean section, with little supporting data. Norway provides a natural experiment in which local variations in the use of caesarean section can be related to health outcomes in the context of free access to high-quality medical services.

Design: Prospective national cohort.

Setting: Norway.

Population: Norwegian deliveries 1995–2014.

Methods: We calculated annual rates of caesarean delivery and health outcomes for 435 municipalities. To avoid hospital referral bias, the mother's municipality of residence was the unit of analysis. Caesarean-delivery rates in each year were based on the 2 years before and after, avoiding indication bias. Analyses were adjusted for year, with additional adjustments in sensitivity analyses.

Main Outcome Measures: Maternal mortality, severe maternal haemorrhage and perineal tears; stillbirth and neonatal death, neonatal encephalopathy and cerebral palsy.

Results: There were 1 172 546 deliveries across 8647 municipality-year combinations over a 20-year period. Caesarean rates across municipalities ranged from about 10% to 20%, with quartile values of 13%, 16% (median) and 18%. Most adverse outcomes were least frequent in municipalities with caesarean rates above 15%. Lower rates of caesarean delivery were associated with more frequent occurrence of perineal tears (OR 1.41, 95% confidence interval 1.36–1.46), neonatal encephalopathy (OR 1.91, 1.71–2.13), cerebral palsy (1.48, 1.24–1.77) and stillbirths (OR 1.07, 0.99–1.17), but also with less frequent maternal haemorrhage (OR 0.81, 0.77–0.85). Further adjustments had minimal effect on estimates.

Conclusion: In Norway, a country with free access to high-quality medical care, a local caesarean-delivery rate of 10% was associated with nearly a two-fold risk of neonatal encephalopathy and a 50% higher occurrence of cerebral palsy compared with areas with a caesarean-delivery rate of 20%.

1 | Introduction

Caesarean delivery can be lifesaving in the face of obstetric emergencies. Caesarean delivery is also performed for a variety of less urgent indications, with rates varying widely within and across countries [1, 2]. The use of caesarean delivery has risen in recent decades, for reasons largely unrelated to medical indication [2–5]. Efforts to estimate an optimum level have been stymied by practical and ethical obstacles to randomised trials [6], and by the difficulties of controlling for confounding by indication in observational data. According to a 2015 WHO report, caesarean-section levels in the range of 10%–15% are ‘optimal.’ WHO also stated that no data were available to show benefit of caesarean-section rates above 10% [1]. The WHO recommendation remains controversial and has had little effect on practice [2].

Caesarean section rates in Norway are relatively low, rising from 13% to 17% between 1999 and 2008 and subsequently plateauing at 16% [7]. Regional differences persist within this overall pattern. Varying local policies on obstetric practice have led to variations in the level of caesarean delivery across hospitals and regions, within a setting of universally accessible health care and high-quality medical registries. These practice variations provide the opportunity for a natural experiment, in which regional differences in clinical practice preferences can be related to regional variations in corresponding health outcomes. We have structured an analysis that assesses maternal and infant outcomes in communities across a range of caesarean section rates, while minimising referral bias and bias by specific indication and controlling for potential confounding. Specifically, we linked data from the population health and insurance registers of Norway to explore whether background variations in the use of caesarean delivery across more than 400 communities are associated with maternal and infant outcomes, including mortality and morbidity.

2 | Methods

2.1 | Study Population

All pregnancies in Norway lasting 16 weeks or more are recorded by law in the Medical Birth Registry [8]. This registry contains information on the mother, father, newborn, and conditions of delivery. In addition, each person’s unique identification number allows personal data to be linked to national health registries.

We had access to all births registered from 1995 through 2014. We included all births with a gestational age of at least 22 weeks. If gestational age was missing, babies with a birthweight of at least 500 g were included. The Medical Birth Registry provides information on mother’s residence, age, parity, presence of a partner, complications of delivery, plural births, stillbirths and infant deaths. If the newborn is transferred to a neonatal ward, the birth registry is updated with diagnoses from neonatal departments including neonatal encephalopathy. Information on cerebral palsy was obtained from the National Insurance Scheme [9]. Parents’ education and immigrant

status were obtained from the National Education Database and Statistics Norway [10]. Study approval was provided by the Regional Committee for Medical and Health Research Ethics, the Norwegian Labour and Welfare Administration, the Medical Birth Registry of Norway, Statistics Norway and the Norwegian Population Register.

