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Prolasso degli organi pelvici severo trattato mediante riparazione fasciale: analisi a lungo termine dell' outcome in 146 pazienti

Abstract

Obiettivi: lo scopo di questo studio è di valutare l'efficacia e la sicurezza della riparazione fasciale vaginale come trattamento chirurgico per il prolasso degli organi pelvici severo (POP severo) e, in secondo luogo, valutare l'impatto della chirurgia sulla qualità di vita (QoL) e la funzione sessuale.

Materiali e Metodi: Le donne con POP sintomatico (≥III stadio secondo il sistema di quantificazione POP-q-system) con o senza incontinenza urinaria da stress (SUI) sono state sottoposte a chirurgia fasciale vaginale. Lo stadio clinico di prolasso, il diario minzionale di 3 giorni e il test urodinamico sono stati valutati rispettivamente. Inoltre sono stati valutati i tempi operatori. Sono stati somministrati I questionari ICIQ–UI SF, PISQ-12 che valuta la funzione sessuale e il questionario sulla qualità della vita nelle pazienti affette da prolasso (P-QoL).

Risultati: sono stati reclutati 146 pazienti. Il follow-up mediano è stato di 48 mesi (36–63). Cinquantadue donne (36%) erano state sottoposte ad una precedente isterectomia e 16 (11%) hanno avuto un precedente intervento per prolasso/incontinenza. Preoperatoriamente, 135 (92,5%), 109 (74,7%) e 98 (67,1%) pazienti avevano uno stadio ≥ III di prolasso anteriore, centrale e posteriore, rispettivamente. Trentadue pazienti (22%) hanno avuto una diagnosi concomitante di SUI. Il tempo operativo mediano è stato di 85 minuti (37–154) e la degenza post-operatoria mediana di 2 giorni (2–4). Non si sono verificate gravi complicanze intraoperatorie. Al follow-up a lungo termine, il tasso di guarigione soggettivo per il prolasso era del 97,3% e il tasso di guarigione obiettivo era del 91,1%. Un miglioramento significativo di ICIQ-UI SF, P-QoL e PISQ-12 è stato registrato al follow-up ($p < 0,001$).

Conclusione: la correzione fasciale vaginale è efficace, sicura e duratura migliorando i sintomi legati al POP e la funzione sessuale.

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GENERAL GYNECOLOGY

Severe pelvic organ prolapse treated by vaginal native tissue repair: long-term analysis of outcomes in 146 patients

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Abstract
Aims The aim of this study was to assess the effectiveness and safety of vaginal native tissue repair (VNTR) as a surgical treatment for severe pelvic organ prolapse (POP) and, second, to evaluate the impact on the quality-of-life (QoL) and sexual function.
Methods Women with symptomatic POP (≥III stage according to POP Quantification System) with or without stress urinary incontinence (SUI) underwent VNTR. The clinical stage, 3-day voiding diary, and urodynamic testing were evaluated in the preoperative and postoperative times, respectively. The International Consultation on Incontinence Questionnaire–Urinary Incontinence Questionnaire Short Form (ICIQ–UI SF), the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12), and the prolapse quality-of-life questionnaire (P-QoL) were administered.
Results One hundred forty-six patients were recruited. The median follow-up was 48 months (36–63). Fifty-two women (36%) had a previous hysterectomy, and 16 (11%) had a previous prolapse/continence surgery. Preoperatively, 135 (92.5%), 109 (74.7%), and 98 (67.1%) patients had anterior, central, and posterior descent ≥III stage, respectively. Thirty-two patients (22%) had concomitant diagnosis of SUI. Median operative time was 85 min (37–154), and median postoperative hospital stay was 2 days (2–4). No intraoperative severe complications occurred. At the long-term follow-up, the subjective cure rate for prolapse was 97.3% and the objective cure rate was 91.1%. A significant improvement of ICIQ-UI SF, the P-QoL, and the PISQ-12 was recorded at the follow-up ($p < 0.001$).
Conclusion VNTR is effective, safe, and durable and improves POP-related symptoms and sexual function.

