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Evidence on: Induction or Cesarean for a Big Baby

What is a big baby?

The medical term for big baby is macrosomia, which literally means "big body." Some researchers consider a baby to be big when it weighs 4,000 grams (8 lbs., 13 oz.) or more at birth, and others say a baby is big if it weighs 4,500 grams (9 lbs., 15 oz.) or more (Rouse et al. 1996). Babies are called "extremely large" if they are born weighing more than 5,000 grams (11 lbs.) (Hehir et al. 2015).

A baby is also called "large for gestational age" if its weight is greater than the 90th percentile at birth, in other words, if it is bigger than 90% of all other babies born at that same gestational age (Rouse et al. 1996).

This article was updated on June 7, 2016 by Rebecca Dekker, PhD, RN, APRN.

How common are big babies?

Table 1 (page 17) shows details on the Percentage of women who have big babies in the United States.

About one in ten babies is born big in the United States (U.S.). Overall, 8.7% of all babies born at 39 weeks or later weigh between 8 lbs., 13 oz., and 9 lbs., 15 oz., and 1.7% are born weighing 9 lbs., 15 oz. or more (U.S. Vital Statistics). In the table on the next page, you can see the percentages listed separately for women who are not diabetic, those who have gestational diabetes, and those who have Type I or Type Il diabetes.

DISCLAIMER: Nothing in this article shall be construed as advice from a healthcare provider (i.e. midwife, nurse, nurse practitioner, doctor or physician assistant). This article is strictly intended to provide general information regarding its subject-matter and may not apply to you as an individual. It is not a substitute for your own healthcare provider's medical care or advice and should not be relied upon by you other than upon the advice of your treating provider. If you need someone to examine you or discuss your pregnancy or baby's health, see a midwife, nurse practitioner, or doctor.







Among women with gestational diabetes, researchers have found that the higher your blood sugar when you're first diagnosed with gestational diabetes, the more likely you are to have a baby who is large for gestational age (Metzger et al. 2008). However, women who manage their gestational diabetes through diet, exercise, or medication, bring down their chances of having a big baby to normal levels (7%) (Landon et al. 2009).

What is routine care for suspected big babies?

The most detailed evidence we have on typical care for big babies comes from the U.S. <u>Listening to Mothers Survey</u>. Although only one in ten babies is born large, researchers found that two out of three American women had an ultrasound at the end of pregnancy to determine the baby's size, and one out of three women in the entire study were told that their babies were too big. In the end, the average birth weight of these suspected "big babies" was only 7 lbs., 13 oz. (<u>Declercq, Sakala et al. 2013</u>).

Of the women who were told that their baby was getting big, two out of three said their care provider discussed inducing labor because of the suspected big baby, and one out of three said their care provider talked about planning a Cesarean because of the big baby.

Most of the women whose care providers talked about induction for big baby ended up being medically induced (67%), and the rest tried to self-induce labor with natural methods (37%). Nearly one in five women said they were not offered a choice when it came to induction—in other words, they were told that they must be induced for their suspected big baby.

When care providers brought up planning a Cesarean for a suspected big baby, one in three women ended up having a planned Cesarean. Two out of five women said that the discussion was framed as if there were no other options—that they must have a Cesarean for their suspected big baby.

In the end, care provider concerns about a suspected big baby were the fourth most common reason for an induction (16% of all inductions), and the fifth most common reason for a Cesarean (9% of all Cesareans). More than half of all mothers (57%) believed that an induction is medically necessary if a care provider suspects a big baby.

So in the U.S., most women have an ultrasound at the end of pregnancy to estimate the baby's size, and if the baby appears large, their care provider will usually recommend either an induction or an elective Cesarean. Is this approach evidence-based?

This approach is based on five major assumptions:

- Big babies are at higher risk for shoulders getting stuck (also known as shoulder dystocia).
- 2. Big babies are at higher risk for other birth problems.
- 3. We can accurately tell if a baby will be big.
- 4. Induction keeps the baby from getting any bigger, which lowers the risk of Cesarean
- 5. Elective Cesareans for big baby are only beneficial; that is, they don't have major risks that could outweigh the benefits





Assumption #1: Big babies are at higher risk for getting their shoulder stuck (shoulder dystocia).

Reality #1: While it is true that 7-15% of big babies have difficulty with the birth of their shoulders, most of these cases are handled by the care provider without any harmful consequences for the baby. Permanent nerve injuries due to stuck shoulders are less common: they happen in 1 out of every 555 babies who weigh between 8 lbs., 13 oz. and 9 lbs., 15 oz., and 1 out of every 175 babies who weigh 9 lbs., 15 oz. or greater.

One of the main concerns with big babies is shoulder dystocia ("dis toh shah"), which is defined as when shoulders are stuck enough that the care provider has to take extra physical action(s) to help get the baby out.

Researchers frequently refer to shoulder dystocia as the "obstetrician's greatest nightmare" (Chauhan 2014). The fear with shoulder dystocia is that it is possible that the baby might not get enough oxygen if the head is out but the body does not come out shortly afterwards. There is also a risk that the baby will experience a permanent nerve injury to the shoulders.