2.2 | Study Design

2.2.1 | Unit of Analysis

The level of caesarean deliveries in Norway is generally low, although with substantial variation across Norwegian hospitals. This variation reflects not only the referral of high-risk pregnancies to tertiary-care hospitals but also differences in hospital policies regarding indications for caesarean delivery. To avoid confounding by indication from referrals, we focus on variations of caesarean section across municipalities of mother’s residence rather than across hospitals or municipalities of delivery. Municipalities in Norway are mutually exclusive and exhaustive administrative units that capture the whole population [11]. The number of municipalities declined from 435 to 428 during the study period. Populations range from 200 to more than 600 000 persons (Oslo), with a median of around 4500 persons [12]. By basing the analysis on municipalities of maternal residence rather than hospital of delivery, the results focus specifically on variations in caesarean delivery due to clinical practice and preference in each community, and are less vulnerable to indication bias.

2.2.2 | Exposure

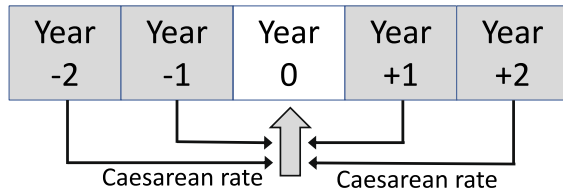
A municipality may by chance have an excess of high-risk pregnancies in a given year and consequently more indicated caesarean deliveries. The resulting association could be misinterpreted as causally due to increased caesarean sections. To avoid this bias, we defined the level of caesarean section for each year as the mean for that municipality in the 2 years before and the 2 years after the year itself (Figure 1). This ‘municipality level’ of caesarean delivery thus represents the more typical practice of hospitals serving that municipality around that time, without allowing influence by random fluctuations of high-risk pregnancies in a specific year. The measured outcomes, meanwhile, were among the deliveries during the given year.

2.2.3 | Outcome Variables

We selected outcomes known or suspected to vary with caesarean delivery. These included increased risk of severe maternal haemorrhage (more than 1500 mL during delivery, with or without need for transfusion), reduced risk of 3rd or 4th degree perineal tears and reduced maternal mortality. The definitions of these maternal diagnoses are provided in Table S1.

Offspring outcomes included stillbirth (delivery of a dead fetus from 22 weeks on), neonatal deaths (death to a live birth in the first 28 days) and neonatal seizures without encephalopathy (definitions in Table S1). Caesarean section may be performed

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Municipalities are assigned a rate of caesarean delivery in each year, based on that municipality's mean rate in the 2 years before and after

FIGURE 1 | Calculation of the projected caesarean delivery rate for a municipality. The assigned level of caesarean delivery in a given year is estimated as the mean observed levels in the 2 years before and the 2 years after for that municipality.

in an attempt to prevent perinatal brain injury [13], so we also explored two neonatal outcomes with possible origins during vaginal delivery. Neonatal encephalopathy is a clinically defined syndrome of disturbed neurologic function in the earliest days of life [14]. Cerebral palsy (CP) is the most common motor disability in childhood [15]. Given that the diagnosis of CP is unreliable in early life, we assessed CP risk only for births occurring through 2012, providing each infant with at least 2 years of follow-up.

In late 1998, the birth registry changed how severe maternal haemorrhage, neonatal encephalopathy and neonatal seizures were recorded. In order to reduce potential misclassification of those outcomes, we restricted the analysis of these specific outcomes to deliveries from 1999 onward.

2.3 | Statistical Analyses

The association between level of caesarean delivery and each outcome was assessed within municipalities in logistic regression models, adjusting for year of birth in single-year categories (1995 through 2014). The estimated level of caesarean delivery was divided into seven categories (<10%, 10% to <12%, 12% to <14%, 14% to <16%, 16 to <18%, 18 to <20% and 20+%). Associations at each level of caesarean delivery were expressed as odds ratios (ORs) with 95% confidence intervals (CIs). We chose the most frequent category (18 to <20% caesarean deliveries, or '18%–19%') as the referent for comparisons. This was also the lowest risk category for several of the health outcomes assessed. In addition, we tested for a linear trend, fitting caesarean-delivery levels as a continuous variable. Linear risks were scaled to express the difference in risk for a decrease in caesarean delivery from 20% to 10%.

