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Research article

Intrauterine contraceptive device rupture. Follow-up of a retrospective cohort and clinical protocol. RUDIUS study☆

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ABSTRACT

Objective: Intrauterine device fracture, as we know it today, is an infrequent event, usually described as isolated cases. The purpose of this study was to look for factors influencing intrauterine fragment retention after device rupture.

Study design: Retrospective cohort study. A total of 135 patients were recruited, and the cohort follow-up ran for three full years from 2018 to 2020.

Results: Thirty-three percent of patients had a retained intrauterine fragment compared to 82 of 123 (66.7%) who had expelled it spontaneously. In the group of patients who had at least one intercurrent period between device fracture and confirmatory fragment persistent test, we found persistence of intrauterine fragment in 18 of 71 (25.4%) patients compared to 53 of 71 (74.6%) who did not ($p = 0.047$). A total of 6 of 39 (15.4%) of the patients with spontaneous rupture of the device presented with persistence of the intrauterine fragment compared to 32 of 81 (39.2%) of the group with fracture after manipulation ($p = 0.006$). The mean time elapsed from the fracture to the confirmatory test in the patients who had persistence of the fragment was 26.97 days (range from 0 to 116), while in those who expelled it spontaneously, a mean of 45.59 days (range 7–267) had elapsed ($p = 0.003$).

Conclusions: The main factors positively influencing complete expulsion of the fragmented IUD were elapsed time of 45 days or more, intercurrent menstruation or spontaneous fracture. Therefore, the proposed protocol calls for expectant management for at least 1.5 months after fracture, allowing at least one intercurrent period to elapse prior to any therapeutic manoeuvre.

1. Introduction

Intrauterine devices (IUDs) are currently the most widely used method of long-acting, reversible contraception in the world [1], with use in up to 40% of some countries, such as Korea and Vietnam [2]. Of all the types of IUDs currently available, metal-based IUDs have a long history dating back to the early 1900s and have undergone significant changes in shape and size over the years [3].

Intrauterine device (IUD) fragmentation is a rare complication whose management is not well established given its low incidence. While fracture rates are documented to be 1%–2% with the use of early IUDs, the frequency of such a complication with modern IUDs was unknown until now [4].

Alerts issued by the manufacturer, Eurogine SL, dated 21 February 2018 [5], reported a manufacturing defect in certain devices leading to an increased risk of breakage. This situation has placed us in a new scenario with an increase in cases that will continue over time due to the useful life of this contraceptive method.

Rupture can occur spontaneously, leading to total or partial expulsion of a fragment, or, more frequently, during mechanical manipulation to remove the IUD.

The device used in our setting and affected by the aforementioned alert is the NOVAPLUS® T 380 Cu, a single-use, T-shaped device, measuring 31 mm wide and 33 mm long. The plastic armature is made of polyethylene and barium sulphate, and its main stem is covered by a copper wire with an active surface area of 380 mm^2. The alert affects

☆ **Implications statement:** Intrauterine device fracture is a rare complication and its clinical management is currently not clearly established. This article provides evidence on factors that influence the spontaneous resolution of this occurrence allowing for the planning of a clinical approach based on evidence.

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batches that began to be marketed in 2014 and were withdrawn from the market in February 2018.

The updated data as of 25 September 2019 [6] are:

- Breakage rate during extraction: 0.25%;
- In situ rupture/spontaneous expulsion rate: 0.08%;
- Known expulsion rate of IUDs in general during five years of use: 1 in 20 women;
- Updated rate of pregnancies probably associated with IUD rupture: 0.003%;
- Overall pregnancy rate in women with IUDs: 0.1–1%;
- Reported rate of uterine perforation for these types of IUDs: 0; and
- Known perforation rate for IUDs in general: 0.1–0.2%.

When we encounter a case of fragmented IUD in the consultation room, it is not easy to establish a clinical approach given the scarce published literature on the management and natural history of fragmented intrauterine IUDs. In the present study, we present and analyse a cohort of cases of fragmented IUDs from January 2018 to December 2020 from the University Hospital of Torrevieja and the attached Sexual and Reproductive Health Unit. We focused mainly on studying those factors that influence the complete expulsion of the IUD, with the intention of clarifying which factors impact a complete resolution and are able to establish an evidence-based clinical approach.