Keywords Pelvic organ prolapse · Vaginal native tissue repair · Sexual function · POP surgery

Introduction

The worldwide prevalence of symptomatic Pelvic Organ Prolapse (POP) in women over 50 years of age is in the range of 30–50%, with a lifetime risk of approximately 20% for POP or incontinence surgery [1]. Recent data showed an increase with aging in the occurrence of pelvic floor disorders of the population in the United States: from 28.1 million in 2010 to 43.8 million in 2050 [2]. The etiology of POP is multifactorial, and the main risk factors are vaginal delivery and conditions associated with increased abdominal strain [3].

To treat genital prolapse, several different surgical procedures have been developed since the last decades of the twentieth century. After the first sacral colpopexy introduced mesh graft material in 1962, a wide variety of techniques concerning the treatment with synthetic mesh were improved.

In 2011, a Food and Drug administration (FDA) update warned clinicians and patients about serious mesh related complications. Mesh erosion, bleeding, pelvic

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pain, dyspareunia, and lower urinary tract symptoms were recorded in 10–20% of women, with a worsening of the quality of life (QoL) [4]. Moreover, the treatment with mesh provided a significant anatomic benefit only in the anterior compartment [5].

Hence, there has been a renewed need to perform native tissue surgery. This involves the endopelvic fascia reconstruction following the De Lancey theory. In fact, it was showed that the endopelvic fascia plays an essential role in the static and dynamic of the pelvic visceral support [6].

Therefore, the repair of the single anatomic defect, reconstructing the damaged endopelvic fascia, appears to be the best way to obtain the anatomic and functional cure [7]. However, only few trials on the long-term efficacy and complications of native tissue repair are described in the literature [8, 9].

In our department, we perform anterior, apical, and posterior native fascial surgery for pelvic organ prolapse.

The aim of this study is to evaluate, with a median 48-month follow-up, the efficacy and safety of native tissue repair for POP surgical treatment in patients with one or more vaginal defects. The second aim of this study is to assess the rate of complications and the impact on sexual function and QoL after surgery.

Materials and methods

From January 2008 to January 2013, 208 consecutive patients affected by genitourinary prolapse ≥III stage according Pelvic Organ Prolapse Quantification System, POP-Q classification, with or without coexisting clinical or latent stress urinary incontinence (SUI), were considered for the study to the Department of Gynecological and Obstetric Sciences, and Urological Sciences, University of Rome "Sapienza". Of these patients, 25 (12%) refused surgery, 27 (12.9%) were excluded, because they had poor performance status (ECOG > 2), and 10 (4.8%) underwent POP surgery, but were lost to follow-up. The remaining 146 patients (70.1%) were enrolled for this study. All data collected were retrospectively evaluated from a prospectively collected urogynecological internal database. The Institutional Review Board approved the study. The preoperative evaluation consisted of an urogynecological interview, clinical exam, 3-day voiding diary and urodynamic testing. The International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF) questionnaire was used to subjectively quantify the patient's perception of the severity of SUI symptoms [10]. The degree of vaginal defects was evaluated by POP-Q classification under maximum straining effort, with the patient in the lithotomy position [11]. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form (PISQ-12) was administered to evaluate sexual function [12]. The prolapse quality-of-life questionnaire (P-QoL) was used to quantify the impact of prolapse symptoms on QoL [13]. The patients who were in menopause received topic hormone replacement therapy for 8 weeks before surgery and they were asked to maintain the therapy during the follow-up. Before surgery, all patients were given low-molecular weight heparin to prevent venous thromboembolism. A short-term antibiotic prophylaxis was performed 30 min before surgery.

