

Retained Placental Tissue as an Emerging Cause for Malpractice Claims

Moshe D. Fejgin MD, Tal Y. Shvit MD, Yael Gershtansky MSc and Tal Biron-Shental MD

Maternal Fetal Unit, Department of Obstetrics and Gynecology, Meir Medical Center, Kfar Saba, affiliated with Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

ABSTRACT: **Background:** Removal of retained placental tissue postpartum and retained products of conception (RPOC) abortion is done by uterine curettage or hysteroscopy. Trauma to the endometrium from surgical procedures, primarily curettage, can cause intrauterine adhesions (Asherman's syndrome) and subsequent infertility. The incidence of malpractice claims relating to intrauterine adhesions is rising, justifying reevaluation of the optimal way of handling these complications.

Objectives: To review malpractice claims regarding intrauterine adhesions, and to explore the clinical approach that might reduce those claims or improve their medical and legal outcomes.

Methods: We examined 42 Asherman's syndrome claims handled by MCI, the largest professional liability insurer in Israel. The clinical chart of each case was reviewed and analyzed by the event preceding the adhesion formations, timing and mode of diagnosis, and outcome. We also assessed whether the adverse outcome was caused by substandard care and if it could have been avoided by different clinical practice. The legal outcome was also evaluated.

Results: Forty-seven percent of the cases occurred following vaginal delivery, 19% followed cesarean section, 28% were RPOC following a first-trimester pregnancy termination, and 2% followed a second-trimester pregnancy termination.

Conclusions: It is apparent that due to the lack of an accepted management protocol for cases of RPOC, it is difficult to legally defend those cases when the complication of Asherman syndrome develops.

IMAJ 2014; 16: 502-505

KEY WORDS: retained products of conception (RPOC), Asherman's syndrome, intrauterine adhesions, litigation

and thus carries his name, Asherman syndrome [1]. Intrauterine adhesions mostly develop as a result of trauma to the basal layer of the endometrium. Most cases are related to curettage for pregnancy termination, postpartum hemorrhage, or delayed removal of RCPO [2]. The role of intrauterine infection in adhesion formation is controversial. Repeated curettage for pregnancy loss increases the risk of developing adhesions from 8% after the first curettage to > 35% with the third. Intrauterine adhesions can be asymptomatic or can cause hypomenorrhea, amenorrhea, pelvic pains, recurrent pregnancy loss, or infertility [2-4]. Infertility is the most common reason patients present for evaluation: 43% of women with intrauterine adhesions have some degree of infertility [2].

The most reliable way to diagnose intrauterine adhesions is by hysteroscopy, which allows diagnosis and treatment at the same time. Another mode of diagnosis is a hysterosalpingogram or a sonohysterogram [3,4]. No randomized trials have been conducted to guide therapy in these patients. When symptomatic, the common treatment is surgical hysteroscopy for adhesiolysis [4,5]. For reducing the risk of reformation of adhesions, estrogen therapy followed by a withdrawal bleed stimulated by progesterone is recommended [2].

Retained placental tissue is a major cause of immediate postpartum hemorrhage. In such cases evacuation of the uterus is obligatory. In contrast, there are no clear guidelines for optimal treatment in cases of suspected asymptomatic retained products of conception. Historically, immediate curettage using a large curette was the standard of care [7]. However, this procedure may damage the basal layer of the endometrium and subsequently lead to the formation of intrauterine adhesions. Therefore, many authors [8] recommend a more conservative approach: holding off the curettage and awaiting spontaneous expulsion of the placental tissue with the aid of prostaglandins. Hysteroscopy-directed removal of the retained tissue is theoretically less traumatic to the uterus than curettage. However, this may be problematic in the immediate postpartum period due to heavy vaginal bleeding and the large size of the uterus. It has been suggested that hysteroscopic selective resection of the retained products of conception should be considered in patients with secondary (delayed) postpartum bleeding [9].

