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Prostatic artery embolization in 420 patients with lower urinary tract symptoms or chronic urinary retention: early outcomes and risk factors in a French multicentric retrospective study

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► To cite this version:

Asmaa Belaouni. Prostatic artery embolization in 420 patients with lower urinary tract symptoms or chronic urinary retention: early outcomes and risk factors in a French multicentric retrospective study. Human health and pathology. 2019. dumas-02868586

HAL Id: dumas-02868586

<https://dumas.ccsd.cnrs.fr/dumas-02868586>

Submitted on 12 Oct 2020

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UNIVERSITE DE MONTPELLIER
FACULTE DE MEDECINE MONTPELLIER-NIMES

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Pour obtenir le titre de
DOCTEUR EN MEDECINE

Présentée et soutenue publiquement
Par
Asmaa BELAOUNI

Le 4 Octobre 2019

Prostatic artery embolization in 420 patients with lower urinary tract symptoms or chronic urinary retention: early outcomes and risk factors in a French multicentric retrospective study.

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REMERCIEMENTS

Aux membres du Jury de thèse :

A Monsieur le Professeur Jean-Paul BEREGI :

Vous me faites le très grand honneur de présider le jury de cette thèse. Je vous remercie pour vos conseils avisés tout au long de mes semestres passés à Nîmes. J'admire votre parcours, votre volonté, votre courage immense pour défendre vos idées et en faire profiter le monde entier. Je sais la chance que j'ai de pouvoir bénéficier de votre enseignement et de vos immenses connaissances. Je vous prie de recevoir l'expression de mon profond respect et de ma sincère reconnaissance.

A Monsieur le Professeur Hélène VERNHET-KOVACSIK :

Vous me faites le très grand honneur de siéger parmi ce jury de thèse. Je suis une grande admiratrice de votre parcours et de votre dévouement pour ce métier. J'ai été honorée de recevoir votre enseignement et plus particulièrement dans le domaine de l'imagerie cardiaque que j'espère avoir l'opportunité de poursuivre dans les prochaines années. Je vous prie de recevoir l'expression de mon profond respect et de ma sincère reconnaissance.

A Monsieur le Professeur Stéphane DROUPY :

Je vous remercie de me faire l'honneur de siéger à ce jury de thèse. Merci également d'avoir accepté d'évaluer mon travail sur ce sujet qui j'espère vous a été utile. Je vous prie de recevoir l'expression de mon respect et de ma sincère reconnaissance.

A Monsieur le Docteur Julien FRANDON :

Merci infiniment pour ta bonne humeur, tes taquineries, tes blagues (parfois inadaptées), ta motivation sans limite qui m'ont donné envie de travailler avec toi. Tu as le don d'obtenir ce que tu veux des autres et je dis ça en pensant au TIPS qu'on a fait ensemble ce fameux samedi matin. Grâce à toi, j'ai fait le tour de la France à l'affut des données sans trop me poser de questions. En travaillant avec toi, j'ai su

que je voulais faire partie de ton équipe. J'ai encore plus d'attrait pour la radiologie interventionnel. Tu as toujours su te montrer rassurant quoi qu'il arrivât en salle et quelques soit les erreurs que je pouvais faire. Tu sais aussi te montrer moqueur dans les situations les plus inconfortables, mais c'est ce qui fait le charme de faire partie de ton équipe. Ton nom et ton ambition sont une marque, j'ai beaucoup de respect pour ça et j'espère être à la hauteur de tes attentes. J'ai encore beaucoup à apprendre et j'en suis impatiente. J'ai une très grande estime pour toi. Je te remercie de m'avoir impliquée dans ce travail qui ne fait à vrai dire que commencer.

A ma famille.

A mon papou, J'aurai tellement aimé que tu sois là, t'avoir auprès de moi aurait été mon vœux le plus cher, toi qui a toujours su me soutenir même quand je n'avais pas été à la hauteur. Tu es parti beaucoup trop tôt. Malgré cela, tu m'as transmis une force mentale qui m'a permis de tenir jusqu'au bout et de garder la tête froide à chaque moment clé de mes études. J'ai toujours eu un amour et une admiration inconditionnels pour toi. Parfois je sens encore ta présence comme pour me donner plus de force quand j'en ai besoin. Je t'aime Papa.

A maman, ma tendre et douce maman, notre relation si fusionnelle a forgé une partie de la personne que je suis aujourd'hui. Je t'ai toujours prise pour exemple, honnête, studieuse, forte, sérieuse, ambitieuse, courageuse, exigeante envers toi-même, voilà ce que j'ai toujours espéré prendre de toi. Tu as été mon pilier toutes ces années, ton soutien en toute épreuve m'a aidé à tout surmonter. Tendre mais caractérielle à la fois, je crois qu'on ne doit pas être si différentes toi et moi. Je te serai toujours reconnaissante de m'avoir fait confiance, de m'avoir encouragée à m'engager dans cette voie-là, sans jamais émettre le moindre doute sur mes capacités, de m'avoir épaulée durant tous ces moments de stress, qui ont pourtant été longs. Cela a été presque vital pour moi, tu m'as rendue plus forte que ce que j'aurai pu être. J'ai toujours voulu te rendre fière car cela a été la source d'un bonheur essentiel dans ma vie. Avec du recul, je pense que j'étais un petit toi en plus timide et réservée mais ayant toujours su que je voulais aller le plus loin possible dans mes ambitions, et sans aucun doute, c'est toi qui me l'a transmis. Enfin, merci pour ton amour inconditionnel, ton affection sans limite et ta bienveillance. Un jour, j'aurai peut-être des enfants et j'espère leur donner autant d'amour que j'ai reçu. Je t'aime Maman.

A mon grand frère Khalid, mon héros, mon meilleur exemple dans la vie, tu es beau intelligent et grand boss, ceux qui me comparent à toi me font le plus beau des compliments. J'admire autant ta force mentale que physique, ton énergie inépuisable te permettant de gérer tout aussi bien ton travail que ta petite famille. Malgré notre différence d'âge, nous n'avons jamais été aussi proche qu'actuellement, tu es une source de lumière dans ma vie et c'est grâce à toi que j'en

suis là. Toute petite déjà, je te vouais une grande admiration, un immense respect, et j'aspirai à être ta version féminine, cela n'a jamais changé. Je te suis reconnaissante de m'avoir encouragé à faire ce métier, c'est principalement grâce à toi que je me suis engagée dans cette voie, tes conseils m'ont toujours été très précieux (même si tu aurais préféré que je sois dentiste :p). Je te remercie également pour tes encouragements et ta présence inconditionnelle, tant dans les moments de joies que les moments difficiles, ton amour et ta bienveillance. Enfin, merci d'avoir été là quand papa est parti, j'aurai sûrement abandonné mon concours sans ton soutien.

Je t'aime tellement fort grand frère chéri.

A Nadia, tu es comme une grande sœur pour moi, tu m'as toujours accueillie avec beaucoup de bienveillance. Tu as toujours été là quand j'avais besoin. Je te suis reconnaissante pour tes nombreux conseils en tout domaine. J'admire ton intelligence, ta capacité incroyable à résoudre le moindre problème et à savoir gérer des milliers de choses à la fois. Tu as ce côté bavard qui chez toi constitue une si grande qualité que j'apprécie spécialement. Mon frère et toi êtes complémentaires sur bien des choses et vous continuerez à l'être. Je t'aime fort.

A Lilya et Adam, mes petits neveux d'amour, je suis heureuse de vous voir grandir, chaque moment passé avec vous est un bonheur pour moi. Lilou, je suis fière de ton parcours et ce que tu as déjà accompli du haut de tes 12 ans. Tu es ma petite danseuse étoile préférée. Gracieuse mais aussi intelligente, l'avenir ne te réservera que de belles aventures, mais n'oublie pas de rester toi-même. Adam, entre l'équitation et le foot, ton cœur balance, mais à 6 ans tu es déjà un petit garçon bien déterminé, fort de caractère mais d'une tendresse intense. Je vous aime mes petits loups.

A ma sœur jumelle, Hasna, à notre complicité incontestable toutes ces années, à être inséparables malgré nos chamailleries d'enfants, à nos différences aussi qui ont forgé nos personnalités peu comparables. J'espère que la distance n'aura pas raison de notre relation si unique. Je te souhaite de tout mon cœur de réussir dans tes projets, même si tu t'es éloignée un peu plus. Je t'aime très fort.

A Mima, ma 2^{ème} maman, je te suis profondément reconnaissante pour l'éducation que tu m'as donnée, si pure, bienveillante, généreuse et tendre, tu m'as appris à toujours vivre dans le respect envers soi et les autres. Tu fais partie de ceux qui ont

rendu mon enfance si heureuse et insouciante. Dès l'âge de 5 ans tu me surnommait déjà « le petit docteur », aujourd'hui je le suis vraiment et j'espère que tu aurais été fière de moi. Je te dédie ce travail. Je t'aime Mima.

A mes tatas et tontons du Maroc, Fadela, Wassila, Youssef, Rachid (2), vous m'avez vu grandir, m'avez chéri et aimé comme votre fille. Vous m'avez apporté beaucoup d'amour et de tendresse, m'avez gâtée d'attention et de cadeaux. Malgré la distance qui nous sépare, votre place dans mon cœur a toujours été grande et le restera. Je vous aime tous très fort.

A mes cousins Salma, Soussou et Meriem, mon enfance n'aurait pas été la même sans vous, tous ces bons moments passés avec vous, à jouer, à rire, à se chamailler me manquent tellement. Nous avons été si proches étions si différents et complémentaires à la fois et malgré la distance qui nous sépare aujourd'hui, les retrouvailles font parties de ces meilleurs moments de l'année. A Salma, je te souhaite une très belle nouvelle vie à Toulouse avec ta petite famille. A Souhail, Singapour et compagnie ça suffit, j'ai bien hâte que tu reviennes après ces 6 années. A Mimi, tu as un bel avenir qui t'attend. Je vous aime fort.

A Rizou, Patrick, merci infiniment d'avoir été là pour moi tout au long des années de médecine et tout particulièrement la 1^{ère}. Vous m'avez si bien accueilli dans votre environnement à Rennes. J'ai tellement aimé passer tous mes moments libres avec vous, même s'ils se faisaient rares. Votre aide et soutien ont été précieux pour moi et je vous dois la réussite de ce fameux concours de 1^{ère} année. Je me suis éloignée mais vous me manquez et comptez tellement pour moi. **A Adam**, mon amour de petit cousin, qui à lui seul a su remplir votre vie de bonheur, et la mienne également. Je vous aime très fort.

A Lamia, Mickael, Camille et Clément, mon petit noyau familial montpelliérain, je vous suis reconnaissante pour votre présence et ces bons moments passés avec vous, ces fêtes de Noël et nouvel an, ces week-end en Espagne et ces soirées tapas.

A mon cousin Tarik, ta douceur et attitude protectrice envers moi m'ont toujours fait me sentir comme ta petite sœur, sans oublier ton petit côté taquin. Je t'admire beaucoup.

A ma famille hollandaise, à tous ces moments partagés avec vous lors de mon enfance, à tous ces instants de jeux, ces journées passées à la plage, ces soirées à se promener.

A mes ami(e)s.

A Alice, je suis ta plus grande admiratrice et je m'estime heureuse de faire partie de ta vie. D'une énergie inépuisable, une gentillesse et bienveillance sans égales, un dévouement pour tes plus proches mais aussi pour ton métier que je ne saurais qualifier, une intelligence exceptionnelle, à toi je te serai l'une des plus fidèles amies. Merci de m'avoir initiée à la planche à voile, au surf et autres activités plus ou moins dangereuses. A tous nos moments passés ensemble. Je t'aime très fort et te souhaite une vie remplie d'aventures, de bonheur et d'amour avec ta tendre Floriane.

A Cécile, ma popinou d'amour, ma co équipière de sports de glisse en tout genre. On s'est adorées dès le 1^{er} regard, je me souviendrai toujours de la première où je t'ai rencontré, depuis mon affection pour toi n'a cessé de grandir. J'adore ta bonne humeur, ton côté aventurière, toujours pétillante et motivée. Nous avons encore tellement de bons moments devant à nous à partager. Je vous souhaite à Pierre et toi tout le bonheur du monde. Je t'aime fort.

A Ghita, mon amie d'enfance, ma seconde moitié, on a toujours su être complémentaire de part nos caractères et nos différences, on a grandi ensemble, inséparables au collège puis au lycée. Depuis ce temps, on a su entretenir cette belle amitié et continuer à partager de délicieux moments de complicité. Je te souhaite d'être heureuse dans tes différents projets. Je t'aime fort.

A Julien, on s'est connu en 1^{ère} année de médecine sans plus jamais se quitter. Tu es l'un de mes plus chers amis et je te dois tellement. Merci à toi et ta famille de m'avoir toujours accueilli à bras ouverts avec tellement de douceur de bienveillance et de générosité. A Cécile, ta maman, Nicolas, ton papa, Marie et Claire, tes deux petites sœurs, ma famille adoptive que j'aime tout autant. Merci de m'avoir supporté ces quelques années d'externat passées ensemble à Rennes. Merci pour m'avoir soutenue psychologiquement face à l'une des pires situations que j'ai pu vivre jusqu'ici. Je vous souhaite plein de bonheur avec Marion. Je t'aime très fort.

A Bahia, ma petite Baba au Rhum d'amour, tu m'as prise sous ton aile en 1^{ère} année de médecine et tu as largement participé à ma réussite, grâce à ton soutien psychologique, à ta bienveillance, à ta douceur, j'avais trouvé une grande sœur à ce moment-là. Je n'oublierai pas nos années de collocations alternant révisions, soirées médecines, moments de rire et d'autres à pleurer. Aujourd'hui te voila grande, mariée et prête à t'installer dans le fin fond de la Bretagne, mais malgré cette distance j'espère que l'on restera aussi proches et je te souhaite le meilleur pour la suite. Je t'aime fort.

A Marlène, ma petite Marly, une fille exceptionnelle à tout point de vue, en plus de ton look sorti tout droit d'un magazine, toujours motivée, pétillante, pleine de bonnes idées et d'une intelligence peu commune. Tu sais autant t'amuser qu'être sérieuse et toujours dans la rigolade. A nos fameuse fraises Tagada paillettes.

A Charles-Eric, Charlichou, à tes blagues, ton flegme, toutes tes bêtises incessantes qui me manquent parfois.

A mes copains du Maroc, Tarik, Tarik, Tarek, Hmidou, à toutes ces soirées, sorties, WE à Marrakech qu'on a pu faire ensemble. Vous avez toujours été bienveillants envers moi, faciles à vivre et surtout vous avez pu supporter mon petit caractère toutes ces années. J'ai pu compter sur chacun de vous dans n'importe quelle situation.

A Hicham, à nos quelques années passées ensemble qui font parties de moi, ma vie et m'ont aidé à grandir et me construire. Tu auras toujours une place importante pour moi.

