The LiNA Librata cordless balloon thermoablation device and bleeding disorders: a quality assurance programme

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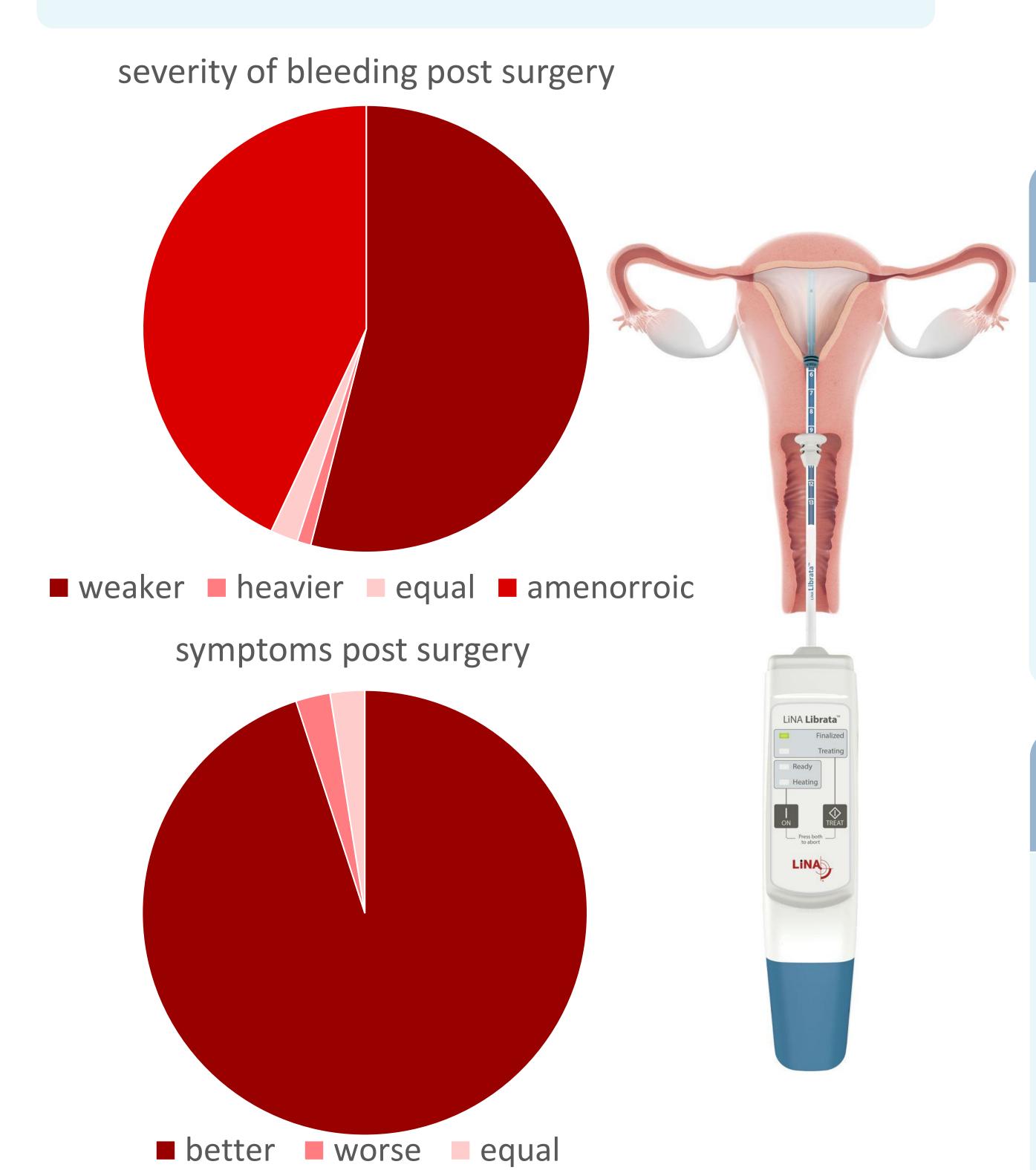


1 Objectives

Heavy and/or prolonged menstrual bleeding is a common reason for gynecologic surgery, which is now frequently performed as a minimally invasive, daycare procedure, mostly using thermoablation. Various devices are available for this procedure, with the relatively new LiNA Librata™ device offering a short treatment time of 2 minutes. Although widely used, scientific data on this device are comparably sparse. This investigation aims to provide real-world data on LiNA Librata™ from two Austrian gynecological departments to help better counsel patients.

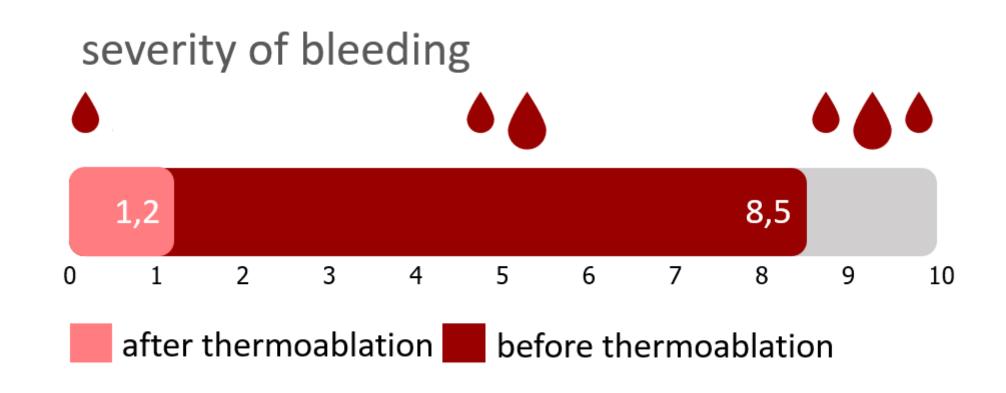
2 Methods

Data were collected from a quality assurance program of two gynecological departments. Patients were contacted by mail and asked to call their treating physician to participate in a structured telephone interview. The interview focused on the success of the procedure, patient satisfaction, and changes in menstrual bleeding before and after thermoablation.



3 Results

A total of 439 patients were contacted, and 175 (39.9%) responded. Three patients were excluded due to requiring hysterectomy for subsequent endometrial pathology. The average follow-up time was 2.5 years, with a mean patient age of 42.1 years and a mean Body Mass Index of 26.6. Patients experienced bothersome bleeding for an average of 89.4 months before treatment, with a pre-surgery severity of bleeding rating 8.5 on a 0-10 numeric rating scale. Myomas were diagnosed in 22% of patients, and 68% had dysmenorrhea. After surgery, 43% were amenorrheic, while 54% reported reduced bleeding, 1% reported increased bleeding and 2% reported equal bleeding. The mean posttreatment bleeding severity was 1.2. Overall, 95% of patients reported improvement, and patient satisfaction was high, with a rating of 9.3/10; 97% would recommend endometrial thermoablatio.



4 Conclusion

These retrospective data, collected via structured telephone interviews, may be subject to biases such as retrospective design and response rate. However, to our knowledge, this represents the first real-world data on the LiNA Librata™ device. The high levels of patient satisfaction, significant reduction in bleeding severity, and improvement in symptoms are comparable to those reported for other thermoablation devices.

5 Contact

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