Retained placental tissue following birth, and retained products of conception following curettage, are not uncommon complications. In most cases, secondary evacuation of the retained tissue ends without any sequelae. However, in a minority of cases this may lead to the formation of intrauterine adhesions and, consequently, fertility problems.

Amenorrhea due to intrauterine adhesions was first described in 1894; it was defined by Asherman in 1948 and 1950

RPOC = retained products of conception

When fertility problems develop secondary to intrauterine adhesions, legal action may be quick to follow. Lately, we have encountered increasing numbers of claims and litigation activity relating to infertility secondary to Asherman syndrome. For some reason, this risk management issue has been somewhat ignored by the medical literature.

In this study we review all Asherman syndrome cases that were reported to Medical Consultants International over a 20 year period and that involved some legal action.

METHODS

We examined all claims related to retained placental tissue and RPOC that were reported/handled by MCI between 1991 and 2011. MCI is the largest professional liability insurer in Israel, providing malpractice coverage to institutions where more than 50% of the obstetric care in the country is conducted. We did not seek Institutional Review Board approval for this study since all the information was obtained from the insurance company (MCI) database (all women signed a release form).

Both the medical and the legal records were reviewed. Each medical file was analyzed with regard to the event preceding the adhesion formations, timing and mode of diagnosis, primary and secondary management, as well as the final medical outcome. The legal file was analyzed regarding the condemnation of the management, weaknesses due to sub-standard management, medical outcome, and legal process and outcome.

RESULTS

We identified 42 charts dealing with retained placental and products of conception in the MCI database. Twenty (47%) of the cases of retained placental tissue followed a vaginal delivery [Figure 1] and 8 cases (19%) followed a cesarean section [Figure 2].

Only in 4 of the 20 vaginal delivery cases was there an immediate diagnosis of retained placenta. In the other 16 the placenta was felt to be “intact” upon inspection following the delivery.

Twelve (28%) of the cases of RPOC followed first-trimester curettage for pregnancy terminations or missed abortions, and 2 cases (4%) followed second-trimester pregnancy terminations.

All 42 cases resulted in the formation of intrauterine adhesions (Asherman syndrome) of various degrees. Permanent infertility occurred in 24 patients.

Two patients delivered prematurely and underwent a postpartum hysterectomy due to placenta accrete.

The reason for legal action in 30 (71%) of the claims was fertility problems. Among other reasons were: permanent com-

Figure 1. Retained placental tissue following vaginal delivery

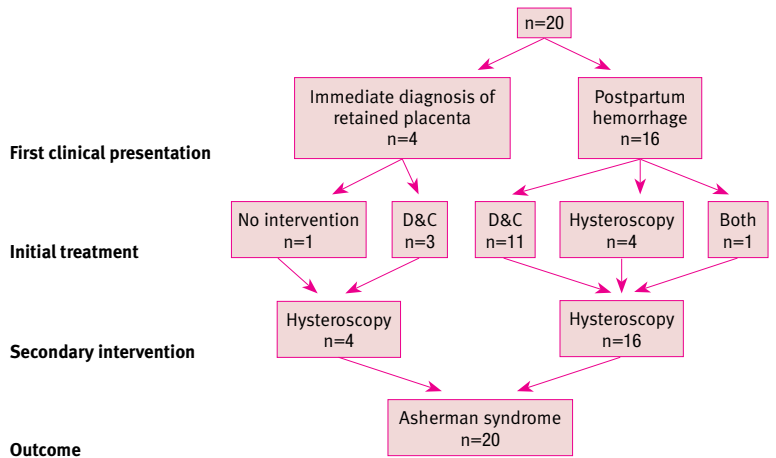
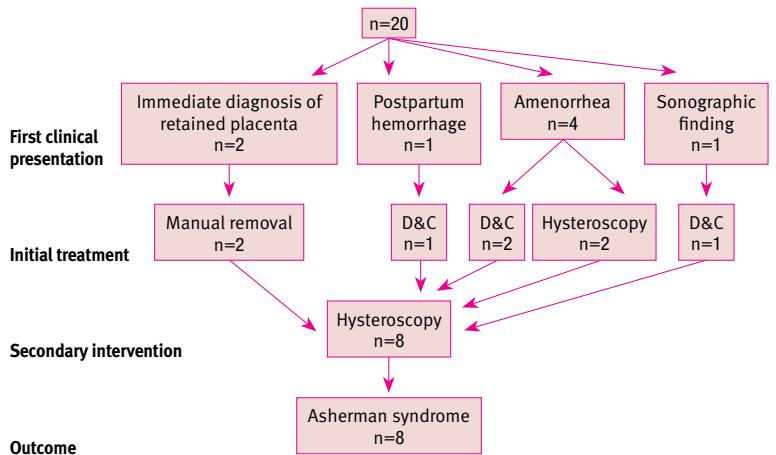