A mes amis de Montpellier,

A Jenny, ou Jenay pour ma part, j'admire ton intelligence assez exceptionnelle qui se cache derrière tant de modestie. Travailler avec toi a été un pur bonheur, toujours motivée, sérieuse et rigolote à la fois, le mélange parfait. J'ai également eu la chance de te découvrir de façon plus intime, à savoir dans des conditions « extrêmes » de trekking en Jordanie où l'on a parfaitement su co-habiter dans la même tente sans

douche pendant 4 jours, et je n'en garde que des bons souvenirs. Je te souhaite de tout réussir, tant sur le plan professionnel que personnel. Je t'aime fort ma Jenini.

A Philou, si différents et pourtant tu es ma plus longue relation de cohabitation après mes parents... Merci de nous avoir supporté mon caractère et moi ces 4 années passées en colocation. Avant de te connaître je ne savais pas qu'on pouvait être autant passionné de poissons et d'aquarium. Tu es aussi original que tes hobbies et cela fait tout ton charme. « Asmou ! je vais nous faire un nouvel aquarium avec des .. crevettes, ..., je vais peindre une baleine bleue sur le mur du salon, je vais faire pousser un ananas du Japon, ... ». Ton imagination débordante et sans limite sera toujours une intrigue pour moi.

A Sandra, à ton naturel, ta beauté et ton dynamisme qui l'ont fait craquer. A votre bonheur et nouvelle vie à tous les 3 qui sera remplie de bonheur, d'amour et d'attention.

A Christophe, ou Chrissou, je suis parmi tes plus grandes admiratrices et tu es mon meilleur coup de cœur de l'internat. Tout est dit.

A la promo « Bisounours » :

A Benjou, tu as été mon 1er co-interne, on a réussi à se soutenir dans les moments les plus difficiles. Chaque stage après ça avec toi a été un régal du point de vue professionnel et surtout personnel. Ta bonne humeur m'a toujours épatée et rendu mes journées tellement plus agréables. Merci pour ta confiance, ta patience, ta présence tout court.

A Antonia, on a plus partagé de soirées, randonnées et autres sorties que de stages ensemble. Simplicité, générosité et fidélité sont tes plus belles qualités. Toujours motivée pour toute sorte de loisir, j'ai adoré passer ces nombreux moments avec toi.

A Charlotte, à ta constante bonne humeur, à ta douceur, ta générosité et bienveillance, ta motivation et ton courage dans tout ce que tu entreprends.

A Anne Hélène, à ton rire, à ta douceur, tu es ma petite lilloise préférée. Tout plein de bonnes choses t'attendent avec ton petit Roméo.

A Taki, merci pour tes bons conseils, de toujours mettre une bonne ambiance, tu as ce côté serein et apaisant qui rend le travail si agréable avec toi.

A mes co-internes,

A Lylia, ta douceur, ta gentillesse, ta motivation et ton sérieux qui font de toi cette jeune femme si unique et que j'apprécie tant. Je regrette ton départ et te souhaite une belle réussite dans ta carrière et tes projets personnels.

A Benoit, à tes blagues bizarres et parfois incompréhensibles, à ton rire inimitable, toujours prêt à rendre service, je n'oublierai jamais ce jour où tu m'as sauvée d'une garde alors que je pensais mourir d'une grippe. J'aurai apprécié travailler d'avantage avec toi les prochaines années. En tout cas je te souhaite le meilleur.

A Alexandre S., ce 1^{er} stage de radio à GdC n'aurait pas été le même sans toi. Tu sais instaurer un climat de sérénité dans la bonne humeur et le sérieux. J'admire ton assurance et ta fausse nonchalance sans oublier ton franc côté blagueur. J'ai bien hâte de (re)travailler avec toi.

A Elaura, merci pour ta douceur et bonne humeur, sans oublier ton joli sourire qui me mettait tout le temps de bonne humeur. Je sens qu'on va continuer à bien s'entendre et surtout à partager quelques activités ensemble (oooooooo).

A Mehdi, avec ton joli sourire toujours prêt à faire une pause-café quoiqu'il arrive. Je pensais être tête en l'air, mais après 6 mois de stage avec toi j'ai compris qu'il y avait bien pire. J'ai été ravie de te découvrir autant en stage qu'en dehors. Merci pour ta bienveillance et d'avoir pris soin de ce « petit poussin » qui te suivait partout dans les rues parisiennes.

A Helene, à ton incroyable bienveillance, ta douceur, ton côté fêtarde que tu as su allier à ta nouvelle vie de maman. Tu es un exemple pour bon nombre d'entre nous. A ta nouvelle vie en Bretagne.

A Nadir, admirative de ta bienveillance, ton sérieux et ton dévouement pour les autres, tu as su te démarquer par ta motivation. J'ai été ravie de travailler avec toi et bien heureuse de ton retour.

A Antoine L., ton énergie, ta motivation inépuisables et ton incroyable intelligence que j'admire tant, restent un mystère pour moi. Notre irremplaçable organisateur officiel de soirées de la radiologie : à toutes ces soirées qui restent à venir.

A Kim, à ton humour et second degré, à ta future carrière de radiologue-paysagiste.

A Margaux H., j'admire ton sérieux, ton intelligence, surtout ton côté perfectionniste où rien ne peut t'échapper, tout cela avec des petites pointes d'humour qui rendent le travail agréable avec toi.

A tous mes autres co-internes, aux plus vieux **Aymeric, Lauranne, Pierre L., Adel, William, Nadia, Satcha, Maelis, Aureline** et aux plus jeunes **Quentin D, Phil L**, merci de m'avoir supportée tous ces stages durant.

A tous les autres internes ou chefs avec qui j'ai eu l'occasion de partager des gardes, des pots de thèse ou boire des coups, **Carole, Céline, Caroline, Brice**.

A mes chefs,

A Florian, mon tout premier chef de clinique, tu m'as connue « bébé » interne et m'a vu grandir et évoluer. C'est toi qui m'a appris à interpréter mes premières imageries, qui m'a aidé me surpasser pendant ces moments de stress des premières gardes, tu as su te montrer ferme quand il le fallait tout autant qu'amusant avec ta bonne humeur et tes « non mais laissez-moi, non mais laissez-moi manger ma banane.. ». En plus d'avoir été un super chef tu es un artiste exceptionnel.

Aux nîmois

A Alban, je ne saurais quantifier ou qualifier la grande admiration et le grand respect que j'ai pour toi, j'aurais aimé profiter de tes connaissances plus longtemps, mais ton bonheur avant tout. Merci pour ton enseignement, ton dévouement pour tes internes, pour tous ces cafés et sans oublier tes discours dignes d'un grand poète.

A Iskander, co-interne puis chef, merci pour ta solidarité lors de certains moments passés à GDC, ton enseignement, avec toi tout est dans la précision, le savoir et la maîtrise des choses, sans oublier bien évidemment ces nombreuses imitations en allant de NL, VC, PM à JF, JG qui m'ont tellement faites rire toutes ces vacances passées avec toi, tu as un talent exceptionnel.

A Jean, à ta patience inépuisable, enfin non pas du tout, à ta sagesse et ta capacité à canaliser Julien. J'apprécie travailler avec toi et ce sera un grand plaisir de continuer à apprendre ce métier à tes côtés.

A Mélinée, à ton dynamisme, constante bonne humeur et bienveillance. Merci pour ta disponibilité en toute circonstance, tous ces avis en pédiatrie et pour toutes les pauses café/potins. Je suis ravie de continuer à travailler avec toi.

A Romain, à ta constante bonne humeur, à ton rire, merci pour ta patience avec moi, tu m'as appris pas mal de tips en geste interventionnel. J'ai beaucoup aimé être ton interne, et je suis ravie de travailler avec toi ces prochaines années.

A Elise, à ton dynamisme, ta bonne humeur, ton investissement auprès de tes internes.

A Ahmed, le Don de la radiologie, mon exemple dans la rigueur, à toutes ces pauses café qu'on faisait parmi les 25 IRM de la vac, mêlées à une gestion parfaite du timing,

A Anca, Anna, Conny, Cyrine merci pour votre disponibilité, votre enseignement et votre bienveillance.

A Pierre, Pierre et Fehmi, les osseux nîmois, merci pour votre enseignement en imagerie ostéo-articulaire, et surtout pour votre patience.

A l'équipe de radio-pédiatrie, a Cathy, merci pour ton enseignement, ta patience, et ton extrême bienveillance, **à Ikram**, merci pour ta douceur, tes précieux conseils et ces petits schémas lors des vacances d'écho, **à Julie**, à ta bonne humeur et ton

dynamisme, à **Olivier** et tes petites blagues, **Stéphanie, Nancy**, merci pour votre enseignement.

A l'équipe de Lapeyronie, au Pr Taourel, à Ingrid, Cécile, Marion, Claire, Emma, Fernanda, merci pour tout ce que vous m'avez appris, pour votre soutien lors des gardes et votre bienveillance.

A Yann, à toutes ces blagues que je n'ai pas souvent comprises, à ta patience et tes connaissances infinies, **A Benjamin**, merci pour ces petits bonbons lors des gardes, et surtout pour avoir veillé sur nous en 1^{er} semestre.

A l'équipe D'Arnaud de Villeneuve, à Sébastien, merci pour ton enseignement, ta confiance et pour m'avoir initiée aux ponctions thoraciques..., **à Hamid, à Valérie, à Juliette et à Cyril**, merci pour votre enseignement en imagerie cardio-vasculaire.

A l'équipe de st Eloi, à Marie-Ange, Elisabeth, Valentina, Laure, Stéphanie merci de m'avoir tout appris de l'imagerie digestive.

A l'équipe de Gui de Chauliac, au Pr Bonafe, à Vincent, Nicolas M., Nicolas L., Gregory, Carlos, à ce 1^{er} stage de radiologie en tant que « bébé » interne. Merci de m'avoir initié à l'imagerie en général et à la neuro-radiologie en particulier.

A l'équipe de Perpignan, à Geoffroy (mon jojo), merci de m'avoir initié et fait aimer la radiologie interventionnelle, à ta patience et ta qualité d'enseignement que je n'oublierai pas, **Aymeric**, merci pour ta bonne humeur et tout ce que tu m'as appris, **Maxime, Sabine, Anna Maria, Sandra, Philippe, Jean-Louis**, vous m'avez formé et fait aimer la radiologie sous toutes ses formes.

A toutes les équipes de manips radio et de secrétaires, je ne peux vous citer un à un mais merci pour tout.

A Charlie, à ta douceur, cachée derrière ta virilité, tes petites attentions, ton humour, ta générosité et surtout ta capacité à lire dans mes pensées (une exceptionnelle qualité) qui m'ont fait craquée et tenir ces derniers mois, en toute maîtrise de moi-même et de la situation. J'admire ta détermination, ton optimisme, ton sens de l'organisation, sans oublier ton audace. Que de belles choses à venir, de belles aventures et de projets.

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ABSTRACT

A. Résumé

Introduction : L'objectif de cette étude multicentrique rétrospective était d'évaluer les résultats cliniques précoces et de déterminer les facteurs prédictifs de bonne réponse de l'embolisation des artères prostatiques (EAP) en France.

Matériel et méthodes : Cette première étude rétrospective multicentrique française incluant 420 patients (âge moyen 69,7; IPSS moyen 20,6) dans 7 centres hospitalo-universitaires de radiologie interventionnelle, atteints d'une HBP symptomatique ou un sondage urinaire réfractaire, traités par EAP de janvier 2017 à avril 2019. Les résultats cliniques (IPSS, QoL), d'imagerie (volume de prostate) et données techniques (durée de procédure, de fluoroscopie, embolisation uni/bilatéral, agents emboliques et volume injecté) ont été recueillis via REDCap (plate-forme web sécurisée). Des analyses uni et multivariée ont été effectués avec l'analyse de régression logistique ajustant des caractéristiques de population pour rechercher des facteurs de risque prédictifs.

Résultats : Le succès technique était de 98,6% avec une durée moyenne de procédure de 132,7 minutes. Le succès clinique a été obtenu chez 269/320 patients présentant un suivi clinique (84,1%) avec une réduction moyenne de l'IPSS de 53,6%, du QoL de 2,9 points et du volume prostatique de 22,7%. 3 nécroses de gland et 3 rétentions urinaires aiguës ont été rapportées sans autre complication majeure. Le suivi était variable de 1 à 31,2 mois.

Conclusion : Cette étude multicentrique confirme l'efficacité et la faisabilité de l'EAP avec des résultats cliniques précoces satisfaisants, d'autant plus chez les patients jeunes (<70 ans), avec une large prostate (>100ml), traités par embolisation bilatéral. D'autres études de suivi à long terme sont nécessaires pour consolider ces résultats fonctionnels.

Mots clés : Embolisation artères prostatiques, Hypertrophie bénigne de prostate, sondage urinaire, multicentrique.

B. Abstract

Introduction: The aim of this a multicentric retrospective French study was to assess the safety, early clinical outcomes and the predictive factors of good clinical outcomes of the prostate artery embolization (PAE).

Materials and methods: This first French multicentric retrospective study enrolled 420 patients (mean age 69.7; mean IPSS 20.6) in 7 French university hospitals centers with bothersome LUTS and/or AUR due to BPH, refractory to medical treatment and managed by PAE from January 2017 to April 2019. Clinical outcomes (IPSS, QoL and subjective findings), imaging outcomes (prostate volume) and technical data (procedural and fluoroscopy times, uni/bilateral embolization, embolic agents, volume injected) using Redcap (a secure web platform). Univariate and multivariate were performed with logistic regression analysis adjusting for population characteristics to search for predictive factors.

Results: Technical success was 98.6% with a mean procedure time of 132,7 minutes. Clinical success was achieved in 269 patients among 320 patients with early clinical follow-up (84,1%) with a mean IPSS reduction of 53,6%, QoL reduction of 2,9 points and prostate volume reduction of 22,7%. 3 gland necrosis and 3 acute urinary retention were reported and no other major complication. Follow-up ranged from 1 to 31,2 months.

Conclusion: This multicentric study strengthen the safety and feasibility of PAE with good early clinical outcomes, especially in young patients (<70 yo), with large prostate gland (>100ml) treated by bilateral embolization. Further long-term follow-up trials are required to consolidate these functional outcomes.

Keywords: Prostatic artery embolization, benign prostatic hyperplasia, indwelling bladder catheter, multicentric.

INTRODUCTION:

Background:

Benign prostatic hyperplasia (BPH), as the most common male disease in urological pathology, represents a serious public health problem in our society. It affects about 50% of men aged 50-60 years and 90% of men aged 85 years or older¹.

In France, there are near two million of men with lower urinary tract symptoms and 100 000 new patients each year (urofrance.org).

Benign prostatic hyperplasia is a histological term and represents the most frequent chronic benign neoplasm in aging men. It can lead to an enlargement of prostatic transitional zone (TZ) due to the proliferation of glandular and fibromuscular elements resulting in the formation of nodules androgen-dependant. There is an imbalance between growth and death programs of stroma cells, leading to increased final stromal volume².