In order to explore the extent of residual confounding, we conducted supplementary analyses adjusting yearly rates by proportion of immigrant parents (both parents born abroad); single mothers (not married or cohabiting); mother's and father's education (separately, using three standard Norwegian categories); mother's age (<18, 18–39 and 40+ years); plural births (yes/no); and parity (0, 1–3 and 4+).

Further sensitivity analyses were carried out to assess the influence of very small municipalities (which could have extreme values due to small denominators) by excluding all municipalities with less than 75 deliveries in a year. We assessed the influence of the largest municipality by excluding the capital, Oslo. Finally, we assessed the influence of multiple births by restricting to single births only.

Statistical analyses were performed using IBM SPSS version 24 (SPSS Inc., Chicago, Illinois). To obtain CIs that accounted for the correlation among observations within the same municipality, we performed supplementary analyses using logistic regression with clustering and robust estimation of variances in Stata version 15 (StataCorp College Station, Texas).

3 | Results

A total of 1 201 693 babies (including twins and other multiple births) were registered in the Norwegian Medical Birth Registry from 1995 through 2014. Of these, 99% (1 193 554) had a gestational age of at least 22 weeks or a birthweight of at least 500 g. There were 325 newborns (0.03%) lacking information on the mother's residence, leaving 1 193 229 newborns for analyses of offspring outcomes and 1 172 546 deliveries for analyses of maternal outcomes.

The annual number of deliveries in municipalities ranged from 0 to 10 555, with a median of 361 and an interquartile range of 137–1891. Overall, 16% of deliveries across the 8647 municipality-year units in the 20-year period were by caesarean section ($N=185\,426$). Figure S1 shows the proportion of births by caesarean delivery across municipalities by year, with quartile values of 13%, 16% (median) and 18%. During these 20 years of data, the mean level of caesarean section increased from 13% to 17%, with substantial variability across municipalities in any given year (Figure S2).

We first explored maternal outcomes associated with caesarean delivery. Severe maternal haemorrhage was less likely in municipalities with lower use of caesarean section (Figure 2, Table S3). This trend was approximately linear across the range of caesarean section use ($p_{\text{trend}} < 0.0001$). Comparing risk at the 10% level of caesarean delivery to risk at the 20% level, the odds of severe maternal haemorrhage were 19% lower (OR 0.81, 0.77–0.85, Table 1). In contrast, a lower level of caesarean section was associated with a 41% higher odds of severe perineal tears (OR 1.41, 0.136–1.46, Table 1) ($p_{\text{trend}} < 0.0001$, Figure 2).

Figure S3 shows the risks of stillbirth and neonatal death across municipalities with a range of caesarean use. There was the suggestion of a higher occurrence of stillbirths in the lower range of 10%–15% caesarean section. A decrease from a 20% to a 10% population rate of caesarean section was associated with a marginally higher stillbirth risk (OR 1.07; 0.99–1.17) (Table 1). Neonatal mortality did not vary appreciably in relation to the level of caesarean section (Table 1, Figure S3). There were few maternal deaths, with an imprecise suggestion of higher maternal mortality with caesarean use less than 10% compared with 10%–11% (OR 2.95; 0.65–13; Table 1, Figure S4).

