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Transcervical intrauterine radiofrequency ablation of fibroids in high-risk patients with bleeding disorder

Short title: TRFA in high-risk patients

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ABSTRACT

Objectives: To show the advantages of transcervical radiofrequency ablation (TRFA) in high-risk patients with bleeding disorder.

Material and methods: It is a retrospective analysis. The study included only patients with known pre-existing conditions (obesity, cardiac and neurological disease, coagulation disorder, anaemia) or post-surgical conditions who were treated with the Sonata® System for fibroid-related bleeding complaints at Academic Hospital Cologne Weyertal between January 2015 and March 2021. These patients were classified as high-risk patients. The fibroids were

mostly determined due transvaginal sonography. Thirty patients were included, and 43 fibroids were determined.

Results: Therapy with the Sonata® system could be performed without complications in all cases. In our analysis, improvement of fibroid-related symptoms was observed in 89% of cases.

Conclusions: The Sonata® System is on the one hand minimally invasive, uncomplicated and fast and on the other hand a successful method of fibroid therapy, which is particularly suitable for high-risk patients with various pre-existing conditions, for whom a minimally invasive, bloodless and short surgical procedure has great advantages.

Key words: Sonata; fibroid; ablation; high risk patients; bleeding disorder; uterus

INTRODUCTION

The estimated prevalence of uterine fibroids ranging from 4.5% to 68.6% [1]. The prevalence is age-dependent [2]. Figures in the literature vary widely, from 217 to 3745 cases per 100 000 women-years [1]. The prevalence in Germany is 48.6% in women aged 30–55 years, with the highest prevalence of 65.2% in the group with patients aged 46–50 years [2]. Fibroids cause different symptoms, and hypermenorrhoea is the main symptom with the prevalence of 40–54%. The next common symptoms are dysmenorrhea and lower abdominal pain [3, 4]. In 48% cases, fibroids are the cause of severe hypermenorrhoea with anaemia [5]. Even nowadays the most common therapy for symptomatic fibroids is a hysterectomy. The main indication for a hysterectomy is still fibroid [6–9].

The classification of fibroids is according to FIGO classification, which serves as basis [10]. The classification of fibroids is very important for prognosis and therapy recommendation. Therefore localization, size and number of fibroids should be well understood [2].

In the therapy, low effective medicament therapy, invasive and drastic therapy such as a removal of uterus are mostly used. To fill the gap between these methods, transcervical radiofrequency ablation (TRF) was developed. This method is safe and effective [11–14]. A meta-analysis of 32 studies with more than 1200 patients treated with TRF ablation showed a statistically significant and clinically relevant reduction in fibroid-related symptoms and improvement in quality of life, with low reintervention rates [11]. The benefit of TRF is that

it is minimally invasive without incision, and the treatment of a broad type of fibroids is possible, especially such fibroids, which cannot be treated with a surgical hysteroscopy (FIGO 3, 4, 5, 6, and 2-5) [8].

Transcervical radiofrequency ablation has FDA (U.S. Food and Drug Administration) approval for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. The system also has a CE mark ("Conformité Européenne" French for "European Conformity") in the European Union [14–16].

TFA is performed by a gynaecologist. The instrument has a small ultrasound probe which is to insert intrauterine [17]. Before the ablation the fibroid is determined sonographically. Usually, a general anaesthesia is required for TFA. The diameter of the device is 8.3 mm. The penetration depth is less than 12 cm. The fibroid is represented due graphical navigation. After graphical visualize of fibroid the ablation is carried out. In this phase a safety zone guaranteed no thermal injury in the surrounding organs (for example bladder, bowel). It is important especially for transmural fibroids that are also located near the bladder and bowels. The procedure allows for optimization of the ablated volume in the targeted fibroid. The puncture of serosa is not necessary. The measurements are registered graphically. The ablation time is 1–7 min depending on the fibroid size (the smallest size of fibroid is 2.0 × 1.3 cm). The temperature of the electrode is about 105^{o}C. A thermal coagulation necrosis is not caused by TFA. This method does not cause a postablation syndrome either. A good knowledge of vaginal ultrasonography and confidence in all other endoscopic fibroid therapy are required, because they can be used at the same time in combination with TRF as needed. Hospital stay time is 1–2 days [17, 18].