Although it is benign, in one half of cases, benign prostatic enlargement causes lower urinary tract symptoms (LUTS) related to benign prostatic obstruction (BPO). LUTS are defined by storing (irritative) symptoms, voiding (obstructive) symptoms and post micturition symptoms³. These several symptoms have been shown to cause a negative impact on the health-related health of life⁴. Symptoms such as urinary incontinence, urgency, frequency and nocturia are such a serious therapeutic problem due to its great impact on the quality of life⁵. The clinical diagnosis of LUTS due to BPH is a multistep diagnosis.

Voiding difficulties due to BPH can be quantified with the International Prostatic Symptom Score (IPSS) consisting of seven symptom categories rating an increasingly

severe symptom scores from 0 through 35. Severity categories admitted are: mildly symptomatic (1-7), moderately symptomatic (8-19), and severely symptomatic (20-35). The IPSS is the most commonly used score but is considered as a subjective evaluation quite as well as the Quality of life score (QoL) related to LUTS, ranging from 0 (delighted) to 6 (terrible) based on eight questions.

Urodynamic testing is more accurate to identify the functional mechanisms that result in LUTS. It provides functional information about bladder filling, urine storage, emptying, distinguish benign prostatic obstruction from other causes of LUTS, and reproduce patient's symptoms to obtain an accurate diagnosis of primary causes of LUTS. The American Urological Association recommends using urodynamic studies to identify LUTS due to BPH if invasive and potentially irreversible treatments are considered. Predicting outcomes after invasive treatments relies on pressure flow study based on maximum flow rate (Qmax) and post void residual (PVR) urine volume. One of the Bladder outlet obstruction complications due to BPH is indwelling bladder catheterization.

Management of BPH and existing therapies:

The primary treatment goal for LUTS due to BPH is to reduce bothersome symptoms, improving quality of life, urinary flow and prevent long term complications such as acute urinary retention. A wide variety of surgical and medical options are currently available for the management of BPO.

The standard management of symptomatic BPH usually depends on the severity of the symptoms and the patient's state of health.

Watchful waiting is indicated in men with mild symptoms, coupled with lifestyle modification, and do not usually require an active intervention but might be monitored

annually by the physician. Knowing that BPH is generally a progressive disease with symptom deterioration, there is no established evidence concerning the timeliest moment to introduce an appropriate treatment⁶.

For Patients with moderate symptoms, the first line therapy consists on medical treatment with two main categories: alpha-blockers and 5 alpha-reductase inhibitors or a combination therapy. There are six Pharmacological classes available alone or in combination: alpha-blockers, 5 alpha-reductase inhibitors, Phytotherapeutics, Anti-muscarinics (AMs), Beta-3 agonists and Phosphodiesterase type 5 inhibitors.

Alpha-blockers are effective in men with small or large prostate (>40mL) and have a rapid onset of action interacting with the contraction of prostatic smooth muscle. However, 5 alpha-reductase inhibitors are more effective on large prostates and contribute to reduce its size and increase the peak urinary flow rate. European Association of Urology (EAU) recommend the combination therapy in patients with moderate to severe symptoms and in cases of large gland and/or a high PSA⁷.

Approximately half of the patients get a medical treatment while surgical approaches are the treatment of choice for patients' refractory or intolerant to medical therapy.

Pharmacological options have many secondary effects such as erectile dysfunction, retrograde ejaculation, decreased libido, orthostatic hypotension and dizziness leading to stop them.

When medical treatments fail to satisfactorily treat bothersome LUTS, either because of medication non-compliance, medication failure or disease progression, procedural treatments are indicated. 25-30% of patients have no response and 7% progress despite therapy⁸.

The American Urological Association (AUA) recommends surgery in cases of BPH-related complications including recurrent urinary tract infections, renal insufficiency,

refractory urinary retention, recurrent bladder stones or gross hematuria, due to BPH and/or with LUTS refractory to other therapies⁹.

Surgical treatment of LUTS due to BPH comprises a variety of treatment modalities.

Two groups of surgical techniques can be distinguished:

-Invasive surgery considered as the best long-term solution such as Transurethral Resection of the Prostate (TURP), open prostatectomy, laser surgery, laparoscopic and robotic prostatectomy.

-Minimally invasive surgery including water vapor therapy, transurethral microwave therapy;

During the last sixty years, monopolar-TURP has been the reference standard for surgical treatment of patients with LUTS due to BPH consisting on removing tissue from the transitional zone of the gland, with a well-documented long-term treatment efficacy¹⁰ with IPSS reduced on average by 70% . Open prostatectomy is performed in cases with large adenomas with volumes greater than 80-100mL. Other various alternative transurethral procedures have been introduced to overcome M-TURPS' flaws. The main new techniques of tissue ablation consist on resection, enucleation and vaporization. Trans-urethral vaporization of the prostate (TUVP) results in equivalent short-term improvement in symptoms and flow rate compared to TURP but with higher rate of post-operative irritative voiding symptoms, dysuria, acute urinary retention and recatheterization¹. Thus, the major contemporary surgical treatments for BPH comprise enucleative and resective techniques, with no difference in efficacy profile at 24 months post operatively but with better efficacy and safety in enucleation¹¹. According to the French urological society, there are three validated laser techniques which are the Holmium laser enucleation of the prostate (HoLEP) technique, the resective laser Thulium technique and the photoselective vaporization (PVP)

technique. PVP and HoLEP are preferred in patient with bleeding risk^{12,13}. For PV greater than 60 ml, HoLEP seems to provide better outcomes than PVP and is now recommended as a size-independent technique (based on AUA and European guidelines).

Minimal invasive techniques include prostatic urethral lift, radiofrequency (TUNA), and thermotherapy (TUMT).

Re-operative rates with M-TURP reported in literature range from 5.6% to 15.5% with an impressive follow-up up to 22 years TURP^{14–17}. Madersbacher et al. reported a global incidence of a secondary procedure after TURP of 5.8%, 12.3% and 14.7% at one, five and years of follow-up¹⁶ of 20 671 patients.

Short-term complications reported with surgical treatments include transurethral resection syndrome (dilutional hyponatremia due to absorbed irrigant solution into bloodstream), hematuria, blood loss, blood transfusion, clot retention, recatheterization, urinary retention, dysuria and urinary tract infection. While long-term complications comprise erectile dysfunction (10%), ejaculatory disorder (65%), urethral stricture (7%), urinary incontinence (2%), bladder neck contracture and reoperation¹⁸.

In TURP, the morbidity rate reported is around 11-20 %^{19,20}; ejaculatory disorder remains the primary side effect in 50-70% of patients²¹.

Despite of being the “gold standard”, prostatic surgery is not available for everyone and the population suitable to it is limited by selection criteria and contraindication, therefore, the number of TURPs performed has declined in the last three decades²².

Prostatic Arterial Embolization:

Prostatic artery embolization (PAE) is an interventional radiological technique which has emerged as a new evolving minimally invasive treatment option for patients with symptomatic benign prostatic hyperplasia. It is also one of the treatment techniques for hematuria caused by prostatic pathology such as HBP, traumatic bladder catheterization, Prostatitis, anticoagulant treatment, surgery etc.

This technique has been introduced since the 1970s to control refractory hematuria of prostatic origin or bleeding after prostatectomy or prostate biopsy^{23,24}

In 2000, Demerit et al. published the first PAE case about a patient with recurrent severe gross hematuria failing to surgical treatments and who also developed an acute urinary retention. In addition to the cessation of bleeding, they noticed for the first time, improved voiding symptoms and a prostate volume reduction with no minor or major complication except transient temperature²⁵.

After that in 2010, Carnevale et al. published the first preliminary case of PAE as an intentional treatment to BPH, using microspheres as a primary treatment in two patients with acute urinary retention (AUR) due to BPH²⁶, confirming the efficacy of the procedure.

Since then, it is being performed by a growing number of interventional radiologists in the world and is becoming a recognized option for the management of benign prostatic obstruction.

This radiological method has been then more recently considered as a minimally invasive alternative therapy to surgery for benign prostatic obstruction (BPO) and the relief of lower urinary symptoms, especially for patients with comorbidities and contraindications to surgery²⁷.

There is up to six years follow up of patients in the literature with an established safety and efficacy. Pisco et al. has proven in a retrospective study, a technical success of 98% among 630 patients and a bilateral PAE in 92%. Clinical success was obtained in 85.1% at short-term, 81.9% at medium-term, and 76.1% at long-term (up to 6.5 years).²⁷

The rationale of PAE is that the prostate gland receives its blood supplies from prostatic arteries arising from each pelvic side. Embolization leads to necrosis of the gland and shrinkage as a consequence.

Indication:

Patients eligible for PAE are those with symptomatic BPH, with failure of medical treatment, presenting a contra indication or refusing to surgery. Authors have proposed PAE for different inclusion criteria. In the UK-ROPE study patients enrolled had IPSS ≥ 14 , QoL > 3 and PV greater than 40 mL²⁸. Amouyal et al. included patients with IPSS ≥ 8 and QoL ≥ 3 ²⁹.

However, PAE is not indicated in cases of urinary obstruction due to causes other than BPH including urethral stricture, sphincter abnormalities bladder dysfunction such as bladder atonia, neurogenic bladder disorders,

A complex arterial anatomy:

One of the major challenge is identification and the navigation through pelvic and prostatic vascular anatomy. As the prostate is a central pelvic organ, it is usually vascularized by arteries from each side. But Vascular anatomy related to PAE is variable among individuals and also between each side of one patient.

This complex arterial anatomy with multiple variants of the pelvic vascularization, and many possibilities of arterial anastomoses represent a high risk of non-target embolization. Knowledge of the branching patterns of internal iliac arteries is essential to perform prostatic arterial embolization. Various nomenclatures have been used for the anatomy of artery supplies to the prostatic gland.

According to /Using Adachi's classification (1928), Yamaki et al. proposed, in 1998, a simplified classification of the pelvic vascular anatomy based on a dissection of 645 pelvic halves of Japanese cadavers³⁰. The branching patterns of the internal iliac artery (IIA) were separated in 4 types (A, B, C and D; Annexes A) and 19 groups; type A being the most frequent. Bilhim et al. studied imaging findings (angio-CT, angio-MRI and Digital Angiography) of the main branching patterns of the male internal iliac arteries in 42 pelvic sides³¹, confirming the simple application of the Yamaki's classification, being be the most reproducible for this complex vascular system and showing a good correlation between cadaveric and imaging findings. As well as in the literature, Group A is the main branching pattern found, corresponding to the superior gluteal artery arising independently and a common gluteal-pudendal trunk (49.1-70.4%).

Generally, IIA is subdivided into two large trunks: anterior (giving rises to the superior and inferior vesical arteries, obturator, middle rectal, inferior gluteal and internal pudendal arteries) and posterior (giving rises to superior gluteal, ilio-lombar and lateral sacral arteries). De Assis et al. proposed an anatomic classification of the arterial prostatic vascularization reviewing angiographic findings in 286 pelvic sides from PAE procedures³². The origin of the Inferior Vesical Artery (IVA) was classified into 5 subtypes (annexe A):

- Type I: from the anterior division of the IIA, from a common trunk with the superior vesical artery (SVA) (28.7%).
- Type II: from the anterior division of the IIA, inferior to the SVA (14.7).
- Type III: from the obturator artery (18.9).
- Type IV: from the internal pudendal artery (31.1%).
- Type V: other less common origins.

Carnevale³³ illustrated the pelvic vascular anatomy relevant to PAE using Digital angiography, based on the PROVISO acronym to recognize the anterior branches related to prostate arterial supply during digital subtract arteriogram²¹ (internal Pudendal, middle Rectal, Obturator, Vesical Inferior and Superior under Oblique view). The main artery that supplies the major part of the prostatic gland is the superior prostatic pedicle also named the prostatic-vesical artery or the inferior vesical artery (IVA). Generally, one main prostatic artery is found each side, arising as the second or third branch of the anterior trunk of the IIA, but the main artery or additional accessory prostatic branch can arise from the superior vesical, internal pudendal, obturator and middle rectal arteries.

In fact, the prostatic artery can arise from several origins and usually bifurcates into two branches: antero-medial for the central gland and postero-lateral for the peripheral zone and the apex.

Technique:

PAE is performed in an interventional operating room and it does not require administration of general anesthetic, making it suitable for managing patients with significant comorbidities and may carry a high risk for surgery. The arterial approach is most commonly performed via the right femoral artery, or less frequently left femoral,

and more recently left radial artery approach. Pelvic navigation is performed with catheter in large and medium vessels and microcatheter in selective small vessels. Angiography is used with pump injection to evaluate iliac vessels and identify vascular supplies to the prostatic gland. Global Cone-Beam-Computed Tomography is usually used to improve pelvic navigation, to identify prostatic arteries and avoid non-target embolization.

In practice, after crossing the aortic bifurcation, selective angiogram of the internal iliac artery is performed to identify the anterior division. Digital Subtraction Angiography (DSA) of the anterior division is performed with ipsilateral anterior oblique view (30-40°). Once the prostatic artery traced, selective catheterization using microcatheter is achieved. Embolic agents widely employed are calibrated PVA Particles. These are mixed up with iodinated contrast and saline and are slowly injected until complete stasis. Slow injection under fluoroscopy guidance is recommended to avoid early proximal occlusion and enable diffuse gland parenchymal ischemia²¹.

There have been some variations in procedure techniques with the “Proximal Embolization First Then Embolize Distal” (PErFecTED) technique consisting in starting by a proximal super-selective embolization in the prostatic artery, then pushing the micro-catheter more distally and injecting more microparticles. This technique has been described by Carnevale and has shown a significantly lower proportion of symptoms recurrence³⁴.

Post-operative hospitalization is not clearly defined, it depends on the departments' routine. From ambulatory to few days of hospitalization (1-2 days) are admitted.

Imaging data:

Pre and post procedural prostatic imaging for PAE is not clearly consensual and the three imaging modalities can be involved in patients' management: Ultrasonography (US), Computed Tomography (CT) and MRI. The first aim of the imaging the prostate gland is to precise its volume, usually employing US or MRI, both to precise the indication and evaluate the morphological data along the follow-up period.

Pre-PAE CT angiogram have been shown to improve prostatic arteries identification³⁵. It is usually performed with administration of sublingual Glyceryl Trinitrate in order to increase the detectability of PA origins, tortuosity, atherosclerotic disease and troublesome anastomoses and facilitate procedural planning. Maclean et al. showed that CT angiography successfully identified prostatic arteries in 214/220 pelvic sides (97.3%) but with a low sensitivity in detecting anastomoses (59.0%).

There is also a lack of sensitivity in identifying small PAs³⁶ and defining prostatic artery origin is paramount to allow selective catheterization.

More recently, per-procedural Cone Beam CT (CBCT) angiography has been introduced and increasingly used for pelvic arterial cartography during PAE. This modality provides high resolution three-dimensional and cross-sectional images that can be reconstructed into angiographic images like and might be performed either global or selective. Adding CBCT to DSA has been established to upgrade identification of PAs and adjacent anastomoses.³⁶⁻⁴⁰

MRI is admitted being the most adequate and powerful imaging technique to analyze prostatic gland⁴¹, providing accurate volumetric assessment and characterization. It is also likely to bring quantitative and qualitative information after PAE such as the changes in T2 signal intensity, the enhancement of the transitional zone, the signal of the peri-prostatic fat, etc. One of the features observed in early follow up MRI is prostatic ischemia which has been shown as a predictive factor of clinical success^{42,43}.