One of the reasons that care providers have a fear of shoulder dystocia is because if the baby experiences an injury, this type of injury is a common cause of litigation. In a recent study at the University of Michigan, researchers found that half of all parents whose children were being treated for shoulder dystocia-related injuries were pursuing litigation (Domino et al. 2014).

How often does shoulder dystocia occur? One high-quality study showed that in in non-diabetic women, shoulder dystocia happened to 0.65% of babies who weighed less than 8 lbs., 13 oz. (6.5 cases out of 1,000 births), 6.7% of babies who weighed between 8 lbs., 13 oz. and 9 lbs., 15 oz. (60 out of 1,000), and 14.5% of babies who weighed 9 lbs., 15 oz. or greater (145 out of 1,000) (Rouse et al. 1996).

Rates of shoulder dystocia were much higher in big babies whose mothers had Type I and Type II diabetes (2.2% of babies that weigh less than 8 lbs., 15 oz., 13.9% of babies that weighed between 8 lb., 15 oz. and 9 lb., 13 oz., and 52.5% of babies that weighed more than 9 lb., 13 oz.) (Rouse et al. 1996).

I was not able to find exact numbers for the percentage of women with gestational diabetes who had a baby with shoulder dystocia, as the rates change depending on each woman's blood sugar level. However, we have strong evidence that treatment for gestational diabetes drastically lowers the chance of having a big baby and shoulder dystocia (To read more, click here).

Although big babies are at higher risk for shoulder dystocia, at least half of all cases of shoulder dystocia happen in smaller or normal sized babies (Morrison et al. 1992; Nath et al. 2015). This is because overall, there are more small and normal size babies born than big babies. In other words, the rate of shoulder dystocia is higher in bigger babies, but the absolute numbers are about the same with bigger and smaller babies. Unfortunately, researchers have found that it is impossible to predict exactly who will have shoulder dystocia and who will not (Foster et al. 2011).

Because at least half of shoulder dystocia cases occur in babies that are not big, and we can't predict who will have a shoulder dystocia, this means that shoulder dystocia will always be a possibility during childbirth, unless women are not allowed any vaginal births and all babies are born by Cesarean. Because requiring everyone to have a Cesarean is unethical and impractical, it is important for health care providers to train for the possibility of a shoulder dystocia.





Other resources on resolving shoulder dystocia:

- There are ways care providers can help prevent and manage a shoulder dystocia. For more information, read this article on shoulder dystocia by Midwife Thinking.
- · Click here for a free training course from the United Kingdom about shoulder dystocia.
- Spinning babies offers an <u>online continuing education</u> course about resolving shoulder dystocia. You
 can also download a free PDF on the FLIP-FLOP technique for managing shoulder dystocia on <u>this</u>
 page.

Brachial plexus palsy

A shoulder dystocia by itself is not considered a "bad outcome." It's only a bad outcome if an injury occurs along with the shoulder dystocia (Personal communication, Emilio Chavirez, MD, FACOG, FSMFM). Although most cases of shoulder dystocia can be safely managed by a care provider during the birth, some can result in a nerve injury in the baby called *brachial plexus palsy*.

Brachial plexus palsy, which lead to weakness or paralysis of the arm, shoulder, or hand, happens in about 1.3 out of every 1,000 vaginal births in the U.S. and other countries. A baby does not have to have shoulder dystocia in order to experience a brachial plexus palsy—in fact, 48%-72% of brachial plexus palsy cases happen without shoulder dystocia. When a brachial plexus palsy happens at the same time as shoulder dystocia, however, it is more likely to end up in a lawsuit than a brachial plexus palsy that did not occur with a shoulder dystocia (Chauhan et al. 2014).

Although rare, brachial plexus palsy can also happen to babies born by Cesarean. In one study that looked at 387 children who experienced brachial plexus palsy, 92% were born vaginally and 8% were born by Cesarean (Chang et al. 2016). Other researchers have found that brachial plexus palsy happens in about 3 per 10,000 Cesarean births (Chauhan et al. 2014).

Some infants who have a brachial plexus palsy (about 10%-18%) will end up with a permanent injury, defined as arm or shoulder weakness that persists for more than a year after birth. It's estimated that there are anywhere from 35,000 to 63,000 people living with permanent brachial plexus injuries in the U.S. (Chauhan et al. 2014). For a blog article about what it's like to grow up with a brachial plexus palsy, read Nicola's story here.

In a recent study of infants who were all extremely large at birth (>5000 g, or >11 lbs.), 17 of 120 infants born vaginally had shoulder dystocia, and three of those 17 had temporary brachial plexus palsy that healed within six months—for an overall rate of about 1 brachial plexus palsy cases per 40 vaginally-born, extremely large babies (Hehir et al. 2015).

In <u>1996</u>, Rouse et al. published rates of shoulder dystocia and brachial plexus palsy by infant weight. Using the more current numbers of permanent disability published by <u>Chauhan et al.</u> in 2014, I created a table that helps show the difference between the weight groups.

Table 2 (page 17) shows details on the Rates of Shoulder Dystocia and Brachial Plexus Palsy in Non-Diabetic Women.

