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The effect of dynamic quadripolar radiofrequency on genitourinary atrophy and sexual satisfaction

A systematic review and meta-analysis

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Abstract

Background: Physiologic processes such as childbirth and menopause can alter vulvovaginal aesthetic appearance, reduce sexual satisfaction, and cause symptoms of vulvovaginal atrophy which affects a woman's quality of life. There is debate about whether dynamic quadripolar radiofrequency (DQRF) can be used to improve such conditions. We conducted a meta-analysis of studies among patients undergoing treatment with DQRF.

Methods: We conducted a literature search without language or article type restriction in PubMed, Cochrane library and Web of Science from inception to June 1, 2022. We included studies that reported outcomes of DQRF treatment. Article selection and data extraction in a predesigned data extraction form were conducted in duplicate. Individual studies reported outcomes in terms of the pre- and post-intervention repeated measures. Meta-analysis combined results across studies to produce effect sizes using random effects model with 95% confidence intervals (CI) taking into account sampling variance to adjust the estimated precision. PROSPERO: CRD42021227752.

Results: The search yielded 781 articles, from which 4 case series (127 participants) were included. Two studies reported a significant improvement in patient and medical evaluation assessments of vulvovaginal aesthetic appearance. Significant improvements were reported by three studies for patient assessed sexual satisfaction/discomfort, vaginal laxity and symptoms of genitourinary syndrome of menopause. Meta-analysis showed a trend towards improvement in aesthetic appearance (4 studies; 0.89; 95% CI –0.15 to 1.93; I^2 75.0%) and sexual satisfaction (2 studies; 0.62; 95% CI –0.03 to 1.27; I^2 0.0%).

Conclusion: Dynamic quaripolar radiofrequency is a potentially promising intervention to improve vaginal laxity, appearance and sexual satisfaction, as observed in four monocentric case series. Further studies with a control group, well-defined methods of patient selection and longer follow-up periods are necessary to reach a definitive conclusion.

Abbreviations: CI = confidence intervals, DQRF = dynamic quadripolar radiofrequency, GSM = genitourinary syndrome of menopause.

Keywords: DQRF, dynamic quadripolar radiofrequency, genitourinary syndrome of menopause, vaginal laxity, vulvovaginal atrophy

1. Introduction

Physiologic changes in a woman's life, such as childbirth may alter the laxity of the vaginal canal, damage the pelvic floor, and devitalize the mucosal tone of the vaginal wall.[1,2] Perimenopausal changes caused by estrogen deficiency may further alter vaginal tone and vulvovaginal appearance due to a decrease in the content of collagen and elastin in tissues, leading to thinning of the epithelium and disappearance of the superficial layer, leading to smooth muscle dysfunction and connective tissue degradation.[1,2] These events often lead to genitourinary symptoms including stress urinary incontinence, vaginal atrophy, dryness, pain, itching, dyspareunia and may cause distress affecting a woman's quality of life, self-confidence, and sexuality.[3]

Various treatment modalities are currently available to manage these indications including surgical procedures, hormone replacement therapy and radiofrequency treatment. Among these radiofrequency treatments are gaining importance due to their noninvasive nature. The radiofrequency device emits

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

Ethical review was not necessary for this study as there was no patient interaction required or identifiable patient data present.

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focused electromagnetic waves generating heat upon meeting tissue impedance. It generates temperatures between 40 °C and 45 °C which induces collagen production through fibroblasts via the activation of heat-shock proteins and initiation of the inflammatory cascade.[4] Among radiofrequency devices, the most novel is the dynamic quadripolar radiofrequency (DQRF) device. DQRF biophysics allow the operator to define the depth and volume of the target vulvar area and drastically reduce administered energy. It also allows electronic control of movements and temperature sensors in the radiofrequency device to allow rigid control of tissue temperature.[5]

To the best of our knowledge, currently no reviews exist that exclusively focus on summarizing evidence on the outcomes of DQRF. Reviews that examine noninvasive procedures for vulvar rejuvenation mix up different therapies making it difficult to decipher the unique effect of each treatment. We conducted a systematic review among patients undergoing treatment with DQRF for genitourinary atrophy and improvement in sexual satisfaction.