2. Material and methods

A retrospective cohort study (RUDIUS study) in which factors that could influence the retention of intrauterine IUD fragments after IUD fracture were sought. A total of 135 patients were recruited between 1 January 2018 and 31 January 2020. The inclusion criteria were to have suffered an IUD rupture during the study period and to have physical proof of the rupture (either at our work centre or by the patient providing the IUD fragment itself). The exclusion criteria were carriers of non-copper IUDs, history of ruptured IUD without physical evidence, patient withdrawal from the health care network after diagnosis, and inability to confirm the IUD fracture.

The outcome variable established was the presence or absence of a retained intrauterine fragment after device fracture, as diagnosed by an imaging test, mainly transvaginal ultrasound, or by hysteroscopy. The independent variables analysed were age, parity, personal history [obesity, high blood pressure (HBP), diabetes mellitus (DM), retroverted uterus, heavy menstrual bleeding with anaemia, uterine fibroids, pelvic inflammatory disease, or previous uterine surgery], type of incident (IUD rupture after manipulation or spontaneously), the presence of breakthrough menstruation, defined as the presence of menses between the time of breakage and the performance of the confirmatory fragment persistence test, and time elapsed from breakage to diagnosis.

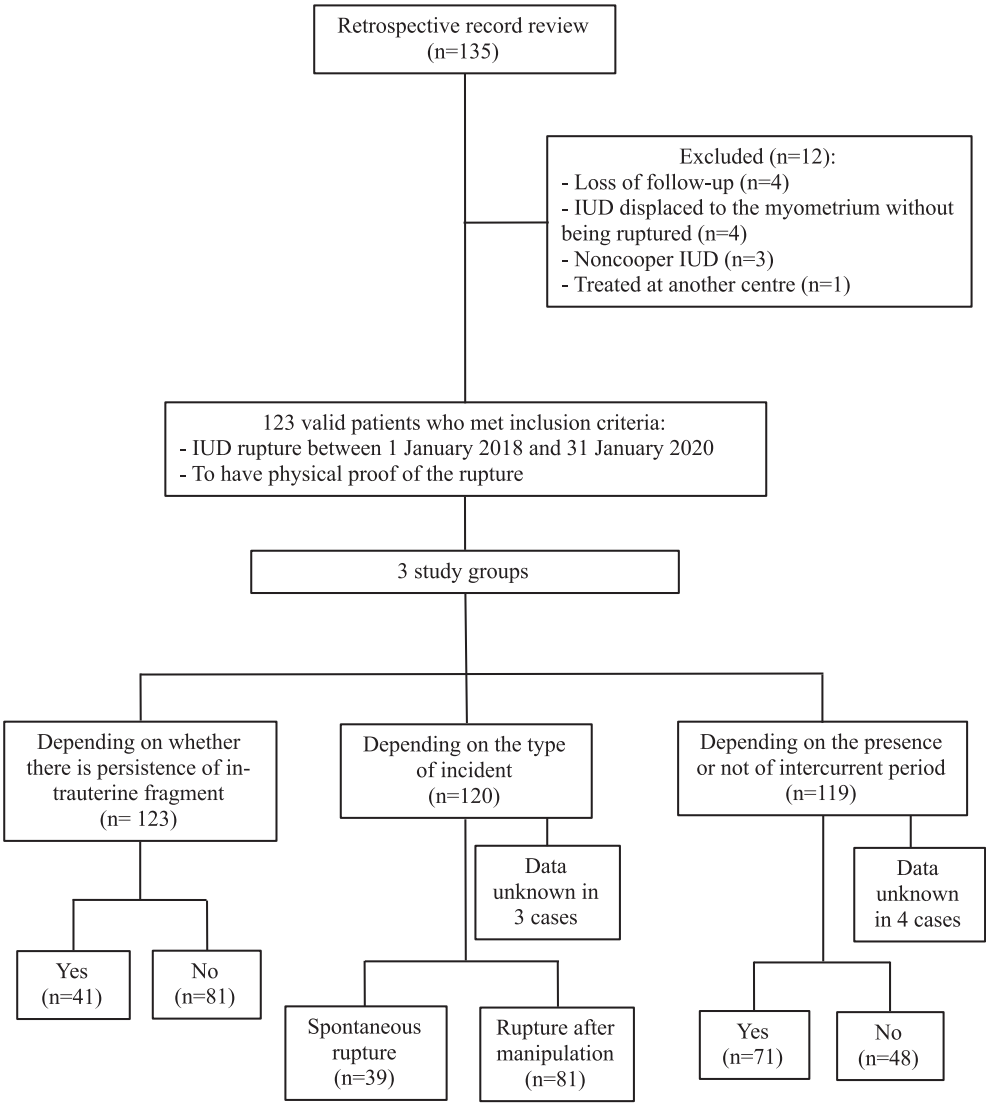


Figure 1. Patient flow-chart from RUDIUS study.