Importantly, research has shown that when health care professionals undergo annual inter-professional training (this means doctors, nurses, and midwives training together as a team) on how to handle shoulder dystocia, they can lower—and in some cases eliminate—brachial plexus palsy among babies who experience shoulder dystocia (Crofts et al. 2016). Doctors have been trying to take this successful





training (called "PROMPT") from the United Kingdom and implement it in the U.S. Results at the University of Kansas showed a decline and then an eventual elimination of permanent cases of brachial plexus palsy with PROMPT annual trainings (Weiner et al. 2015).

To watch a news video about the PROMPT training, click here. To visit the PROMPT foundation website, click here.

Can a baby die from shoulder dystocia?

Deaths from shoulder dystocia are possible but rare. In 1996, researchers looked at all the studies so far that had reported the rate of death due to shoulder dystocia. In 15 studies, there were 1,100 cases of shoulder dystocia and no deaths (a death rate of 0%). In two other studies, the rates of infant death were 1% (one baby out of 101 "died at delivery," possibly due to the dystocia) and 2.5% (one infant died out of 40 cases of shoulder dystocia) (Rouse et al. 1996).

In a study published by Hoffman et al. in 2011, researchers looked at 132,098 women who gave birth at term to a live baby in head-first position. About 1.5% of the babies had a shoulder dystocia (2,018 cases), and of those, 101 newborns were injured. Most of the injuries were brachial plexus palsy or collar bone fractures. Out of the 101 injured infants, there were zero deaths and six cases of brain damage due to lack of oxygen. With the six brain-damaged infants, it took an average of 11 minutes between the birth of the head and the body.

Assumption #2: Big babies can lead to a higher risk of other health problems in either the mother or baby.

Reality #2: It's possible that giving birth to a big baby can increase the risk of certain health problems for both the mother and the baby. However, the care provider's "suspicion" of a big baby carries its own set of risks.

Perineal Tears

It is possible that women who give birth to big babies are more likely to have severe perineal tears (3rd or 4th degree). However, research studies have found conflicting results. For example, one large study found no difference in 3rd and 4th degree perineal tears between women who had big babies and those who had normal size babies (Weissmann-Brenner et al. 2012). By contrast, another study of hospital births in California between 1995 and 1999 found a higher rate of 4th degree tears in big babies who were born vaginally (Stotland et al. 2004). However, 4th degree tear rates in this particular study were very high, even among normal weight babies (1.5%), and the authors did not describe how many women had episiotomies, which is a leading cause of severe tears.

Although having a big baby may be a risk factor for severe tears, it may be helpful to compare this risk to other situations that can also increase the risk of tears. For example, one large study found that the risk of a severe tear with a big baby ranged from 0.2% to 0.6% (Weissmann-Brenner et al. 2012), while other researchers have found that a vacuum delivery increases the risk of a severe tear by 11 times (so if your baseline risk was 0.2%, it would increase to 2.2%), and the use of forceps increases the risk of a severe tear by 39 times (from 0.2% to 7.8%) (Sheiner et al. 2005).





Postpartum Hemorrhage

Women who give birth to big babies may be at higher risk for postpartum hemorrhage. In one large study, researchers found that women who gave birth to babies weighing more than 9 lbs., 15 oz. were more likely to have a postpartum hemorrhage (1.7%) compared to women who had average size babies (0.3%) (Weissmann-Brenner et al. 2012). However, it is not clear whether this higher rate of postpartum hemorrhage is due to the big baby itself or the inductions and Cesareans that care providers often recommend for a big baby (Fuchs et al. 2013)—as both these procedures can increase the risk of postpartum hemorrhage (Magann et al. 2005).

Newborn complications

One study compared 2,766 large babies born to non-diabetic mothers with 2,766 infants who had normal birth weights (Linder et al. 2014). They found that big babies were more likely to have low blood sugar after birth (1.2% vs. 0.5%), temporary rapid breathing (also known as "transient tachypnea" or "wet lung," 1.5% vs. 0.5%), high temperature (0.6% vs. 0.1%), and birth trauma (2% vs. 0.7%).

The researchers did not say whether care providers suspected that the babies were large before labor began, or if their care was managed differently. More large infants in this study were born by Cesarean (33% vs. 15%), which could have played a role in the higher rates of breathing problems, since breathing problems are more common with Cesarean-born babies.

Stillbirth

Some doctors recommend Cesareans for big babies because they believe there is a higher risk of stillbirth. I have only been able to find one research study that covered this topic.

In 2014, researchers published a study where they looked back in time at 784,576 births that took place in Scotland between the years 1992 and 2008. They included all babies who were born at term or postterm (between 37 and 43 weeks). They did not include multiples or any babies who died from congenital anomalies (Moraitis et al. 2014).

Babies in this study were grouped according to their size for gestational age—4th to 10th percentile, 11th to 20th percentile, 21st to 80th percentile (considered the normal group), 81st to 90th percentile, 91st to 97th percentile, and 98th to 100th percentile. The gestational age of each baby was confirmed by ultrasounds that took place in the first half of pregnancy.

