Post-Uterine Artery Embolization Pain and Clinical Outcomes for Symptomatic Myomas Using Gelfoam Pledgets Alone Versus Embospheres Plus Gelfoam Pledgets: A Comparative Pilot Study

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Abstract

Background: To evaluate the efficacy and post-procedural pain associated with uterine artery embolization (UAE) using Gelfoam alone versus Embospheres plus Gelfoam in women with symptomatic uterine fibroids.

Method: We conducted a prospective, non-randomized pilot study. Fluoroscopy-guided trans-femoral artery UAE was performed using Gelfoam pledgets alone or Embospheres (500 to 700 μg) plus Gelfoam under conscious sedation and local anaesthesia. This was followed by patient-controlled analgesia (PCA) using a morphine pump overnight.

Post-procedural pain was assessed by the mean amount of self-administered morphine delivered by PCA pump (mL) from 0 to 19 hours in each group. The mean volumes of the uterus and the dominant fibroid were calculated by ultrasound at baseline, three months, six months, and 12 months.

Results: A total of 17 women participated in the study. Bilateral uterine artery occlusion was performed in eight women using Gelfoam alone, and in nine women using Embosphere + Gelfoam. One woman in the Embosphere + Gelfoam group developed a puncture-site hematoma requiring further intervention one week later. The mean (SD) amount of morphine self-administered by PCA pump at time 0, 1, and 2 hours was 3.4 mg (3.1), 2.9 mg (2.2), and 2.4 mg (3.3) in the Gelfoam-only group and 6.1 mg (3.0), 9.6 mg (7.1), and 5.3 mg (4.4) in the Embosphere + Gelfoam group, respectively. After three hours, the amount of morphine used was equal in both groups. The mean (SD) total dose of morphine used was 29.5 mg (18.6) in the Gelfoam group and 41.1 mg (19.3) in the Embosphere + Gelfoam group (P = 0.228). At 12 months, the reduction in median total uterine volume and median dominant fibroid volume in each group was equal.

Conclusion: Clinical outcomes were equivalent after uterine artery embolization using Gelfoam alone versus Gelfoam + Embospheres. Although the amount of immediate post-procedure pain may be less with Gelfoam alone, we could not demonstrate this objectively using morphine use as a measure of pain.

Key Words: Fibroids, myomas, leiomyomas, abnormal uterine bleeding, uterine artery embolization, Gelfoam, Embospheres

Competing Interests: None declared.

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Résumé

Contexte : Évaluer l'efficacité et la douleur post-interventionnelle associées à l'embolisation de l'artère utérine (EAU) au seul moyen du produit Gelfoam, par comparaison avec l'utilisation combinée des produits Embosphere et Gelfoam, chez des femmes présentant des fibromes utérins symptomatiques.

Méthode : Nous avons mené une étude pilote non randomisée prospective. Une EAU par voie transfémorale guidée par fluoroscopie a été menée seulement au moyen de tampons Gelfoam ou au moyen des produits Embosphere (500-700 μg) et Gelfoam, sous sédation consciente et anesthésie locale, le tout ayant été suivi par la mise en œuvre d'une analgésie contrôlée par la patiente (ACP) pendant la nuit suivant l'intervention (au moyen d'une pompe à morphine).

La douleur post-interventionnelle a été évaluée en fonction de la quantité moyenne de morphine auto-administrée au moyen de la pompe d'ACP (ml) entre 0 et 19 heures au sein de chaque groupe. Les volumes moyens de l'utérus et du fibrome dominant ont été calculés par échographie au départ, à trois mois, à six mois et à 12 mois.

Résultats : Au total, 17 femmes ont participé à l'étude. Une occlusion bilatérale de l'artère utérine a été menée chez huit femmes en n'utilisant que le produit Gelfoam et la même intervention a été menée au moyen des produits Embosphere et Gelfoam chez neuf autres femmes. Une des femmes du groupe « Embosphere et Gelfoam » en est venue à présenter un hématome au point de ponction ayant nécessité une autre intervention, une semaine plus tard. La quantité moyenne (σ) de morphine auto-administrée au moyen de la pompe d'ACP à 0, à 1 et à 2 heures a été de 3,4 mg (3,1), de 2,9 mg (2,2) et de 2,4 mg (3,3), au sein du groupe « Gelfoam seulement », et de 6,1 mg (3,0), de 9,6 mg (7,1) et de 5,3 mg (4,4), au sein du groupe « Embosphere et Gelfoam », respectivement. Après trois heures, la quantité de morphine utilisée était équivalente au sein des deux groupes. La dose totale moyenne (σ) de morphine utilisée a été de 29,5 mg (18,6) au sein du groupe « Gelfoam seulement » et de 41,1 mg (19,3) au sein du groupe « Embosphere et Gelfoam » (P = 0,228). À 12 mois, la diminution du volume utérin total médian et du volume médian du fibrome dominant était équivalente au sein des deux groupes.