Operative technique

Patients with severe uterine prolapse ≥III stage underwent vaginal hysterectomy with an intrafascial technique and vaginal vault suspension according to the Shull technique [14]. A vaginal submucosal infiltration with diluted epinephrine solution (1/400.000) was performed. The surgical technique included circular colpotomy. In the patients with complete eversion of the vaginal canal, the incision extended from 1.5 cm under the urethral orifice to the cervix and from the cervix to the perineal body. Patients with primary vaginal vault prolapse after the previous hysterectomy underwent Shull suspension: the vaginal vault was suspended to the cranial part of the uterosacral ligaments, to the rectovaginal fascia posteriorly, and to the pubocervical fascia anteriorly with polydioxanone monofilament long-term absorbable 0 sutures. In case of anterior defect ≥III stage, an anterior median longitudinal colpotomy was performed and the pubocervical fascia was reached, detaching the vaginal wall from the vesico-vaginal septum [15]. The anterior repair was performed by placing 2–0 synthetic absorbable sutures at the pubocervical fascia, 1 cm below and 3 cm laterally from the urethral meatus and with 2–3 interrupted absorbable sutures to eliminate the hiatus. The surplus of the vaginal epithelium was removed (5 cm in length and 1–1.5 cm in width), and the vaginal mucosa was closed. In case of posterior defect ≥III stages, a vertical incision in the posterior vaginal mucosa was performed and the rectovaginal fascia was dissected by the posterior vaginal mucosa. The intact rectovaginal fascia was identified and reconnected to the uterosacral ligaments at the top of the vagina, to the vescical fascia anteriorly, and sutured inferiorly to the superficial transverse perineal muscle. The rectovaginal fascia was repaired with single, absorbable sutures. Posterior colporrhaphy was performed. In patients with SUI, polypropylene Transobturator Tape (TOT) was inserted as previously described [16].

Operative and postoperative assessment

After surgery, a bladder catheter and a vaginal pack were positioned and were removed after 48 h. Patients with

voiding dysfunction were discharged with the catheter in place and re-evaluated after 1 week.

Operative time, blood transfusions, spontaneous voiding, perioperative complications, postoperative hospital stay, and postoperative complications (early within 30 days and late after 30 days) were considered. The following questionnaires were administered: ICIQ-UI SF, P-QoL, and PISQ-12. A clinical examination and urodynamic investigation were performed 1, 12, and at least 36 months after surgery. In this study, we assessed only the long-term follow-up (>36 months). The outcome of the incontinence/prolapse surgical treatment was evaluated both subjectively and objectively. Subjective cure was defined as no urinary or prolapse symptoms after surgery. Objective cure for SUI was defined as no leakage of urine while performing the cough stress test with 300 ml of saline solution in the bladder and at a mean pressure transmission ratio (PTR) >90% for the proximal three-fourths of the urethra. Objective cure for prolapse was defined when the vaginal defects was stage (0–I), evaluated by POP-Q classification under maximum straining effort with the patient in the lithotomy position. Objective improvement for SUI and prolapse was defined as a significant reduction of urinary incontinence related to position (from supine to standing position) during cough stress test with a mean pressure transmission ratio <90% for the proximal three-fourths of the urethra and a lower degree of vaginal defects or reduction prolapse symptoms than before surgery, respectively. Recurrence of prolapse was defined as stage II or higher prolapse based upon the POP-Q classification. Statistical analysis was carried out with Wilcoxon matched pairs test for the continuous variables and χ-square test for the frequency data. All analyses were conducted using the Statistical Package for the Social Sciences (SPSS) 22.0 for Mac (SSPS, Chicago, IL, USA). Significance was set at a p value of <0.05.