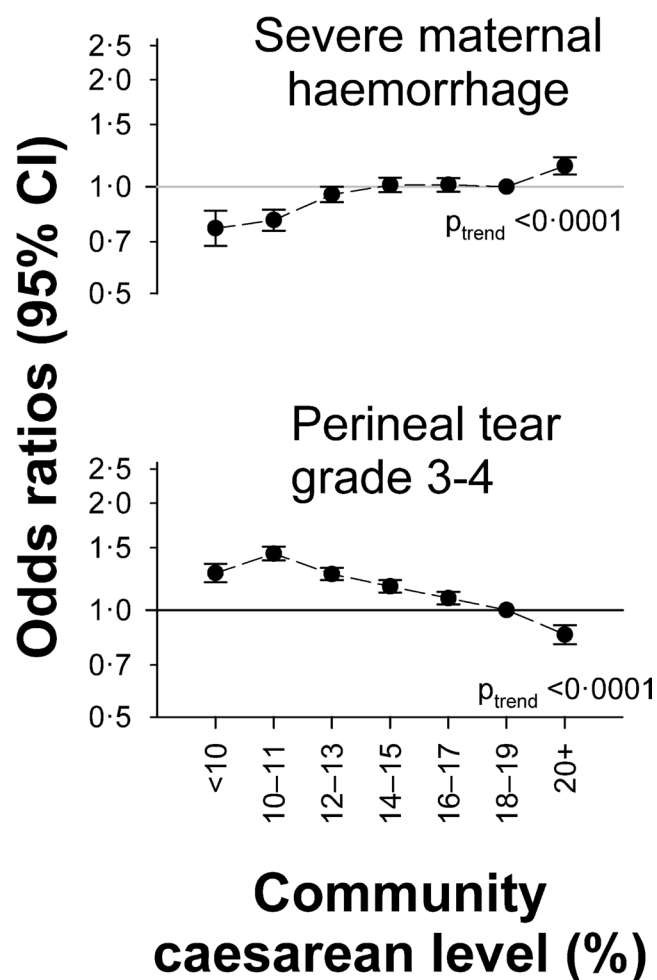


FIGURE 2 | Risk of severe maternal haemorrhage (more than 1500 mL or need for transfusion) and maternal perineal tear grades 3–4, related to the communities' caesarean section level. Analyses are adjusted for year of birth.

TABLE 1 | Total number of births, numbers with actual outcomes, prevalence rates and linear trends for outcomes related to communities' caesarean delivery rate. Odds ratio (95% confidence interval) for a decrease of a 10% step in the municipality caesarean rate, for example from a 20% to a 10% rate of caesarean delivery.

	Births	N	Prevalence, %	OR (95% CI) ^a	OR (95% CI) ^b
Maternal outcomes					
Severe maternal haemorrhage ^c	936 794	17 422	1.86	0.81 (0.77–0.85)	0.83 (0.79–0.87)
Perineal tear grade 3–4	1 172 546	30 424	2.59	1.41 (1.36–1.46)	1.54 (1.48–1.61)
Maternal death ^c	936 794	25	0.003	2.26 (0.69–7.36)	2.43 (0.75–7.89)
Fetal/neonatal outcomes					
Stillbirths	1 193 229	5707	0.48	1.07 (0.99–1.17)	1.12 (1.02–1.23)
Neonatal deaths	1 187 522	2578	0.22	0.95 (0.84–1.08)	0.95 (0.83–1.09)
Neonatal encephalopathy (NE) ^c	949 281	3190	0.34	1.91 (1.71–2.13)	1.74 (1.54–1.96)
Cerebral palsy ^d	1 068 020	1399	0.13	1.48 (1.24–1.77)	1.33 (1.11–1.61)
Neonatal seizures without NE ^c	949 281	1741	0.18	1.07 (0.92–1.24)	1.06 (0.90–1.24)

^aAdjusted for year of birth.

^bAdjusted for year of birth, immigrant parents, single mothers, mother's and father's education independently, mother's age, plural births and parity.

^cBirth years 1999–2014.

^dBirth years 1995–2012.

Neonatal encephalopathy and cerebral palsy occurred more frequently in municipalities with less than 15% caesarean section (Figure 3, Table S3). When expressed as a linear trend, the municipality-level occurrence of neonatal encephalopathy was nearly twice as high at 10% levels of caesarean section compared with 20% levels (OR 1.91; 1.71–2.13) (Table 1). Across the same range of caesarean delivery, the risk of cerebral palsy was higher by half (OR 1.48; 1.24–1.77) (Table 1). Neonatal seizures were only weakly associated with a lower rate of caesarean section ($p_{\text{trend}} = 0.40$) (Figure 3, Table 1). Table 1 also provides prevalence data for each of the adverse outcomes.

A key assumption of these analyses is the absence of confounding by risk factors that might vary across municipalities. We explored this by adjusting for candidate risk factors (mother's age, parity and marital status, education of mother and father, immigrant parents and plural births). These adjustments for potential confounding had virtually no effect on estimates (Table 1). Similarly, there were no changes in estimates after excluding municipality-years with relatively few deliveries (less than 75 births), after excluding the largest city (Oslo), or after excluding multiple births (Table S2). Finally, we used robust estimation of variances to account for correlation among observations within the same municipality; results were practically identical.

