Pelvic congestion syndrome - treatment with pelvic varicose veins embolization

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The Guidelines Project, an initiative of the Brazilian Medical Association, aims to combine information from the medical field in order to standardize producers to assist the reasoning and decision-making of doctors.

The information provided through this project must be assessed and criticized by the physician responsible for the conduct that will be adopted, depending on the conditions and the clinical status of each patient.

INTRODUCTION

The etiology of chronic pelvic pain includes irritable bowel syndrome, endometriosis, adenomyosis, pelvic congestion syndrome, atypical menstrual pain, urological disorders, and psychosocial problems^{1,2}. One of the underestimated causes of chronic pelvic pain (CPP) in women, especially multiparous at reproductive age, can be pelvic congestion syndrome (PCS), also known as pelvic pain syndrome or pelvic venous incompetence, which is defined as the presence of ovarian and pelvic varicose veins associated with non-cyclical chronic pain in the pelvic region. The pain is present for more than 6 months and is intensified with long periods in orthostatic position, coitus, and menstruation^{3.4}. Pelvic varicose veins and CPP are striking characteristics of the PCS, but women diagnosed with pelvic varicose veins can be asymptomatic⁴. The incidence of CPP in women aged between 18 and 50 years was estimated at approximately 20%. It constitutes 10% to 40% of all gynecological ambulatory consultations4.

In PCS, the pelvic examination can show pelvic sensitivity, congestion of the vaginal walls, and varicose veins⁵. Pelvic varicose veins can be seen in 10% of women in the general population, and up to 60% of patients with pelvic varicose veins may develop PCS. Varicose veins can be seen on the vulva, buttocks, and legs⁶.

The PCS is characterized by pelvic varicose veins, causing swelling and venous stasis of the organs of the cavity and, consequently, chronic pain. The venous dysfunction is caused by a multifactor process, within which the increase in intra-abdominal pressure and the action of the female hormones appear to be key factors. These aspects may explain the higher incidence of this syndrome in multiparous women in fertile age and the disappearance of symptoms during the climacteric.

The left gonadal and right internal iliac veins are the most affected (58% each) by reflux and in most cases (54%), there is an insufficiency of more than one major pelvic veins⁸.

Anatomic abnormalities that obstruct the pelvic venous system can lead to secondary PCS⁹. The extrinsic compression of the left renal vein, blocking the flow to the inferior vena cava (nutcracker phenomenon), is one of the causes to be considered of pelvic varicose veins and insufficiency of the left gonadal vein¹⁰. By a similar mechanism, the Left Common Iliac Vein Compression Syndrome (May-Thurner) can also be the source of the dysfunction¹¹.

Along with the clinical and physical examinations, there are additional resources for the diagnosis of PCS, such as the eco-color Doppler examination (abdominal or transvaginal ultrasound), which provides easier access and allows the dynamic study of the venous flow, with the visualization of venous stasis and reflux12. The assessment can also be done through computed tomography angiography (CTA), nuclear magnetic resonance angiography (NMR), laparoscopy, and venography 13,14. An ovarian vein diameter of 8 mm in the CTA or NMR is considered a diagnostic of PCS15. Venography is the gold standard for diagnosis, and the following findings must be present: gonadal vein with a diameter > 6 mm; retrograde venous flow; presence of several collateral veins with a tortuous path, and the delay in the drainage of the contrast after the injection9.

The resolution can be surgical (hysterectomy with or without bilateral salpingo-oophorectomy, ligation of ovarian veins), hormonal (medroxyprogesterone), or endovascular (embolization) ¹⁶⁻¹⁸.

Hysterectomy and bilateral oophorectomy with hormone replacement therapy are considered options for an effective cure or at least for the symptomatic improvement of two-thirds of patients with PCS¹⁹. This surgical option, however, is not as effective as the ligation of ovarian veins, for which a cure rate of 73% has been reported and with 78% of patients presenting symptomatic improvement. However, ligation also sections the nerves of the pelvis and allows the establishment of side effects and recurrence of symptoms²⁹.