Prostatic artery embolization is considered as one of the most technically challenging interventional radiology procedure. Challenges such as anatomical variations, navigating arteries with atherosclerosis, avoiding the non-target embolization to the pelvic structures are common during embolization and a technical skill is required to catheterize such small arteries. PAE remains a relatively new technique and no scientist society has admitted it yet as a therapy for BPH, considering PAE as a technique still being experimental.

The purpose of this retrospective study is to evaluate the clinical outcomes of PAE, for patients with LUTS/BPH or with indwelling bladder catheter and to establish the predictive factors of clinical success from a multicentric French registry.

MATERIELS AND METHODS:

Study population:

This French multi-centric retrospective study was initiated in our local institution and ethical approval was taken from the Institutional Review Board (IRB). Every single center gave its authorization to process the existing data. Study data were collected and managed using REDCap electronic data capture tools hosted at the university hospital of Nimes. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trail for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability for with external sources^{44,45}. The variables were validated by an administrator making sure of medical confidentiality. Data was collected by a single radiologist who had to move around all the centers using the local clinical and imaging softwares. From January 2017 to March 2019, patients who underwent PAE for the relief of LUTS due to BPH and/or with indwelling bladder catheterization, failing medical management, were included (420/477; 87,6%). Of 420 patients, 82 (19,6%) had been recused to surgery, 151/420 (36,1%) were eligible but refused surgery or wanted to try a less invasive technique, 122 were supposed to be directed by their urologist as a first treatment after medical therapy failure, and we didn't find the information for 63/420 (15,1%) patients. 342 patients were treated for moderate to severe LUTS/BPH and 78 presented acute urinary retention or chronic indwelling catheter bladder.

Patients excluded were those with potentially confounding bladder disease (detrusor hyperactivity, hypocontractility, neurogenic/inflammatory bladder disease, bladder stones) or urethral disease (urethral stricture), active bladder cancer or known prostate cancer, previous prostate surgery or embolization and all other urinary obstruction due to other causes than BPH.

After we applied inclusion and exclusion criteria, 57 patients were excluded for various reasons. Thus, 420 patients were included in our study.

All procedures were performed by interventional radiologists of each center, with a various level of experience, knowing that most of them were trained during the HEGP (Hôpital Européen Georges Pompidou) interventional radiology department's workshops.

Patient evaluation:

All measurements and variable were recorded retrospectively. There consisted of International Prostate Symptom Score (IPSS), Quality-of-Life-related symptoms (QoL), uroflowmetry variables including Qmax and post void residual volume (PVR) and serum prostate-specific antigen (PSA). Baseline values are shown in Table 1.

Comorbidities were also noticed and reported as cardio-vascular, anticoagulant treatment, chronic respiratory disease, chronic renal insufficiency, neurologic disease and evolutive neoplasm.

Prostate volume and Imaging characteristics

Prostate size evaluation was calculated by the same radiologist when a prostatic MRI imaging was available with axial and sagittal T2 sequences. The three incidences formula used for volume calculation was transversal diameter x cranio-caudal diameter

x antero-posterior diameter x 0.52. When MRI was not accessible or not performed, volume was calculated using pre-procedural CT. Every time a pre-procedural prostate US was performed, volume was recorded from the radiologist report.

Main MRI sequences were axial and sagittal T2-weighted turbo/fast spin echo sequence and dynamic pre and post-contrast T1-weighted volumetric interpolated sequences. In addition of prostate volume, pre-procedural MRI characteristics included central volume (CV), peripheral volume (PV).

The post procedural MRI characteristics reported were the volume features (global volume, CV and PV) on the basis of which we calculated the percentage of reduction for each numerical data.

Pre-procedural pelvic angio-CT imaging characteristics were analyzed to identify arterial atherosclerotic lesions assessed as none, middle, moderate or severe, existing arterial occlusions, iliac vessels tortuosity qualified following the same patterns and the viewability of the main artery supplying the prostate gland.

All imaging techniques were analyzed by one radiologist.

Embolization procedure

A variety of technical data relating to the procedure was collected. As the procedures were performed by a heterogeneous group of radiologists and departments we noted for each patient number of embolization, whether it was under local or general anesthesia, the arterial puncture site (right femoral, left femoral, humeral or radial approach), the diameter of the introducer (4, 5 or 6-French introducer), the catheter type (Cobra, Side, Vertebral, Multipurpose or other), the microcatheter size (1.7, 2.0, 2.4, 2.7, 2.8 or other), the embolic agent (Microparticles, Glue or coil), the size of microparticles (<100, 100-300, 300-500), the volume of diluted microparticles injected

in each side, the microparticles' brand (Meritt Medical, Terumo, Boston scientific, BTG, other). The PErFecTED technique was recorded if noted in the procedure report with specifying right, left, both sides or none. Protective embolization of extra prostatic anastomoses to avoid non-target pelvic structures was notified outlining the side (right or left) and the pelvic artery concerned (middle rectal, vesical, internal pudendale, accessory internal pudental or penile artery).

All these variables were reported using the radiologist report and the procedure imaging (DSA, CBCT). We specified whenever bilateral embolization was achieved. If unilateral embolization only was performed, the side (right or left) was indicated. The cause(s) of the other side's failure was taking into consideration anatomical factor (occlusion, inaccessibility of prostatic artery, spasm or dissection and non-target dangerous anastomoses), technical factor such as material failure, patient condition and long-lasting procedure not allowing further treatment.

Procedural data were also collected including overall procedural time (minutes), fluoroscopy time (minutes), skin dose (mGy), dose area product (mGy.cm²), Kair (mGy) and number of images when available.

Immediate and short-term post procedural complications were searched in the clinical reports and summarized in Table 5. Minor complications were considered if the patient did not undergo any extended hospitalization or severe life/health consequence including most kind of pains (pelvic, perineal, urethral), hematuria, dysuria, fever, hematochezia, hematospermia, puncture site complications. Major complications included death, severe infection, severe hematuria, renal insufficiency and loco-regional necrosis (penile, rectal or vesical).

Post PAE syndrome was defined by mild symptoms occurring 2-5 days after embolization including dysuria, urethral burning, pelvic and perineal pain and fever.

Adverse events were evaluated for severity using Clavien Dindo classification which is based on the therapy used to correct a specific complication in order to rank in an objective manner. It consists on 7 grades (Annexes G).

PAE Follow up

Patients' follow-up after PAE was divided in clinical and imaging data. Concerning clinical data, we yielded if patients were lost to follow-up and if not, reported the dates of monitoring and evaluation. Concerning patients treated for AUR or chronic use of indwelling catheter bladder, clinical success was assessed as catheter removal, precisising the delay with PAE, and successful permanent spontaneous voiding.

LUTS severity post embolization was assessed using urologists' and radiologists' reports. Clinical numerical scores (IPSS, QoL, IIEF) and subjective evaluation of the physician were reported when indicated in order to estimate patient's symptoms improvement. It was noticed as: no remaining symptom, middle, moderate or severe remaining symptoms. Percentage reduction of the clinical scores were calculated. Uroflowmetry (Qmax, PVR) and PSA variables were collected when available.

We pointed out every post procedural MRI precisising its delay (<1 month, between 1-3 months, 3-6 months, 6-12 months and > 12 months after embolization). Post procedural MRI characteristics were compared to pre-procedural when available.

Intercurrent events including death, prostatic surgery, acute urinary retention, etc., were collected.

Technical and clinical success

Technical success was considered when at least one side of selective prostatic arterial catheterization and embolization of prostatic arteries was achieved.

We defined clinical success by the following criteria:

- Concerning patients treated for AUR or chronic use of indwelling catheter bladder, clinical success was assessed as catheter removal, precising the delay with PAE, and successful permanent spontaneous voiding.
- LUTS improvements were assessed according to IPSS, QoL and when unavailable, by subjective evaluation according to physician report. Clinical success was defined by $IPSS \leq 8$ or a decrease rate $\geq 25\%$, $QoL \leq 3$ or decrease by ≥ 1 point^{29,46,47}.

Recurrence of symptoms was defined if there were a need of reintervention including surgery or second PAE.

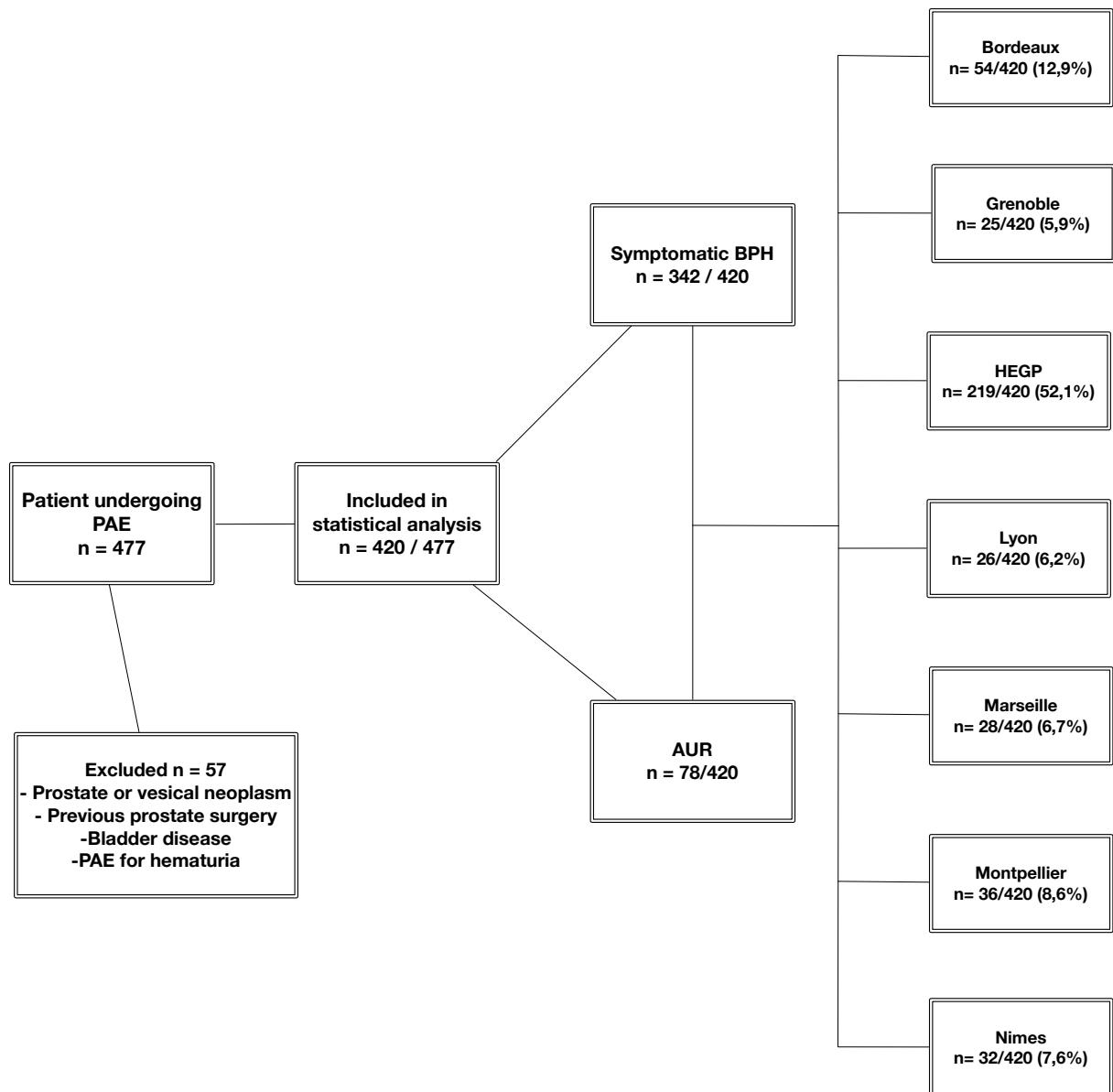


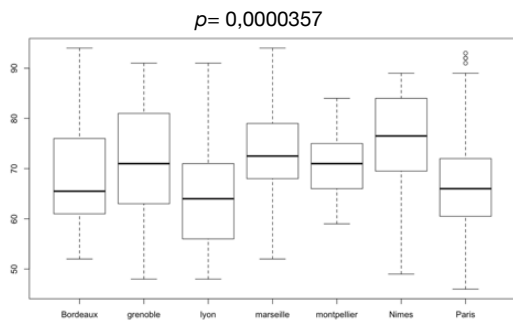
Fig. 1: flow chart.

AUR= acute urinary retention; PAE = prostate artery embolization, BPH = benign prostatic hyperplasia

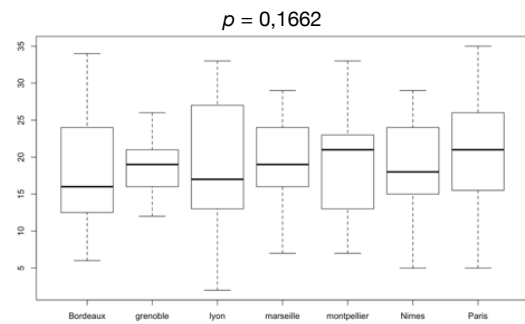
Table 1: Baseline data in the study population according to individual center

Mean +/-SD	Age	IPSS	QoI	PV (cm ³)	PVR (ml)	PSA (ng/ml)	Qmax (ml/s)
Centers							
Bordeaux n= 54	69,9 +/- 11,1	17,8 +/- 6,6	4,6 +/- 1,3	95,7 +/- 41,0	164,5 +/- 162,2	5,93 +/- 5,35	10,06 +/- 4,65
Grenoble n=25	74,3 +/- 10,6	19,1 +/- 3,9	4,2 +/- 0,8	97,1 +/- 44,1	192,8 +/- 204,7	9,85 +/- 7,71	7,60 +/- 1,67
Lyon n=26	66,0 +/- 11,8	18,1 +/- 9,1	4,1 +/- 1,8	87,2 +/- 55,4	124,6 +/-162,6	5,70 +/- 3,12	7,69 +/- 4,56
Marseille n=28	72,9 +/- 10,6	20,8 +/- 6,4	4,7 +/- 0,7	119,0 +/- 76,5	102 +/- 107,1	4,15 +/- 5,40	—
Montpellier n=36	71,3 +/- 5,9	19,9 +/- 8,5	4,2 +/- 1,2	111,3 +/- 57,6	92,4 +/- 80,1	5,85 +/- 5,72	9,10 +/- 3,53
Nimes n=32	76,5 +/- 9,8	18,7 +/- 6,8	4,5 +/- 1,1	99,1 +/- 44,9	130 +/- 112,2	8,54 +/- 8,23	4,00 —
Paris n=219	67,2 +/- 9,1	21,0 +/- 7,0	5,8 +/- 1,2	92,8 +/- 41,6	129,0 +/- 131,9	6,05 +/- 4,50	8,12 +/- 3,80
Total / Mean n=420	71,2	19,3	5,2	100 ,3	133,6	6,58	7,76

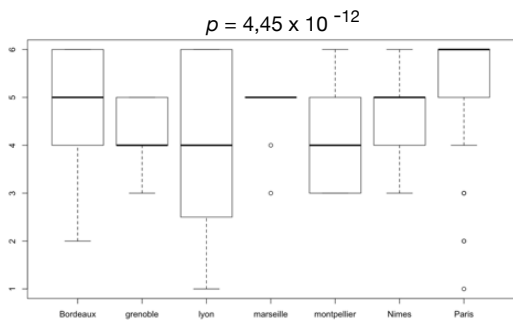
IPSS= International Prostate Symptom Score; QoI= quality of life; PV= Prostate volume; PVR= post-void residual; PSA= Prostate specific Antigen; Qmax= maximal flow rate.