Results

One hundred forty-six patients were enrolled in the study. Patients' characteristics are shown in Table 1. Thirty-two patients (22%) had a diagnosis of stress urinary incontinence. All the 118 patients (80.8%) in menopause received topic hormone replacement therapy for 8 weeks before surgery and after surgery during the follow-up. All patients underwent reconstructive vaginal surgery, with or without TOT insertion. The median follow-up was 48 months (36–63). Preoperatively, 135 (92.5%), 109 (74.7%), and 98 (67.1%) patients had respectively anterior, central, and posterior descent ≥III stage, respectively. These defects were associated with variable degrees of loss of support at the other vaginal sites considered: 98 patients (67.1%) showed descent in all three compartments, 30 (20.5%) in two compartments, and 18 (12.4%) in only one compartment (12 anterior descent and 6 apical descent). The cases with stress urinary incontinence underwent additional intervention by TOT. Surgical procedures are shown in Table 1. Intraoperative and postoperative results were collected. The median operative time was 85 min (37–154), the median spontaneous voiding was 2 days (1–6), and median postoperative hospital stay was 2 days (2–4). Neither severe intraoperative complications occurred nor blood transfusions were necessary. Early postoperative complications included: five cases (3.4%) of unknown fever and eight (5.4%) of urinary tract infections. Only ten patients (6.8%) needed self-catheterization at home for a median of 6 days (5–8). Late complications are reported in Table 2. At 1-month follow-up, subjectively, 32 out of 32 incontinent patients were cured of SUI, whereas objective evaluation showed a cure rate of 93.8% (30 out of 32 patients), an improvement of SUI for one patient and a procedure failure for one other. After 12 months, subjectively, 31 out of 32 incontinent patients (96.9%) were cured for SUI, whereas an objective evaluation showed a cure rate of 87.5% (28 out of 32 patients), an improvement of SUI for 3, and a procedure failure for 1 out of 32. At a median follow-up of 48 months, subjectively, 30 out of 32 incontinent patients (93.8%) were cured of SUI after surgery, whereas objective evaluation showed a cure rate of 84.4% (27 out of 32 patients), an improvement of SUI for 3, and a procedure failure for 2 out of 32. Valsalva Leak Point Pressure (VLPP) before and at least 36 months after surgery was, respectively, 45.64 ± 18.27 vs 35.02 ± 12.60, ($p < 0.001$).

Table 1 Clinic pathological characteristics and surgical procedures in 146 patients

Clinical variables	*n*
Mean age (SD)	61.61 (8.83)
Median vaginal delivery (range)	2 (1–5)
Mean BMI (SD)	27.34 (3.82)
Menopause status (%)	118 (80.8)
Smokers (%)	26 (17.8)
Previous Hysterectomy (%)	52 (35.6)
Previous POP surgery and/or continence surgery (%)	16 (11)
Concomitant stress urinary incontinence (%)	32 (22)
Surgical procedures	
Vaginal hysterectomy (%)	91 (62.3)
Bilateral adnexectomy (%)	82 (56.1)
Shull suspension (%)	109 (69.2)
Anterior colphorraphy (%)	135 (92.5)
Posterior colphorraphy (%)	98 (67.1)
TOT insertion (%)	32 (22)

SD standard deviation, *BMI* Body Mass Index, *POP* pelvic organ prolapse, *TOT* transobturator tape

Table 2 Late complications in 146 patients after surgery (median follow-up)

Complications	Number of patients	%
Gluteal pain	4	2.6
Vaginal cuff granuloma	3	2.1
Vaginal cuff dehiscence	4	2.6
Vaginal stenosis	3	2.1
Dyspareunia	4*	2.6
Stress urinary incontinence	5	3.4
Recurrent urinary tract infections	5	3.4
Urgency	10	6.8
Urge urinary incontinence "de novo"	6	4.2
Difficult voiding	5	3.4
Constipation	3	2.1

* 2/4 Patients new onset

In particular, before surgery, 32 patients showed a positive cough stress test and a positive VLPP (32 patients had a VLPP >60 cm H_2O), whereas at the median follow-up, these two tests were positive only in five patients (15.6%) $p < 0.001$.

The mean difference of the Q-Tip test degree was, respectively, before and after surgery 59 ± 17.9 vs 21 ± 5.97, ($p < 0.001$). Respectively, 9 (6.2%) and 6 (4.2%) patients suffered urge incontinence before and after surgical intervention ($p = 0.59$). These six patients experienced de novo urge incontinence after POP surgery.

The mean differences after surgery of peak urinary flow rate was -3.52 ± 2.26 ml/s, of post-void residual (PVR) -13.31 ± 8.06 ml, of Maximum Urethral Closure Pressure (MUCP) $+3.35 \pm 1.15$ cm H_2O and of the mean pressure transmission ratio (PTR) +18%. Urodynamic assessment is reported in Table 3.