The use of medroxyprogesterone has been revealing to be the primary therapy, although symptomatic relief is not sustained for a prolonged period²⁰.

For the treatment of the PCS, embolization of gonadal veins through a minimally invasive endovascular procedure is performed using the same catheterization of the diagnostic venography. The location of the embolization depends on the presence of collateral circulation. The embolization is performed centrally and peripherally²¹. Microcoils of stainless steel or platinum can be used, coated with fibers that induce the formation of blood clots. Several coils can be placed in long varicose veins; it is usually necessary to use 5 to 10 microcoils to embolize all insufficient vessels ^{21,22}. Currently, controlled-release coils from 6 mm to 14 mm are used preferably, since the gonadal vein is approximately 5 mm wide, and it is important to maintain a margin of oversizing that impedes the displacement of the coil. Other embolization options include the use of foam, glue or sclerosing substances. Once a dilated vein is occluded, venous blood is diverted through other veins of the pelvic region.

METHODOLOGY

A systematic review was conducted to evaluate the effects of percutaneous endovascular treatment of pelvic congestion syndrome (PCS) through the technique of embolization. The search resulted in 664 articles, of which 29 studies were included. The following search strategy was used: ((pelvic congestion syndrome OR pelvic venous congestion syndrome OR PCS OR Pelvic Pain OR chronic pelvic pain OR Pelvic Veins) AND (pelvic vein embolization OR Embolization, Therapeutic OR Sclerotherapy)) OR ((((embolization OR embolotherapies OR embolotherapy OR embolizations OR embolizations therapeutic))) AND (pelvic OR pelvis OR perirenal) AND (congestion syndrome OR venous insufficiency OR varices OR varicose veins OR pain)) OR ((pelvic congestion syndrome OR pelvic veins OR Pelvic Pain OR chronic pelvic pain) AND (embolisation OR sclerotherapy)).

The measurements used to express the benefit and harm varied according to the outcomes expressed. The continuous variables were analyzed by the mean and standard deviation, and the results were expressed in mean differences between the intervention and the control, with a confidence interval (CI) of 95%.

RESULTS

A single randomized clinical trial was recovered to answer the clinical question²⁶. In this study, of total of 118 randomized patients, 106 (loss of 10%) women with a diagnosis of PCS were included (90 with left unilateral PVCS, 8 with right unilateral PCS, and 8 with bilateral PCS) confirmed by diagnostic lapa-

roscopy and venography of the ovarian and internal iliac veins, irresponsive to therapy with medroxyprogesterone acetate (MPA) for 4-6 months. The patients were randomized into 3 groups: embolization of the ovarian vein and/or internal iliac vein with microcoils (Group A, n = 32), hysterectomy with bilateral oophorectomy and hormone replacement therapy with MPA [Group B, n = 34] or hysterectomy with unilateral oophorectomy. In group B, five patients with myoma were excluded; in Group C, four patients with adenomyomatosis and three who had had a hysterectomy with unilateral oophorectomy, although they had bilateral involvement. Therefore, a total of 52 patients we analyzed in the "embolization" group, 27 in the hysterectomy with bilateral oophorectomy and hormone replacement therapy group (HBOHR) and 27 in the hysterectomy with unilateral oophorectomy group (HUO). The outcomes evaluated were: pelvic pain using the visual analog scale (VAS), in which the intensity of pain was measured on a visual scale from 0 - 10, with 0 indicating the absence of pain and 10 meaning unbearable pain; pain reduction according to the levels of stress as measured by the revised Social Readjustment Rating Scale (SRRS), which classifies as typical level (100 to 199), moderate/high (200 to 299) and very high level (>300), in a retrospective comparison with the preoperative situation. The complications of the three interventions were also evaluated. The follow-up time was 12 months (Table 1).