This technique could be of importance in the treatment of fibroids in high-risk patients (*e.g.*, obesity, cardiac disease, coagulopathy, multiple previous surgeries), as it offers the most minimally invasive and effective approach, with short surgical time. Therefore, this study was conducted to analyse the results of the Sonata® System in high-risk patients.

MATERIAL AND METHODS

Transcervical radiofrequency ablation has been performed in our department since 2011. The retrospective study included only patients with known pre-existing conditions (obesity, cardiac and neurological disease, coagulation disorder, anaemia) or post-surgical conditions who were treated with the Sonata® System for fibroid-related bleeding complaints

at Academic Hospital Cologne Weyertal between January 2015 and March 2021. These patients were classified as high-risk patients. Diagnosis was mostly performed by transvaginal sonography. Thirty patients were included, and 43 fibroids were determined.

Therapy with the Sonata® System was carried out complications free in all cases. During the operations, the device could be inserted without any difficulty. First, the ablation zone and the safety zone were adjusted and then the fibroid was fixed with the central spike (“introducer”). After checking the safety zone, the electrodes were inserted. After checking the safety zone again, the fibroids were ablated with a temperature of 105^{O}C. All patients without any complications.

RESULTS

The age of the patients ranged from 34 to 54 years. All patients had abnormal uterine bleeding mostly hypermenorrhoea and two patients still had the desire to become pregnant.

A total of 43 fibroids were detected in 30 patients. Nineteen patients had one fibroid, 10 patients had two fibroids, and one patient had four fibroids.

The fibroids were classified according to FIGO classification. Figure 2 shows the number of fibroids based on FIGO classification. The majority of fibroids were classified as of FIGO 2–5 fibroids 62.8% (27 fibroids) and the minority consisted of FIGO 4 fibroids 2.3% (one fibroid).

F-fibroid

For better visualization, the fibroids were divided into six groups depending on their size. Figure 3 shows this division.

Table 1 shows the risks/pre-existing conditions of the patients. Twenty-two patients had one and eight patients had two risk factors/pre-existing conditions.

Three patients had third-degree-obesity: with a BMI of 45 kg/m² in two patients and 56 kg/m² in one patient. Seven patients had a large transmural fibroid of ≥ 7 cm, one patient had two fibroids of 6 cm and all these patients had strongly desired an organ-preserving minimally invasive approach. Laparoscopic fibroid removal in this case would be associated with a high risk of bleeding and a laparotomy.

Intraoperative results

The shortest ablation time of a fibroid was 1 minute 13 seconds and the longest was 25 minutes 6 seconds. Table 2 shows the ablation time of a fibroid in relation to the number of fibroids.

The ablation time and the number of ablation steps vary depending on the fibroid size. As it can be seen in Table 3, both ablation time and ablation steps increase with fibroid size.

Postoperative results

Twenty-six patients came to follow-up (Fig. 4). Twenty-three of 26 patients reported subjective improvement in symptoms, with 21 patients reporting marked improvement and two patients reporting a mild improvement. Three patients had no improvement and in one of them a hysterectomy by laparotomy was performed during follow-up. In this case the respective uterus showed four FIGO 2–5 fibroids, three of which were approximately 5 cm. The patient had already undergone two surgeries by transverse laparotomy, so the hysterectomy was also performed by laparotomy in the presence of adhesions. Therefore, an improvement of the complaints was 89%.

Special cases

Two patients with severe hypermenorrhoea still had a desire to become pregnant, of which one patient had a current desire and one had a potential desire. In both cases, significant improvement of hypermenorrhoea was observed.

The patient with the current fertility desire had a FIGO 2–5 fibroid of 7 cm. Prior to presentation at our department, a laparoscopy was performed in another hospital. A hysterectomy was recommended to the patient, due to the size of the fibroid. In our department, the ablation of the fibroid was performed using the Sonata® System. Two ablation steps were performed, 7 minutes and 5 minutes 12 seconds. After 15 months, the patient had a vaginal delivery in our department without any complications.