4 | Discussion

4.1 | Main Findings

Norway provides a useful setting for the evaluation of low population levels of caesarean section in the context of high-quality and freely available medical care. Using local variations in caesarean delivery based on arbitrary differences in clinical practice, we find higher frequencies of neonatal encephalopathy and

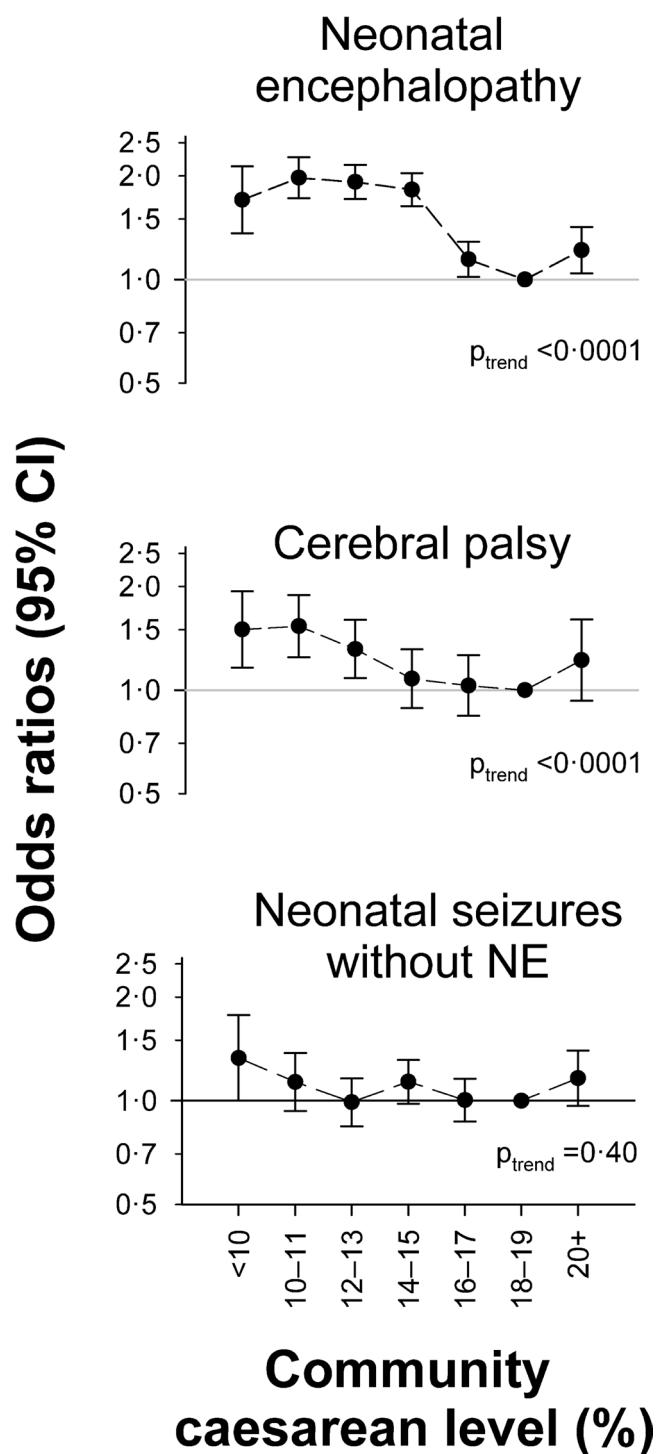


FIGURE 3 | Risk of neonatal encephalopathy, cerebral palsy and neonatal seizures without neonatal encephalopathy, related to the communities' caesarean section level. Analyses are adjusted for year of birth.

cerebral palsy in communities with caesarean delivery rates in the low range of 10%–15% compared with communities with higher rates of caesarean deliveries.

4.2 | Strengths and Limitations

Strengths of the analysis include a large sample size (nearly 1.2 million births), a well-organised system of high-quality medical care, population-based registries with virtually complete and unbiased ascertainment and follow-up, a relatively homogeneous population with low income inequality [16], and practice-related variations in caesarean delivery rates across municipalities. Using a quasi-experimental design [17], we were able to consider both mortality and morbidity outcomes at a population level, including outcomes that have not previously been addressed [1].