Conclusion : La tenue d'une embolisation de l'artère utérine en n'utilisant que le produit Gelfoam ou au moyen des produits Gelfoam et Embosphere a donné lieu à des issues cliniques équivalentes. Bien que la douleur post-interventionnelle immédiate puisse être moins intense lorsque l'on n'a recours qu'au produit Gelfoam, nous n'avons pas été en mesure de le démontrer de façon objective en utilisant la quantité de morphine auto-administrée à titre de mesure de la douleur.

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INTRODUCTION

Uterine fibroids are common in reproductive-aged women, affecting 40% by age 35 years and 70% by age 50 years.[1] Most fibroids are asymptomatic, but 20% to 50% of women with fibroids require treatment for menstrual disorders and/or bulk effects.[2] Most fibroids appear de novo and continue to grow until menopause if untreated. Historically, the commonest treatment provided has been hysterectomy.[2]

Uterine artery embolization (UAE) is an effective treatment for management of symptomatic fibroids.[3] It results in a reduction in fibroid size of 40% to 60%[4,5] and a 50% mean reduction in blood loss.[5] In a recent meta-analysis, the pooled rates of improvement in menorrhagia, bulk symptoms, and dysmenorrhea at one to two years of follow-up were 90.1%, 82%, and 84.4% respectively.[6] UAE is currently an accepted alternative to hysterectomy in the treatment of fibroids.[7]

Embolization of the uterine arteries is most commonly accomplished using inert permanent particles such as polyvinyl alcohol particles or tris-acryl gelatin microspheres, usually ranging from 500 to 700 μm in diameter. Tris-acryl gelatin microspheres (Embospheres, Merit Medical Systems Inc., South Jordan UT) are a commonly used occlusion material in our centre. Particles are injected until arterial stasis or near-stasis is achieved. The volume of particles required varies with fibroid and uterine size and vascular anatomy.

Uterine artery occlusion results in blood stasis, clot formation, and temporary tissue ischemia of the entire uterus. Autolysis of clots occurs within six hours, resulting in reperfusion of the uterus by collateral circulation derived mainly, but not exclusively, from the ovarian arteries.[8] Evidence of collateral circulation is shown in angiography of anastomoses between uterine and utero-ovarian vessels which occur in up to 40 % of patients.[9–11]

Pain following UAE has at least two distinct etiologies, each with its own consistent timeline. Pain immediately after UAE, lasting four to six hours and sometimes up to 24 hours, has been well documented. This pain is likely caused by transient ischemia of the myometrium[12–15] and inflammation.[16,17]

A second form of pain begins several days after UAE and is seen in 3% to 4% of patients.[6,18] This is commonly referred to as post-embolization syndrome; it is thought to be caused by an inflammatory response to tissue necrosis of both myometrium and fibroid tissue.[19] It is characterized by leukocytosis, fever, and prolonged pain lasting up to seven days, and is a common reason for re-hospitalization and possible re-intervention, including hysterectomy.[20]

Pledgets of Gelfoam (Pfizer Canada Inc., Kirkland QC) can be used as an alternative occlusion material in combination with or in lieu of micro-particles for UAE. Gelfoam pledgets are readily available at most centres performing UAE, are significantly less expensive than other hemostatic options, and are completely dissolved in vivo within seven to 21 days. Gelfoam is available either in powder form or in sheets that are cut into smaller pledgets and dissolved in saline. The size of pledgets can be customized by the interventionalist according to preference.[21] The larger the particles, the less likely they are to migrate beyond the uterine arteries, reducing the chance of misembolization. At our centre, we typically use a combination of Gelfoam and Embospheres for most uterine artery embolizations.

The present study was designed to compare the feasibility and immediate post-procedure efficacy of UAE using Gelfoam alone versus Embospheres + Gelfoam. The primary outcome measured was post-procedural pain. Secondary outcomes included uterine and dominant fibroid reduction and re-intervention rate.

METHODS

This was a prospective, non-randomized, patient-blinded cohort study assessing post-procedural pain following UAE with Gelfoam alone versus Gelfoam + Embospheres. Informed consent was obtained from all patients enrolled in