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ORIGINAL ARTICLE

Is an episiotomy always necessary during an operative vaginal delivery with vacuum? A longitudinal study

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ABSTRACT

Objective: The use of episiotomy during operative vaginal birth (OVB) is rather debated among operators and in literature. It is also important to evaluate the indications for which episiotomy is performed. In fact, the consequences of an episiotomy can be invalidating for patients with long-lasting results. The aim of this study is the evaluation of the role of episiotomy during OVB with the vacuum extractor and its correlation with Obstetric Anal Sphincter Injuries (OASIs).

Methods: On of 9165 vaginal births, a total of 498 OVB (5.4%) were enrolled in a longitudinal prospective observational study. The incidence of OASIs was evaluated in our population after OVB performed with the vacuum extractor, during which the execution of episiotomy was performed indicated by clinician in charge.

Results: OASIs occurred in 4% of the patients ($n = 20$). Episiotomy was performed in 39% of them ($n = 181$). OASIs incidence was 6% ($n = 17$) in the No Episiotomy and 1.8% ($n = 3$) in Episiotomy group ($p < .001$). Performance of episiotomy during OVB determined a protective effect against OASIs ($p = 0.025$ in full cohort and $p = 0.013$ in the primiparous group). An expulsive phase under one hour was an almost significant protective factor ($p = 0.052$).

Conclusions: The use of episiotomy during OVB was associated with much lower OASIs rates in nulliparous women with a vacuum extraction; OR 0.23 (CI 95% 0.07-0.81) $p = 0.037$ in nulliparous women and the number necessary to treat was 18 among nulliparous women to prevent 1 OASIs. A further risk factor that emerged from the analysis is a prolonged expulsive period, whereas fundal pressure does not seem to have a statistically significant influence.

Abbreviations: OVB: Operative vaginal birth; OASIs: Obstetric Anal Sphincter Injuries

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Operative vaginal birth; obstetric anal sphincter injuries; OASIs; episiotomy; perineal tear

Introduction

Using the vacuum extractor during OVB in the second stage of labor is an alternative to a cesarean section and it can reduce the risk of maternal complications, allowing the extraction of the fetus more quickly [1,2]. Different studies have noted that the use of episiotomy after vaginal delivery is associated to an increased rate of several obstetric complications in the short term (<6 months), including urinary and anal sphincter incontinence, postpartum hemorrhage, perineal pain, decreased sexual functioning as well as sexual desire, arousal, and orgasm [3–7]. A recent Cochrane review, evaluating the outcome of episiotomy after vaginal delivery, highlighted that in the long term (>6 months) there are no increased risks of urinary incontinence (low certainty evidence) and moderate/severe dyspareunia (moderate certainty evidence) [8].

OVB is an important risk factor for the development of Obstetric Anal Sphincter Injuries (OASIs) (approximately fourfold increase in the risk compared to spontaneous vaginal delivery) and anal incontinence during subsequent months and years despite an early diagnosis and a correct surgical repair of perineal lacerations [9,10]. Beyond OVB, several risk factors for OASIs have been studied; different studies conclude that primiparous and fetal macrosomia increase the

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risk of OASIs. Other contributing risk factors are age, ethnicity and epidural anesthesia [11].

Based on actual evidence, performing episiotomy routinely in spontaneous vaginal delivery for perineal protection is not justified [8]. Currently, the role of episiotomy in OVB has not been established yet, other than in case of fetal distress. According to the recent WHO report recommendations, episiotomy should not be performed systematically, but only if necessary, considering that its systematic execution cannot prevent OASIs [12].

In case of OVB with vacuum extractor, the protective effect of episiotomy on OASIs is nowadays still widely debated and literature data are controversial [8]. It's important to underly that episiotomy is not a treatment for OASIs but instead, it is a risk-modifying factor. Well-designed observational studies might help to understand whether episiotomy is successful to prevent OASIs during OVB [13].

Given the lack of standardization of episiotomy during OVB, our research group proposes a prospective observational study with the aim of evaluating its role during OVB with the vacuum extractor and its eventual correlation with OASIs.