Table 1. Percentage of persistence of retained intrauterine fragment by type of occurrence: spontaneous fracture versus breakage of the device after manipulation.

			Persistence of intrauterine fragment		Total
			No	Yes	
Type of occurrence	Spontaneous fracture	N (%)	33 (84.6)	6 (15.4)	39 (100)
	Breakage after manipulation	N (%)	49 (60.5)	32 (39.5)	81 (100)
Total		N (%)	82 (68.3)	38 (31.7)	120*(100)
					p = 0.006

* N = 120. There were a total of 3 patients in whom it was not possible to know the nature of the device rupture and were excluded from this analysis.

Table 2. Absolute number and percentages of patients who experienced at least one intercurrent period between device fracture and confirmatory fragment persistence test, classified according to whether or not they experienced such an event.

			Persistence of intrauterine fragment		Total
			No	Yes	
Intercurrent period	No	N (%)	27 (56.3)	21 (43.8)	48 (100)
	Yes	N (%)	53 (74.6)	18 (25.4)	71 (100)
Total		N (%)	80 (67.2)	39 (32.8)	119* (100)
					p = 0.047

* N = 119. There were a total of four patients for whom it was not possible to obtain data on whether or not an intercurrent period had elapsed, and they were, therefore, excluded from this analysis.

The data were obtained retrospectively from the records of patients who had suffered or were suspected of having suffered an IUD fracture in the outpatient clinic or emergency department of our hospital or its associated sexual and reproductive health unit between 2018 and 2020.

The protocol applied at initial contact with a patient with a ruptured IUD was, first, to obtain an adequate clinical history of the patient, reason for consultation, and circumstances of the IUD fracture. Subsequently, a gynaecological examination and transvaginal ultrasound were performed to attempt to rule out the possible presence of a retained intrauterine fragment. After this, if a retained intrauterine fragment was suspected, the patient was recommended for delayed diagnostic hysteroscopy. If an intrauterine fragment was not detected by ultrasound, approaches varied, ranging from requesting an additional imaging test, such as an X-ray, to repeating an ultrasound examination in a few months, or even requesting a hysteroscopy to rule out a possible false negative transvaginal ultrasound.

Data processing was performed in an anonymised form with the creation of a coded database. Statistical analyses were performed with IBM SPSS Statistics 26.0. For normal variables, descriptive data of central tendency were applied, while categorical variables were described as percentages. For the statistical analysis of categorical variables, the chi-square test was used, while for the analysis of continuous variables, logistic regression models and t-tests for equality of means were applied. Missing values were not included in the analyses.

This study was approved by the Ethics Committee of the University Hospitals of Torrevieja-Vinalopó (registration number: 2019.091).

3. Results

A total of 135 patients met the inclusion criteria and were recruited. Of these, a total of 12 patients were excluded for the following reasons: four left the network before the relevant examinations could be performed; one reported a history of a ruptured IUD that had already been resolved at another centre and could not be verified; three had a non-copper IUD; and four patients had myometrially embedded IUDs with suspected fracture that were ultimately confirmed not to be ruptured. The final number of valid patients was 123. The patient flow-chart is shown in Figure 1.

A total of 41 of 123 patients (33.3%) had a retained intrauterine fragment compared to 82 of 123 patients (66.7%) who expelled it spontaneously. A total of 81of 120 (67.5%) patients had rupture after manipulation for device removal compared to 39 of 120 (32.5%) patients with spontaneous rupture. There was a total of three patients in whom it was not possible to ascertain the nature of the device rupture, and they were excluded from this analysis. Of the patients with spontaneous device rupture, 6 of 39 (15.4%) had persistence of the intrauterine fragment compared to 32 of 81 (39.5%) in the group with fracture after manipulation (Table 1). Significant differences were found (p = 0.006).