The second patient with a potential desire to become pregnant had the condition after midline laparotomy with the removal of 1700 gr of fibroids. She had a FIGO 2 fibroid of 2.7 x 2 x 2 cm, which was ≥ 90% intramural. Transcervical radiofrequency ablation was performed with two ablation steps, 1 min 42 seconds and 2 minutes. Transvaginal ultrasound after three months showed a significant regression to 1.7 × 1.5 × 1.4 cm. Moreover, the position of the fibroid shifted from FIGO 2 to FIGO 4 with sufficient distance from the endometrium, which is highly relevant for fertility.

DISCUSSION

For the therapy of fibroids there are a wide spectrum of options, from medicament treatment to a removal of uterus [6–9, 11–14]. Several factors must be considered in the therapy of fibroid, as a FIGO type, size, number of fibroids, severity of symptoms, patient's life stage (fertile, peri- or postmenopausal), health risk factors, medical contraindications as well the patient's wishes.

In a study, almost a thousand women with symptomatic fibroids were asked about the therapy desire. Almost 80% of respondents did not want an invasive method and the half of respondents wanted avoid a hysterectomy [9]. In the therapy of fibroids is a need for less invasive organ-preserving therapy without incision, that is available for wide spectrums of fibroids [14–16]. For this reason, TRF was developed. This method is effective and safe [11–14]. According to the literature review as well as in our analysis, no specific intraoperative or postoperative complications were found.

In Luke's et al. [19] study, patient satisfaction with TRF was 94% (99/105) and 88% of patient had an improvement of symptoms. Toub reported an improvement in 90% of cases [14]. In our analysis, an improvement of fibroid-related symptoms was observed in 89% of cases.

The long-term results after TRF are available. The reintervention rate is 11.8% [20]. it is slightly higher than after an abdominal myomectomy (9%) and the same as with laparoscopic myomectomy (11%), but significantly lower compared to other methods (17% after uterine artery embolization, 21% after hysteroscopic fibroid resection) [21].

Bipolar operative hysteroscopy is most suitable for submucosal fibroids [2]. For large (> 3 cm), multiple (n > 3), and type-2 fibroids the hysteroscopy can be difficult. In this case there is a 20–50% chance for least one additional resection for complete treatment [2, 22, 23]. Hysteroscopy has a low intraoperative complication rate [24]. Postoperative complications in terms of intrauterine adhesions occur in 10% to 37.5% for the resection of one fibroid and up to 45% for multiple fibroids [2, 25].

Intramural and subserosal fibroids can be removed by laparoscopy and/or laparotomy. In a meta-analysis involving 576 patients, laparoscopic and abdominal removal of fibroids were compared. In the meta-analysis, the advantages of laparoscopy over laparotomy were shown, including faster postoperative recovery of patients, less blood loss

and less postoperative pain. Therefore, laparotomy should be performed only in certain cases [2, 26].

Intraoperative complications of laparoscopic fibroid removal arise from inadequate hysterotomy, enucleation, haemostasis, and morcellation. Postoperative complications include hematomas after a hysterotomy, uterine adhesions, abdominal adhesions, and parasitic fibroids [27–29]. In an analysis with the laparoscopic resection of 654 fibroids (average size 5.3 cm), intraoperative complications occurred in 2.6% cases and postoperative complications in 5.7% cases [27]. Another study of 2050 laparoscopic fibroid resections showed an overall complication rate of 11.1% (225/2050) [30]. The increase of complications with laparoscopic myoma enucleation is observed [27, 31]. One possible reason for this is the increasing number of gynaecologists with lack of experience in laparoscopic fibroid removal, laparoscopic suturing, as well as electromechanical morcellation [32].

The complication rate of laparoscopy increases in patients with additional risks. Driessen et al. [33] compared two groups of patients with and without risks. Among all, BMI, number of previous surgeries and uterus size were considered. A total of 2237 laparoscopic hysterectomies were analysed. The complication rate in the group with known risks was significantly higher (10.5% vs 4.8%), blood loss 167.6 mL vs 110.1 mL and operation time 114.3 minutes vs 95.3 minutes.