As shown in Table 1, the adverse outcomes in our analysis are rare, so that the odds ratios can accurately be interpreted as valid estimates of relative risk. The low prevalence of these outcomes also shows the relatively small population burden in Norway related to municipality-level variations in the use of caesarean section. Adverse effects related to variations in caesarean section are presumably buffered in Norway by broad access to high-quality medical care. In settings lacking such access, the risks associated with low levels of caesarean section may well be greater.

Prior population-level studies have attempted to describe how overall levels of caesarean section affect mother and offspring health [1]. Those population-level analyses are almost invariably limited by structural biases. Ecologic studies that correlate time trends in caesarean section with clinical outcomes are inadequate for causal inference. More sophisticated analytic designs have been country-based [18–20] or hospital-based [21, 22]—designs that remain vulnerable to many sources of bias and confounding.

Furthermore, population-level studies (including ours) do not address specific biological pathways that might link caesarean delivery and health outcomes [1–3]. Approaches that focus more directly on indications for caesarean section, most notably Robson's 10-group classification [23], are useful for auditing hospital practices and making quality improvements. However, such approaches do not easily translate into optimum population levels of caesarean section—a public health perspective that is a focus of policy makers.

Perhaps more important, our lack of information on indications for caesarean delivery cannot explain our main results. Unmeasured confounding by indication would inflate the observed risk at higher levels of caesarean delivery. Our findings of higher infant health risks at lower levels of caesarean delivery would not be explained by this confounding.

Our approach assumes that the observed variations in caesarean delivery rates across residential municipalities are solely a reflection of differences in clinical preference among hospitals serving the municipalities and not the level of maternal health in that municipality. For example, Norway's university hospitals vary in their policies regarding caesarean delivery, with rates ranging from 13% to 26%. In order to test whether residential differences in underlying maternal or perinatal risk might also have contributed to our results (and thus add bias), we adjusted our analyses for a host of municipality-level characteristics related to pregnancy risk. Estimates remained virtually unchanged (Table 1).

As with other recommendations that have been made regarding desirable population levels of caesarean delivery, we do not address risks within subsets of the population, such as within strata of parity or maternal age. Such analyses may be a useful next step for analysis but are beyond our scope here.

The diagnosis of clinical outcomes invariably has some subjectivity. Our analysis includes outcomes diagnosed by physicians other than the obstetrician, which reduces the possibility that obstetricians' preferences in the practice of caesarean section might also be related to their preferences in the diagnosis of outcomes.

As in any observational study, causality is a tenuous inference. We cannot rule out the possibility of unmeasured bias or confounding that might contribute to this finding, even though adjustment by known variables had little effect. It is still possible that the associations of these outcomes are not strictly with caesarean section. The use of caesarean section is part of a constellation of medical and non-medical practices, and the surgical intervention itself may not be fully responsible for the associations we observe.

Norway is a high-income country with free access to antenatal, perinatal, and postnatal health care at no cost. Norwegian women have an average of 12 antenatal appointments with health professionals during pregnancy, and more than 99% of all births are attended by skilled health staff [24, 25]. Maternity care is differentiated into three levels according to women's known risk factors, with rapid referral to a higher level if needed [26]. While our results apply most directly to similar high-resource settings, there is little reason to think that lower-resource populations would not be at least as vulnerable to the risks we observe in Norway with low use of caesarean delivery.

4.3 | Interpretation

In 2015, WHO suggested that a 10% level of caesarean delivery was adequate to minimise maternal and infant mortality [1]. Our findings support this conclusion about mortality—we found no improvement in maternal or neonatal survival with caesarean deliveries above 10% (Figure S4). However, WHO lacked data on other important outcomes including stillbirths and maternal and infant morbidity. To our knowledge, our finding of higher risks of childhood morbidity at 10%–15% levels compared with higher levels of caesarean delivery has not previously been reported. Our findings that adverse outcomes were least common in municipalities with caesarean rates of 15% to 20% support the suggestions by the European Association of Perinatal Medicine and the European Midwives Association (as well as others) that caesarean delivery rates at a country level should be in the 15%–20% range [18, 27].