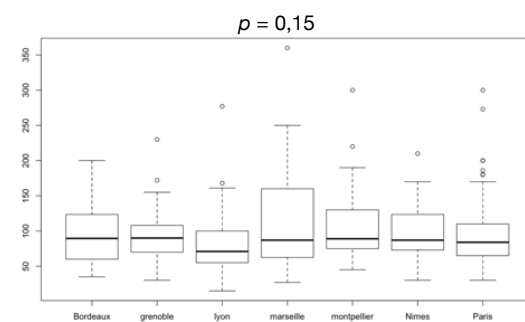
a.



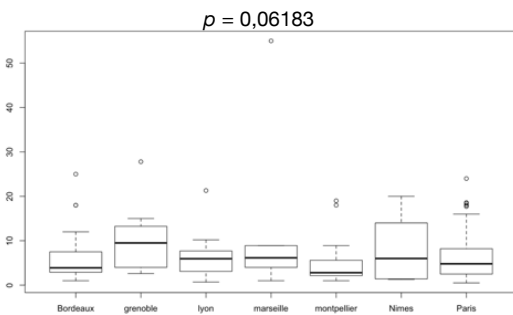
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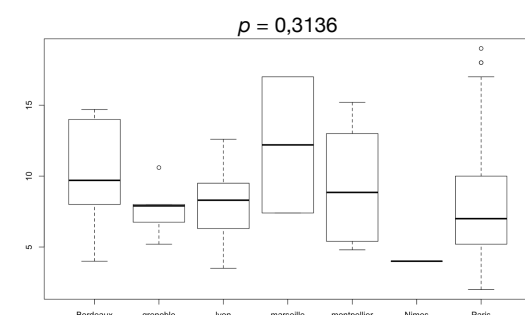
c.



d.



e.



f.

Fig. 2: Baseline characteristics according to individual centers, with statistical analysis: age (a), IPSS (b), Qol (c), prostate volume (d), PSA (e), Q max (f).

Table 2: Procedural details according to individual centers and means.

Mean Centers	Procedural time (min) ($p = 2,319.10^{-14}$)	Fluoroscopy time (min)	Dose Area Product (mGy.cm ²)	Kair (mGy)
Nimes	144,40	48,20	277861,60	1577,30
HEGP	144,80	43,00	298580,70	-
Grenoble	103,20	59,10	337772,60	3049,80
Marseille	101,60	44,00	-	1109,00
Lyon	192,10	50,60	258066,60	1344,00
Bordeaux	110,20	43,50	163979,00	2044,90
Montpellier	-	39,00	284283,80	1105,30
Global Mean	132,72	46,77	270090,72	1705,05

Table 3: Technical details according to individual centers

Variables	Centers	Bordeaux	Grenoble	HEGP	Lyon	Marseille	Montpellier	Nimes
Embolic agent size (n)								
100-300 μ		5	13	25	0	-	0	0
300-500 μ		45	11	216	25	-	36	30
Global Volume injected (ml)		15	-	15,6	14,7	-	6,5	6,7
Volume injected in the right artery (ml)		6,6	-	6,1	7	-	3,9	2,7
Volume injected in the left artery (ml)		9	-	9,7	7,6	-	2,8	3,8
Use of PErFeTED technique (n)		6	19	134	16	0	5	5
Embolization of anastomoses (n)		2	1	11	8	0	9	8

STATISTICAL ANALYSES

Patients were separated into two groups: patients with bothersome LUTS due to BPH and patients treated for acute/chronic urinary retention. Descriptive statistics, including means and standard deviation, and ranges were used to summarize the continuous variables in this study. Continuous variables included for analysis were demographical and baseline data (age, prostate volume, PSA, IPSS, QoI, urine flow rate), imaging data (global prostate volume, central prostate volume, percentage of prostate volume decrease for global and central after embolization) and embolization data (technical and procedural details), were analyzed using an analysis of variance (ANOVA). Categorical variables were expressed as percentage.

Demographic data were compared using t test for the continuous variables and Chi-square test for the categorical variable. Univariate and multivariate analyses were performed with logistic regression analysis adjusting for population characteristics to search for risk factors to predict early outcomes. The significant threshold was set as $p < 0.02$.

RESULTS

We collected data from seven different radiology departments set within university hospitals and reported characteristics on Table 1.

Technical data:

PAE was technically successful in patients (98.5%). Bilateral embolization was performed in 368 (89,3%) and unilateral in 38 (9,2%). PAE was carried out in one side essentially because of anatomical reasons with PA occluded by atherosclerosis or in out of reach because of extreme tortuosity, atheromatous stenosis, spasm or dissection. In some reports, unilateral failure was explained by the existence of dangerous anastomoses, not reachable for protective embolization. Technical failure was mainly due to atherosclerosis (5 patients).

PAE procedure time ranged from 40 to 300 minutes (mean 132,7 +/- 39 minutes) with a mean Fluoroscopy time of 46,8 +/- 6,1 min. No skin injuries or other complication related to radiation exposure have been reported during follow up. Procedures were achieved under local anesthesia (Scarpa's triangle) and/or sedation in the majority of centers, aside Nimes' radiological department where a systematic anesthesiologist consultation recommending in some cases general anesthesia (GA) for patients' comfort (19 patients among 23 cases of GA). The most common approach was the single right femoral with 5F introducer (84,5%). Bilateral femoral approach was used in 7 patients due to severe iliac artery tortuosity. Various types of hydrophilic intravascular catheters shape (Cobra, Sidewire, etc) and microcatheters were used, the most frequently was the 2.0 Progreat® (Terumo, Tokyo, Japan), to facilitate distal catheterization and embolization. Cone-Beam computed Tomography (CBCT) was noted in 348 patients, and not used in cases of inadequate morphology, in some

situations of inoperative machine or if not needed. We also considered CBCT as not performed in cases where procedural imaging was not available and with no mention about CBCT in the PAE report. The most frequent embolic agent used above the different department was a trisacryl microparticles (Embosphere® 300-500 μ , Merit Medical, Salt Lake City, USA) with a mixture of contrast and saline. The mean global volume of embolic agent injected was 14,8 mL +/- 7,2 mL with a mean of 5,6 mL in the right arteries and 7,6 mL in the left arteries. The PErFecTED technique as described by Carnevale, was performed in 183 patients. Preventive embolization of dangerous anastomoses was performed in 38 patients using micro-coils (1 or 2 mm).

Clinical data:

Among this series of 420 patients, 84 were referred to PAE after being recused to surgery, 255 patients with no contra-indication to surgery, choose PAE as an alternative treatment or were directly addressed by their urologist, 41 refused surgery and for 40 patients we did not find the reason why PAE was indicated. Global comorbidities were reported for 193 patients and cardiovascular comorbidities for 111 patients. Urological mean follow-up before PAE was estimated at 48,5 months. We reported 350 patients undergoing medical treatment before PAE, among them 302 were treated by alpha-blockers, 73 by 5 alpha-reductase inhibitors and of which 66 by combination therapy. Most of the patients with no medical treatment before PAE had to stop them because of the secondary effects affecting the quality of life such as retrograde ejaculation. Mean follow up after PAE was 82,2 days with a maximum follow up of 937 days.

Out of 105 patients who had indwelling bladder catheterization due to acute urinary retention 59 were removed among 85 patients with follow up (69,4%).

At the latest follow-up available, out of patients who were treated for severe LUTS, IPSS mean improvement was 53,6 % (+/- 6,4%). Mean QoL after embolization was 1,73 with a mean improvement of 2,89 points. Global Clinical success during follow up, including patients treated for LUTS/BPH and patients with indwelling catheter, was achieved in 269 patients among 320 (84,1%). Global mean Qmax post embolization was 12,3 mL/s with an average increase of 3,4 points.

PSA decreased below baseline at follow up by an average of 2,1 +/- 0,8 points with a mean of 3,55 ng/mL after PAE which is considered as normal (< 4 ng/ml). An average decrease in PVR post embolization of 51,8 +/- 26,8 ml (mean +/- SD) was noted.

91 patients were lost to follow up.

Complications observed were essentially minor with no need of hospitalization including pelvic pain (18), perineal (4), rectal (3), or penile pain (3), dysuria (10), minor hematuria (5), hematospermia (3), rectal bleeding (2) and isolated fever (15). More serious complications were noted in few patients such as transitional penile ulceration in 3 patients, resolutive after local treatments and acute urinary retention (3). We reported one case of prostatitis with abscess of the prostatic gland. No case of retrograde ejaculation or erectile dysfunction were reported outside of BPH medical treatment's side effects existing before PAE. No major complication such as death, blood loss, severe urosepsis or prolonged hospitalization for other reasons due to PAE were observed.

Imaging data:

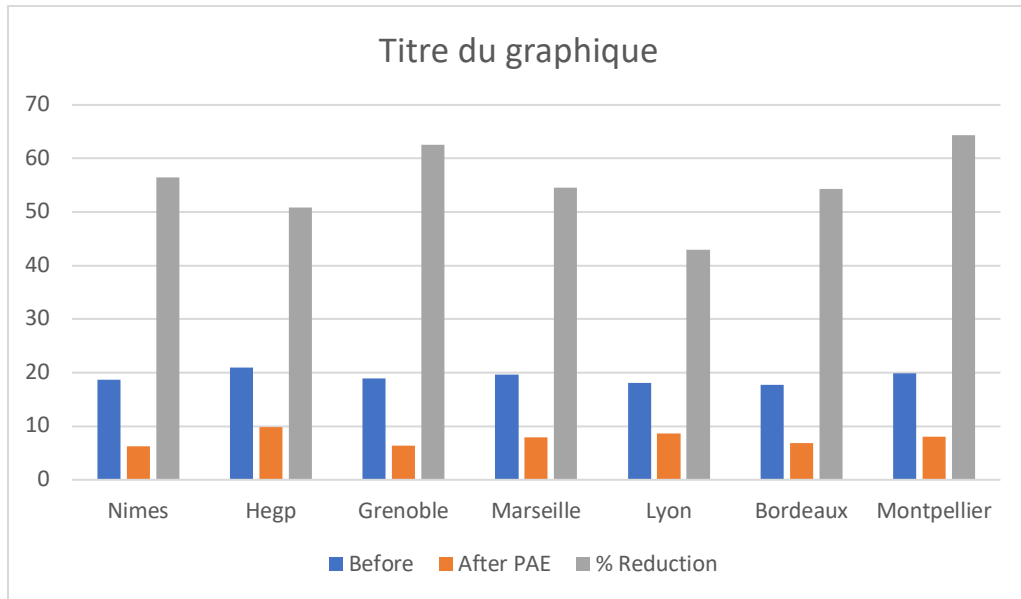
We reported a total of 502 MRI (261 before PAE and 241 after PAE) and could analyze 188 MRI in this study, among them 57 patients had pre and post procedural MRI. Not all patients had an MRI follow up and an unknown number of patients have had their

MRI pre/post PAE outside the different radiology departments where data were collected, and we couldn't have access to the imaging data. Imaging follow-up was essentially through MRI from 1 to 12 months after PAE. We found 50 MRI performed at 1 month or before, 128 between 1 and 3 months, 41 between 3 and 6 months and 22 after 6 months. We noted some variations concerning the delay between the departments in this study, with early imaging follow-up in 2 centers (< 1 month), to assess the infarct area expansion and more delayed in the others (> 1 month) in order to evaluate the prostate volume decrease and the regression of adenomatous zones. MRI sequences usually included a two plan T2-weighted and fat-suppressed T1-Weighted pre and post-contrast. This was globally similar except in one center in which early MRI protocol consisted on at-suppressed T1-Weighted pre and post-contrast to for infarct volumes. Mean prostate global volume (PV) reduction was 22,7 %, and central volume (CV) 16,7%.

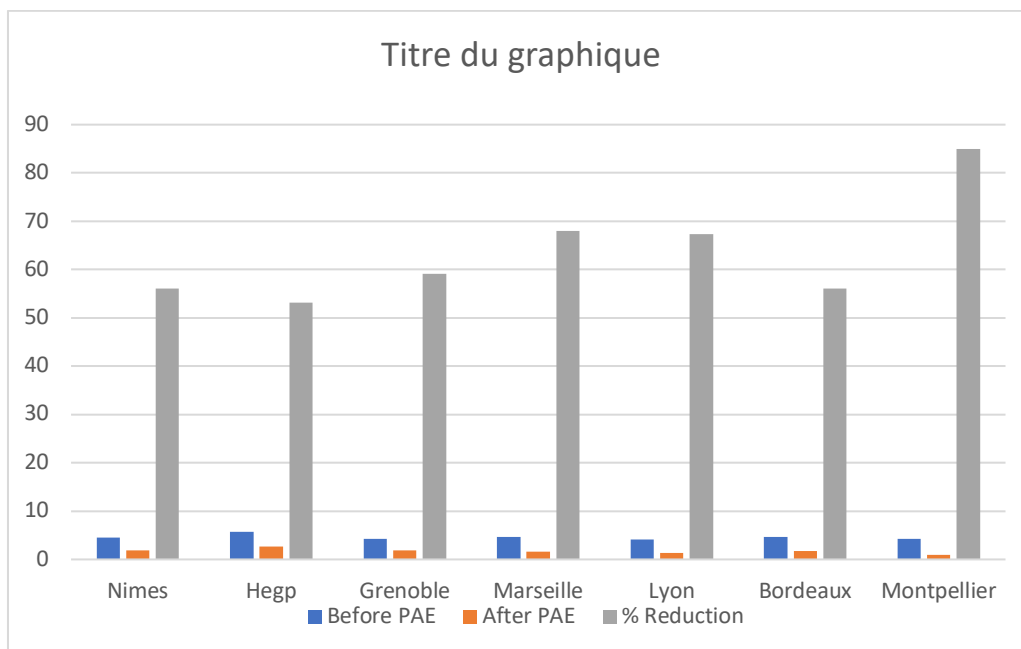
Table 4 : Technical and clinical success according to individual centers.