Especially in high-risk patients with fibroids, that more difficult to reach, the therapy should be chosen very carefully. Our study shows that fibroid therapy with the Sonata® System is suitable for FIGO 2 to 5, whereas FIGO 2 to 4 fibroids are rather difficult to reach for the other surgical option. This method can also be used to treat multiple fibroids in a single session. The method is particularly suitable for patients with anaemia, as there is hardly any bleeding with the Sonata® System compared to other surgical measures.

Therefore, the Sonata® System is on the one hand minimally invasive, uncomplicated and fast and on the other hand a successful method of fibroid therapy, which is particularly suitable for high-risk patients with various pre-existing conditions, for whom a minimally invasive, bloodless and short surgical procedure has great advantages.

Ethical approval

According to §15 of the professional code of the North Rhine Medical Association, neither advice nor an ethics vote is necessary for a retrospective study.

Conflict of interest

Elvin Piriyev has no conflict of interest. Ralf Bends, Sven Schiermeier and Thomas Römer are consultants for the Sonata System. The authors report no other conflicts of interest in this work.

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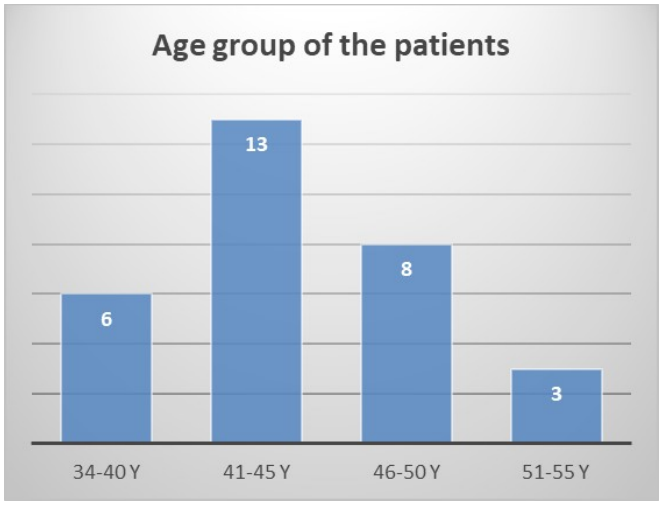
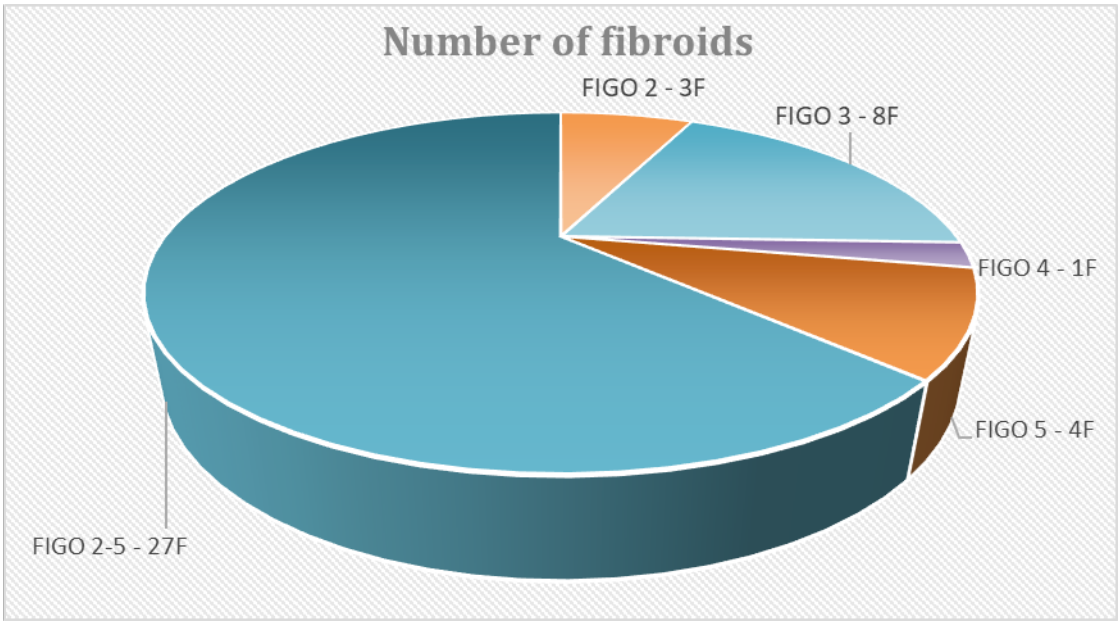