2. Materials and Methods

This systematic review was conducted after protocol registration in PROSPERO and reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. PROSPERO: CRD42021227752.[6]

2.1. Search and selection

Randomized controlled trials, cohort studies, case series and case reports that reported patient outcomes following DQRF for the treatment of pelvic floor dysfunction were included. Inclusion of a variety of study designs ensured that all the available evidence on the topic was included and reviewed. The comparison group consisted of no treatment, other types of radiofrequency treatment, surgery, medication, pelvic floor exercises. Articles without a comparison group were also included. No restrictions regarding year of publication or language of the article were applied. The exclusion criteria consisted of articles that only existed in registries as protocols only.

On June 1, 2022, the databases of PubMed, Web of Science, and Cochrane Library were systematically searched. The following keywords were used: "female", "girl', "woman", "vulvar", "vaginal', "vulvovaginal", "genitourinary", "genital", "genitourinary syndrome of menopause", "Genitourinary syndrome of menopause (GSM)", "atrophy", "laxity", "dryness", "dysuria", "incontinence", "sexual activity", "sexual function", "sexual satisfaction", "altered sensation", "aesthetic improvement", "pelvic floor dysfunction", "pelvic organ prolapse", "low-energy DQRF", "DQRF", "radiofrequency", "energy-based", "thermal energy", "low-energy" and "multipolar radiofrequency" (Table S1, Supplemental Digital Content, http://links.lww.com/MD/H514). Duplicate citations were removed electronically from the records retrieved from the databases. References of the included studies were checked to find possible relevant articles and a citation search was also performed. Titles and abstracts of the articles were reviewed independently by two reviewers (WR and MHE) and the full texts of the articles that either reviewer found relevant were acquired with the input of a library consultant. Full texts were then assessed independently by two reviewers (WR and MHE) for relevancy and disagreements were settled by discussion with the third author (KSK).

2.2. Data extraction and study quality assessment

Data was extracted independently by two reviewers. Any disagreements were resolved by discussion between the two reviewers. Data on the following variables were extracted: study population (number, age, indication for treatment), details of the procedure, study design, funding sources, conflict of interest and outcomes (data extraction forms available from authors on request). Primary outcomes consisted of improvement in sexual satisfaction, vulvovaginal aesthetic appearance and symptoms of vulvovaginal atrophy. These outcomes were defined and measured according to published tools.

The methodological quality of the case series was evaluated using the tool for evaluating the methodological quality of case series and case reports.[7] It consists of eight items, categorized into four domains: selection, ascertainment, causality and reporting. Five items pertinent to this review were selected by the authors. Each item was given 1 point and measured as "Yes" (low risk of bias) or "No" (high risk of bias). The total score was then calculated by adding the score allotted to each item. Disagreements between the two reviewers (WR and MHE) in judgement of the quality of the study were settled by discussion with the third author (KSK). The conflict of interest and source of funding reported by all the studies included was also recorded.

2.3. Data synthesis

Mean and standard deviation of the outcomes reported in the included studies was summarized in a table and the significance of the differences was recorded. Individual studies reported outcomes in terms of the pre- and post-intervention repeated measures. Meta-analysis combined results across studies that had similar outcomes measured at the same follow-up visit after baseline using random effects model to produce effect sizes (standardized mean difference from baseline) with 95% confidence intervals (CI) taking into account sampling variance to adjust the estimated precision considering moderate correlation (pre-post $R = 0.5$).[8] A sensitivity analysis was carried to perform meta-analysis with adjustment for low correlation (pre-post $R = 0.1$). Heterogeneity was examined in a forest plot visually and estimated using I^2 statistic to capture the variations of results beyond chance.

3. Results

3.1. Study selection

A total of 781 articles were identified from literature databases and through reference and citation searches. After exclusion of duplicates, there were 672 remaining, which were assessed for relevance by reviewing the title and abstract. Thirty-eight articles were found relevant and were in English and German. After the exclusion criteria were applied, a total of 4 articles were included in the final systematic review[5,9–11] (Fig. 1).