At median follow-up of 48 months after surgery, subjectively, 142 out of 146 patients (97.3%) were cured for prolapse, whereas objective evaluation showed a cure rate of 91.1% (133 out of 146 patients). Thirteen patients (8.9%) showed recurrent vaginal descent ≥II stage according POP-Q classification. The change of vaginal segment descent at 1 and 12 months, and at median follow-Up, according to the POP classification score, is shown in Table 4. At the clinical exam, no differences were noted in the 32 patients with SUI between the group successfully treated (27/32, 84.4%) and the group with improved/failed (5/32, 15.6%). The bladder neck hypermobility and the presence of the central or lateral vaginal defect were the only two different factors that caused postoperative SUI. The Q-Tip test remained positive in 5 out of 32 patients (16%) of whom 4 (80%) were in the improved/failed group

Table 3 Preoperative and postoperative (median follow-up) urodynamic evaluations

Urodynamic data	Preoperative	Postoperative	*p* value
Peak flow (ml/s)	21.66 ± 2.87	25.19 ± 5.05	<0.0001
Flow time (ml/s)	27.64 ± 5.37	27.48 ± 5.21	0.53
Post-void residual (ml)	30.37 ± 15.18	17.06 ± 8.52	<0.0001
First voiding desire (ml)	181.92 ± 19.33	182.21 ± 17.98	0.14
Maximum cystometric capacity (ml)	486.70 ± 18.57	485.89 ± 20.76	0.20
Detrusorial pressure at peak flow (cmH_2O)	17.02 ± 4.43	17.66 ± 5.31	0.09
Maximum urethral closure pressure (cmH_2O)	68.59 ± 9.30	72.15 ± 8.52	<0.0001
Urethral functional length (mm)	26.87 ± 1.84	26.79 ± 1.77	0.43
Pressure transmission ratio (%)	67.60 ± 12.89	86.17 ± 14.72	<0.0001

Table 4 Pre- and postoperative POP-Q score classification, ICIQ-UI-SF, P-QoL, and PISQ-12

Variables	Preoperative	1 months follow-up	*p* value	12 months follow-up	*p* value	Median follow-up	*p* value
Anterior (Ba)	3.21 ± 2.85	-2.89 ± 0.93	<0.001	-2.72 ± 0.89	<0.001	-2.64 ± 0.96	<0.001
Posterior (Bp)	1.50 ± 1.91	-3.74 ± 1.02	<0.001	-3.72 ± 0.92	<0.001	-3.52 ± 0.84	<0.001
Cervix (C)	2.26 ± 2.48	-6.65 ± 2.41	<0.001	-6.43 ± 2.23	<0.001	-6.07 ± 2.16	<0.001
ICIQ-UI-SF	14.84 ± 4.09	5.23 ± 1.95	<0.001	4.56 ± 2.43	<0.001	4.36 ± 2.71	<0.001
P-QoL	63.84 ± 16.13	31.03 ± 7.56	<0.001	26.65 ± 7.45	<0.001	24.72 ± 6.75	<0.001
PISQ-12	29.08 ± 6.12	35.75 ± 5.92	<0.001	35.89 ± 4.98	<0.001	37.58 ± 5.43	<0.001

POP-Q score pelvic organ prolapse quantification score, *ICIQ-UI-SF* International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form, *P-QoL* Prolapse Quality-of-Life Questionnaire, *PISQ-12* Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire short form

($p < 0.0001$). At the follow-up, the anterior-central or lateral vaginal defect was present in 7 out of 146 patients (4.8%) and 5 patients were in the SUI improved/failed group.

Before surgery, 64 patients (43.8%) reported having regular sexual intercourse; 11 (17.2%) of these had dyspareunia. Whereas after surgery, 83 patients (53.2%) reported having regular sexual intercourse and 4 (4.8%) had dyspareunia. In two of these four, dyspareunia appears to be with new onset.

The ICIQ-UI SF, the P-QoL, and PISQ-12 scores were 14.84 ± 4.09 vs 4.36 ± 2.71; 63.84 ± 16.13 vs 24.72 ± 6.75; and 29.08 ± 6.12 vs 37.58 ± 5.43 ($p < 0.001$) at preoperative and median follow-ups. Changes at 1 and 12 months of follow-up and median follow-up are reported in Table 4.

Discussion

The present study supports the efficacy and the safety of the VNTR for the POP treatment. At a median follow-up of 48 months, the objective anatomic cure rate was 91.1% with a low rate of the early and late complications and with a recurrence rate in 13 (8.9%) patients.