When we analyse the patients who had at least one intercurrent period between device fracture and confirmatory fragment persistent test (n = 71), we found persistence of intrauterine fragment in 18 of 71 (25.4%) patients compared to 53 of 71 (74.6%) that did not have persistence of intrauterine fragment (p = 0.047) (Table 2). There was a total of four patients for whom it was not possible to obtain data on whether or not an intercurrent period had elapsed, and they were, therefore, excluded from this analysis.

The mean time elapsed from device fracture to confirmatory test for fragment persistence (hysteroscopy) was 40.51 days (range 0–267, n = 106) (Figure 2). The mean time from fracture to confirmatory test in patients who had fragment persistence was 26.97 days (range 0–116), while in those who spontaneously expelled a fragment a mean of 45.59 days (range 7–267) had elapsed. A significant difference was found (p = 0.003).

The age of the patients (n = 123) showed a normal distribution, with a mean of 38.89 ± 7.02 years. Patients who had had a previous pregnancy were 121 of 123 (98.4%) and 2 of 123 (1.6%) were nulligravidae. Four of the patients that were pregnant had had only miscarriages and therefore the total number of women who had had children were 117. Of these patients, 103 of 117 (88.0%) had had only previous vaginal delivery, 8 of 117 (6.8%) had had only previous caesarean section, and 6 of 117 (5.1%) had had vaginal delivery and caesarean section. Pathological clinical history, such as obesity, HBP, DM, and retroverted uterus, among others, were also taken into account. Table 3 shows the description of these characteristics according to the persistence or not of intrauterine fragment.

The variables that did show some relationship with persistence of intrauterine fragment were the presence of intercurrent menstruation (p = 0.047) and the time elapsed from occurrence to confirmatory test (p = 0.003), both acting as protective factors against persistence of intrauterine fragments. A significant relationship was also found with regard to the type of occurrence (i.e., spontaneous rupture versus rupture after manipulation, p = 0.006). No relationship was found between the persistence of intrauterine fragments and the following factors: pregnancy (p = 0.77); vaginal delivery (p = 0.51); obesity (p = 0.24); HBP (p = 0.103); retroverted uterus (p = 1); heavy menstrual bleeding (p = 1); uterine fibroids (p = 0.66); or previous uterine surgery (p = 1).

Regarding patient management, all patients underwent transvaginal ultrasound at their first contact with our centre. Subsequently, 1 patient of 123 (0.8%) required an additional imaging test (X-ray). A total of 106 patients (86.2%) underwent diagnostic hysteroscopy, which confirmed the persistence of retained fragments in 42 of 106 (39.6%). Of these hysteroscopies, 100% were successful in removing the retained fragment. The remaining 17 patients did not undergo hysteroscopy for the following reasons: ten brought the spontaneously expelled fragment to the consultation and, thus, hysteroscopic confirmation was not necessary; three had the fragment extracted with ultrasound-guided forceps; three underwent a delayed ultrasound check and, as no intrauterine debris was evident, hysteroscopy was not indicated; and one resulted in an unwanted pregnancy and, therefore, hysteroscopy could not be performed.