Figure 2. Retained placental tissue following cesarean section



plete amenorrhea (2 cases, 4.7%), requirement for hysterectomy (2 cases, 4.7%), and psychiatric damage (2 cases, 4.7%).

THE LEGAL OUTCOME

The main clinical criticism by the plaintiff’s expert witness related to the selection of “aggressive” D+C as the primary procedure for removal of retained tissue and the delay in the diagnosis of retained tissue, which caused a delay in evacuating the uterus. Other criticism related to not prescribing antibiotics and estrogens.

Most cases (n=20) resulted in an out-of-court settlement. Eight cases were handled by the courts; in two of them the decision was in favor of the plaintive and one case was rejected. Five cases are awaiting a court decision but will most likely be settled

MCI = Medical Consultants International

D + C = dilation and curettage

before the court decision. In 14 cases the file was closed due to the lack of legal activity or to statute of limitation. The mean compensation was \$56,300.

DISCUSSION

The threat of medical malpractice claims has a huge effect on clinical practice, especially in obstetrics. Malpractice claims regarding intrauterine adhesions and their consequences have become more common in Israel in recent years. This trend is not reflected in the international medical literature. In view of the fact that there are no clear clinical guidelines for reducing the risk of intrauterine adhesion development, as well as the lack of risk management guidelines to reduce the risk of litigation and compensation, we decided to review the experience that has accumulated in the MCI over the last 20 years.

MEDICAL MANAGEMENT ISSUES

It is well known that failure to remove all placental tissue following birth, or incomplete evacuation of the products of conception during D+C, usually cause delayed bleeding with or without fever. In a few cases amenorrhea may occur. Our data show that in most of the cases there was no clinical suspicion of retained placental tissue prior to the onset of symptoms.

Delayed vaginal bleeding was the typical presenting symptom, occurring in all the cases that followed vaginal delivery (in none of the cases was amenorrhea the presenting symptom), while in the first-trimester curettage group amenorrhea was the presenting symptom in 41% of the cases.

While the first step in all bleeding cases was to evaluate the uterine cavity by ultrasound, sometimes it was difficult to distinguish between placental tissue and blood clots. Ultrasound is the best predictor of RPOC in women with a suspicion of incomplete miscarriage after spontaneous first-trimester miscarriage that was evacuated surgically, compared to clinical predictors such as vaginal bleeding and abdominal pains [10]. Shaamash et al. [11] used ultrasound to examine postpartum women to determine if there is a relationship between the findings on routine postpartum ultrasonographic scanning and puerperal uterine complications. According to the study intrauterine echogenic/heterogeneous mass was the most predictive variable for delayed heavy bleeding [11].

Once there is a suspicion of retained placental tissue, the initial approach is controversial: should we proceed directly to surgical intervention or try medical treatment (uterotonics) first. It has been shown that in a majority of cases spontaneous expulsion of the placental tissue occurs within 2–4 weeks [9].

