

Uterine rupture during induced labor after myomectomy and risk of lawsuits

Dear Editor,

Rising myomectomy rates in the world represent an important obstetric issue: uterine scarring and possible uterine rupture-related complications. Fibroids constitute one of the most frequent gynecologic pathology associated with infertility, and myomectomy is considered an effective-treatment. However abdominal, hysteroscopic and laparoscopic (traditional or robotic) myomectomy unavoidably produces a scarred uterus and increases the risk of uterine rupture in pregnancy, which generally occurs in the third trimester (after 36 weeks) or during labor and delivery. The incidence of uterine rupture reported in literature is very low (ranging from 1/40000 and 1/50000)¹. Although myomectomy cannot be considered a prophylactic measure prior to conception, in the last 30 years an increasingly high number of women aged from 35 to 50 has required a myomectomy before undertaking a pregnancy, especially with IVF techniques^{2,3}. Literature reports favorable short-term outcomes in laparoscopic myomectomy in comparison with laparotomic myomectomy but there are no available data on long-term results in women with scarring uterus, particularly with reference to uterine rupture⁴. A recent Cochrane review suggests that laparoscopic myomectomy is a procedure associated with less subjectively reported postoperative pain, lower postoperative fever and shorter hospital stay compared with all types of open myomectomy; yet, no evidence shows a difference between laparoscopic and open myomectomy on rates of uterine rupture⁵. Only SOGC guideline on the management of uterine leiomyomas mentions the issue of uterine rupture during pregnancy after myomectomy⁶. Uterine rupture during pregnancy after myomectomy has been reported to possibly be linked to the absence of multi-layer closure in cases of deep intramural leiomyoma, lack of deep suturing or to the excessive use of electrosurgical energy⁷. The literature data suggest that induction of labor are associated with an increased risk of uterine rupture among women with scarred uterus, and this association are highest when prostaglandin E gel, especially misoprostol, are used^{8,9}. There is no consensus as to the optimal interval between myomectomy and conception. Several authors report that the mean interval between laparoscopic myomectomy and pregnancy was 14 months, and only 3 (0.6%) cases of uterine rupture occurred during pregnancy. In analysis, by reviewing the published cases of uterine rupture, we found that the mean diameter, myoma number and type, and the rate of uterine suture were similar between the ruptured cases and all of our cases of laparoscopic myometctomy¹⁰. To date, available literature is inconsistent on evidence-based management, according to RCOG Green Top Guideline No. 45 "Birth after previous cesarean birth", which states that there is insufficient and conflicting information on whether the risk of uterine rupture is increased in women with previous myomectomy¹¹. Ultimately, uterine rupture represents an uncommon event. Yet, it may cause catastrophic maternal and fetal complications (such as severe post-hemorrhagic anemia, major puerperal infection, hysterectomy with fertility loss, and maternal and fetal death)¹², which are significantly higher in women with uterine rupture than in women without uterine rupture. In case of hysterectomy, the women become eligible for ARTs (Assisted Reproduction Technologies) or for uterine transplant^{13,14}. Moreover, such outcomes are hardly acceptable by those who are affected by them within the context of a natural event such as birth, therefore the risk of litigation is high¹⁵. For these reasons in obstetric practice

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such a risk will have to be considered with greater attention. The absence of unequivocal good practices on the issue suggests a cautious approach during pregnancy and delivery. That is why obstetricians are unable to justify their conduct on the basis of guidelines and clinical protocols. It is to be expected that, if litigation arises, professional behavior - because of a lack of guidelines - will be judged according to a set of rules devised with extreme care. The medical concept of complication comprises any damage arising during therapy which may result in an unfavorable deviation over the expected clinical path. Such definition, widely accepted in medicine, does not meet legal standards. Legal approaches which came to be in medical malpractice cases, both in common law and in civil law countries, consider meaningless the fact that clinical statistics regard a particular adverse event as a complication. In legal setting the concept of complication is much more restrictive than that applied in medicine. In fact, the only complication that does not entail accountability is the so-called unpredictable or unavoidable event. In particular, unpredictability or inevitability of complications rules out liability if the expected favorable outcome is not achievable in practice, not just on the basis of statistical data. In Italy, this principle has been repeatedly stated in court decisions and has been recently confirmed by the Supreme Court¹⁶. The rationale behind this approach is: in elective treatments (i.e., treatments performed not in emergency conditions) a favorable outcome should follow the treatment on the basis of the principle of clinical-statistical regularity. That notion is closely related to the doctrine of res ipsa loquitur, which is applied in most European countries and in the US¹⁷. Aside from those reasons, a cautious approach is desirable even because it is very difficult to know in depth risk factors linked to surgical technique: if appropriate myoma enucleation, electrosurgery use or optimal suturing has been carried out in previous myomectomy. For these reasons we suggest that all patients be considered as high-risk pregnancies. It is important to distinguish between post myomectomy uterine or dehiscence rupture in pregnancy outside of labor^{18,19}, in which the risk factors play an unpredictable role, both in early and late pregnancies, even in absence of warning signs²⁰, and rupture during labor. ACOG Guideline No. 184 affirm that for women with previous classical uterine incision or T-incision, prior uterine rupture or extensive transfundal uterine surgery vaginal delivery is contraindicated and thus they are not generally candidates for planned trial of labor after cesarean (TOLAC)²¹. Such a contraindication does not openly include all previous myomectomy, but in case of TOLAC, the compounding on the part of obstetricians of risk factors such as fundal pressure²², use of prostaglandins or oxytocin on a scarred uterus will be viewed as negligence in court, especially if the rupture occurs in coincidence with the uterine scar. In this context, unlike what is claimed by Claesys et al²³, the practitioners who may opt for elective cesarean section, in our view, would not be held accountable.

Conflict of interest

The authors declare no conflicts of interest.

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