Our study design has elements of a natural experiment. We assess variations in caesarean delivery rates across Norwegian municipalities (differences due largely to differences in hospital policy and clinical patterns of practice) as they relate to maternal and offspring outcomes. Variations in clinical practice have proven useful for exploring other aetiological questions [22],

particularly in the evaluation of drug therapies [28]. We know of no study that has used this approach for the evaluation of caesarean delivery.

Our analytic structure was specifically crafted to minimise bias by indication or referral. This approach nonetheless requires a critical assumption of no confounding by municipality-level variations in perinatal or maternal risk. We tested this assumption by adjusting for a host of maternal and infant variables at the municipality level. These adjustments produced virtually no changes in risk estimates, suggesting minimal confounding from other related sources.

The validity of our approach is supported by the confirmation of associations with outcomes that are plausibly related a priori to caesarean section. We found a dose–response relationship between a reduced use of caesarean section and more frequent maternal perineal lacerations (a complication of vaginal delivery) (Figure 2) [29]. The absence of such an association in our data would have raised questions about the validity of our method. Expectations concerning severe haemorrhage are less certain, in that the literature on the link between severe haemorrhage and caesarean section is less consistent [29–31]. Our data suggest that heavy bleeding is in fact more frequent with increased use of this surgical procedure (Figure 2).

Fetal distress during labour is an indication for caesarean delivery, and caesarean section may therefore benefit fetal and infant survival. We found only limited evidence that increased caesarean section was associated with fewer stillbirths, and no evidence of fewer neonatal deaths. We did find that increased levels of caesarean delivery were associated with lower levels of serious neurological morbidity. Both neonatal encephalopathy and cerebral palsy were more frequent with caesarean sections less than 15% (Table 1 and Figure 3). Neonatal encephalopathy is a heterogeneous disorder, often thought to be caused by global hypoxic ischaemia due to failure of fetal cerebral perfusion following uterine, placental, or umbilical cord compromise [32]. It is plausible that a well-selected intervention by caesarean section could reduce this risk. In contrast, neonatal seizures in the absence of encephalopathy are less often caused by hypoxic ischaemia and may be less related to birth asphyxia [33]. This is also supported by our data, with a much weaker association of newborn seizures without encephalopathy at the lowest rates of caesarean delivery (Figure 3).

Birth asphyxia is thought to have a minor role in the aetiology of cerebral palsy, given that most cases of CP likely have their origins earlier in pregnancy [34, 35]. The strong link we find between reduced use of caesarean section and more frequent cerebral palsy thus deserves comment. It is possible that caesarean delivery could protect against prenatal causes of CP if the underlying prenatal pathology were to make the fetus more vulnerable to the stresses of a difficult delivery.

While the Norwegian data provide limited information about the safety of caesarean section at levels of 20% or higher, we see little evidence of benefit to the infant and even the possibility of adverse effects when population levels of caesarean section reach 20% (Figure 3).

5 | Conclusion

The optimum level of caesarean section has been regarded since at least 1985 as between 10% and 15%—although this recommendation is admittedly based on sparse information [1]. Our data suggest that levels of 10%–15% are not the safest, with lower frequencies of infant morbidity occurring with 15%–20% caesarean section. Even in Norway, a country with an excellent distribution of medical resources and a high level of maternal and child health, population-based caesarean section rates in the range of 10%–15% appear to put infants at increased risk of neurologic damage. While our analysis of a natural experiment cannot be replicated in every setting, there are countries (in Scandinavia and elsewhere) where similar analyses could be conducted. Should our findings be confirmed in other settings, the results could be of benefit in setting health policies on the practice of caesarean section.

Author Contributions

D.M., A.J.W. and R.T.L. conceived and designed the study. D.M. obtained access to data, conducted the data analyses and drafted the initial version of the manuscript. A.J.W. and R.T.L. provided important insight during the data analyses. All authors contributed to the interpretation of the data and critically revised the manuscript. All authors had full access to tables and figures in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. D.M. is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethics Statement

This study was approved by the regional ethics committee in Norway (2010/2949), with an exemption from written informed consent.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

No additional data are available. The study has utilised Norwegian governmental registries, and legal restrictions do not permit the authors to share the data that support this study. The main data utilised may be available from the data owners after obtaining approval from the Regional Committee for Medical Research Ethics for researchers who meet the criteria for access to confidential data.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.