3.2. Study characteristics

A total of 127 subjects were undergoing treatment with DQRF in the four included case series.[5,9–11] There were no cohort studies. The patients were undergoing treatment for vaginal laxity and vulvovaginal atrophy/GSM with symptoms consisting of sexual dissatisfaction, discomfort, low self-esteem. The DQRF was used with a setting of 55 W and 42 °C in all studies with varying duration of the session ranging from 5 to 20 minutes. The mean follow-up time was 6.5 months. (Table 1) Mean age of the patients ranged from 34 to 61.1 years. BMI and menopause status of the women was reported by three studies. BMI ranged from 23.1 to 24.5 kg/m^2 and two studies included an arm of women with menopause. (Table S2, Supplemental Digital Content, http://links.lww.com/MD/H515)

3.3. Risk of bias within studies

The case series received a score of 5 to 4 according to the tool for evaluating the methodological quality of case series and case

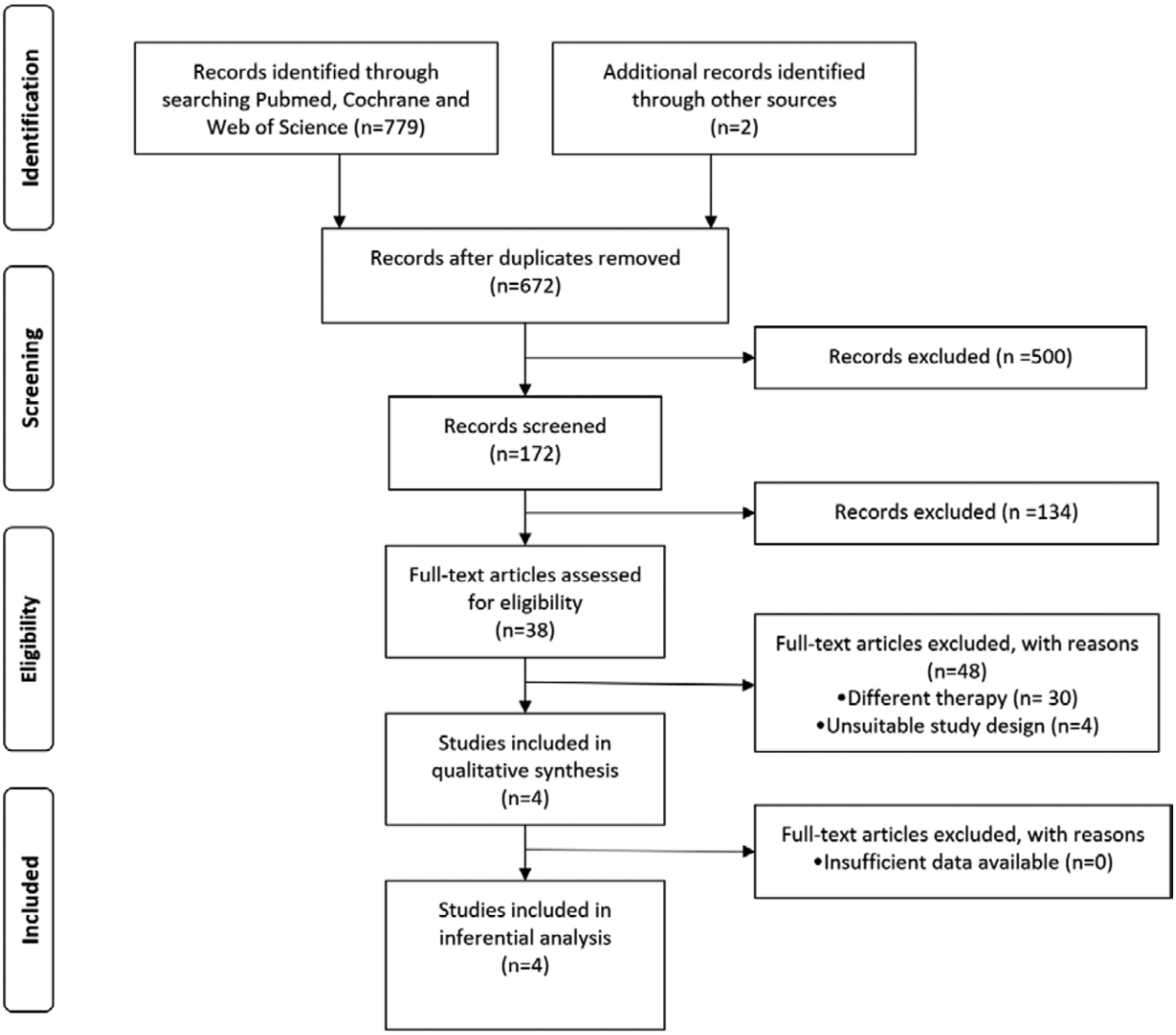

Figure 1. Flow chart for selection of studies for the meta-analysis.

reports, indicating good quality. There were some concerns present, however, in the domain of selection as three studies did not outline the technique for selecting the population included[5,10,11] (Table 2).

One study reported that no funding had not been received and declared no conflict of interest.[10] One study confirmed that no conflict of interest was present but did not report funding sources.[5] One study declared a conflict of interest.[9] Finally, one study did not report sources of funding or conflict of interest.[11]

3.4. Vulvovaginal aesthetic appearance

Vulvovaginal aesthetic appearance was reported in two studies.[9,10] It was assessed by the patient as well as by a medical evaluator/author who was blinded to the demographic details of the patient using tools such as the visual analogue scale and the global aesthetic improvement scale. A significant improvement was reported in the patient's and evaluator's assessment of vulvar aesthetics in both studies. Fasola et al reported a significant improvement after the first session and at the follow-up visit.[10] Beninca et al reported a significant improvement in patient's assessment of vulvar aesthetic appearance after the first session, the third session and subsequent follow-up visits.