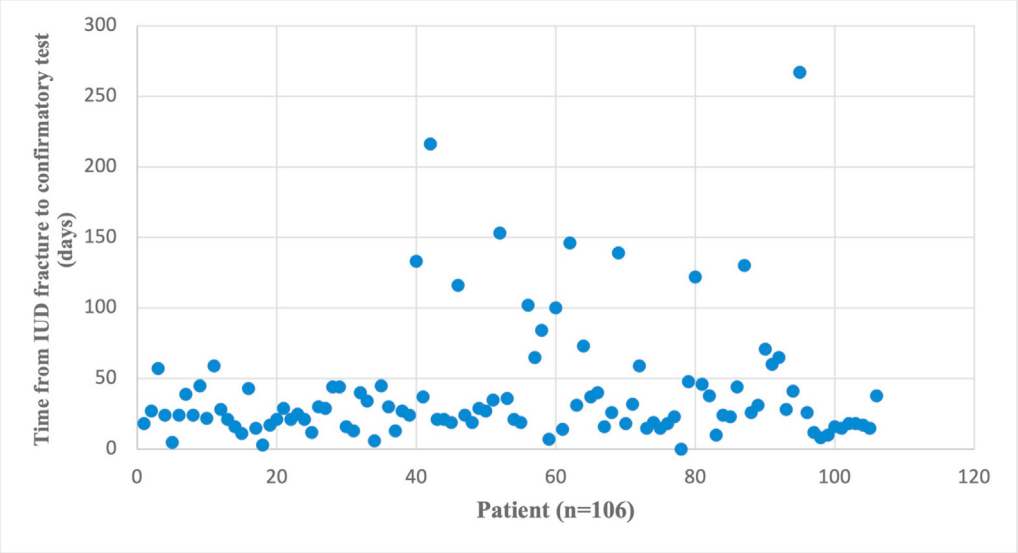


Figure 2. Dot plot showing time elapsed from device fracture to confirmatory test (hysteroscopy) for IUD fragment persistence in 106 patients (x-axis: patient; y-axis: time in days).

Table 3. Description of the sample according to gestations, parity and clinical history for the two study groups: patients with persistent intrauterine fragment (N = 41) and patients without persistent intrauterine fragment (N = 82).

		Patients with persistence of intrauterine fragment N (%)	Patients without persistence of intrauterine fragment N (%)	Total population N (%)
Pregnancies	0	0 (0)	2 (2.5)	2 (1.6)
	1	12 (29.3)	17 (20.7)	29 (23.6)
	>1	29 (70.7)	63 (76.8)	92 (74.8)
	Total	41 (100)	82 (100)	123 (100)
Vaginal deliveries	0	6 (14.6)	8 (9.8)	14 (11.4)
	≥1	35 (85.4)	74 (90.2)	109 (88.6)
	Total	41 (100)	82 (100)	123 (100)
Caesarean sections	0	35 (85.4)	74 (90.2)	109 (88.6)
	≥1	6 (14.6)	8 (9.8)	14 (11.4)
	Total	41 (100)	82 (100)	123 (100)
Personal clinical history	No	23 (56.1)	67 (81.7)	90 (73.2)
	Obesity	7 (17.1)	8 (9.6)	15 (12.1)
	HBP	3 (7.3)	2 (2.5)	4 (3.2)
	Diabetes Mellitus	0 (0)	0 (0)	0 (0)
	Retroverted uterus	3 (7.3)	5 (6.1)	8 (6.5)
	Heavy menstrual bleeding with anaemia	0 (0)	1 (1.2)	1 (0.8)
	Uterine fibroids	1 (2.4)	4 (4.9)	5 (4.1)
	Pelvic inflammatory disease	0 (0)	0 (0)	0 (0)
	Previous uterine surgery	0 (0)	4 (4.9)	4 (3.3)

In 21 of 123 patients (17.1%), ultrasound-guided fragment removal was attempted in the outpatient clinic and was successful in only three cases (or 14.3% of the total number of ultrasound-guided removal attempts), so an additional hysteroscopy in 18 of these patients was performed.