Centers	Bordeaux	Grenoble	HEGP	Lyon	Marseille	Montpellier	Nimes
Technical success %	96,3	100	100	100	92,9	97,2	96,9
Clinical success %	81,1	80	86,4	95,7	66,7	75	82,1
PV decrease %	26,4	36,6	19,2	35,4	-	31,6	9,4

PV = prostate volume



a.

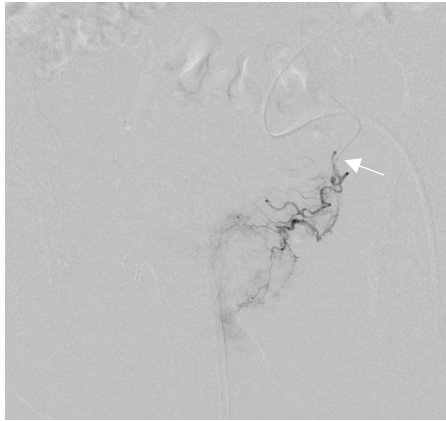


b.

Fig 3 : IPSS (a) and QoL (b) before and after PAE according to each center with % of reduction rate.

Table 5: PAE-related minor and major complications

Adverse events	N° patients	%
Major	5	1,2
-Penile ulceration	3	0,7
-AUR	3	0,7
-Prostatitis + abscess	1	0,2
Minor	60	14,5
-Dysuria	10	2,4
-Hematuria	5	1,2
-Hematospermia	3	0,7
-Pelvic pain	18	4,3
-Perineal pain	4	1
-Penile pain	3	0,7
-Rectal pain	3	0,7
-Rectal bleeding	2	0,5
-Fever	15	3,6

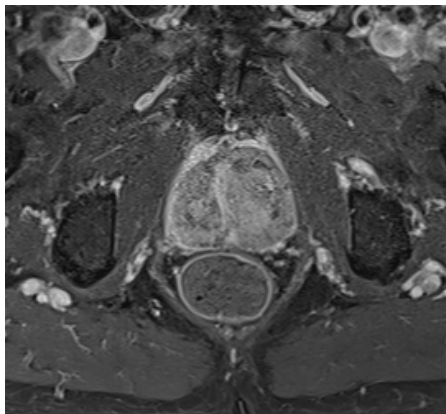


a.

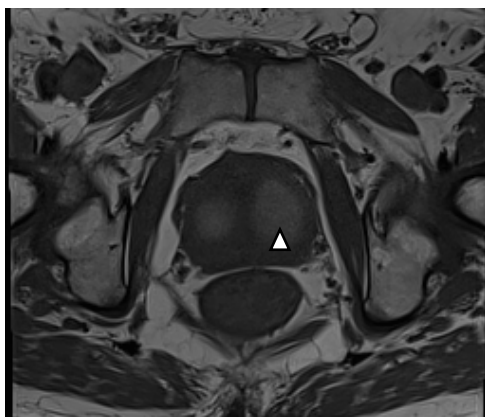


b.

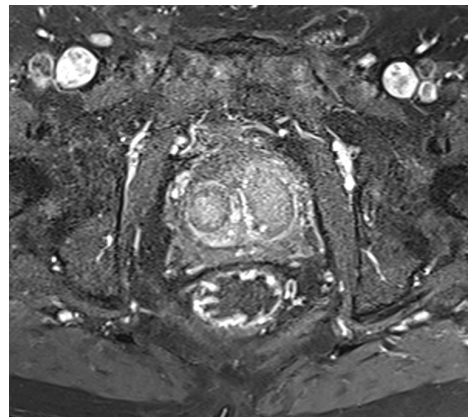
Fig 4: (a) DSA image with microcatheter (arrow) in the left prostatic artery demonstrates large-volume BPH. (b) CBCT image for the same patient obtained after contrast medium injection in the left prostatic artery depicts glandular perfusion (asterisk). No sites of potential non-target embolization are identified.



a.



b.



c.

Fig. 5 : Prostate MRI imaging. (a) axial dynamic contrast-enhanced T1-weighted fat-suppressed before PAE showing the enlarged enhanced prostate gland. (c) Three weeks after PAE, MRI before (b) and after enhancement (c), showing bilateral large areas of non-enhanced gland with hemorrhage (Δ).

DISCUSSION

PAE clinical outcomes:

Minimally invasive procedures for the treatment of LUTS/BPH has become a substantial research area.

This study supports findings of previous studies which suggest that the procedure of PAE is safe and with low rates of morbidity and good outcomes. None of these several reports was based on a French multicentric study. This paper tends to describe the results of a large multicenter observational study of French patients across 7 centers.

A large area of indications for PAE and patients' characteristics with no real limits concerning age, prostate volume (ranging from 15 to 360 ml), IPSS (≥ 5), QoI (≥ 3), Qmax (from 2,5 to 19 ml/s), PVR (from 0 to 650 ml) was reported and compared between the different centers. Significant difference in populations' mean age was found between the studied centers ($p < 0,02$), with the younger patients in Paris, Bordeaux and Lyon (respectively 66, 65,5 and 64 yo). Patients were usually sent by their urologists whose convictions in PAE efficacy might differ, some prefers to address older patients with comorbidities hoping to avoid surgery, and others were maybe more permissive to other mini-invasive treatment for their younger patients. Also, numeral patients have chosen PAE when urologists expose the RTUP secondary effects and other alternatives such as embolization, however we cannot affirm the incidence as we didn't classify all patients to whom PAE was proposed. No statistically significant difference was observed in pre-procedural prostate volume and IPSS score, these variables being certainly correlated to PAE indications^{46,48,49}.

Differences in PSA, QoI and Qmax were to take with caution since significant data were missing while collecting.

Through this work, we did demonstrate that PAE has several potential advantages over traditional surgery therapies. It is usually performed under conscious sedation, minimally invasive (via single arterial puncture), with a feasible outpatient procedure. Global clinical success obtained was 84,0 % +/- 9,0 (mean +/- SD) with no statistically significance difference between centers and in accordance with previous studies (80,7 – 97,1%). We present a median post PAE IPSS score of 7,7 with a mean reduction of 11,4 points and 53,1%. In terms of QoL, our PAE patients made a mean improvement of 2,9 +/- 0,3 points with a mean Qol after PAE of 1,7 +/- 0,5.

We also found that PAE is more effective in case of symptomatic BPH than in indwelling bladder catheter. This can result from the fact that patients with indwelling catheters are older with more pathological vessels, impacting the embolization success (89,3% of success rate for patients with symptomatic LUTS and versus 69,4% in patients with indwelling catheter). We can also assume that this group of patients is more refractory because of an advanced pathological condition.

The rate of technical and clinical success between the different departments is not significantly different. However, there are significant difference in baseline patients' characteristics concerning age, Qol score, PSA and Qmax. These differences in results can be explained by the fact that each clinical team has its own clinical judgement to make patients suitable for PAE and that the inclusion et exclusion criteria are more flexible than randomized studies where morphological, clinical and urodynamics parameters are more severe. Most clinical failures occurred at short-term follow up (1 to 3 months).

Previous study showed a clinical success rate of 76.3% at long-term follow-up with low morbidity, indicating PAE as a leading treatment option for patients with symptomatic BPH²⁷.

A statistically significant difference was observed concerning the procedural time with a mean of 132,7 +/- 35,1 min. PAE requires a well-trained interventional radiologist with a high level of expertise because of the complex prostatic vascular anatomy. We know that there is a learning curve of 10-20 patients until the radiologist develops appropriate skills. At the beginning of our experience, patients addressed for PAE were essentially elderly men with high comorbidities recused to surgery and with no other alternative therapy. These patients had atherosclerosis with stenosis and tortuosity making the procedure more difficult and challenging, increasing the procedure time, fluoroscopy time and radiation dose. More recently, PAE has been offered to patients being refractory to medical treatment, and eligible to surgery, or some of them refusing invasive therapies, being afraid from the secondary effects such as erectile dysfunction et retrograde ejaculation and with less (vascular) comorbidities. This recent enrolled population have contributed to improve technical and clinical results. According to these facts and differences of BPH management and patients' eligibility to PAE, we may explain this observation.

Factors affecting clinical outcomes

Baseline characteristics:

No difference in clinical success was revealed between the different centers, HEGP being the reference trainer center. We can explain this similitude by the national workshops organized by the HEGP. This suggest that despite of its technical difficulties, PAE is widely feasible by interventional radiologists.

Age: a higher clinical success rate was observed for patients < 70 (88%) versus >70 (80%).

Medical treatment for LUTS due to BPH before PAE didn't significantly influence the clinical success of PAE. However, this variable must be taken carefully because of the lack of uniformity even though the reference treatment consists on the alpha-blockers, patients reports annoying side effects influencing their compliance.

Technical factors:

Embolic agent: Clinical success obtained was correlated to the volume of microparticles injected with a higher rate when the global volume was > 15mL (92%) versus > 15mL (85%), but with no significant difference. We also found a non-significant difference of volume injected between right and left arteries, to the advantage of the left artery which is almost always the first one to be embolized. This can be explained by the existing intra prostatic anastomoses which are not necessarily seen during the procedure.

Questions have been raised about the embolic agent sizes. In the literature, clinical success has been achieved with different types of embolic agent and sizes ranging from 100 to 500 μ m. In the present series, the most commonly used embolic agent were the 300-500 μ m microsphere PVA particles. We can explain this similitude by the national workshops organized by the HEGP. It has been presumed in some studies that smaller particles would induce greater ischemia and PV reduction based on the theory that it would permit a better penetration into the prostatic microvascular bed and occlude the small intraprostatic anastomoses (<100 μ m) without additional complications⁵⁰. Hwang et al. has shown a significant difference in PV decrease after PAE with microspheres compared to non-spherical PVA assuming that microspheres have more chance to perform distal embolization. Torres et al. compared in a prospective randomized trial, three groups of patients undergoing PAE with 100-300

versus 300-500 versus 100-300 + 300-500 μ m, resulting in no significant difference in outcomes at short and medium-term follow-up (18 months)⁵¹.

Procedure time and fluoroscopy: significant variability in procedure time have been reported in this study as well as in the literature (De assis et al.⁵²: 158 et 54min; Pisco et al.⁴⁸ 2013: 76 et 18 min; respectively procedure time and fluoroscopy time). Iliac vessel tortuosity, pelvic vasculature variability and atherosclerosis may contribute to procedural difficulty and challenge⁵³. Du Pisani et al. found that subjective iliac artery tortuosity grade and presence of intern iliac atherosclerosis are associated with increased dose area product, fluoroscopy time and contrast volume⁵⁴. Besides, this study concerns only university hospitals counting a numerous of radiologists operating with a various level of experience. Variables such as learning curve, small caliber branches and elderly are thus involved in PAE increased difficulty. Knowledge of pelvic arterial anatomy and peri procedural planning are essential to reduce procedure time and non-target-embolization.

Unilatéral vs bilateral PAE: we reported 9,2% of unilateral PAE, considered as a partial technical success with some operators planning a systematic re-embolization to further enhance PAE improvement, when possible. Unilateral embolization reported rates range approximatively from 0 to 15 %^{55,56}. Some studies have shown clinical relief following unilateral PAE. Herein, we reported a better clinical success with bilateral embolization (86%) compared to unilateral (68%) with a statistically significant difference ($p < 0,02$). Bilhim et al. reported better clinical outcomes with bilateral PAE compared to unilateral (75 % vs 50 %)⁵⁵. This was strengthened by Carnevale et al. finding more LUTS recurrence after unilateral PAE³⁴. Our analyses support prior

observations, that is to say unilateral PAE was performed due to cases of atherosclerosis stenosis/occlusion, vessels being too tortuous, which are correlated to patient's age.

Use of CBCT vs pre PAE CT

Correctly identifying PAs can be difficult and the use of ipsilateral oblique angiography is not always sufficient especially with the overlapping of pelvic arteries. Pre-procedural conventional angio-CT, with or without sublingual Glyceryl Trinitrate, have been shown to improve PAs identification but is less used in our series. Pre-PAE CT has a significant advantage in planning the procedure taking into account atherosclerotic disease, evaluating stenosis and tortuosity, leading to an alternative primary access site, and even aborting the procedure if technical success is compromised. Angio-CBCT has become a common technique during PAE, allowing a three-dimensional view of the detailed pelvic vascular anatomy and visualization of the parenchymal enhancement of the prostatic gland. The rare cases where CBCT wasn't performed concerned overweighted patients. CBCT is a per procedural technique, which can be performed either global, selective or both, and despite the increase in noise and artifact, the intra-aortic/artery injection of contrast result in improvement of contrast to noise ratio allowing a high-quality imaging recognizing PAs and dangerous anastomoses. There is no RCT comparing prospectively the two techniques which can be interesting to initiate in order to unify the planification of PAE procedure.

Other:

Arterial access: PAE is typically performed via transfemoral access (TFA) which is widely used in our series (383/420; 91,2 % of procedures). However trans-radial

access is an increasing common method for arterial embolization in radiological interventional procedures⁵⁷⁻⁵⁹. A more recent study concluded that PAE via trans-radial or ulnar artery was not only safe but also associated with shorter procedure and fluoroscopy time and lower contrast volume than TFA⁶⁰. In our case, trans-radial access was performed in a few proportion (35/420; 8,3%) and in more experienced centers, because of the potential challenge related to the small artery diameter, accessibility to appropriate material and the increased distance from the wrist to pelvic vasculature not being in radiologists' practice habits. Another advantage to be noticed is the shorter time to ambulation resulting of less access site complications.

Clinical and imaging factors:

Prostate size: we found a correlation between prostate volume and clinical improvement with PAE being more effective in large prostate gland higher than 100g. This result represents the literature reports, demonstrating PAE effectiveness on large prostate volume. Three published study of prospective single centers have shown PAE efficacy with prostate volume greater than 80 and 90 ml^{52,61,62}, including less than 90 patients. Herein, we strengthened these findings by evaluating this variable in 281 patients. Its reliability as a predictor of good clinical outcome has been contentious in the literature, some studies supporting prostate size as an influence factor^{63,64} and others disproving that⁴⁸. Some patients presented a significant decrease of PV with no clinical improvement, this can be explained by the existing of other causes of LUTS not sufficiently explored before PAE such as bladder dysfunction. To optimize PAE results it can be interesting to recommend a complete urodynamic assessment to help insure that LUTS are due to BPH.

Thus, the potential for PAE as an alternative treatment for prostates > 80-90g is promising compared to surgical therapies, especially with OP remaining the reference of care in men with very enlarged prostatic gland compared with TURP not being considered for this population. In this perspective, we should also take into account the volume decreases after PAE making patients eligible to TURP if additional treatment is needed.

Post PAE MRI is widely used to evaluate the prostate volume because of its reproducibility but also to assess structural and perfusion changes, estimating the infarct pattern with the presence or absence of areas of devascularization⁶⁵. The percentage of necrosis can be correlated to the percentage of volume decrease over time because the expected shrinking of the infarcts zones. It can be interesting to analyze these variables in a long-term follow up.