[9] The medical evaluator assessed appearance before the final session and at the 3-month follow-up visit and reported significant improvement. (Table 3) Meta-analysis showed a trend towards improvement in aesthetic appearance (4 studies; 0.89; 95% CI –0.15 to 1.93; I^2 75.0%) (Fig. 2). The sensitivity analysis showed that at the lower level of correlation, the meta-analytic summary was consistent (0.69; 95% CI –0.11 to 1.49).

3.5. Sexual satisfaction

Sexual satisfaction and patient discomfort were reported in three studies.[5,9,11] Patient reported outcomes including the visual analogue scale, vaginal laxity questionnaire, sexual satisfaction questionnaire and the pelvic organ prolapse/urinary incontinence sexual questionnaire were used for assessment (Table 3). A significant improvement was reported by Fasola et al the first session and at the follow-up session[10] while Beninca et al reported a significant improvement after the first session, the third session and subsequent follow-up visits (Table 3).[9] Meta-analysis showed a trend towards improvement in sexual satisfaction (2 studies; 0.62; 95% CI –0.03 to 1.27; I^2 0.0%) (Fig. 3). The sensitivity analysis showed that at the lower level

Table 1

Characteristics of studies included in systematic review on the effect of DQRF on genitourinary atrophy and sexual satisfaction.

			DQRF treatment details						Sample size; loss to FU		
Study details	Study type	Disease	No. of sessions	Duration (min)	Interval* (d ± SD)	Setting (Mhz)	Temp. (°C)	Power (W)	Group A	Group B	FU time (mo)
Benincà et al[9]	Case series	labia minor laxity, vulvar/ vestibular dryness	4	10	14 ± 1	1	42	55	25; 3	NA	5
Fasola et al[10]	Case series	Stage I/II vulvar hypotrophy†	3	10	7-10	1	42	55	20; 0	NA	2
Vicariotto et al[5]	Case series	Group A: vaginal laxity Group B: VVA/GSM‡	Group A: 5 Group B: 4	Group A: 20 Group B: 10	Group A:14 ± 1 Group B:10 ± 1	1	42	55	12; 1	13; 1	Group A: 4 Group B: 3
Vicariotto et al[11]	Case series	Group A: vaginal laxity Group B: VVA/GSM‡	4–6	15–20	14 ± 1	1	42	55	25; 2	32; 0	12

DQRF = dynamic quadripolar radiofrequency, FU = follow up, GSM = genitourinary syndrome of menopause, No. = number, Mhz = MegaHertz, min = minute, SD = Standard Deviation, temp. = temperature, W = Watt.