The risk of bias for this study²⁵ was very high considering the following items: if the issue was focal, appropriate randomization, blinded allocation, double-blind, losses (>20%), prognostic characteristics, outcomes (time, adequacy, measurement), analysis by intention to treat (ITT), sample size calculation, and JADAD scale²³ (Table 2).

Embolotherapy compared with hysterectomy and bilateral oophorectomy combined with hormone replacement therapy with medroxyprogesterone reduced pelvic pain, in up to 12 months, evaluated by VAS (ranging from 0 to 10), on average, by 1.4 points (MD) with 95% confidence interval (CI) of 95% -1.85 to -0.94; p < 0.0001, (Table 3).

In comparison with the unilateral oophorectomy, embolotherapy reduced pelvic pain, in up to 12 months, evaluated by VAS (0 - 10), on average, by -2.4 (MD); 95% CI -2.80 to -1.99; p <0.0001 (Table 4).

This RCT²⁵ does not provide data on mean and SD, concerning pain in different scores of stress (Revised

Social Readjustment Rating Scale) for the periods of postoperative follow-up, thus preventing a comparison of different interventions for this outcome.

In the embolotherapy group, there were two patients (3.84%) that presented migration of one coil (one for the pulmonary circulation and the other for the renal circulation), but there was no death.

There was 1 complication in the hysterectomy with bilateral oophorectomy group and 1 complication in the hysterectomy with unilateral oophorectomy group, however, there is no reference to the type of complication. There was no death in these groups.

Adverse events with embolotherapy in case series studies

The results of 28 series of cases 8,22,26-51 showed the following complications from the embolization of pelvic varicose veins in the treatment of PCS: migration of coils to the pulmonary circulation with embolism and symptomatic or asymptomatic patients; migration of coils to the right external iliac arc vein or left renal vein; migration of glue fragment to the pulmonary circulation with embolism; venous perforation (ovarian vein, common iliac vein, internal iliac vein). However, there was no death in these studies.

SUMMARY OF THE RESULTS

This guideline aimed to identify, assess, and quantify the benefit and the harm from the use of percutaneous embolization (coils, foam, glue or sclerosing substances) of pelvic veins (ovarian and/or internal iliac veins or other collaterals) in women with PCS, as a method of treatment, compared to other treatment options.

The search for evidence retrieved 664 papers, of which 29 were selected to support the conclusions. Stratifying by study design, 1 (one) randomized controlled clinical trial²⁵, and 28 (twenty-eight) series of cases were included ^{8,22,26-51}.

The randomized controlled clinical trial was used to evaluate the effectiveness and harm, and the series of cases only for complications.

The only randomized controlled clinical trial included in this guideline presents a very high risk of bias (Table 2).

In this study, embolotherapy compared with hysterectomy and bilateral oophorectomy combined with hormone replacement therapy with medroxyprogesterone reduced pelvic pain in up to 12 months, on av-

erage, by 1.4 points 95% CI -1.85 to -0.94, p < 0.0001 in the evaluation using VAS, which ranged from 0 - 10 points, therefore, with a very small magnitude of effect. STRENGTH OF EVIDENCE VERY WEAK.

In comparison with the unilateral oophorectomy, embolotherapy reduced pelvic pain, in up to 12 months, evaluated by VAS (0 - 10), on average, by -2.4; 95% CI -2.80 to -1.99; p <0.0001, with a small magnitude of the effect. STRENGTH OF EVIDENCE VERY WEAK.

