Fibroid Centers to Promote Early Intervention for Uterine Fibroids

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Introduction

Objectives: There is a four years delay before women would seek treatment for symptomatic fibroids. A key reason is due to the common notion that surgery, especially hysterectomy, is what one would face if seeking treatment for fibroids - 80% women with uterine fibroids prefer no invasive treatment. Paradoxically, the delay in seeking treatment often results in needing more invasive measures due to the increase in fibroid burdens during the delay. The objective of this study is to explore options that would enable women with symptomatic uterine fibroids to seek professional help early on to avoid more invasive treatments, ideally in the setting of a fibroid center.

Methods

Methods: *Summary* - Explore the concept of fibroid centers that are designed to educate the public to change the mindset that symptomatic fibroid means surgery, especially hysterectomy. Explore the options of non-invasive treatments that the fibroid centers can provide to cost-effectively treat the women with symptomatic fibroids at an earlier stage, and therefore decrease the need of invasive procedures, risks, and healthcare costs and burdens associated with uterine fibroids. Review of non-invasive treatment options in treating symptomatic uterine fibroids, including the latest procedural technologies.

Context:

- Up to 80% women have uterine fibroids; up to 50% of those symptomatic
- Uterine fibroid negatively impacts a woman's quality of life – work, social, relationship, and emotional
- Up to four years delay before seeking treatment in spite of obvious uterine fibroid symptoms
- Delay in treatment often leads to the need for more invasive treatment due to increase in the severity of the fibroids – in fibroid burden and symptoms

Reasons for the delay in seeking treatment for uterine fibroids[1]:

- Altered perception of normal – thinking it is normal to have heavy periods or pain with sex
- Limited knowledge and limited perceived risk
- Engagement in avoidance-based coping strategies
- Dissociating themselves from their fibroids
- Fear of surgery, especially the potential of loss of womanhood or fertility

Possible solutions to address the delay in treatment for uterine fibroids:

- Better public health education on the prevalence, reality, impacts and risks of uterine fibroids
- Proper and early counselling for women with uterine fibroids, especially in dealing with the emotional, social, relationship, and phycological aspects impacting those women
- Offer early treatment options that are non-invasive and less threatening to the identity of being a woman
- Provide uterine and reproduction preservation options as first-line treatment if feasible
- Provide non-invasive, office-based treatment options if drug treatments are not adequate
- Comprehensive coordinated treatment approach leveraging multiple healthcare resources to provide the patients with incentives for early intervention for uterine fibroids to avoid more complications with delayed treatment

Proposals for a dedicated Fibroid Center:

- Dedicated space for consultation, education, diagnosis and treatment
- Staffed with gynecologists, radiologists, nurses, psychologists, fibroid counselors/educators, and patient advocates
- Facility and equipment for diagnosis – diagnostic ultrasound, office hysteroscopy, endometrial biopsy for example; and in-office treatment modalities for uterine fibroids, without the need to send patients out for such services except for in-hospital surgery
- Ideally revenue positive or at least revenue neutral as a cost center

Innovations in Ambulatory Treatment for Uterine Fibroids in the Fibroid Centers

Requirements for an office-based treatment modality:

- For many patients with symptomatic fibroids, they prefer non-invasive treatment options as the first-line therapy – hormonal medications, progesterone- IUD, anti-fibrinolytic drugs, or NSAIDs for examples. However, often these measures do not work due to sub-optimal efficacy or side effects.
- Second-line treatment could include ambulatory non-invasive procedures or minimally invasive procedures that should meet the following requirements —
    - Not requiring any general or regional anesthesia
    - No discomfort, or minimal discomfort that can be mitigated with medications
    - Not requiring sterile operating room setup
    - Effective, even for larger fibroids
    - Safe
    - Treatment time ideally should be under an hour in total, including setup time – more tolerable for patients, and time efficient for the clinic
    - Reasonable medical economics for patient, physician, clinic, and payor

New Innovation:

A new innovative high-speed Ultrasound Image guided High Intensity Focused Ultrasound (HIFU) Ablation of Uterine Fibroid System has recently received CE Mark approval. The Mirabilis HIFU System addresses the aforementioned requirements[2], making it a desirable ambulatory treatment option for uterine fibroids in a fibroid center setting:

- No anesthesia is required
- Minimal discomfort can be readily mitigated with pre-treatment medications or small bolus of intra-procedure medication
- Only regular office or treatment room setup is needed
- Highly effective for even larger fibroids
- Excellent safety demonstrated through clinical studies
- High speed – can treat a 5 cm. diameter size fibroid in less than 10 minutes
- Reasonable global reimbursement model with cost structure similar to that of office endometrial ablation

Conclusions

Conclusions: By using fibroid centers to educate and change the mindset of women with symptomatic fibroids, and to offer early non-invasive intervention options, it is possible to decrease the need of costly invasive interventions for those women and the associated personal healthcare costs and the public health burdens for a condition affecting a large population of women in the reproductive age group. Innovations in ambulatory non-invasive treatment of uterine fibroids allow the diagnosis, counselling, and effective and safe treatment of patients with uterine fibroids, even the larger ones.

References:

1. M. Ghant, et al. "*An Altered Perception of Normal Understanding Causes for Treatment Delay in Women with Symptomatic Uterine Fibroids*" Journal of Women's Health 2016 25(8): p 846-853
2. J. Parsons et al. "*Pilot Study of the Mirabilis System Prototype for Rapid Noninvasive Uterine Myoma Treatment Using an Ultrasound-Guided Volumetric Shell Ablation Technique* " Journal of Minimally Invasive Gynecology 2017 24(4) p 579-592

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Disclosure: Dr. Lau is the Chief Medical Officer of Mirabilis Medica, Inc.