*Interval between sessions.

†Classification of vulvar hypotrophy: Stage 1 (mild) hypotrophy consists of symmetrical distribution of adipose tissue, none to mild cutaneous hypotrophy, usually asymptomatic or any follow weight loss; Stage II (moderate) hypotrophy consists of asymmetrical distribution of adipose tissue, moderate cutaneous laxity, dryness, dyspareunia and soreness.

‡Vaginal dryness, Vaginal itching, Vaginal burning, Dyspareunia, Dysuria/incontinence.

Table 2

Quality assessment of studies included in review on the effect of dynamic quadripolar radiofrequency on genitourinary atrophy and sexual satisfaction.

	Study	Beninca et al[9]	Fasola et al[10]	Vicariotto et al[5]	Vicariotto et al[11]
	Selection				
1.	Representative population	1	0	0	0
	Ascertainment				
2.	Exposure ascertainment	1	1	1	1
3.	Outcome ascertainment	1	1	1	1
	Causality				
4.	Alternative causes	NA	NA	NA	NA
5.	Challenge/re-challenge	NA	NA	NA	NA
6.	Dose-response effect	NA	NA	NA	NA
7.	Length of follow-up	1	1	1	1
	Reporting				
8.	Replication	1	1	1	1
	Total score	5	4	4	4

NA: not applicable.

Selection: 1. Does the patient(s) represent(s) the whole experience of the investigator (center) or is the selection method unclear to the extent that other patients with similar presentation may not have been reported?

Ascertainment: 2. Was the exposure adequately ascertained? 3. Was the outcome adequately ascertained?

Causality: 4. Were other alternative causes that may explain the observation ruled out? 5. Was there a challenge/re-challenge phenomenon? 6. Was there a dose-response effect? 7. Was follow-up long enough for outcomes to occur?

Reporting: 8. Is the case(s) described with sufficient details to allow other investigators to replicate the research or to allow practitioners make inferences related to their own practice?

of correlation, the meta-analytic summary was consistent (0.48; 95% CI –0.17 to 1.14).

3.6. Severity of vulvovaginal atrophy

Severity of vulvovaginal atrophy/genitourinary syndrome of menopause was reported in two studies.[5,11] It was further categorized into vaginal dryness, vaginal itching, vaginal burning, dyspareunia and dysuria and assessed at 1 month[5] and at 12 months.[11] The studies reported a significant improvement in all parameters at all follow-up visits. (Table 3)

4. Discussion

Our review showed that treatment with DQRF significantly improves vulvovaginal aesthetic appearance, sexual satisfaction, and symptoms of vulvovaginal atrophy. This is the first systematic review and meta-analysis focused exclusively on summarizing evidence on the novel, DQRF. Summarizing evidence on the effectiveness of DQRF helps to provide guidance on the adequate radiofrequency device to be selected for a patient and to determine the direction of further research for the assessment of the effectiveness of treatment with DQRF.

We conducted the systematic review using a prospective protocol, an exhaustive search and study quality assessment, limiting risk of bias in the evidence synthesis. Our review captured the conflict-of-interest thoroughly, even when it was not mentioned in the individual studies. It was seen that the studies included in the review were conducted by individuals who are members of Novavision Group, manufacturer of the DQRF technology. This is a possible cause of bias that should be considered when interpreting the significant improvements in the outcomes, particularly because the studies were too few to formally assess the effect of missing studies in funnel plot analysis. The criteria for selection of patients in the included studies excluded patients who were in late stages of their respective disease considering only stage I and II of

Table 3

Outcomes measured in studies included on review on the effect of dynamic quadripolar radiofrequency on genitourinary atrophy and sexual satisfaction.