Good clinical outcomes in both obstructive and irritative symptoms after PAE suggest that prostate tissue changes, along with volume reduction, take part in improving symptoms. However, the reasons to explain why some develops infarcts areas and others not, remain unclear. Some authors suggest potential factors such as embolization technique, type and volume of embolic agents, existing of collaterals and tissue component⁴³. T2 signal intensity in prostatic gland is known to be associated with the histological substance of hyperplasia e.g. glandular and/or stromal. We can hypothesize that these different components can be related to the vascularization of the gland and that the correlation between T2 signal intensity and perfusion in pre-procedural MRI and decrease of prostatic gland after PAE can be potentially associated. Herein, neither these variables nor exact volume of infarction areas were

evaluated and that might present an interesting information in the comparative statistics within the predictive factors.

Adverse events/Complications:

PAE has a low complication rate and no major complication was observed in the present series. Three patients presented a transitional penile ulceration, three others an acute urinary retention post embolization and one case of prostatitis with abscess of the prostatic gland was reported. The other minor complications were locoregional pain with the post-embolization syndrome and few cases of dysuria.

No patient needed a prolonged hospitalization except for elderly patients with comorbidities. The role of Cone-beam 3D angiography paired with digital subtraction angiography is known to be useful to analyze carefully anastomoses and identify non-target vessels to avoid non-prostatic embolization. However, we surely underestimated the rate of minor complications, especially the post embolization syndrome, because patients were either examined by an outside physician with no tracing of the information or did not think necessary to consult as they were well informed about the minor risks and were provided appropriate preventive treatments.

Additionally, not only PAE can be an alternative to patients recused to surgery because of comorbidities, but the demonstrated advantages of PAE regarding to outcome such as no sexual dysfunction or ejaculatory disorder, low morbidity, no need of hospitalization with a quick recovery and the possibility of ending the medical therapy make it a good alternative for relatively young patients without comorbidities, refusing surgery or taking an opportunity to postpone it. Furthermore, we strengthened that this mini-invasive therapy has also shown its efficacy for large prostate gland^{21,52,62,66}.

A variety of other minimally invasive therapies have been developed in recent years to limit surgical morbidity. This includes the water vapor thermal therapy (Rezüm™ system, Boston Scientific), transforming sterile water into thermal energy causing prostate cell necrosis via a transurethral approach. It has shown its safety and effectiveness with significant mean improvement in IPSS and QoL, and no major reports of sexual dysfunction⁶⁷. However, it concerns PV<80 ml and no evidence of the long-term efficacy has been demonstrated yet. Aquablation consists on dissection of prostate tissue via a high-pressure saline, with a procedure time under 10 minutes, but is not suitable for large prostates (>100mL) and with no long-term study. The transurethral microwave therapy (TUMT) is not developed in France and is less efficient than RTUP especially in cases of AUR. Mechanical strategies include prostatic urethral lift (Urolift™), intra prostatic stents and temporary implantable nitinol device which are quick procedures, under local anesthesia, yet limited techniques in cases of obstructive median lobe, previous prostate surgery and large prostate volume. These techniques provide a less significant symptom improvement compared to TURP⁹. Intra-Prostatic stents are also not well tolerated (increase of LUTS and perineal pain) with a failure rate of 16% at one year and 27% at 5 years and should be proposed in exceptional cases of surgical contra indication⁹.

All these techniques, which many are under study, challenge the reference technique (RTUP), allowing personalized approaches for a select group of patients and with less urinary and sexual side effects. Nevertheless, prostate size represents their major limit (less than 100-120mL)⁶⁸.

PAE has some disadvantages, it can be technically limited by major atherosclerosis condition with stenosis, occlusion and vessels tortuosity. Minor side effects suggest

that nontarget embolization may occur even if not detected during the procedure because of very small anastomoses hardly detected despite the available techniques. Radiation exposure should be carefully monitored because of the prolonged fluoroscopy time that occasionally happens. PAE clinical failure rate can be explained by multiple reasons. First, the very large inclusion criteria reported in this study compared to the literature, especially the prostate volume size and IPSS score variables might contribute to the non-response rate and the fact that we obtained a clinical success rate in the low average of previous study reports. Besides, we compared PAE with a heterogenous population of radiologists performing this challenging procedure with its complex pelvic artery anatomy.

This study has some limitations. The most important one was the retrospective multicentric characteristic generating some bias and several patients were lost to follow-up. In this large multicentric study, heterogeneous groups of patients' management, various techniques and practices of PAE with diverse follow-up terms and imaging modalities were collected. In addition, in this non-randomized study, there was no control group of patients undergoing other BPH therapies.

Furthermore, there is a significant gap in the number of patients recruited for PAE between centers, some of them performing few procedures per a month compared to a bigger department of interventional radiology such as "HEGP", operating 3 to 4 PAE per a week, probably influencing the clinical and technical success. In addition, procedures can be executed by a various population of radiologists which we didn't aim to analyze in this study but can be an impacting factor on some variables.

As a consequence, the heterogeneity of radiologists' practice and experience level can confound associations found in this study. Clinical outcomes may therefore not reflect

the real potential of PAE for the treatment of symptomatic BPH. Besides, operating time and dose outcomes can also be related to radiologist's experience, which is necessary to optimize techniques.

Different modalities of volume measurements were used including MRI, US and CT imaging with US involving different operator with a considerable variability generating an important measurement bias.

The patients recruited and treated by PAE may have different epidemiological characteristics above the different centers, partly explained by urologists' patterns of working and convictions, PAE being considered as an experience procedure due to long-term follow up lacking compared to TURP. Available equipment may also differ between centers and lead to confounding results in addition to radiologist experience while performing PAE.

A High non-response rate of the patients to the questionnaires (IPSS, QoL) was observed. The IPSS overall response rate after PAE was 106 over 310 patients with symptomatic BPH.

Adding to this, a monitoring bias and the lack of long-term follow up data are to take into account, especially in comparison with conventional surgical treatments. Knowing that revascularization and regrowth of the prostate gland may occur at long-term follow up causing symptoms recurrence, rigorous longer monitoring up to 6 years and more is to be intended.

We didn't report in the present study the cases where medical treatment has been definitely/never stopped or took back in some period. This variable is important because some patients were eligible to PAE because of the secondary effects of the medical treatments and in some cases, they had to pursue this therapy because of insufficient effect. Furthermore, some physicians maintain voluntarily the medical

therapy after PAE especially in cases of severe LUTS and that represents another confounding variable in our study. In fact, it influences results after PAE skewing the clinical scores and particularly the sexual function.

Data collection and image interpretation was an obstacle in this retrospective study, and all of the variables were gathered by a fifth-year radiological student in a short time period with possible mistakes. Some variables had a low patient number compared to others which can explain their limit of significance in statistical analysis.

However, this registry study design has the benefit to point out a more real-world regarding to PAE in France. The greatest advantage of this study was to provide a multicentric data collection with a consequent number of patients (420), which is lacking in the literature. Although it has been recommended to select patients eligible for PAE with strict inclusion criteria, we obtained good clinical outcomes among the different centers with their similarities and discrepancies. Along with predictive models, these results can help patient selection, planning procedural technique and initiate trainee to this challenging technique.

Conclusion

The main aim of this study was to provide a snapshot of PAE technique in France.

We also confirm the safety and feasibility of PAE in the different centers with no mortality and a very low rate of morbidity.

The findings can inform future clinical practice and policy guidance on the treatment of LUTS / BPH. Although it is not a randomized controlled trial (RCT), this multicentric French study based on PAE can be a complementary perspective to international RCTs, with reflecting a more real-life practice by recruiting a varied patient group.

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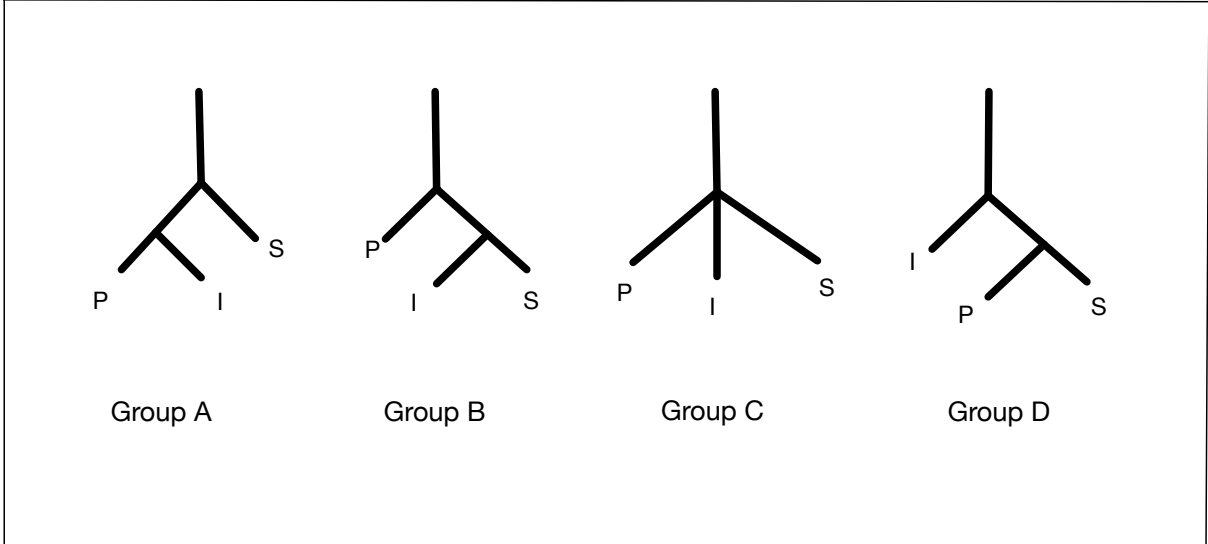
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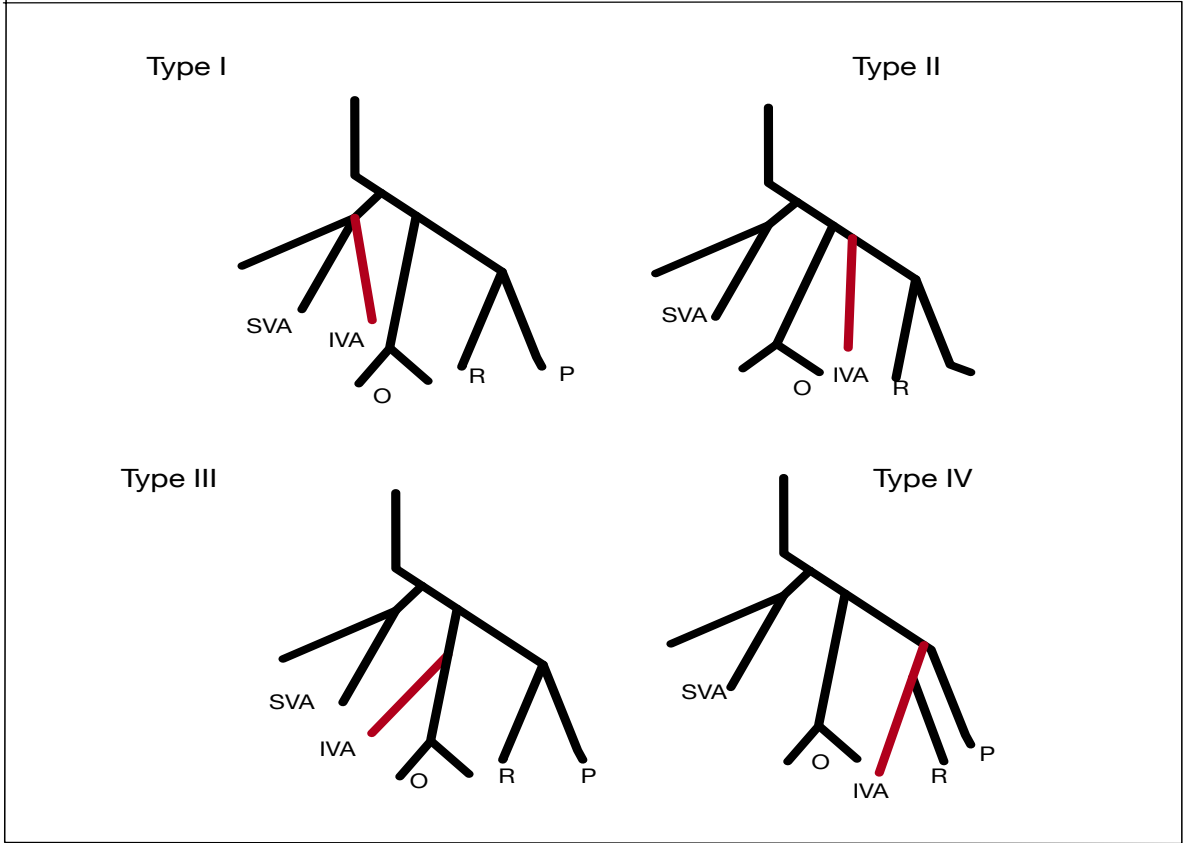
Annexes

A. The branching patterns of the intern iliac artery based on (a) Yamaki et al. classification; (b) anatomic classification of the arterial prostatic vascularization proposed by De Assis et al.

a.



b.