Figure 1. Overview of patients depending on age group



F — fibroid

Figure 2. Number of fibroids related to FIGO classification

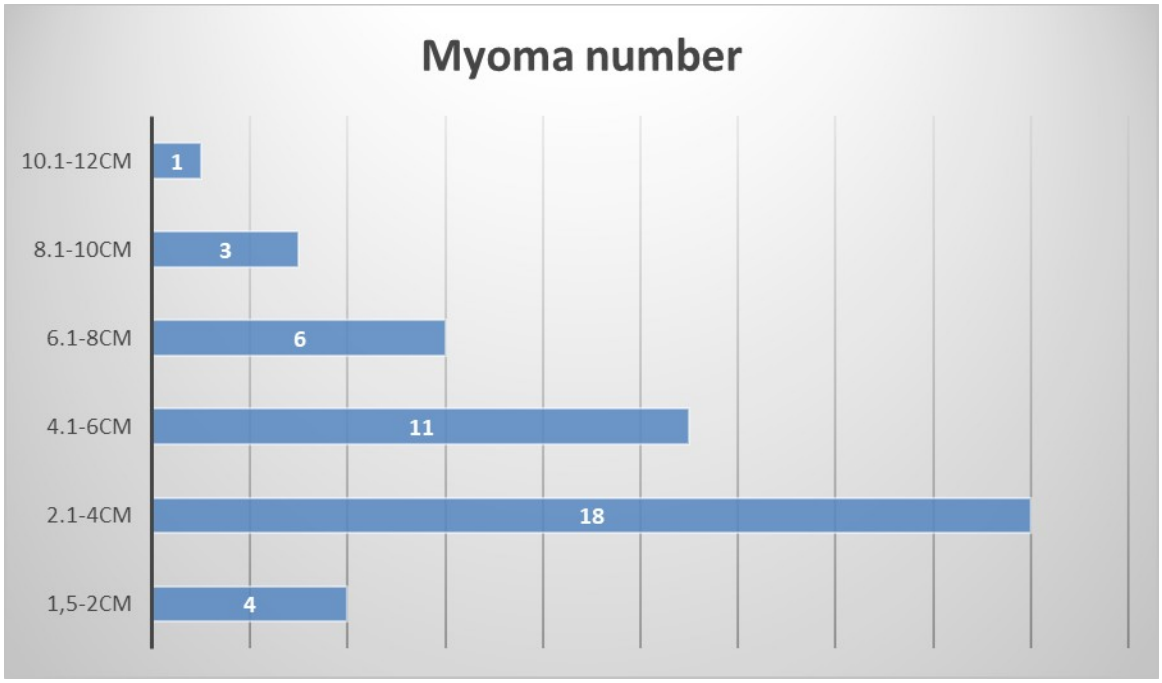


Figure 3. Myoma number related to myoma size

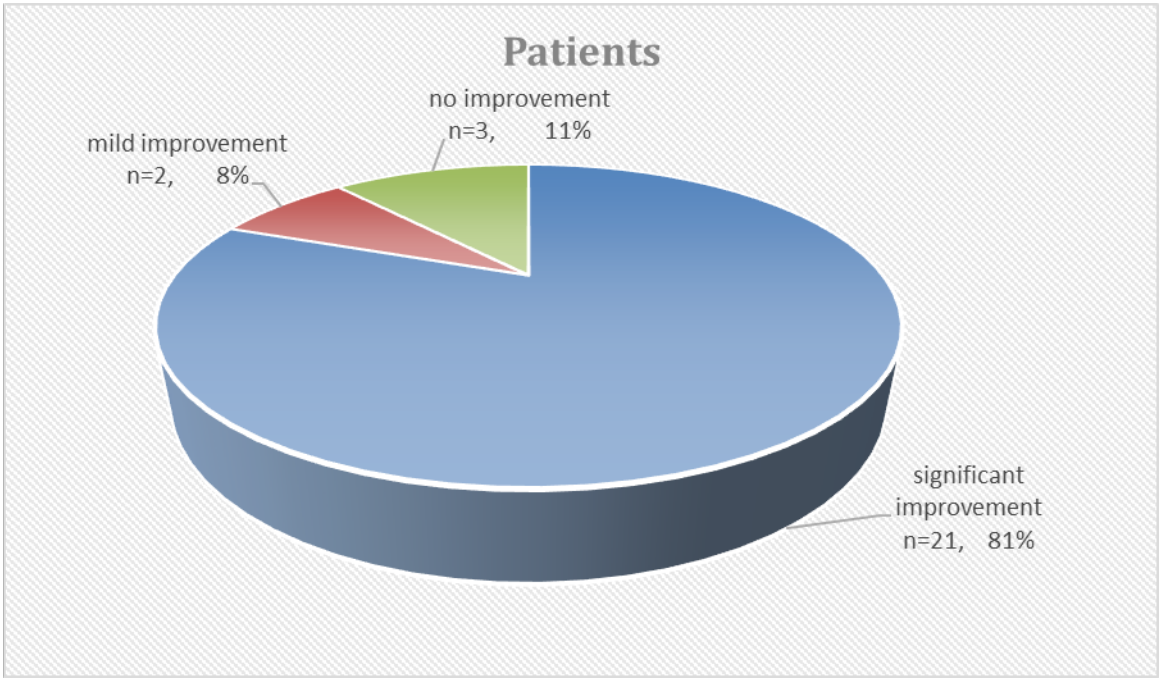


Figure 4. Postoperative results in the follow up group in percentages

Table 1. Overview of risks in relation to number of patients

Number of patients	Risk groups	Risk subgroup	Number of patients
4	Coagulation disorder	Thrombosis	2
		Immune thrombocytopenia	1
		AT III Deficiency	1
7	Obesity	BMI 30–35 kg/m² (I°)	1
		BMI 35–40 kg/m² (II°)	3
		BMI > 40 kg/m² (III°)	3
9	Previous operations	1 × midline laparotomy	4
		1 × LSK, 1 × midline laparotomy	1
		2 × midline laparotomy	2
		4 × midline laparotomy	1
		4 × LSK	1
6	Anaemia (Hb)	8–9 g/dL	1
		7–8 g/dL	3
		6–7 g/dL	2
2	Neurological diseases	Apoplexy cerebral vessel	1
		Brain pacemaker by strong depression	1
2	Cardiac diseases	Hypertension	1
		AVNRT	1