Study details and time point	Outcome					Outcome					Outcome		
	Outcome/ Outcome tool	Score ± SD			*P* value*	Outcome/Outcome tool	Score ± SD			*P* value*	Outcome/Outcome tool	Score ± SD	*P* value*
Beninca et al[8]													
	Discomfort† (pt. assessed)/	NS	PS	FS HS		Vulvar aesthetic imp. (pt. assessed)/VAS-NS, PS, FS, HS	NS	PS	FS HS		Vulvar aesthetics (evaluator assessed)/VAS	4 ± 4	
Baseline	VAS-NS, PS, FS, HS	14	11	0 0			16	9	0 0				
Bef. 2nd session		4	9	11 1	<.05		5	9	8 3	<.05			
Bef. 3rd session		0	1	15 9			0	2	8 15				
Bef. 4th session		0	0	8 17	<.01		0	1	8 16	<.01		7 ± 8	<.05
3-mo FU		0	1	5 16	<.01		0	0	7 15	<.01		7 ± 6	<.05
Fasola et al[9]													
Baseline	Vulvar aesthetic imp./GAIS score (pt. assessed)	4.7 ± 1.15				Vulvar aesthetic imp./GAIS score (evaluator assessed)	5.2 ± 1.27						
Bef. 2nd session		6.8 ± 0.94			.05		6.8 ± 0.94			.05			
1-mo FU		8.6 ± 0.79			.01		8.1 ± 0.79			.01			
Vicariotto et al[5]													
Baseline	Vaginal introital laxity (Group A)/VLQ	2 ± 3				Overall sexual satisfaction (Group A)/VAS	4 ± 3				VVA and GSM severity Group B)/VAS‡	34 ± 5	
Bef. 5th session		4 ± 6			<.05		7 ± 0			<.05		38 ± 5	<.05
1-mo FU		4 ± 8			<.05		6 ± 9			<.05		40 ± 0	<.05
2-mo FU		5 ± 0			<.05		7 ± 7			<.05		40 ± 5	<.05
	Severity of VVA and GSM (Group B)/VAS: VD, VI	VD		VI		Severity of VVA and GSM (Group B)/VAS: VB, DP	VB		DP		Severity of VVA and GSM (Group B)/VAS: DU	DU	
Baseline		8.8 ± 2.4		7.5 ± 2.7			7.2 ± 2.5		8.7 ± 2.2			5.5 ± 2.6	
Bef. 5th session		4.3 ± 1.8		3.7 ± 1.9	<.01		3.4 ± 1.8		4.5 ± 1.9	<.01		3.0 ± 1.9	<.01
1-mo FU		3.4 ± 1.7		3.0 ± 1.6	<.01		3.0 ± 1.7		3.0 ± 1.8	<.01		2.9 ± 1.6	<.01
2-mo FU		3.2 ± 1.9		2.6 ± 1.3	<.01		2.8 ± 1.4		3.1 ± 1.9	<.01		2.6 ± 1.5	<.01
Vicariotto et al[10]													
Baseline	Vaginal introital laxity (Group A)/VLQ	2 ± 2				Sexual satisfaction (Group A)/ SSQ	2 ± 2				Pelvic organ prolapse (Group A)/ PISQ-12	34 ± 3	
post last session		4 ± 6			<.05		3 ± 7			<.05		38 ± 4	<.05
1-mo FU		4 ± 9			<.05		4 ± 3			<.05		39 ± 5	<.05
2-mo FU		5 ± 0			<.05		4 ± 3			<.05		40 ± 7	<.01
6-mo FU		5 ± 3			n.s.		4 ± 1			<.05		41 ± 0	<.01
9-mo FU		4 ± 9			n.s.		3 ± 6			<.05		43 ± 3	<.01
12-mo FU		4 ± 8			n.s.		3 ± 5			<.05		40 ± 8	<.01
Vicariotto et al[10]							Outcome						
							VD		VI	VB	DP	DU	
Baseline	Overall sexual function (Group B)/VAS	4 ± 2				Severity of VVA and GSM (Group B)/VAS: VD, VI, VB, DP, DU	8.9 ± 2.4		7.6 ± 2.8	7.2 ± 2.5	8.8 ± 2.2	5.9 ± 2.5	
post last session		7 ± 1			<.05		4.3 ± 1.9		3.8 ± 1.8	3.5 ± 1.8	4.4 ± 1.7	2.9 ± 1.9	<.05
1-mo FU		7 ± 0			<.05		3.4 ± 1.7		3.0 ± 1.7	3.0 ± 1.8	2.9 ± 1.8	2.8 ± 1.5	<.05
2-mo FU		7 ± 6			<.05		3.2 ± 1.6		2.6 ± 1.8	2.9 ± 1.6	2.8 ± 1.8	2.7 ± 1.6	<.05
6-mo FU		7 ± 8			<.05		3.0 ± 1.5		2.4 ± 1.6	2.6 ± 1.7	2.4 ± 1.5	2.5 ± 1.8	<.05
9-mo FU		8 ± 0			<.05		3.1 ± 1.1		2.3 ± 1.3	2.5 ± 1.2	2.4 ± 1.3	2.4 ± 1.4	<.05
12-mo FU		7 ± 8			<.05		3.1 ± 1.3		2.3 ± 1.2	2.6 ± 1.1	2.3 ± 1.2	2.5 ± 1.3	<.05

