Does vaginal erbium laser affect subsequent vaginal deliveries?

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ABSTRACT

Vaginal erbium laser (VEL) treatments with the SMOOTH™ technology are becoming a popular minimally invasive solution for treating various conditions connected to pelvic floor dysfunction. There have thus far been no published data, however, on the impact of these treatments on subsequent (post-laser treatment) vaginal deliveries. A patient survey for patients who gave birth after laser treatment was designed to take into consideration several other factors that could potentially impact vaginal delivery, e.g. infant weight, pregnancy complications, mother's BMI, etc. The questionnaire was distributed to patients from three international centers – 37 patients responded to the survey. The results showed no impact of vaginal VEL SMOOTH™ treatments on subsequent deliveries.

The results indicate that vaginal erbium laser with SMOOTH™ technology is a safe option for treating pre-menopausal women between deliveries.

KEYWORDS

Vaginal erbium laser, post-laser vaginal delivery, patient survey.

Introduction

Vaginal erbium laser (VEL) with SMOOTH™ technology has emerged in the last decade as a promising treatment for the functional improvement of various pelvic floor disorders in women. The unique SMOOTH™ mode thermal technology utilizes bursts of short, non-ablative pulses delivered by an erbium:YAG laser, which has a wavelength of 2940 nm. As this wavelength is highly absorbed on the tissue surface, the laser pulses result in thermal pulsing and heating of the upper mucosal layers. Vaginal erbium SMOOTH™ laser applications affect the tissue surface through a dual-tissue regeneration mechanism – short heat pulses trigger regenerative signaling pathways, while the slow build-up of heat induces collagen remodeling and stimulates fibroblasts to produce new collagen [1,2]. The result is a thicker epithelium with improved vascularization and improved tissue architecture. An important component of these treatments is the remodeling of existing collagen fibers and the stimulation of new collagen synthesis through fibroblast activation, resulting in a firmer and thicker vaginal wall [2]. Several published clinical studies have shown the effectiveness and safety of VEL in the treatment of stress urinary incontinence (SUI), genitourinary syndrome of menopause (GSM), pelvic organ prolapse (POP), and vaginal laxity [3–7]. All of these studies have reported only mild, transient and rare side effects.

VEL SMOOTH™ treatments constitute a novel, non-surgical approach to the treatment of pelvic floor disorders. They are especially suitable for women who would like to lead an active lifestyle throughout their middle-age years and after the onset of menopause, and who would also like to prevent or maximally delay surgical management of their pelvic floor disorders. Younger, premenopausal women mostly seek treatments for vaginal tightening (IntimaLase®) and urinary incontinence (IncontiLase®).

Article history

Received: 16 Mar 2020 - Accepted: 11 Jun 2020

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One of the main factors in pelvic floor dysfunction is laxity in the vagina and its supporting ligaments due to increasing age and vaginal childbirth. The prevalence of vaginal laxity has started to be systematically addressed only recently, with two studies [8,9] finding that 28% to 40% of surveyed women (patients in urogynecological clinics) suffered from vaginal laxity that negatively affected their quality of life. In one published study that examined data from 337 women [8], vaginal laxity was present in 28% of patients, who assigned an average bother score of 5.7 on a 0-10 VAS scale. The researchers also found a strong concurrence of vaginal laxity with early pelvic prolapse stages, and proposed that vaginal laxity may be a first stage in the development of POP [8].

Stress urinary incontinence following vaginal delivery is also very common, affecting approximately a third of women following vaginal childbirth [10]. It can be detrimental to quality of life, since it can prevent normal activities that typically form part of a healthy young woman's lifestyle.

As surgical management of pelvic floor disorders is often not advised in young women planning to have more children, non-invasive laser procedures, such as the vaginal non-ablative erbium SMOOTH™ laser, are becoming increasingly pop-

ular to treat these conditions. As the treatments have proven beneficial also in these younger, pre-menopausal women with post-partum incontinence or vaginal laxity, the question arises as to whether the VEL SMOOTH™ treatments could render possible subsequent vaginal deliveries more difficult.

The aim of the present retrospective survey was to investigate whether VEL laser treatment can adversely influence subsequent (i.e. post-laser treatment) vaginal deliveries. This question is very important since data on this topic are currently lacking.

Methods

The questionnaire contained 14 questions directed at patients. The questions are divided into four categories – questions about the laser procedure that was received, questions about the pregnancy, questions about the vaginal delivery, and questions about the recovery period.

Data collection took place between April and July 2019.

Three principal investigators participated in the survey, from centers in Argentina, Ukraine and Venezuela.

The questionnaire was sent to all pre-menopausal laser patients from the three centers who have had vaginal deliveries following laser treatment. The questionnaires received were anonymized and entered into an electronic datasheet (Microsoft Excel). Prism statistical software (GraphPad, USA) was used for all statistical analyses of the anonymized data (descriptive statistics and comparative statistics).

Results

In total, 37 patients responded to the survey – 23 from Argentina, 8 from Ukraine and 6 from Venezuela.