In this study, there were 1,157 stillbirths, and the risk of stillbirth was highest in the groups with the smallest babies (1st to 3rd and 4th to 10th percentiles). The third highest risk of stillbirth death was seen in the babies who were in the 98th to 100th percentiles for weight (extremely large for gestational age). Using the American Academy of Pediatrics growth curve for gestational age, the 98th to 100th percentiles would be roughly equivalent to a baby who is born weighing 9 lbs., 15 oz. or greater at 41

Meanwhile, the lowest rates of stillbirth were in babies who were in the 91st to 97th percentiles. The increase in stillbirth risk in the largest group (98th to 100th percentile) was partly explained by maternal diabetes; however, there was also a higher risk of unexplained stillbirth for babies in the 98th to 100th percentile. Overall, the absolute risk of an extremely large for gestational age baby (98th to 100th percentile) experiencing stillbirth between 37 and 43 weeks was about 1 in 500, compared to 1 in 1,000 for babies who are in the 91st to 97th percentile.





The risk of stillbirth has historically been higher in women with Type I or Type II diabetes. However, in recent years the stillbirth rate for women with Type I or Type II diabetes has drastically declined due to improvements in how we manage diabetes during pregnancy (Gabbe et al. 2012). As far as gestational diabetes goes, the largest study ever done on gestational diabetes found no link between gestational diabetes and stillbirth (Metzger et al. 2008).

Is it Harmful to Suspect a Big Baby?

When a big baby is suspected, women are more likely to experience a change in how their care providers see and manage labor and delivery. This leads to a higher Cesarean rate and a higher rate of women inaccurately being told that labor is taking too long or the baby does not "fit."

In fact, research has consistently shown that the care provider's perception that a baby is big can be more harmful than an actual big baby by itself.

Overall, a total of nine different studies from 1992 to 2015 have all shown that it is the suspicion of a big baby-not big babies themselves-that leads to higher induction rates, higher Cesarean rates, and higher diagnoses of stalled labor (Levine et al. 1992; Weeks et al. 1995; Parry et al. 2000; Weiner et al. 2002; Sadeh-Mestechkin et al. 2008; Blackwell et al. 2009; Melamed et al. 2010; Little et al. 2012; Peleg et al. 2015).

In one study, researchers compared what happened to women who were suspected of having a big baby (>8 lbs., 13 oz.) to what happened to women who were not suspected of having a big baby-but who ended up having one (Sadeh-Mestechkin et al. 2008).

The end results were astonishing. Women who were suspected of having a big baby (and actually ended up having one) had triple the induction rate; more than triple the Cesarean rate, and a quadrupling of the maternal complication rate, compared to women who were not suspected of having a big baby but had one anyway.

Complications were most often due to Cesareans and included bleeding (hemorrhage), wound infection, wound separation, fever, and need for antibiotics. There were no differences in shoulder dystocia between the two groups. In other words, when a care provider "suspected" a big baby (as compared to not knowing the baby was going to be big), this tripled the Cesarean rates and made mothers more likely to experience complications, without affecting the rate of shoulder dystocia (Sadeh-Mestechkin et al.

Table 3 (page 18) shows details on which is more harmful, a big baby or a care provider's suspicion of a big baby.

These results were confirmed by another study published by Peleg et al. in 2015. At their hospital, physicians had a policy to counsel all women with suspected big babies (suspected of being 8 lbs., 13 oz. and higher (24,000 grams) about the "risks" of big babies. Elective Cesareans were not encouraged, but they were performed if the mother requested one after the discussion. There were 238 women who had suspected big babies (that ended up truly being large at birth) and were counseled, and 205 women who had unsuspected big babies (that ended up being truly large at birth) who were not counseled.

Despite the fact that the babies were all about the same size, only 52% of women in the suspected big baby group had a vaginal birth, compared to 91% of women in the non-suspected big baby group. This increase in Cesarean rate in the suspected big baby group was primarily due to an increase in the





mothers requesting elective Cesareans after the "counseling" session about big babies. There was only one case of shoulder dystocia in the unsuspected big baby group, and two cases in the suspected big baby group. None of these babies experienced injuries. There was no difference in severe maternal tears between the two groups. The authors concluded that obstetricians should NOT be counseling women about the risks of big babies thought to be 8 lbs 13 oz or higher, because it leads to an increase in the number of unnecessary Cesareans without any benefit to the mother or baby. They suggested that researchers should study using a higher weight cut-off (such as 9 lbs., 15 oz.) to trigger counseling.

Other researchers have found that when a first-time mom is incorrectly suspected of having a big baby, care providers have less patience with labor and are more likely to recommend a Cesarean for stalled labor. In this study, researchers followed 340 first-time moms who were all induced at term. They compared the ultrasound estimate of the baby's weight with the actual birth weight. When the ultrasound incorrectly said the baby was going to weigh more than 15% higher than it actually ended up weighing at birth, physicians were more than twice as likely to diagnose "stalled labor" and perform a Cesarean for that reason (35%) than if there was no overestimation of weight (13%) (Blackwell et al. 2009b).