Materials and methods

Study design

The study is a prospective, longitudinal, multicenter, observational study and it was conducted in three Italian Obstetric Units (Pisa, Massa Carrara, and Prato). This study was approved by the Institutional Review Board. Informed consent was obtained from all the study participants. From April 2017 to January 2019, a total of 9165 vaginal births and a total of 498 OVB (5.4%) were enrolled from Gynecology and Obstetrics departments of the aforementioned hospitals. Patients were adequately informed about the study and the possibility of being included in the study if OVB was performed, with or without episiotomy.

Study population

Patients were enrolled during the entrance in the delivery room, and they submitted informed consent at the time of active labor in the delivery room, in case it was necessary to perform an OVB.

Inclusion criteria were nulliparous and multiparous women with a live single fetus in a longitudinal situation and cephalic presentation at full-term. Labor was either spontaneous or induced.

Exclusion criteria were contraindication to vacuum-assisted delivery, multiple pregnancies, non-cephalic presentation, placenta previa and known major malformation and genetic fetus disorders.

Procedures

Participant recruitment did not influence treatment strategies. Patients were managed according to the usual clinical practice and according to the judgment of the consultant doctor and attending physician. During labor the epidural analgesia was performed with Sufentanyl and Ropivacaine. Evaluation of CTG traces during second stage of labor was performed from a board consisting of the consultant doctor and attending physician, assessing the appropriateness of indications for OVB. CTG traces were evaluated according to ACOG classification [14]. The transition phase was defined as the time between the complete dilation and the appearance of the patient's need to push. The expulsive phase was defined as the time elapsed between the beginning of the patient's voluntary pushing and the expulsion of the fetal presenting part. The use of oxytocin in the second phase of delivery was performed for induction in all patients who needed it, with a low doses protocol (Initial dose: 0.5 to 2 mU/min, Increase interval every 30-60 min; Increment dose: 1 to 2 mU/min; Maximum dose before revaluation: 30mU/min). Once labor started, the use of oxytocin was suspended. If the contractions were not considered adequate, the intravenous oxytocin was reintroduced according to low doses protocol. The operators used oxytocin until the level of the presenting part was about zero, while fundal pressure was used, if necessary, only after the engagement of the presenting part (level +4).

The indications for episiotomy were non-reassuring fetal heart rate, inadequate tissue distension during OVB, previous severe lacerations with scarring outcomes. A mediolateral episiotomy with incision at 60° was performed. The vacuum extractor was applied by the consultant doctor or attending physician (all with over 10 years of experience working in the delivery room), with the patient's verbal consent, if clinically indicated to perform the OVB. In all hospitals, OVB were carried out with the application of a vacuum extractor with the same soft cup devices (Omnicup Kiwi®).

After OVB the diagnosis of perineal laceration and its following episiorrhaphies were performed by a consultant doctor or an attending physician. During data collection, tears were classified according to the RCOG

guidelines from 1st to 4th degree [15]. 3rd and 4th degree tears, defined as severe perineal tears, were grouped as OASIs. The diagnosis of OAISs was confirmed by a second clinician present in the delivery room. Episiotomy was considered as a 2nd degree laceration at least.

Statistical analysis

All data were collected on an Excel sheet in a computer of the delivery room by attending physician and resident doctor. A dichotomous variable was created, assuming the value one for the occurrence of OASIs while assuming the value zero otherwise. Bivariate analyses (χ^2 tests) were run to explore the risk of tears according to the performance of episiotomy and the demographic and clinical features of the researched patients. The number needed to treat (NNT) was also computed as the inverse of the absolute risk reduction, to investigate how many patients should receive episiotomy to avoid the risk of one additional OASIs. Then, by employing those variables for which a statistical difference emerged from bivariate analyses, regression models were built to further explore the risk of tears. A binary logistic regression model was run to detect the risk factors for undergoing OASIs vs non-OASIs. The same analysis was replicated just for primiparous women. The number of patients required for the study was calculated based on 90% power to detect a significant difference in the incidence of OASIs between the groups with and without episiotomy at a 5% significant level; the estimated incidence in both groups was obtained from the literature [16]. The number of patients to reach statistical significance was 157 in each group.

Results

The demographic and clinical features of the cohort are reported in Table 1. 498 patients were assessed for eligibility. 32 patients are excluded: 8 for contraindications to vacuum-assisted delivery, 3 for multiple pregnancies, 2 for known major malformation and 19 patients declined to participate (Figure 1).

