Clinical Improvement after ESSURE® devices removal: a systematic review

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Introduction

Essure® implant is a permanent minimally invasive control birth device implanted to 750000 patients worldwide between 2002 and 2018. Many side-effects were reported by patients. Essure®-related-symptoms were both local signs (pelvic pain, heavy menstrual bleeding (HMB), dyspareunia…) and general signs (asthenia, arthralgia, cognitive impairment…). Possible corrosion of the implant may be suggested with release of toxic metal elements such as nickel, chromium and tin in surrounding tissues and peritoneal fluid of symptomatic patients[1-2]. Increasingly explantation surgery are realized in symptomatic patients. However, strong studies about clinical improvement after removal are missing.

Materials and methods

A review of English literature was conducted using PubMed and Embase databases. Single cases reports and abstracts without detailed article were excluded. Data were synthesized under following categories: global improvement, pain, prevalence of Essure®-attributed symptoms, and quality of life (QoL). Statistical analysis were realized by Fisher's exact test.

Results

Literature search

18 studies were included from 2014 to January 2022, among which only 2 were prospective studies. Design and outcomes were heterogenous.

Patients & technique of removal

We collected informations about 981 explanted patients of which 922 with clinical follow-up. Technique of explantation were hysterectomy (36%), cornuectomy (28%), salpingectomy (26%), hysteroscopy (<1%), or unspecified (9%). Clinical assessment was mostly collected a few weeks after surgery.

Global improvement

Clinical improvement, at least partial, was reported from 73% to 98% of patients (Table 1).

	Time after surgery (months)	Improvement: Total or almost total (%)	Improvement: Partial (%)	No improvement (%)	Worsening (%)
Jegaden[4] (n=90)	1 to 2 24	47 83	51	2	-
Maasen[5] (n=73)	1.5	40	45	15	-
Leleu (n=57)	1.5 to 2	33	60	7	-
Merviel[7] (n=52)	1, 3 and 6	21			
Siemons[8] (n=51)	3	57			
van Drongelen[9] (n=49)	Unspecified	29	59	12	-
Eychenne[10] (n=90) (n=82)	2 6	91 98		8 1	1 1
Clark[11] (n=32)	1	87			
Nolan[12] (n=19)	1	89			
Brito[13] (n=11)	Unspecified (until 4 years)	73		9	18

Table 1: Studies evaluating global improvement after Essure® removal: rates of patient with "improvement", "no improvement" and "worsening situation".

Pain

Pelvic pain

3 studies assessed prevalence of pelvic pain resolution after removal of device without mentioning other Essure®-attributed symptoms. In a large case series including 4 274 women, Arjona[14] reported 7 patients requiring device removal for chronic pelvic pain. Pain disappeared in all cases after surgery and until 6 months follow-up. In 2016, Casey[15] reported resolution for 88,5% of explanted patients (23/26). In 2017, Casey[16] reported pain resolution for 78% of patients (32/41) at the post-operative visit.

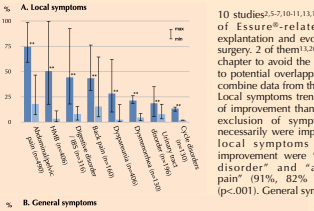
Pain score

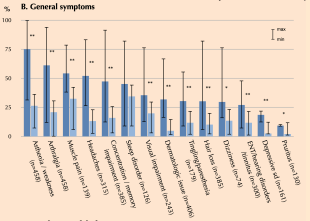
Pain was significantly improved after surgery regardless the scales used by authors (Table 2).

	Endpoint	Time after removal (month)	VAS before (/10)	VAS after (/10)
Chene[17] (n=80)	Global pain	1 - 3 - 6	3.6	1.4* - 0.8* - 1.5
Nolan[12] (n=19)	Global pain	1	8,5	0.75*
Catinon[3] (n=17)	Pelvic pain	3	4,9	1.9*

Table 2: Studies assessing pain score before and after removal. VAS: Visual Analogic Scale. * p<.05 compared to VAS before removal

Essure®-attributed-symptoms





10 studies[2,5-7,10-11,13,18-20] described prevalence of Essure®-related-symptoms before explantation and evolution a few weeks after surgery. 2 of them[13,20] were excluded from this chapter to avoid the risk of sampling bias due to potential overlapping populations. Figure 1 combine data from the 8 remaining studies. Local symptoms trended to have a better rate of improvement than general symptoms. After exclusion of symptoms like "HMB" that necessarily were improved by hysterectomies, local symptoms with better rate of improvement were "dyspareunia", "digestive disorder" and "abdominal or pelvic pain" (91%, 82% and 76%, respectively) (p<.001). General symptoms with better rate of improvement were "depressive syndrome», "dermatologic issue" and "pruritus" (87%, 85% and 77%, respectively) (p<.05).

Figure 1: Prevalence of Essure®-attributed-symptoms before and after removal of device combining data from 8 studies. * p<.05, ** p<.001

Quality of life

After Essure® removal, significant improvement ranged from 65% to 100% of patients depending on studies. Mean QoL scores were also improved (table 3).

	Used score	Time after removal	Rate of patient with improvement of QoL (%)	Mean QoL score: Before	Mean QoL score: After
Francini[18] (n=83)	SF-36	3 months	For PCS: 80 For MCS: 83 For PCS + MCS: 71		
Clark[11] (n=32)		1 month	75		
Brito[13] (n=11)		Until 4 years	82		
Cassidy[19] (n=86)	Score 0-5	Until 4 years	98	1.4 / 5	4.2 / 5
Chene[17] (n=80)	SF-12	1-3-6 months	58 - 65 - 65	MCS: 34 PCS: 36	49* - 53* - 50* 43* - 44* - 48*
Nolan[12] (n=19)	Score 0-7	1 month		5.9 / 7	1.5 / 7*

Table 3: Studies assessing evolution of QoL after Essure® removal for device-attributed-symptoms. * p<.05 vs «before» PCS: Physical Component Scale. MCS: Mental Component Scale.

Conclusion

Removal of Essure® in symptomatic patients may improve symptoms and quality of life. The pathophysiological mechanisms underlying Essure®-attributed-symptoms remains unclear, but could probably be related to release of metallic elements. Managing patients without any improvement of symptomatology remain a challenge. Furthermore, studies are heterogenous and often retrospective so a prospective study with long time follow-up is needed.

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