The first question asked what kind of VEL treatment the patients had received and how many sessions of the treatment had been performed. Of the 37 patients, 23 (62.2%) received IntimaLase® treatment for laser vaginal tightening, while 14 (37.8%) received IncontiLase® treatment for SUI. The patients received 2.4 treatments on average; the average number of IncontiLase® treatments received was a little higher (2.6 treatments) than the average number of IntimaLase® treatments (2.3 treatments), although the difference was not significant. None of the patients reported complications after laser treatment (Question 2, N=35, 2 patients did not answer).

The average time from the laser treatment to delivery (Question 3) was 1.6 years (CI 1.2-2). None of the patients reported complications during pregnancy (Question 4, N=36, 1 patient did not answer).

Question 5 asked about the mother's BMI at the time of post-VEL delivery. The majority of the patients (N=30) had a normal BMI at the time of delivery (Question 5); 6 were overweight and 1 patient was underweight.

Of the patients who reported previous pregnancies (N=34), 26 (76.5%) did not considerably gain weight (more than 20% of body weight) between their last two pregnancies, while 7 (20.6%) gained considerable weight (Question7). The average number of previous deliveries (Question 6) was 1.29, ranging from 0 to 3 (CI 1-1.6).

When asked to compare the difficulty of the post-VEL delivery to the previous one, patients who had had previous deliveries (N=34) answered that the latest one was the same as or similar (N=18, 52.9%), or easier with less trauma (N=17, 50%). One patient marked two answers – same/similar and easier with less trauma. None of the patients judged their post-VEL delivery to have been more difficult (Question 8).

Only one patient reported complications during delivery (N=1), but did not elaborate on what kind of complications were experienced. 36 patients did not report complications during delivery (Question 9).

Of the 37 patients, 20 had a tear or episiotomy, while 17 did not (Question 10). Just one patient specified that she had only had a tear.

The child's birthweight was average in 28 patients (75.7%), lower than average in 4 patients (10.8%), and higher than average in 4 patients (10.8%) (Question 11).

At the time of the survey, an average of 2.15 (CI 1.7-2.6) years had elapsed since the post-VEL delivery (Question 12). It took the patients 1.33 months on average (CI 1.1-1.6) to return to their normal physical activities (Question 13).

The last question asked the patients to compare the post-VEL experience with previous deliveries. Only one patient described her post-VEL delivery as longer, while none of the patients described their post-VEL delivery as more difficult or more complicated than previous deliveries.

The results for all surveyed patients are shown in Table 1.

Discussion

To date there are no published data on how laser treatment may affect possible vaginal delivery post laser treatment. This is not surprising, since even for commonly performed sling insertion surgical procedures, data on their impact on subsequent deliveries are scarce. Pollard and colleagues [11] performed a thorough literature review, which identified data on 117 patients and suggested that surgical procedures do not pose a great risk for complications, except for a small risk of urinary retention during the subsequent pregnancy.

Since VEL treatments have been introduced only in the past decade, long-term published data on their safety and effectiveness 10 years or more after treatment are still unavailable. Gambacciani and colleagues [4], in a study that followed up patients two years after repeated VEL SMOOTH™ treatments, showed that adverse events were very mild and transient. Moreover, in the absence of maintenance treatments, the symptoms of GSM returned between 18 and 24 months after the initial treatments. This indicates a reversibility of the effects achieved with VEL treatment, unlike with SUI surgery, which is irreversible. Histological image analysis of pre- and post-treatment tissues [2,7] has shown the absence of fibrosis and scarring, and improved tissue quality. The vaginal epithelium was shown to be thicker by 64.5%, with improved tissue architecture: increased glycogen load, new vessel formation, and more active fibroblasts with signs of new collagen and elastin fiber synthesis. As the erbium

Table 1 Results of the patient survey. The table shows the survey questions on the left and answers from each separate center, as well as total for the population on the right. * - denotes questions where certain patients marked more than one possible answer. Numbers are expressed as the number of patients choosing a certain proposed answer (N), or as a mean ± standard deviation if the question required a numerical answer.