From analysis result the relationship between the risk of OASIs and the performance of episiotomy both in the full cohort, primiparous and multiparous subgroups the risk of OASIs is significantly higher in women not receiving episiotomy in the full cohort of patients ($p = 0.025$), and in the primiparous subgroup ($p = 0.013$) but no in the multiparous subgroup ($p = 0.625$). NNT (Number Needed to Treat) calculation shows that, to avoid the risk of one additional 3rd or 4th degree tear, 5% of women (23 in the full cohort and 18 in the primiparous cohort) needed to receive episiotomy, equivalent to a 2nd degree laceration.

Considering both primiparous and multiparous women (full cohort), an OASIs event occurs in 6% of women not receiving episiotomy, while occurs in just 2% of women receiving episiotomy. However, 65% of women not receiving episiotomy also avoided a 2nd degree tear, which is the corresponding degree of laceration of the episiotomy itself. A similar effect pattern was observed among primiparous women.

Results of the other bivariate analyses were omitted as the variables for which a statistical difference emerged were further employed in regression models. The binary logistic regression models that confirmed the protective effect of episiotomy against OASIs both in the full cohort ($p = 0.036$) and among primiparous ($p = 0.022$). Unadjusted and adjusted binary logistic regression models were performed both in the full cohort and in the Primiparous cohort to explore the risk of OASIs versus not by employing the dichotomous variable was reported in Table 2.

Discussion

During OVB multiple factors contribute to the risk of development of OASIs and not all of them can always be predicted. There are predictive factors such as parity and duration of the expulsive phase, but there is nothing that can modify the clinical conduct. A similar discussion should be made regarding the potential protective effect of episiotomy on OASIs during OVB.

The incidence of episiotomies in Europe in OVB has a variability range of 17-97%; however, Italy is not included among the countries the data refers to [17]. In Italy and, specifically, in the hospitals involved in the study, we find a homogeneous incidence of episiotomy during OVB (36-45%), clashing with the data abovementioned of Europe. The low incidence of episiotomy was probably linked to Italian guidelines that do not recommend routinarious episiotomy during OVB compared to other nations guidelines [18].

The data shown in this paper report a reduction of prevalence of OASIs in the episiotomy group indicates the protective effect of episiotomy against OASIs during OVB (OR 0.23; CI 0.07 to 0.81) $p = 0.037$ in nulliparous women, in line with what is found in the literature. Jang et al. (2014) performed a retrospective cohort study with 214 256 primiparous women that reported a similar conclusion. The employment of vacuum extraction in OVB without episiotomy was a

Table 1. Descriptive analysis of our cohort of women ($n = 466$).