In a retrospective cohort study of 200 patients, Pather and co-authors [7] assessed whether delivery details, clinical features at presentation, and laboratory investigations could accurately predict the presence of RPOC. They found that the sensitivity and specificity of ultrasound in detecting RPOC

was 94% and 16%, respectively; the presence of an echogenic focus together with a thickened endometrium of more than 10 mm was the most accurate ultrasound feature of RPOC (positive predictive value 80%). Seventeen patients (8.5%) experienced major morbidity following curettage and 14 (7%) underwent a repeat procedure with further morbidity. Patients presenting with pelvic infection were more likely to experience postoperative morbidity. They concluded that a postpartum curettage has a low diagnostic yield and is associated with a significant complication rate. While the therapeutic benefit of this procedure is unclear, the authors felt that expectant management is appropriate [7].

Another question yet to be determined is the primary surgical intervention: curettage or hysteroscopy. Our data show that in most of the cases with poor outcome an immediate curettage was performed. A conservative approach was taken in only a few of the more recent cases.

Hysteroscopy and surgical hysteroscopy have been the gold standard of diagnosis and treatment of Asherman syndrome. This syndrome occurs mainly as a result of trauma to the gravid uterine cavity, which leads to the formation of intrauterine and/or intracervical adhesions. Despite the advances in hysteroscopic surgery, the treatment of moderate to severe Asherman syndrome still presents a challenge. Furthermore, pregnancy following treatment remains high risk, with complications including spontaneous abortion, preterm delivery, intrauterine growth restriction, placenta accrete or placenta previa, and even uterine rupture [9,11].

In many of our cases the medical record specified that curettage was performed under ultrasonographic guidance. However, this information was available in only a few charts.

Goldenberg et al. [13] reported their experience with 18 patients (16 post-abortion and 2 postpartum) who underwent a hysteroscopy for removal of residual trophoblastic tissue causing continuous bleeding. Complete removal of the residual tissue was achieved in all patients. No short-term complications were reported. The authors concluded that selective curettage of residual trophoblastic tissue performed under hysteroscopy is an easy and rapid procedure and might be preferable to conventional, non-selective, blind curettage [13].

Since the placenta is removed manually during a C-section, the number of cases of retained placentas following a C-section was surprising: 8 of 28 birth-related cases (28%). In 25% of them there was a clinical picture of placenta accrete. In two cases, one following B-Lynch uterine suturing for compression [14], sutures were observed in the uterine cavity on hysteroscopy.

LEGAL ISSUES

Our review of the medical and legal literature failed to reveal even a single study addressing legal experience with Asherman's syndrome. However, we did find several reports on internet sites published by private law firms describing the

legal outcome of single cases managed by those offices. The common ground for the lawsuits was negligence and deviation from the “standard of care” when managing cases with retained products of conception and retained placentas postpartum. These case reports are descriptive in nature and are without recommendations.

The problem when dealing with legal cases of RPOC is that there is no real “standard of care.” It is not clear which approach is better: the active (immediate surgical intervention) or the conservative one (await spontaneous expulsion). Also, although recently the most common initial intervention is by hysteroscopy, a D+C is still considered an optional procedure. Due to these difficulties, MCI consultants adopted a “reduction of risk” attitude in these cases and recommended settlement in most cases, especially those with an immediate intervention by D+C. The consultants felt that there was no defense for such an aggressive approach.

RECOMMENDATIONS

Although our study group includes only the poor outcome cases, several repeated issues among our cases generate some management recommendations that might reduce the risk of uterine injury, adhesions formation, infertility, and malpractice claims:

• **POST-DELIVERY**

- ▷ Every placenta should be inspected after expulsion
- ▷ Manual exploration of the uterus should be performed in doubtful cases, followed by immediate ultrasound
- ▷ Postpartum hemorrhage requires curettage with a large blunt curette under ultrasound guidance
- ▷ In doubtful asymptomatic cases ultrasound should be performed before discharge from the hospital. Unless there is a large amount of residual placental tissue (> 5 cm) that requires surgical intervention, observation alone is recommended. Ultrasound should be repeated after 2 weeks. If the patient becomes symptomatic or if the uterus does not seem to be empty by 6 weeks, intervention is recommended
- ▷ Unless there is major bleeding, hysteroscopy is the procedure of choice
- ▷ Antibiotics should be used in febrile cases
- ▷ The addition of estrogens may be useful.