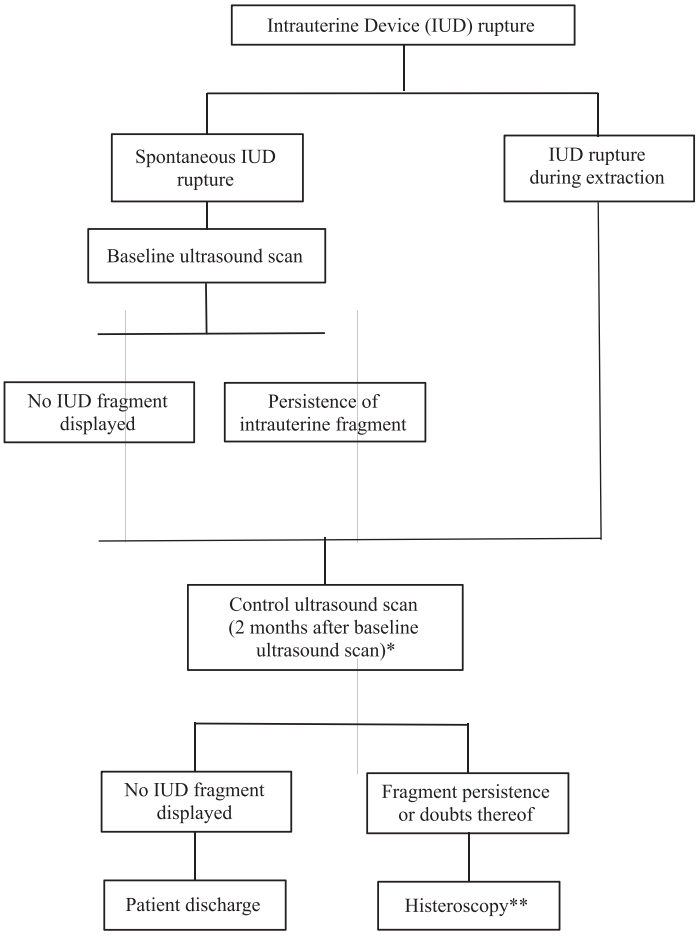
4. Discussion

The copper IUD, developed in 1972 [7], is the most widely used long-acting reversible contraceptive device in the world [1]. In 1974, Van Os et al. [8] first published their experience with the copper IUD and, not long after in 1977, Jackson [9] reported the first intrauterine fracture of a copper IUD.

Although some series of intrauterine device fractures had already been reported in the past, such as the series published in 1972 by Lang [10] on 15 patients with ruptures of Lippes loop IUDs, copper IUD fracture, as we know it today, was an infrequent event, usually described as isolated cases [11, 12, 13] or as rare series of no more than a couple of dozen patients [14].

The alert issued by Eurogine, which affected several batches of copper IUDs, caused IUD fracture cases to skyrocket in our setting, allowing us not only to present the longest series thus far published on patients with copper IUD fracture but also to give us the opportunity to develop an evidence-based clinical protocol and approach, something that is so lacking in the current literature every time one tries to search for literature on this occurrence.

Until today, the published article that came closest to providing guidance or suggesting a clinical approach to an IUD fracture was the one published by Wilson et al. in 2013 [14], which compiled the experiences of several professionals who had had a case of IUD fracture; it was limited due to its being a set of isolated cases from different centres, which gave a



** Patients will be advised to use an alternative contraceptive method until the removal of the intrauterine fragment or definitive diagnosis of expulsion.*

*** An active approach may be adopted with hysteroscopy indicated after the first visit if there is great anxiety on the part of the patient, or if circumstances make it inadvisable to delay the resolution of the event*

Figure 3. Clinical protocol for the management of intrauterine device (IUD) rupture.

certain heterogeneity to both the resources available and the follow-up of the cases, making it difficult to compare each of the strategies proposed.

For all these reasons, we launched the RUDIUS study, which comprises a retrospective cohort of 123 patients. The main limitation of our study is precisely its retrospective nature based on a review of clinical records of closed cases, which at times limited our ability to retrieve all the information necessary for the analysis. Those cases for which it was not possible to obtain the information were excluded from the analysis; results were calculated based on the total number of available data and not on the total number of cases in the sample.

Another limitation to be considered was the sample size itself, which, although not negligible considering the infrequency of this complication, was insufficient to analyse certain criteria, such as the relationship between fragment persistence and patient pathological history. It would not be unreasonable to think that conditions, such as a retroverted uterus or the presence of heavy metrorrhagia, could be related to or influence in some way the persistence or expulsion of the intrauterine fragment after its fracture. However, in our series, they represented a small percentage that limited the significance of the results obtained. It would be interesting in the future to extend the present study in this direction, trying to relate the patient's history of interest to the resolution of the device fracture.

In our study, the factors that were associated with the complete expulsion of the device were the presence of intercurrent menstruation and the time elapsed after the fracture, as well as the circumstance of the fracture, with spontaneous expulsion of the fractured device being a factor favouring spontaneous expulsion of the intrauterine fragment.

The mean time elapsed from device fracture to hysteroscopy in the group with retained intrauterine fragments was 26 days, compared to 45 days in the group of patients who did not retain any fragment. Thus, we believe it would be prudent to suggest that, after diagnosing an IUD fracture, consideration should be given to waiting between 1.5 and 2 months before establishing a definitive diagnosis of a retained fragment or considering any invasive strategy. Allowing this time would also give the opportunity for the second factor that also influences spontaneous expulsion of the fragment to take place: menstruation.