		No episiotomy ($n = 285$)	Episiotomy ($n = 181$)	p-value
Number of patients per hospital, n (%)	Hospital 1	155 (54.4)	132 (72.9)	**<.001**
	Hospital 2	116 (40.7)	34 (18.8)	
	Hospital 3	14 (4.9)	15 (8.3)	
Age class, n (%)	18-29 years old	75 (26.5)	59 (32.7)	N.S.
	30-39 years old	184 (65.0)	105 (58.3)	
	>40 years old	24 (8.5)	16 (8.9)	
	Missing	2	1	
Parity, n (%)	Primigravidae	217 (76.1)	165 (91.2)	**<.001**
	Multiparous	68 (23.9)	16 (8.8)	
Maternal BMI, n (%)	<18.5	9 (3.2)	4 (2.2)	N.S.
	<25.0	94 (33.0)	57 (31.5)	
	<30.0	114 (40.0)	74 (40.9)	
	≥30	68 (23.8)	46 (25.4)	
Maternal ethnicity, n (%)	Caucasian	234 (82.1)	148 (81.8)	N.S.
	Hispanic	9 (3.2)	7 (3.9)	
	Afro-American	25 (8.8)	15 (8.3)	
	Asian	17 (5.9)	11 (6.0)	
Previous Cesarean Section, n (%)	0	273 (95.8)	172 (95.0)	N.S.
	1	12 (4.2)	9 (5.0)	
	2	0	0	
	>2	0	0	
Tears, n (%)	No tear / grade I	186 (65.2)	–	**<.001**
	Grade II	82 (28.8)	178 (98.3)	
	Grade III / IV	17 (6.0)	3 (1.7)	
Labor, n (%)	Spontaneous	200 (70.2)	117 (64.6)	N.S.
	Induced	85 (29.8)	64 (35.4)	
Indication to operative delivery, n (%)	CTG category II	155 (54.4)	87 (48.1)	**.024**
	CTG category III	9 (3.1)	2 (1.1)	
	Abnormal labor progression	62 (21.8)	61 (33.7)	
	Exhausting during labor	56 (19.7)	27 (14.9)	
	Elective shortening stage II of labor	3 (1.0)	4 (2.2)	
Transition, n (%)	No	192 (67.4)	131 (72.4)	N.S.
	Yes	93 (32.6)	50 (27.6)	
Epidural analgesia, n (%)	No	143 (50.2)	94 (51.9)	N.S.
	Yes	142 (49.8)	87 (48.1)	
Fetal birthweight, mean (±SD)	–	3,328 (409)	3,371 (429)	N.S.
Fetal birthweight, n (%)	<2500 gr	16 (5.6)	8 (4.5)	N.S.
	<4000 gr	257 (90.2)	157 (86.7)	
	>4000 gr	12 (4.2)	16 (8.8)	
Fetal presentation, n (%)	Occiput Anterior	231 (85.6)	141 (82.5)	N.S.
	Occiput Posterior	29 (10.7)	22 (12.8)	
	Occiput Temporal	10 (3.7)	8 (4.7)	
	Missing	15	10	
Fundal pressure, n (%)	No	117 (42.5)	51 (28.3)	**.002**
	Yes	158 (57.5)	129 (71.7)	
	Missing	10	1	
Number of contractions, n (%)	Zero	35 (12.3)	8 (4.4)	N.S.
	One	115 (40.4)	62 (34.3)	
	Two	93 (32.6)	75 (41.4)	
	Three	34 (11.9)	23 (12.7)	
	More than four	8 (2.8)	13 (7.2)	
CTG interpretation, n (%)	Proper interpretation	71 (32.3)	53 (35.6)	N.S.
	Not proper interpretation	81 (36.8)	53 (35.6)	
	CTG not readable	68 (30.9)	43 (29.8)	
	Missing	65	32	
Expulsive phase duration, n (%)	< 1 h	86 (30.2)	54 (29.8)	N.S.
	1-2 h	147 (51.6)	84 (46.4)	
	> 2 h	52 (18.2)	43 (23.8)	

significant risk factor of OASIs (aOR, 2.99; 95% CI, 2.86-3.12; $p<.0001$), and episiotomy was protective in vacuum-assisted deliveries compared with vacuum-assisted deliveries without episiotomy (aOR, 0.60; 95% CI, 0.56-0.65; $p<.0001$) [19]. Other large observational studies support the use of mediolateral and lateral episiotomy during OVB [16,20–22].

In this study, the number of NNT patients to prevent an episode of OASIs (about 18 in nulliparous women) appears to be in agreement with the literature indicating a lower number of NTTs. This is considered by Lund et al. an acceptable number compared to the complications in the long-term OASIs [20]. It is important to underline that episiotomy is not an OASIs treatment, but a risk factor modulator that can reduce it, rather than avoiding it. For this reason, we believe that the NNT of 18 for the systematic execution during OVB should be avoided and modulated by