Although no deaths occurred, the complications found in the randomized clinical trial25 and in the 28 series of cases8,22,26-51, that used percutaneous embolization (coils, foam, glue or sclerosing substances) of pelvic veins (ovarian and/or internal iliac veins or other collaterals) in women with PCS were: migration of coils to the pulmonary circulation with embolism and symptomatic or asymptomatic patients; migration of coils to the right external iliac vein or left renal vein; migration of glue fragment

TABLE 1. DESCRIPTIVE TABLE OF THE CHARACTERISTICS OF THE RCT STUDY

STUDY	POPULATION (N)	INTERVENTION (N)	COMPARISON (N)	OUTCOME	FOLLOW-UP TIME
Chung MH, et al., 2003 ²⁵	Included 106 women with a diagnosis of PVI, confirmed by diagnostic laparoscopy and venography of the ovarian and internal iliac veins, irresponsive to MPA for 4-6 months. Exclusion: other pathologies (myoma, endometriosis, adherence). Excluded: - Group B: n=5 (myoma) - Group C: n=7 (4 due to adenomyomatosis and 3 who had had unilateral oophorectomy and hysterectomy although they had bilateral involvement)	Group A: Embolization of the ovarian and/or internal iliac vein with microcoils (n=52)	Group B: Hysterectomy with bilateral oophorectomy and hormone replacement therapy (32 randomized and included n=27) Group C: Hysterectomy with unilateral oophorectomy (34 randomized and included n=27)	- Pain (VAS) - Reduction of pain (VAS) per levels of stress (SRRS): retrospective Comparison with preoperative situation - Complications	3, 6, and 12 months

MPA = medroxyprogesterone acetate; PVI = pelvic venous insufficiency; VAS = visual analogue scale; SRRS = Revised Social Readjustment Rating Scale [classifies the level of stress: typical level (100 to 199), moderate/high level (200 to 299), very high level (>300)]

TABLE 2. DESCRIPTIVE TABLE OF THE BIASES IN THERAPEUTIC STUDIES (CHUNG MH, ET AL., 200325)

STUDY	FOCAL ISSUE	RANDOM- IZATION	BLINDED ALLOCATION	BLINDING	LOSSES	PROGNOSTIC DIFFERENCES		ITT
Chung MH, et al., 2003	Yes	Not described	No	No	10% excluded after randomization (reasons reported)	Yes	Yes	No

ITT = intention-to-treat analysis; ADAD²³ = 1; SAMPLE SIZE CALCULATION: There was none

TABLE 3. DESCRIPTIVE TABLE OF THE RESULTS (CHUNG MH, ET AL., 200325)

OUTCOME	(N) - Mean ± SD on EMBO- LOTHERAPY	(N) - Mean ± SD in hysterectomy with bilateral oophorectomy and hormonal replacement therapy	Mean differences (MD)	CI 95%	P-value
Pain (VAS score) in 12 months	(N = 52) 3.2 ± 0.9	(N = 27) 4.6 ± 1.1	-1.4	-1.85 a -0.94	<0.0001

VAS - visual analog scale of pain (score 0 to 10); SD = standard deviation; CI = confidence interval

TABLE 4. DESCRIPTIVE TABLE OF THE RESULTS (CHUNG MH, ET AL., 2003²⁵)

OUTCOME	(N) - Mean ± SD on EMBOLOTHERAPY	(N) - Mean ± SD in hys- terectomy with unilateral oophorectomy	Mean differences	CI 95%	P-value
Pain (VAS score) in 12 months	(N = 52) 3.2 ± 0.9	(N = 27) 5.6 ± 0.8	-2.4	-2.80 a -1.99	<0.0001

to the pulmonary circulation with embolism; venous perforation (ovarian vein, common iliac vein, internal iliac vein). STRENGTH OF EVIDENCE VERY WEAK

RECOMMENDATION

This guideline had access to a single randomized controlled clinical trial, with a high risk of bias, and no other comparative study for the evaluation of the evidence (effectiveness and harm) of percutaneous endovascular treatment in pelvic congestion syndrome using the technique of embolization. Therefore, the results are associated with a high degree of uncertainty which hinders the establishment of a firm conclusion that allows this procedure to be considered a standard treatment option for PCS. (STRENGTH OF EVIDENCE VERY WEAK)

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