Bef.= before, DP = Dyspareunia, DU = Dysuria, FS = fairly satisfied, FU = follow-up, GAIS = Global Aesthetic Improvement Scale, HS = highly satisfied, NS = not satisfied, PISQ-12 = Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, short form, PS = poorly satisfied, SSQ = Sexual Satisfaction Questionnaire, VAS = Visual Analogue Scale, VB = Vaginal burning, VD = Vaginal dryness, VI = Vaginal itching, VLQ = Vaginal Laxity Questionnaire (Short form of Pelvic organ prolapse/Urinary incontinence Sexual Questionnaire), VVA and GSM = vuvlvo-vaginal atrophy/genitourinary syndrome of menopause.

**P* value compared to baseline.

†Discomfort in everyday life, loss of self-esteem, problems with sexual life and couple relationship and other difficulties.

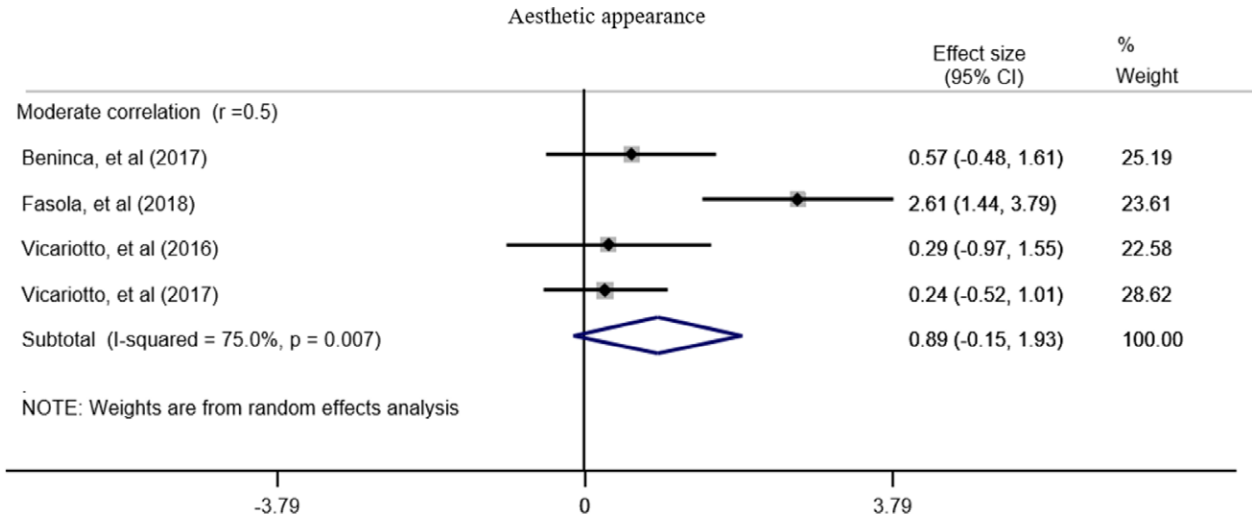

Figure 2. Effect size meta-analysis on the effect of DQRF on aesthetic appearance. DQRF = dynamic quadripolar radiofrequency.