It's not surprising that physicians are more likely to turn to Cesarean in these situations, given the cultural fear of big babies. In a recent medical journal editorial, an obstetrician with a clear bias towards Cesarean for big babies said that, "Flagging up all cases of predicted fetal macrosomia is vitally important, so that the attendants in the labor suite will recommend Cesarean if there is any delay in cervical dilatation or arrest of head rotation or descent. Cesarean should also be the preferred option if an abnormal fetal heart tracing develops" (Campbell 2014).

So in summary, although big babies are at higher risk for some problems, the care provider's perception that there is a big baby carries its own set of risks. This perception—whether it is true or false—changes the way the care provider behaves and how they talk to women about their ability to give birth, which, in turn, increases the chance of Cesarean.

Assumption #3: We can tell which babies will be big at birth.

Reality #3: Both physical exams and ultrasounds are equally bad at predicting whether a baby will be big at birth.

Time and time again, researchers have found that it is very difficult to predict a baby's size before it is born. Although two out of three U.S. women receive an ultrasound at the end of pregnancy (<u>Declercq et al. 2013</u>) to "estimate the baby's size," both the care provider's estimate of the baby's size and ultrasound results are very unreliable.

In 2005, researchers looked at all of the studies that had ever been done on ultrasound and estimating the baby's weight at the end of pregnancy. They found 14 studies that looked at ultrasound and its ability to predict that a baby would weigh more than 8 lbs., 13 oz. Ultrasound was accurate 17% to 79% of the time, with most studies showing that the accuracy ("post-test probability") was less than 50%. This means that for every ten babies that ultrasound predicts will weigh more than 8 lbs., 13 oz., five babies will weigh more than that and the other five will weigh less (Chauhan et al. 2005).

Ultrasound is even worse at trying to predict babies who will be born weighing 9 lbs., 15 oz. or greater. In five studies that were done, the accuracy of ultrasounds to predict extra-large babies was only 20 to 30%. This means that for every ten babies the ultrasound identified as weighing more than 9 lbs., 15





oz., only two to three babies actually weighed more, while the other seven to eight babies weighed less (Chauhan et al. 2005).

The researchers found four studies that looked at the ability of ultrasound to predict big babies in women with diabetes. The accuracy of these ultrasounds was 61 to 63%, which means that for every ten babies of diabetic women who are thought to weigh more than 8 lbs., 13 oz., six will weigh more and four will weigh less. The ultrasound test probably performs better in diabetic women simply because diabetic women are more likely to have big babies. In other words, it's easier to predict a big baby in someone who is much more likely to have a big baby to begin with.

Compared to using ultrasound, care providers are equally inaccurate when it comes to using a physical exam to estimate the size of the baby. When a care provider estimates that a baby is going to weigh more than 8 lbs., 13 oz., the overall accuracy is only 40-53%. This means that out of all the babies that are thought to weigh more than 8 lbs., 13 oz., half will weigh more than 8 lbs., 13 oz. and half will weigh less.

The care provider's accuracy goes up if the woman has diabetes or is post-term, again, probably because the chance of having a big baby is higher among these women. Unfortunately, all of the studies that looked at diabetes and the accuracy of ultrasound lumped women with gestational diabetes and those with Type I or Type II diabetes into the same groups, limiting our ability to interpret these results.

A recent systematic review concluded that there is "no clear consensus with regard to the prenatal identification, prediction, and management of macrosomia." The authors stated that the main problem with big babies is that it is very difficult to diagnose macrosomia before birth—it's a diagnosis that can only be made after birth (Rossi et al. 2013).

Even the "best" way to predict a big baby is going to have problems identifying actual big babies. In a 2010 study (Rosati et al. 2010), researchers tested different ultrasound "formulas" to figure out an infant's estimated weight. The best formula for predicting birth weight was the "Warsof2" formula, which is based solely on the baby's abdominal measurement. The results of this formula came within ±15% of the baby's actual weight in 98% of cases. As an example, if your baby's actual weight was 8 lbs. (3,629 grams), the ultrasound could estimate the baby's weight to be anywhere between 6 lbs., 13 oz. (3,090 grams) and 9 lbs., 3 oz. (4,450 grams).

Assumption #4: Induction allows the baby to be born at a smaller weight, which helps avoid shoulder dystocia and reduces the risk of Cesarean.

Reality #4: There is conflicting evidence about whether induction for suspected big babies can improve the health of mothers and babies.

We will talk about four main pieces of evidence in this section:

- 1) A 2016 Cochrane review (when researchers combined multiple randomized trials together)
- 2) The second-largest study (published in 1997) from the Cochrane review
- 3) The largest study (published in 2015) from the Cochrane review







Cochrane Review

In a 2016 Cochrane review, researchers (<u>Boulvain et al. 2016</u>) combined four studies in which 1,190 women with suspected big babies were randomly assigned (like flipping a coin) to either 1) induction between 37 and 40 weeks or 2) waiting for spontaneous labor.

When researchers compared the induction group to the waiting group, they found a decrease in rates of shoulder dystocia in the induction group—about 41 cases per 1,000 births in the elective induction group, down from 68 cases per 1,000 in the waiting group. They also found a decrease in collarbone fractures (4 per 1,000 vs. 20 per 1,000).