In our case, the suggested gold standard for both confirmation and resolution of a retained IUD fragment was hysteroscopy, with 100% success in removing the retained fragment. By contrast, ultrasound-guided forceps extraction of the retained intrauterine fragment did not have good results in our setting.

In view of the above, the protocol of action we propose in a case of IUD fracture would be: after diagnosis of the event, a watchful waiting approach would be indicated, allowing at least 1.5–2 months to elapse until the next examination, ideally providing for one or two menstrual periods during this period. At the next visit, an ultrasound scan would be performed to confirm, or rule out, the presence of residual intrauterine

fragments. In the event of confirmation of persistence of a fragment or doubts thereof, a hysteroscopy would be indicated, which would be both the gold standard for confirming spontaneous expulsion and the definitive treatment, as the retained fragment could be removed at the same time (Figure 3).

This wait-and-see approach may be modified depending on the clinical situation and type of patient, and an active approach may be adopted with hysteroscopy indicated after the first visit if there is great anxiety on the part of the patient, or if circumstances make it inadvisable to delay the resolution of the event. In all cases, patients will be advised to use an alternative contraceptive method until the removal of the intrauterine fragment or definitive diagnosis of expulsion.

5. Conclusion

In conclusion, the factors that most favour spontaneous expulsion of the intrauterine fragment are the presence of menstruation, spontaneous fracture of the device, and time. Hysteroscopy appears to be a highly effective test that can perform both the diagnosis of persistence of the fragment as well as its removal during the same procedure. By contrast, the extraction of the persistent fragment with ultrasound-guided forceps did not have good results in our setting.

Declarations

Author contribution statement

Esther Cánovas: Conceived and designed the experiments; Wrote the paper.

Duska Beric: Performed the experiments; Contributed reagents, materials, analysis tools or data.

Rebeca Jara: Contributed reagents, materials, analysis tools or data.

Eduardo Cazorla: Analyzed and interpreted the data.

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Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare no conflict of interest.

Additional information

No additional information is available for this paper.

References

[1] H.B. Peterson, K.M. Curtis, Review clinical practice. Long-acting methods of contraception, N. Engl. J. Med. 353 (2005) 2169–2175.
[2] United Nations, Department of Economic, Social Affairs, Population Division, New York: World Contraceptive Use 2011, United Nations Publication, 2011.
[3] L. Margulies, History of intrauterine devices, Bull. N. Y. Acad. Med. 5 (1975) 662–667. PMID: 1093589.
[4] R.W. Sobal, Y. Vittoz-Meynard, Intrauterine devices broken in situ, Contraception 2 (1970) 407.
[5] Alerta de vigilancia de productos sanitarios. [INTERNET], 2019. Available in: https://sinaem4.aemps.es/alertas/documentos/c65ghz1DVLA.
[6] Actualización de información relativa a nota de aviso. [INTERNET], 2019. Available in: https://www.aemps.gob.es/informa/notasInformativas/productosSanitarios/seguridad/2019/docs/FSN-21022018-actualizacion-informacion-relativa-nota-aviso.pdf.
[7] W.A.A. Van Os, D.A. Edelman, Fifteen years´ experience with the Multiload IUD, Adv. Contracept 4 (1988) 165–178.
[8] W.A.A. Van Os, P.E. Rhemrev, L. Bomert, E.J. Aortsen, Experience with a Combined Multiload Intrauterine Device. VII World Congress on Fertility and Sterility. Buenos Aires, 1974. Abstract 165.
[9] M.C. Jackson, Breakage of IUDs in utero. (Letter), IPPF Med. Bull. 11 (3) (1977). PMID: 12335213.
[10] J.R. Lang, Fracture of Lippes loop, Br. Med. J. 30 (1972) 795.
[11] K. Mohanty, Breakage of arm of Multiload intrauterine device during removal, Int. J. STD AIDS 20 (2009) 512–514.
[12] P.E. Korber, B.H. Goldstein, The Management of a patient with a fragmented intrauterine device embedded within the cervical canal, Contraception 99 (2019) 67–69.
[13] R.A. McCool, J. Springer, Ultrasound imaging of a fragmented copper wire IUD, Arch. Gynecol. Obstet. 298 (2018) 1043–1044.
[14] S. Wilson, G. Tan, M. Baylson, C. Schreiber, Controversies in family planning: how to manage a fractured IUD, Contraception 88 (2013) 599–603.