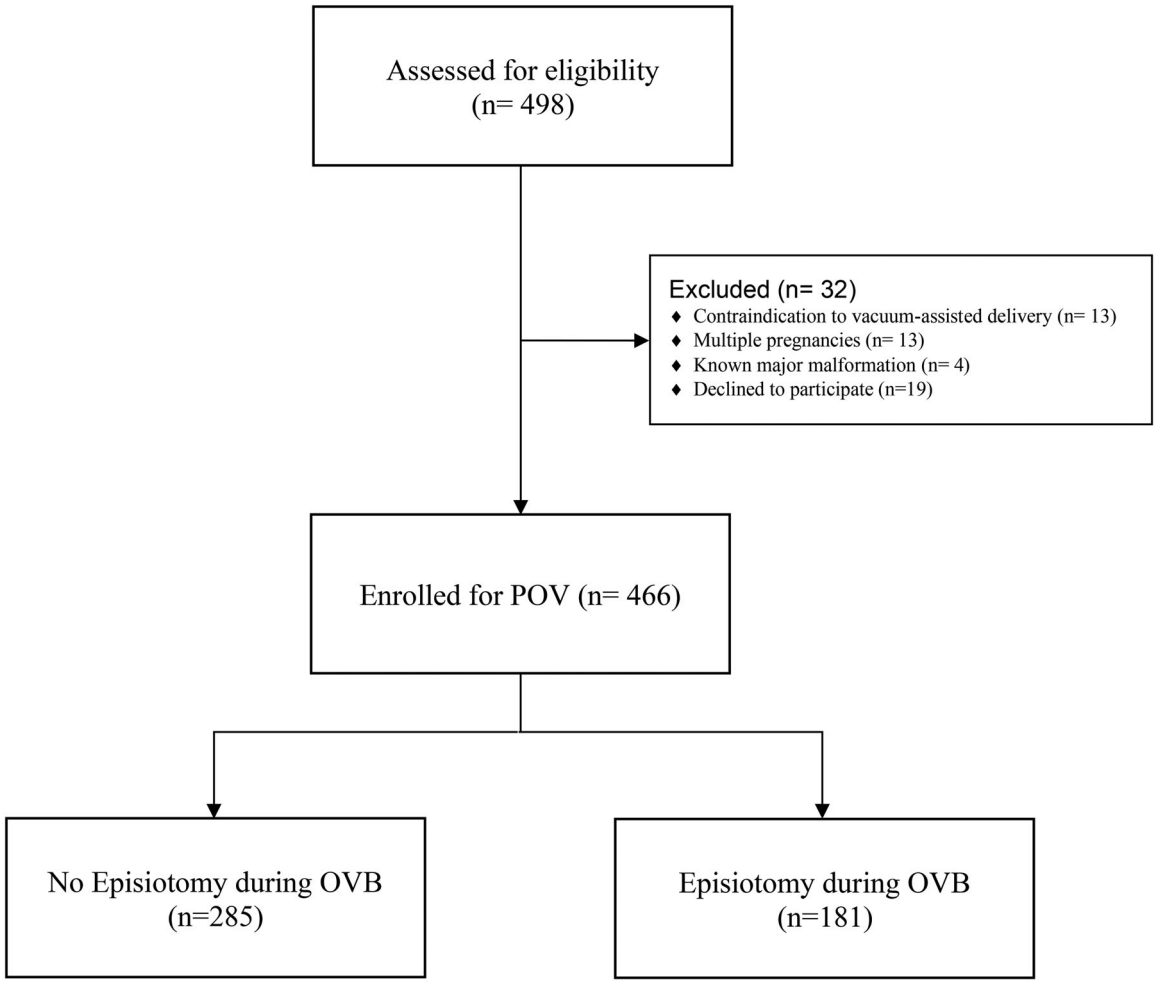

Figure 1. Flow chart.

Table 2. Regression models for the risk of OASIs.

OASIs vs not

	All women ($n = 466$)			Just primigravidae ($n = 382$)		
	Odds Ratio	**95% CI**	**p-value**	**Odds Ratio**	**95% CI**	**p-value**
Episiotomy vs not	0.25	0.07–0.88	**0.031**	0.26	0.07–0.92	**0.037**
Expulsive phase < 1h vs 1-2h	0.18	0.05–0.69	**0.012**	0.23	0.06–0.87	**0.030**
Expulsive phase > 2h vs 1-2h	0.55	0.17–1.81	0.325	0.59	0.18–1.96	0.388
Multiparous vs primigravida	0.35	0.04–2.87	0.330	–	–	–
Fundal pressure, yes vs not	1.55	0.53–4.54	0.428	1.40	0.47–4.16	0.548

Note. Unadjusted and adjusted binary logistic regression models were performed both in the full cohort and in the Primiparous cohort to explore the risk of OASIs vs not by employing the dichotomous variable. The selection of covariates for inclusion in the models was done using a stepwise approach, gradually adding each covariate to the model and excluding nonsignificant variables at each step. This approach was used to overcome the limitation of low sample size.
Binary logistic regression: no OASIS = 0; OASIS = 1.

the choice of the clinician based on the different risk factors.

Data present in this paper like other papers in the literature, raise a very relevant question: how many perineum need to be treated with an episiotomy to prevent OASIs?