On the other hand, they found an increase in severe perineal tears in the induction group (26 per 1,000 in the induction group vs. 7 per 1,000 in the waiting group), as well as an increase in the treatment of jaundice (11% vs. 7%).

There were no differences between groups in rates of Cesarean, instrumental delivery, NICU admissions, brachial plexus palsy, or low Apgar scores. Three of the four studies reported death rates, and there were zero deaths in either group.

Researchers did not look at mothers' satisfaction with care or any long-term health results for mothers or babies.

Second-largest study in the Cochrane Review

The <u>Gonen et al. (1997)</u> study was the second-largest study in the Cochrane review (with 273 women). In this study, women were included if they were at least 38 weeks, had a suspected big baby (8 lbs., 13 oz. to 9 lbs., 15 oz.), did not have gestational diabetes, and had not had a previous Cesarean. Less than half the women were giving birth for the first time. Women were randomly assigned to either immediate induction with oxytocin (sometimes with cervical ripening) or waiting for spontaneous labor.

The results? Women in the spontaneous labor group went into labor about five days later than women who were immediately induced. Although women in the spontaneous labor group tended to have slightly bigger babies (on average, 3.5 oz. or 99 grams heavier), there was no difference in shoulder dystocia or Cesarean rates. All 11 cases of shoulder dystocia, spread across both groups, were easily managed without any nerve damage or trauma. Two infants in the waiting-for-labor group had temporary and mild brachial plexus palsy, but neither of these two infants had shoulder dystocia. Finally, ultrasound overestimated the baby's weight 70% of the time and under-estimated the baby's weight 28% of the time.

In summary, the researchers found that: 1) ultrasound estimation of weight was inaccurate, 2) shoulder dystocia and nerve injury were unpredictable, and 3) induction for big baby did not decrease the Cesarean rate or the risk of shoulder dystocia.

Largest study in Cochrane review (2015)

The study published by <u>Boulvain et al. 2015</u> was the largest study in the Cochrane review. In this study, researchers followed 818 women with suspected big babies who were randomly assigned to receive either a) inducing labor between 37 to 38 weeks, or b) waiting for labor to start on its own until 41 weeks. This is the largest randomized trial that has ever been done on women with suspected big babies.







Women could be in the study if they had a single baby in head-down position, whose estimated weight was in the 95th percentile (>7 lbs., 11 oz. at 36 weeks, 8 lbs., 3 oz. at 37 weeks, or 8 lbs., 10 oz. at 38 weeks). About 10% of the women in this study had gestational diabetes.

There was some cross-over between groups: 11% of women in the induction group went into labor on their own, and 28% of women in the waiting-for-labor group were induced.

The researchers found that women randomly assigned to the induction group (whether or not they were actually induced) had fewer cases of shoulder dystocia: 1% of women in the induction group (5 out of 407) had true shoulder dystocia compared with 4% (16 out of 411) of women in the expectant management group. None of the babies in either group experienced any brachial plexus palsy injuries, and collarbone fracture rates were low in both groups (1 to 2%).

The chances of having a spontaneous vaginal birth was slightly more common in the induction group (59% vs. 52%), but there was no difference in the rates of Cesarean and the use of forceps or vacuum. There were no other differences in maternal outcomes, including any tears or hemorrhage.

The infants in the induction group were more likely to have jaundice (9% vs. 3%) and receive phototherapy treatment (11% vs. 7%). There were no differences in NICU admission rates or any other newborn differences between groups.

In summary, this study found that early induction (at 37-38 weeks) lowered the rate of shoulder dystocia, but without any accompanying impact on actual brachial plexus palsy rates, collarbone fractures, or NICU admissions.

The authors suggested that the main reason they found different results from the earlier randomized trial (Gonen et al. 1997), is because they checked fetal weight earlier and induced babies earlier—between 37 to 39 weeks, instead of waiting until 38 to 39 weeks. This meant that they induced labor when a fetus is large for gestational age, but before it was technically "big," resulting in the birth of a normally sized baby a few weeks early. For example, in the Gonen et al. study discussed earlier, women were not included in the study until they were at least 38 weeks pregnant and their estimated fetal weight reached 8 lbs., 13 oz. Meanwhile, in the newer trail by Boulvain et al., of the 411 infants in the waiting-for-labor group, 62% weighed more than 4000 g (8 lbs., 13 oz.) at birth, compared with 31% of those who were induced. This means that the women who waited for labor to start on its own ended up with big babies, while the women who were induced early gave birth before their babies could become large.

The authors of the <u>Boulvain</u> study think that previous studies have not found a benefit to induction because providers waited too long to intervene, and they missed their chance for the mother to birth a smaller baby and reduce the risk of shoulder dystocia. Although this approach—inducing labor between 37 and 39 weeks—resulted in lower rates of shoulder dystocia, it also led to higher rates of newborn jaundice, and it did not have any impact on "hard" outcomes such as brachial plexus palsy or NICU admission.





Assumption #5: Elective Cesarean for big baby has benefits that outweigh the potential harms.

Reality #5: No researchers have ever enrolled women in a study to determine the effects of elective Cesareans for suspected big babies.