B. IPSS Score

IPSS : International Prostate Score Symptom						
	Jamais	Environ 1 fois sur 5	Environ 1 fois sur 3	Environ 1 fois sur 2	Environ 2 fois sur 3	Presque toujours
Au cours du dernier mois, avec quelle fréquence avez vous eu la sensation que votre vessie n'était pas complètement vidée après avoir uriné ?	0	1	2	3	4	5
Au cours du dernier mois, avec quelle fréquence avez vous eu besoin d'uriner moins de 2 heures après avoir fini d'uriner ?	0	1	2	3	4	5
Au cours du dernier mois, avec quelle fréquence avez vous eu une interruption du jet d'urine c'est à dire démarrage de la miction puis arrêt puis redémarrage ?	0	1	2	3	4	5
Au cours du dernier mois, après avoir ressenti le besoin d'uriner, avec quelle fréquence avez vous eu des difficultés à vous retenir d'uriner ?	0	1	2	3	4	5
Au cours du dernier mois, avec quelle fréquence avez vous eu une diminution de la taille ou de la force du jet d'urine ?	0	1	2	3	4	5
Au cours du dernier mois, avec quelle fréquence avez vous dû forcer ou pousser pour commencer à uriner ?	0	1	2	3	4	5
	Jamais	1 fois	2 fois	3 fois	4 fois	5 fois
Au cours du dernier mois écoulé, combien de fois par nuit, en moyenne, vous êtes-vous levé pour uriner (entre le moment de votre coucher le soir et celui de votre lever définitif le matin ?	0	1	2	3	4	5

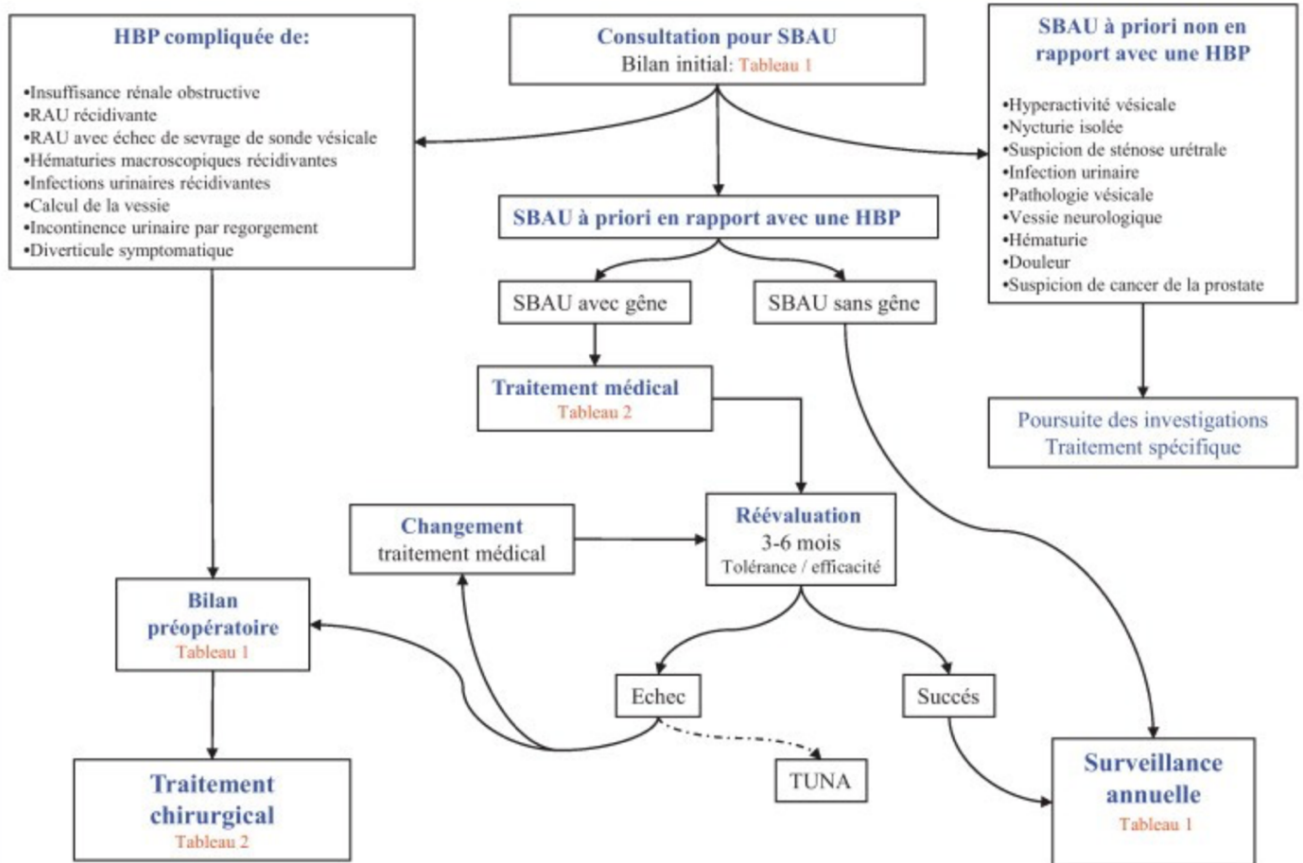
- 0 – 7 = léger
- 8 – 19 = modéré
- 20 – 35 = sévère

Total = IPSS :

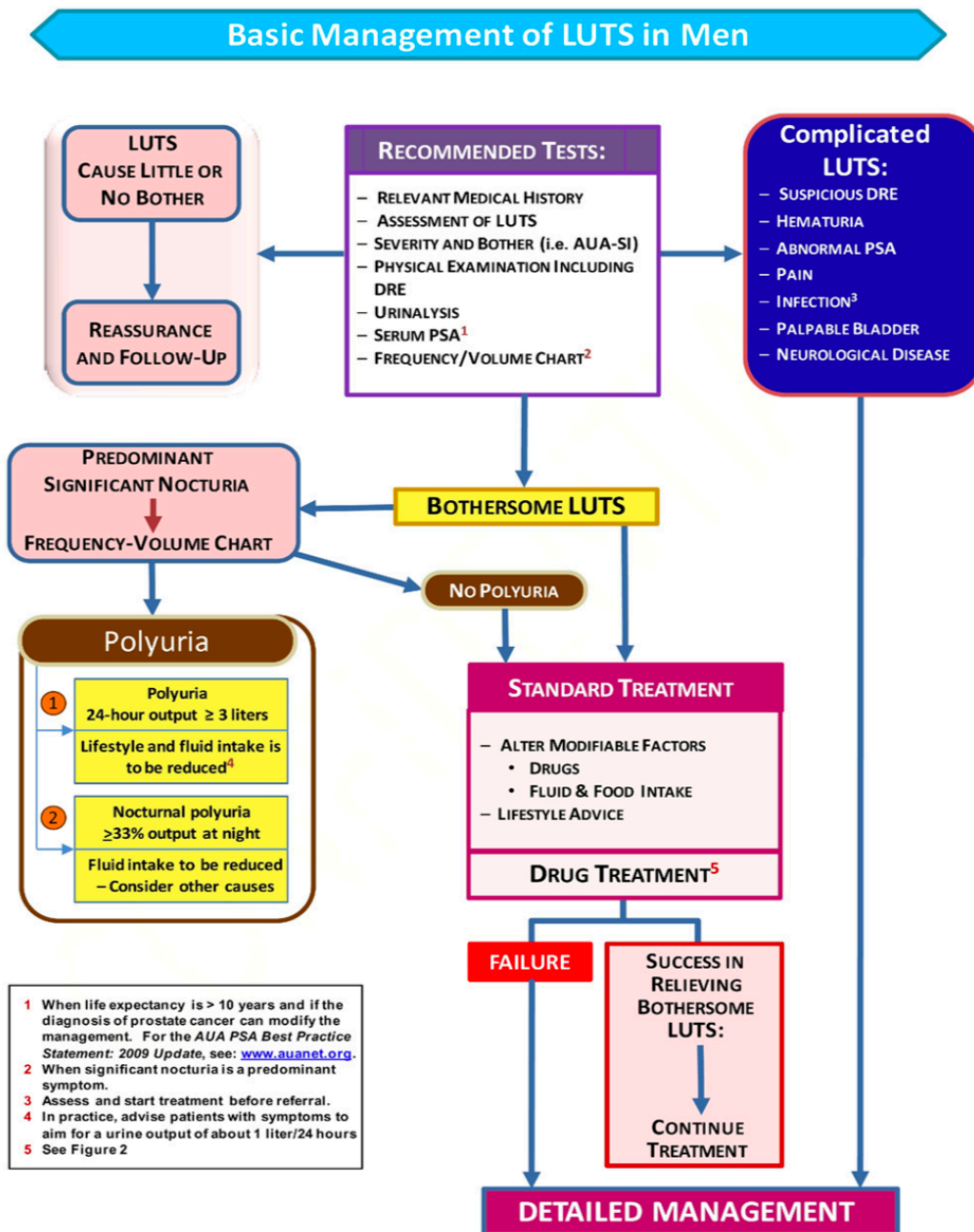
C. QoI score

Évaluation de la qualité de vie liée aux symptômes urinaires							
	Très satisfait	Satisfait	Plutôt satisfait	Partagé (ni satisfait, ni ennuyé)	Plutôt ennuyé	Ennuyé	Très ennuyé
Si vous deviez vivre le restant de votre vie avec cette manière d'uriner, diriez-vous que vous en seriez :	0	1	2	3	4	5	6

D. Diagram of basic management of LUTS due to benign prostatic hyperplasia based on the French Urology Society

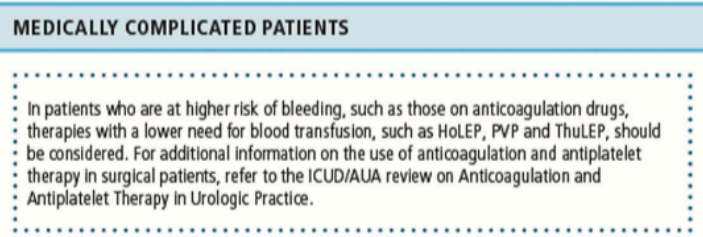
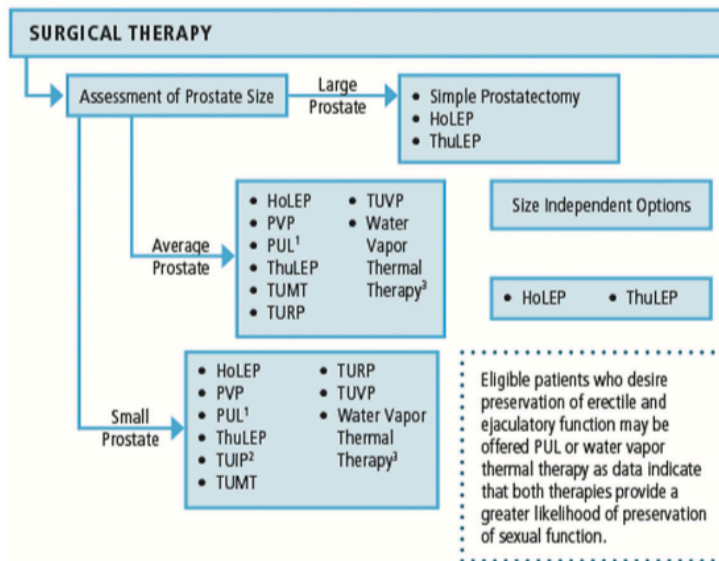
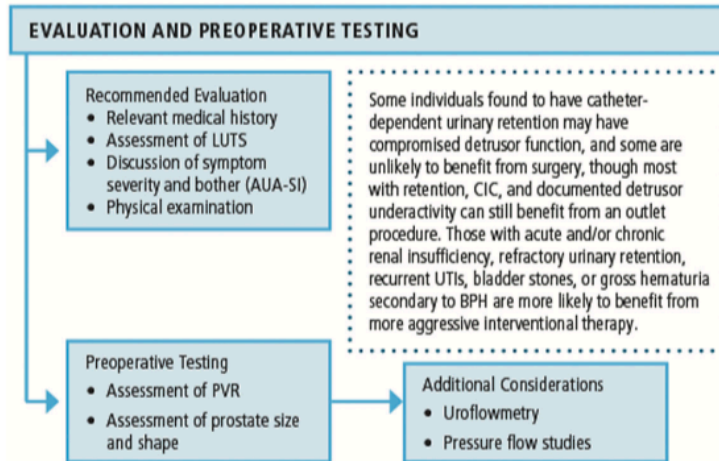


E. Diagram of basic management of LUTS due to benign prostatic hyperplasia: diagnosis and treatment based on the 2011 AUA guidelines



F. Diagram of surgical management of LUTS due to benign prostatic hyperplasia based on the updated 2018 AUA guidelines.

Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia



¹Eligibility for a PUL procedure is dependent upon absence of obstructing midline prostate tissue and prostate volume <80g

²Eligibility for a TUIP procedure is dependent upon prostate volume <30g

³Eligibility for a Water Vapor Thermal Therapy procedure is dependent upon prostate volume <80g

G. Clavien Dindo score

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic or radiological intervention
- IIIa	Intervention not under general anesthesia
- IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU-management
- IVa	single organ dysfunction (including dialysis)
- IVb	multiorgan dysfunction
Grade V	Death of a patient

**brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks (TIA); IC: Intermediate care; ICU: Intensive care unit.*

List of abbreviations:

AMs: anti-muscarinics
AUA: American urological association
AUR: acute urinary retention
BPH: benign prostatic hyperplasia
BPO: benign prostatic obstruction
CBCT: cone-beam computed tomography
CT: computed tomography
DSA: digital subtraction angiography
EAU: European association of urology
GA: general anesthesia
HoLEP: Holmium laser enucleation of the prostate
IIA: internal iliac artery
IPSS: international prostate symptom score
IRB: institutional review board
IVA: inferior vesical artery
LUTS: lower urinary tract symptoms
MRI: magnetic resonance imaging
PAE: prostate artery embolization
PAs: prostatic arteries
PErFecTED: proximal embolization first then embolize distal
PSA: prostate specific antigen
PV: prostate volume
PVA: polyvinyl alcohol
PVP: photo selective vaporization of the prostate
PVR: post-void residual
Qmax: maximal flow rate
QoL: quality of life
REDCap: Research Electronic Data Capture
SVA: superior vesical artery
TUMT: trans-urethral microwave therapy
TURP: trans-urethral resection of the prostate
TUVP: trans-urethral vaporization of the prostate

TZ : transitionnel zone

UK-Rope : UK registry of prostate artery embolization

SERMENT

- *En présence des Maîtres de cette école, de mes chers condisciples et devant l'effigie d'Hippocrate, je promets et je jure, au nom de l'Être suprême, d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la médecine.*
- *Je donnerai mes soins gratuits à l'indigent et n'exigerai jamais un salaire au-dessus de mon travail.*
- *Admis (e) dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés, et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.*
- *Respectueux (se) et reconnaissant (e) envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.*
- *Que les hommes m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert (e) d'opprobre et méprisé (e) de mes confrères si j'y manque.*

Résumé

Introduction : L'objectif de cette étude multicentrique rétrospective était d'évaluer les résultats cliniques précoces et de déterminer les facteurs prédictifs de bonne réponse de l'embolisation des artères prostatiques (EAP) en France.

Matériel et méthodes : Cette première étude rétrospective multicentrique française incluant 420 patients (âge moyen 69,7; IPSS moyen 20,6) dans 7 centres hospitalo-universitaires de radiologie interventionnelle, atteints d'une HBP symptomatique ou un sondage urinaire réfractaire, traités par EAP de janvier 2017 à avril 2019. Les résultats cliniques (IPSS, QoL), d'imagerie (volume de prostate) et données techniques (durée de procédure, de fluoroscopie, embolisation uni/bilatéral, agents emboliques et volume injecté) ont été recueillis via REDCap (plate-forme web sécurisée). Des analyses uni et multivariée ont été effectués avec l'analyse de régression logistique ajustant des caractéristiques de population pour rechercher des facteurs de risque prédictifs.

Résultats : Le succès technique était de 98,6% avec une durée moyenne de procédure de 132,7 minutes. Le succès clinique a été obtenu chez 269/320 patients présentant un suivi clinique (84,1%) avec une réduction moyenne de l'IPSS de 53,6%, du QoL de 2,9 points et du volume prostatique de 22,7%. 3 nécroses de gland et 3 rétentions urinaires aiguës ont été rapportées sans autre complication majeure. Le suivi était variable de 1 à 31,2 mois.

Conclusion : Cette étude multicentrique confirme l'efficacité et la faisabilité de l'EAP avec des résultats cliniques précoces satisfaisants, d'autant plus chez les patients jeunes (<70 ans), avec une large prostate (>100ml), traités par embolisation bilatéral. D'autres études de suivi à long terme sont nécessaires pour consolider ces résultats fonctionnels.

Mots clés : Embolisation artères prostatiques, Hypertrophie bénigne de prostate, sondage urinaire, multicentrique.