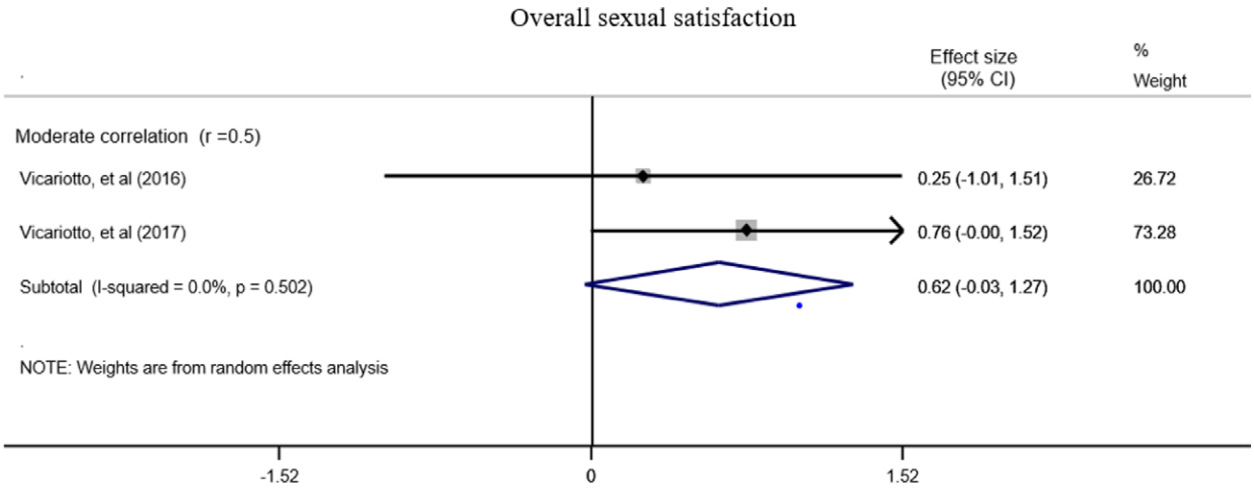

Figure 3. Effect size meta-analysis on the effect of DQRF on sexual satisfaction. DQRF = dynamic quadripolar radiofrequency.

vulvovaginal hypotrophy. Doing so limits the generalizability of the findings for a wider population which may have advanced stages of hypotrophy. There was heterogeneity in the meta-analysis of aesthetic appearance, but studies were too few to reliably explore causes of variation of findings between studies. Finally, the studies included did not contain a control group to assess confounding factors and three studies did not mention the method of selection of patients.[5,10,11] It is necessary in the future to have a control group to robustly assess the effect of DQRF treatment. In the meantime, our meta-analytic method for combining results across studies of repeated measures design, with all effect sizes transformed into a common metric and adjusted for sampling variance to reflect the precision, provides the most reliable current evidence.[8]

Recently, light and radiofrequency-based therapies have been gaining popularity due to their noninvasive nature, less down-time and easier logistics when compared to surgical procedures.[12] Patient interest in the such procedures is also increasing as it is becoming common to undergo cosmetic procedures for the improvement of vulvovaginal aesthetic appearance, as evidenced by the recent increase in labiaplasty procedures.[9,13] Patients are also overcoming social inhibitions and seeking treatment for genitourinary conditions like vaginal laxity or GSM.[14] Within radiofrequency treatments, DQRF is a novel therapy that allows the operator to convey energy with high tridimensional precision to the subepithelial layers of the vulva using four steel dynamic electrodes that electronically cycle between the receiver and transmitter states and create repelling electric fields. It also removes the necessity for the grounding pad on the upper thigh and heavy energy burdens because of Ohm's resistances in tissues.[5] Our review gives insight into outcomes of DQRF therapy based on contemporary literature.

5. Conclusion

Dynamic quaripolar radiofrequency is a potentially promising intervention for improvement in vaginal laxity, appearance, and sexual satisfaction, as observed in four monocentric case series of small patient cohorts and low level of evidence. Further studies with a control group, well-defined methods of patient selection and longer follow-up periods are necessary to reach a conclusion regarding the effect of DQRF on women's health.

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