		CENTER 1 (ARGENTINA N=23)	CENTER 2 (UKRAINE N=8)	CENTER 3 (VENEZUELA N=6)	TOTAL N (%)/ MEAN±SD
1. a) Laser treatment received prior to last delivery (N)	IncontiLase®	10	3	1	14 (37.8%)
	IntimaLase®	13	5	5	23 (62.2%)
b) Number of laser sessions (mean±SD)		2.3±1	2.2±0.9	2.8±1.2	2.4±1
2. Complications after laser treatment (N)	yes	0	0	0	0
	no	21	8	6	35 (94.6%)
	no answer	2	0	0	2 (5.4%)
3. Period (years) between laser treatment and last pregnancy? (mean±SD)		1.6±1.1	1.4±1	2.1±2	1.6±1.3
4. Presence of pregnancy complications? (N)	yes	0	0	0	0
	no	22	8	6	36 (97.3%)
	no answer	1	0	0	1 (2.7%)
5. BMI at the time of delivery (N)	underweight	0	1	0	1 (2.7%)
	normal	19	5	6	30 (81.1%)
	overweight	4	2	0	6 (16.2)
6. Number of prior deliveries (mean±SD)		1.3±0.9	1.4±0.5	1±0.6	1.3±0.8
7. Significant weight gain between last and previous pregnancy (N)	yes	4	4	0	8 (21.6%)
	no	19	4	5	28 (75.7%)
	no answer	0	0	1	1 (2.7%)
8. Difficulty of last delivery compared with previous one (N)	same/ similar	11	7*	3	21 (56.7%)
	easier	8	4*	2	13 (35.1%)
	more difficult	0	0	0	0
	no answer	4	0	1	5 (13.5%)
9. Complications during delivery (N)	yes	0	0	1	1 (2.7%)
	no	23	8	5	36 (97.3%)
	no answer	0	0	0	0
10. Tear or an episiotomy during last delivery (N)	yes	15	1	4	20 (54.1%)
	no	8	7	2	17 (45.9%)
	no answer	0	0	0	0
11. Child's birthweight (N)	lower than average	11	7*	3	21 (56.7%)
	average	8	4*	2	13 (35.1%)
	higher than average	0	0	0	0
	no answer	4	0	1	5 (13.5%)
12. Years elapsed since post-VEL vaginal delivery (mean±SD)		2.1±1.2	1.9±0.9	2.6±1.7	2.2±1.2
13. Months to complete postpartum recovery (mean±SD)		1±0.1	1.9±0.8	1.7±1.1	1.3±0.7
14. Overall comparison of post-VEL delivery to previous ones (N)	shorter	13	8*	5*	26 (70.3%)
	longer	0	8*	5*	13 (35.1%)
	easier	8	8*	5*	13 (35.1%)
	more difficult	0	0	0	0
	with lesscomplications	0	0	0	0
	with more complications	0	0	0	0
	no answer	2	0	1	3 (8.1%)

SMOOTH™ laser does not damage the surface of the mucosa, the risk of adverse events and long-term tissue damage, such as fibrosis, is minimized. As the depth of the VEL light penetration is relatively low, it impacts only the surface of the vaginal epithelium, while other structures that are important for vaginal delivery remain intact. Therefore, we hypothesized that there would be no difference between vaginal delivery pre- and post-VEL treatment, and more specifically, that VEL treatment does not adversely impact subsequent vaginal deliveries.

The questionnaire was an original, non-validated patient survey that was designed to take into consideration several factors that could potentially impact vaginal delivery, e.g. infant weight, pregnancy complications, mother's BMI, etc.

The survey revealed that more responders had sought treatment for vaginal laxity than for SUI. The difference in the average numbers of treatments between these two groups was not significant. There were no complications during or after laser treatments in any of the surveyed patients. A higher BMI at the time of delivery and weight gain between deliveries did not influence the difficulty of post-VEL vaginal deliveries.

Of the 37 patients, 20 had a tear or episiotomy, while 17 did not. Just one patient specified that she had only had a tear. This was the only question that showed significant differences between the centers: of the 8 Ukrainian responders, only 1 (12.5%) reported a tear or an episiotomy; of the 23 Argentinian patients, 15 (65.2%) reported a tear or an episiotomy, while of the 6 Venezuelan patients, 4 (66.7%) reported a tear or an episiotomy. These data are in accordance with published papers: while low routine episiotomy rates (19.4-36.8) have been reported in Ukraine [12], Latin American countries still report standard episiotomy in a large majority (>80%) of vaginal deliveries [13].

The infant's weight is one of the factors that could adversely affect vaginal delivery, however, in the current survey, patients with heavier babies did not report any impact of this on the difficulty of delivery.

It took the patients 1.33 months on average to return to their normal physical activity, which is consistent with the standard six-week recovery period after vaginal delivery.

The last question asked the patients to compare their post-VEL delivery with previous deliveries. Only one patient described her post-VEL delivery as longer, while none of the patients described their post-VEL delivery as more difficult or more complicated than previous deliveries.

In summary, the results did not indicate that laser treatment had an adverse effect on subsequent vaginal delivery. Differences between the centers were seen in the rates of episiotomy, but these have been attributed to differences in the standard use of episiotomy during vaginal labor in different countries. The rates reported by the survey participants were generally lower than the episiotomy rates reported in the published literature. Although the results were consistent between the three centers, the sample is small and selection bias is possible, since this was a retrospective survey of patients from a small number of centers. More data gathered from large registries would be needed to further corroborate our results. However, we believe that this study offers relevant insights into a very important question in clinical practice.

Conclusions

The gathered data from three centers has indicated that VEL treatments did not have an impact on post-VEL vaginal deliveries. Although more data from large registries are needed to confirm our results, this study provides valuable information for physicians and pre-menopausal patients considering VEL SMOOTH™ treatments for SUI and vaginal laxity.

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