Although some care providers will recommend an induction for a big baby, many skip this step and go straight to recommending an elective Cesarean. However, researchers have estimated that this type of approach is extremely expensive and that it would take thousands of unnecessary Cesareans to prevent one case of permanent brachial plexus palsy.

In 1996, an important analysis published in the Journal of the American Medical Association proposed that a policy of elective Cesareans for all suspected big babies was not cost-effective and that there were more potential harms than potential benefits (Rouse et al. 1996).

In this analysis, the researchers calculated the potential effects of three different types of policies:

- 1) No routine ultrasounds to estimate the babies' sizes
- 2) Routine ultrasounds, then elective Cesarean for babies weighing 8 lbs., 13 oz. or more
- 3) Routine ultrasounds, then elective Cesarean for babies weighing 9 lbs., 15 oz. or more

The researchers looked at the results separately for diabetic and non-diabetic women. Unfortunately, most research up to this time point did not distinguish between Type 1 or Type II diabetes and gestational diabetes. So the term "diabetic" could refer to all three types.

Among non-diabetic women, a policy of elective Cesarean for all suspected big babies over 8 lbs., 13 oz. means that a large number of women and babies would experience unnecessary surgeries. In order to prevent one permanent brachial plexus palsy in babies suspected to be over 8 lbs., 13 oz., 2,345 women would have unnecessary Cesareans at a cost of \$4.9 million dollars per injury prevented (costs were estimated using year 1995 dollars).

With a policy of elective Cesareans for all suspected big babies over 9 lbs., 15 oz., even more women would have surgeries found to be unnecessary in retrospect, because ultrasounds are even less accurate in higher suspected weight ranges (Chauhan et al. 2005). In order to prevent one permanent brachial plexus palsy in babies suspected to be over 9 lbs., 15 oz., 3,695 women would need to undergo unnecessary Cesareans at a cost of \$8.7 million per injury prevented.

Such policies would increase rates of known risks from Cesarean, like serious maternal infections, blood clot disorders, postpartum bleeding (hemorrhage) requiring blood transfusions, and newborn breathing problems (see "C-sections: Best Evidence" from ChildbirthConnection.org.)

Among diabetic women, the results were different—mostly because ultrasound is slightly more reliable at predicting big babies in women who are diabetic, and because shoulder dystocia is more common in these women as well. If diabetic women were offered an elective Cesarean for every baby that is suspected of weighing more than 8 lbs., 13 oz., it would take 489 unnecessary surgeries to prevent one case of permanent nerve damage, at a cost of \$930,000 per injury avoided. If diabetic women had elective Cesareans when their babies were suspected of being 9 lbs., 15 oz. or greater, it would take 443 unnecessary surgeries to prevent one case of permanent brachial plexus palsy, at a cost of \$880,000 per injury avoided.





Please note: A cost-effectiveness analysis is only as good as its assumptions--the numbers that they use to plug into the analysis. For example, how did they determine how frequently shoulder dystocia occurs, the accuracy of ultrasounds, and how many permanent injuries occur? In the Rouse et al. (1996) paper, the authors did a very high-quality literature review to determine these factors. One drawback of this analysis is that the costs they reported did not include the cost of lawsuits. Another drawback is that this analysis is now 20 years old.

Since the landmark <u>Rouse et al.</u> paper was published, two newer cost-effectiveness analyses have been published. However, both of these newer papers had major problems—one of them did not take into account the inaccuracy of ultrasound (<u>Herbst, 2005</u>), and the other researchers had a poor quality systematic review—using numbers in their assumptions that overestimate the accuracy of ultrasound (<u>Culligan et al. 2005</u>). Because the researchers did not do a good job of making their assumptions, we cannot trust the results of their analyses, and so their results are not included in this paper.

In summary, evidence does not support elective Cesareans for all suspected big babies, especially among non-diabetic women. There have been no randomized, controlled trials testing this intervention for big babies, and no high-quality research studies to see what happens when this intervention is used on a mass-scale in real life.

In fact, non-diabetic women may be given one-sided information by their care providers if elective Cesarean is presented as a completely "safe" or "safer" option than vaginal birth for a suspected big baby. Although vaginal birth with a big baby carries risks, Cesarean surgery also carries potential harms for the mother, infant, and children born in future pregnancies. It is important to have full information on both options in order to make a decision. To read more about the potential benefits and harms of Cesarean versus vaginal birth, you may want to read: "Vaginal or Cesarean Birth: What is at Stake for Women and Babies?" or the consumer booklet, "What every woman should know about Cesarean Section" from Childbirth Connection.

Guidelines

In 2016, the American Congress of Obstetricians and Gynecologists (ACOG) released an opinion stating that induction is not recommended for women who are pregnant with suspected big babies, because induction does not improve outcomes for mothers or babies (recommendation based on "Level B evidence = limited or inconsistent evidence"). This recommendation was similar to their 2002 guidelines that were reaffirmed in 2008 and 2015, and eventually replaced by this new position statement published in 2016. In 2008, the National Institutes for Health and Clinical Excellence (NICE) in the United Kingdom also recommended against elective induction for suspected big babies.