Surgical techniques for female POP have changed drastically due to emerging technologies and techniques [17]. Historically, surgeons have relied on patients native tissue through vaginal reconstructive procedures, because in normal anatomy, the interaction between level I and level II is responsible for correct vaginal orientation and physiological organs functions [8]. Later, the vaginal mesh introduction was not the panacea originally thought. In fact, a recent systematic review showed a very high early and late complication rate: erosion (10.3%), wound granulation (7.8%), dyspareunia (9.1%), and de novo SUI (12.3%) [18].

Moreover, the cure rate was higher in the mesh group regarding only the anterior compartment, but no statistical difference was seen in the apical and posterior compartments [19].

In our retrospective study at median follow-up of 48 months after surgery, recurrent anterior defect ≥stage II was present only in seven patients (4.8%). In the literature, the reoperation rate for anterior prolapse recurrence after VNTR vs mesh surgery is similar, but the rate of cumulative surgery for complications is higher in the mesh group [20, 21].

In the present study, we performed 109 apical POP surgeries by Shull suspension, with a cure rate of 98%. According to the recent literature, Shull and McCall techniques showed optimal anatomical outcomes and the recurrence rates are similar at any anatomical site, with the superiority of Shull suspension for sexually active and young patients, due to the feeling, that the cranial third of the vagina has a wider and more habitable shape [22–24].

Based on currently available data concerning posterior compartment, VNTR has similar outcomes to synthetic mesh, without the risks and higher cost inherent with the mesh application [25]. According to our data, posterior descent recurrence with a stage ≥II was 2% at the median follow-up, demonstrating that the VNTR is effective and safe. Unfortunately, our cases were too few to comment on clinical outcomes, such as flatus or fecal incontinence.

Mesh application in only one vaginal compartment is associated with a higher de novo prolapse rate in the untreated compartments, compared to conventional VNTR in women with recurrent pelvic organ prolapse [26, 27].

Concerning urinary incontinence, both coexisting or occult stress incontinence occurs in 36–80% of women with severe POP; hence, it is always appropriate to associate mid-urethral sling insertion to reduce postoperative incontinence. Conversely, the anti-incontinent surgery is not advisable in continent women without occult SUI due to the increase in adverse effects [28].

Moreover, no significant change in urodynamic findings after surgery was recorded in surgically treated patients with POP [29] as confirmed by our data.

Sexual dysfunction has been reported in one-third of the women with POP [30]. The improvement of postoperative sexual function depends on the surgical technique. A high rate of sexual dysfunctions, such as pelvic pain, dyspareunia, or inability, to achieve vaginal intercourse, in patients who undergone mesh repair is well known [31–33]. In our series, we reported an improvement of dyspareunia.

In the context of the recent data available and the FDA report, the use of the VNTR is recommended.

Compliance with ethical standards

Conflict of interest Author Michele Carlo Schiavi declares that he has no conflict of interest. Author Giorgia Perniola declares that she has no conflict of interest. Author Violante Di Donato declares that he has no conflict of interest. Author Virginia Sibilla Visentin declares that she has no conflict of interest. Author Flaminia Vena declares that she has no conflict of interest. Author Anna Di Pinto declares that she has no conflict of interest. Author Mario Angelo Zullo declares that he has no conflict of interest. Author Marco Monti declares that he has no conflict of interest. Author Pierluigi Benedetti Panici declares that he has no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Authors' contributions All the authors contributed equally to this study. Michele Carlo Schiavi: Project development, Data Collection, Manuscript writing. Giorgia Perniola: Project development, Data Col-

lection, Manuscript writing. Violante Di Donato: Project development, Data Collection, Manuscript writing. Marco Monti: Project development, Data Collection, Manuscript writing. Virginia Sibilla Visentin: Project development, Data Collection, Manuscript writing. Flaminia Vena: Project development, Data Collection, Manuscript writing. Anna Di Pinto: Project development, Data Collection, Manuscript writing. Marzio Angelo Zullo: Project development, Data Collection, Manuscript writing. Pierluigi Benedetti Panici: Project development, Data Collection, Manuscript writing.

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