8	Large fibroid with a request for organ-preserving therapy	2 × 6 cm	1
		7–8 cm	4
		9–12 cm	3

AT III — antithrombin III; AVNRT — atrioventricular nodal reentrant tachycardia; BMI — body mass index; LSK — laparoscopy

Table 2. Ablation time in relation to the number of fibroids

Ablation time	**Number of fibroids**
1–5 minutes	26
> 5–10 minutes	8
> 10–15 minutes	3
> 15–20 minutes	4
> 20–25 minutes	2

Table 3. Ablation time and number of ablation steps in relation to fibroid size

Fibroid size [cm]	Fibroid number	Ablation step	Ablation time [min]
1.5–2 cm	4	1 step	1:13–2:06
> 2–4 cm	18	12 fibroids — 1 step	1:30–5:00
		6 fibroids — 2 steps	3:13–4:06*
> 4–6 cm	11	6 fibroids — 1 step	3:00–5:42
		4 fibroids — 2 steps	5:48–7:24*
		1 fibroid — 3 steps	10:06
> 6–8 cm	6	3 fibroids — 2 steps	6:00–12:12*
		3 fibroids — 3 steps	15:18–17:00*
> 8–10 cm	3	2 fibroids — 3 steps	13:32–18:50*
		1 fibroid — 4 steps	22:12*
>10–12 cm	1	4 steps	25:06*

*— Total time of all ablation steps