Furthermore, the NNT obtained of 23 in the full cohort is necessary to prevent a single OASIs tear, too much to justify such a universal procedure. It is unrealistic to perform systematic episiotomies during OVB as it would result in overtreatment and an unjustified increase of perineum morbidity. Data reported by this paper, as well as the other studies in the literature, must be observed with common sense and a critical approach. An expert clinician is necessary, being the one who can determine the real need for episiotomy during OVB, as it is a complex choice based on numerous variables, including

the anamnestic condition of the patient as well as the anatomical condition.

From the study, we obtained other results that are not part of the study outcome but are worth discussing.

The first is about the duration of the expulsive period which lasts, on average, about 1 h in nulliparous patients and about 30-40 min in multiparous patients, despite the variability of age, ethnicity, etc. This timing is important because, if the passage of the fetal head occurs quicker than the adaptation of perineal muscles to the distension and lengthening, laceration takes place more easily.

This paper reports that an expulsive period expulsion phase $<$ 1 h is a protective factor for OASIs compared to an expulsion phase of 1-2 h in all subpopulations OR 0.23 (CI95% 0.06 to 0.87) $p = 0.030$. Our data concur with other studies in the literature, although most studies tend to emphasize that the correlation is weak, limited, and associated with sphincter injuries in vacuum extraction [4,23–26].

The data reported in this paper report that increasing the duration of the expulsive phase leads to a statistically significant correlation with OASIs. This data obtained from our study must be contextualized with the literature. In fact, the correlation with OASIs is not correlated to an increased duration of the expulsive period as much as to a prolongation of the phase itself.

The last interesting result is that of the fundal pressure, which during OVB is not correlated with an increased risk of OASIs in our analysis, both in the with and without episiotomy groups. In the literature, there are controversial results referred to spontaneous vaginal birth (not trial for OVB) and fundal pressure, which reveal a positive correlation with risk of *elevator ani* muscle lesions or anal sphincter lesions [27–29]. The lack of positive correlation between fundal pressure and OASIs surprised the authors of this paipar. The scientific interpretation that was given to this result is probably related to a bais of the study itself. In fact, in the hospitals involved a gentle fundal pressure was performed and not a true Kristeller maneuver considering that the patients were already undergoing OVB which basically increases the risk of OASIs. Indeed, during OVB, excessive fundic pressure would cause a deflection of the fetal head that would reduce the bending action of vacuum cup required during OVB.

In this study are present some limiting factors that need to be considered.

In this population, the incidence of OASIs was lower than cutoff $<$5%, as this variable is considered as a maternity care quality indicator [29]. Despite it is a pleasing quality-of-care point of view, it is a weakness in assessing the true incidence of OASIs after OVB.

Low sample numerosity prevented the execution of a multivariate analysis that would help us to identify multiple risk factors beyond the duration of the expulsive phase and parity.

A limitation factor is that the data obtained came from three independent hospitals joining their research while maintaining their independent protocols. Despite the different numbers of patients enrolled by hospitals, we have a similar incidence of episiotomy between the three different hospitals. Furthermore, various operators with different experiences participated in this study with different outcomes. Another limiting factor of the study is that the decision of performing episiotomy lacks randomization, potentially introducing a significant bias. Finally, there is no subsequent perineal evaluation during the follow-up.

Conclusions

Episiotomy is an obstetric surgical procedure that must be evaluated during OVB as a useful method to reduce the risk of OASIs. The use of episiotomy during OVB was associated with much lower OASIs rates in nulliparous women with a vacuum extraction; OR 0.23 (CI 95% 0.07-0.81) $p = 0.037$ in nulliparous women and the number necessary to treat was 18 among nulliparous women to prevent 1 OASIs. The results of our study confirm that episiotomy during OVB has a statistically significant protective effect against OASIs only in nulliparous women. A further risk factor that emerged from the analysis is a prolonged expulsive period, whereas fundal pressure does not seem to have a statistically significant influence. Further studies are needed to confirm this result.

Ethics approval

This study was approved by Institutional Review Board (IRB for clinical trial Tuscany: AREA VASTA NORD OVEST, Stabilimento di Santa Chiara, Pisa, Prot n 60166)

Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by all authors. AF analyzed and interpreted the patient data. The first draft of the manuscript was written by AR, FF, AS, PM and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Disclosure statement

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Data availability statement

The data that support the findings of this study are available from the corresponding author, F.F., upon reasonable request.

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