• **POST D+C**

- ▷ At the end of the procedure ultrasound should be used to demonstrate an empty uterus

- ▷ When there is a delayed suspicion of retained products of conception, hysteroscopy should be used. Adhesions should be separated during the same procedure
- ▷ Estrogens may be used in all these cases.

In conclusion, retained placental tissue following delivery, as well as retained products of conception, are common clinical complications that may carry a heavy medico-legal burden. Our accumulated experience may assist the clinician in selecting the safest approach.

Correspondence

Dr. T. Biron-Shental

Dept. of Obstetrics and Gynecology, Meir Medical Center, Kfar Saba 44281, Israel
 email: shental@inter.net.il

References

1. Asherman JG. Amenorrhea traumatica. *J Obstet Gynaec Brit Emp* 1948; 55: 23-30.
2. Schenker JG. Etiology of and therapeutic approach to synechia uteri. *Eur J Obstet Gynecol Reprod Biol* 1996; 65: 109-13.
3. Roma Dalfo A, Ubeda B, Ubeda A. Diagnostic value of hysterosalpingography in the detection of intrauterine abnormalities: a comparison with hysteroscopy. *AJR Am J Roentgenol* 2004; 183: 1405-9.
4. Farhi J, Ben-Haroush A. Distribution of causes of infertility in patients attending primary fertility clinics in Israel. *IMAJ* 2011; 13 (1): 51-4.
5. Silberstein T, Saphier O, van Voorhis BJ, Plosker SM. Endometrial polyps in reproductive-age fertile and infertile women. *IMAJ* 2006; 8 (3): 192-5.
6. Fernandez H, Gervaise A, de Tayrac R. Operative hysteroscopy for infertility using normal saline solution and a coaxial bipolar electrode: a pilot study. *Hum Reprod* 2000; 15: 1773-5.
7. Pather S, Ford M, Reid R, Sykes P. Postpartum curettage: an audit of 200 cases. *Aust N Z J Obstet Gynaecol* 2005; 45 (5): 368-71.
8. Matijevic R, Knezevic M, Grgic O, Zlodi-Hrsak L. Diagnostic accuracy of sonographic and clinical parameters in the prediction of retained products of conception. *J Ultrasound Med* 2009; 28 (3): 295-9.
9. Cohen SB, Kalter-Ferber A, Weisz BS, et al. Hysteroscopy may be the method of choice for management of residual trophoblastic tissue. *J Am Assoc Gynecol Laparosc* 2001; 8 (2): 199-202.
10. Abbasi S, Jamal A, Eslamian L, Marsousi V. Role of clinical and ultrasound findings in the diagnosis of retained products of conception. *Ultrasound Obstet Gynecol* 2008; 32 (5): 704-7.
11. Shaamash AH, Ahmed AG, Abdel Latef MM, Abdullah SA. Routine postpartum ultrasonography in the prediction of puerperal uterine complications. *Int J Gynaecol Obstet* 2007; 98 (2): 93-9.
12. Yu D, Wong YM, Cheong Y, Xia E, Li TC. Asherman syndrome – one century later. *Fertil Steril* 2008; 89 (4): 759-79.
13. Goldenberg M, Schiff E, Achiron R, Lipitz S, Mashiach S. Managing residual trophoblastic tissue. Hysteroscopy for directing curettage. *J Reprod Med* 1997; 42 (1): 26-8.
14. Poujade O, Grosseti A, Mougél L, Ceccaldi PF, Ducarme G, Luton D. Risk of synechiae following uterine compression sutures in the management of major postpartum haemorrhage. *B/OG* 2011; 118 (4): 433-9.

“It’s fine to celebrate success but it is more important to heed the lessons of failure”

Bill Gates

“The greatest dangers to liberty lurk in the insidious encroachment by men of zeal, well meaning but without understanding”

Louis D. Brandeis