In all of their opinion statements since 2002, ACOG has stated that planned Cesarean to prevent shoulder dystocia may be considered for suspected big babies with estimated fetal weights more than 11 lbs. (5,000 grams) in women without diabetes, and 9 lbs., 15 oz. (4,500 grams) in women with diabetes and gestational diabetes. They state the evidence is "Grade C," meaning this recommendation is based on consensus and expert opinion only, not research evidence (ACOG 2002; ACOG 2013; ACOG 2016).

The Royal College of Obstetricians and Gynecologists (RCOG) has published an opinion stating that elective Cesarean should be considered with a diagnosis of diabetes or gestational diabetes, but only if the baby is estimated to weigh more than 9 lbs., 15 oz. (4,500 grams). RCOG rated this recommendation as "Level 3," meaning that evidence was obtained from case reports.





What is the bottom line?

In summary, for non-diabetic moms:

- If a care provider predicts a big baby based on an ultrasound or physical exam, they will be right half the time and wrong half the time. Ultrasound weight results at the end of pregnancy can fall anywhere from 15% above or below the baby's actual weight.
- About 7 to 15% of big babies have difficulty with the birth of their shoulders, which is known as shoulder dystocia. The chance of a permanent nerve injury due to shoulder happens in 1 out of every 555 babies who weigh between 8 lbs., 13 oz. and 9 lbs., 15 oz., and 1 out of every 175 babies who weigh 9 lbs., 15 oz. or greater. Regular training is important for health care providers to keep up their skills in managing shoulder dystocia, as this can help prevent injuries.
- If a care provider thinks that you are going to have a big baby, this thought is sometimes more
 harmful than the actual big baby itself. This is because the suspicion of a big baby leads many
 care providers to manage a woman's care in a way that increases the risk of Cesarean and
 complications.
- Although a policy of very early induction (37 to 38 weeks) can prevent some shoulder dystocia
 cases from occurring, researchers have not been able to show that induction decreases the risk of
 brachial plexus palsy, and very early induction may carry other risks to the mother or baby.
- A policy of elective Cesareans for big babies likely does more harm than good for most women: It would take nearly 3,700 elective Cesareans to prevent one permanent case of brachial plexus palsy in babies who are suspected of weighing more than 9 lbs., 15 oz.

For mothers with diabetes or gestational diabetes:

- Ultrasounds are slightly more accurate at predicting a big baby, because these moms are at higher risk of having a big baby to begin with
- Elective Cesareans may be more cost-effective in women who have Type I or Type II diabetes than they would be in women without diabetes
- Management of gestational diabetes (diet, exercise, or medication) lowers the chance of having a big baby and shoulder dystocia down to normal levels

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Additional Resources

- For an interesting article about women's experiences being told they have suspected big babies, <u>click</u> here.
- · For a video demonstrating why you should not pull on a baby's head during shoulder dystocia, click here.
- To follow the Erb's Palsy Facebook page (for Brachial Plexus Palsy) <u>click here</u>, and to join their public support group ("Oliver's Friends"), <u>click here</u>.

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Table 1: Percentage of women who have big babies in the United States

Actual Weight at Birth	*Not diabetic (≥39 wks)	*Gestational diabetes (≥39 wks)	**Type I or Type II diabetes (≥39 wks)
Less than 8 lbs., 13 oz.	90.3%	87.3 %	76.8%
Between 8 lbs., 13 oz. and 9 lbs., 15 oz.	8.2%	11.1%	17.1%
9 lbs., 15 oz. or more	1.5%	2.6%	6.1%

^{*}Data from the 2010 U.S. National Vital Statistics. **Data from a large trial (Collaborative Group on Preterm Birth Prevention (1993) that may have included women with both gestational diabetes and Type I and Type II diabetes.

Table 2: Rates of Shoulder Dystocia and Brachial Plexus Palsy in Non-Diabetic Women

Actual Weight at Birth	Rate of shoulder dystocia in non-diabetic women	If there is a shoulder dystocia, the rate of brachial plexus palsy	If there is a brachial plexus palsy, the rate of permanent disability	Overall rate of permanent nerve disability among all babies in this weight range
Less than 8 lbs., 13 oz.	0.65%	9%	15%	0.009% (1 in 11,111)
Between 8 lbs., 13 oz. and 9 lbs., 15 oz.	6.7%	18%	15%	0.18% (1 in 555)
9 lbs., 15 oz. or more	14.5%	26%	15%	0.57% (1 in 175)

Percentages taken from Rouse et al. 1996 and Chauhan et al. 2014. Curious how to do the math? (example using the 2nd row): $6.7\% \times 18\% \times 15\%$ or $.067 \times 0.18 \times .15 = .0018$ (.18%) or 1 in 555.





Table 3: Which is more harmful: A big baby or a care provider's suspicion of a big baby?

Actual Weight at Birth	Women were suspected of having a big baby (and actually had one)	Women were NOT suspected of having a big baby (and actually had one)
Induction rate	42%	14%
Cesarean section rate	57%	17%
Maternal complication rate	17%	4%
Shoulder dystocia	No difference (0%)	No difference (1.7%)

Data from Sadeh et al., 2009; there were no significant statistical differences in rates of shoulder dystocia between groups

