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Fertility Outcomes After Hysteroscopic Morcellation of Polyps and Fibroids

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Scheiber-Chen-041417

Dr. Chen:
An estimated 11% of U.S. females age 14 to 44 years old experience infertility for a multitude of reasons and causes, one of which is the presence of lesions inside the uterine cavity. Evidence shows that intrauterine lesions like polyps and fibroids and adhesions are associated with a failure to conceive and recurrent pregnancy loss. In fact, one study shows that 60% of women with infertility have intrauterine pathology. On this program we will first address the clinical issues of infertility due to intrauterine pathology; second, consider best practices for diagnosis and treatment; and third, reflect on the results of an associated study in the Journal of Reproductive Medicine that looked retrospectively at women with intrauterine pathology and infertility or recurrent pregnancy loss, and who underwent hysteroscopic polypectomy and myomectomy. The main outcome measures were postop pregnancies and live births.
My name is Serena Chen. I'm a reproductive endocrinologist and Director of Reproductive Medicine at the Institute for Reproductive Medicine and Science at St. Barnabas in New Jersey. Joining me is my co-author of the study, I mentioned, Dr. Michael Scheiber, who is Director of Reproductive Research and Co-Director of IVF, In Vitro Fertilization Services, at the Institute for Reproductive Health in Cincinnati, Ohio. Dr. Scheiber, thank you for joining me.

Dr. Scheiber:
Thanks for having me, Dr. Chen.

Dr. Chen:
Before we dive into the study, what are your thoughts regarding the importance of evaluating the uterine cavity in the context of fertility?

Dr. Scheiber:
Well, I think, as infertility specialists, you and I can both agree that the uterine environment is a critical factor for successful outcome for both conception and the carriage of a healthy pregnancy. We know that intrauterine pathology can both hamper conception as well as implantation, and we know that it can also cause recurrent pregnancy loss as well. So, for patients who are trying to conceive, or certainly those with a history of recurrent pregnancy loss, it's certainly imperative that we do some sort of appropriate evaluation of the cavity of the uterus. During those evaluations, we'd often find intrauterine pathology, the most common of which is probably polyps. Oftentimes we see submucous fibroids and other intrauterine pathology, and less commonly, perhaps, intrauterine synechiae and adhesions, and occasionally uterine anomalies, the most common of which that we see is certainly the uterine septum.

Dr. Chen:
So, intrauterine pathology can sometimes also occlude the tubes and, as you mentioned, can create an abnormal environment for implantation, so be associated with an increased risk for miscarriage and infertility. It's especially important for our patients undergoing assisted reproductive technology like IUI, intrauterine insemination, and IVF, in vitro fertilization.

Dr. Scheiber:
You and I clearly both agree that this is an important aspect of treatment for these patients, to properly evaluate the cavity prior to treatment, so given that fact, what do you do to evaluate your patients prior to these treatments and how does that evaluation potentially effect how you manage your patients down the line?

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Dr. Chen:
So, I think the main three modalities are shown in the slide. All of us, I know you and I both as part of our new patient evaluation, do a routine transvaginal pelvic ultrasound on every single patient. And the transvaginal ultrasound can give us a great picture of the uterus, but often it does not show us the inside of the uterine cavity, and because the uterus is kind of like a sandwich, where literally the two halves upfront and the back half of the uterus are kind of stuck together, seeing the inside of the uterus often requires things like saline infusion sonography, SIS, or hysteroscopy where you can actually go inside the cavity, distend it, and be able to see things like polyps or fibroids. Without that, you can often mistake pathology that's outside the cavity for being inside, and vice versa.

Dr. Scheiber:
And I couldn't agree with your more. And just as a side note, I think that it's important to remember, go a little bit old school, but hysterosalpingography, or the old HSG, actually does an excellent job at evaluating the fallopian tubes, which is, of course, an important part of any fertility evaluation. That can also be done, perhaps, with a little bit less sensitivity with saline sono infusion or sono hysterography as well. But the HSG is really not very specific or sensitive for intracavitary lesions, so I agree with you, that further evaluation there is definitely warranted. Also, the other advantage to saline sono or uterus, is it allows you also to evaluate the ovaries in these patients and examine, if the pathology does invade into the uterine cavity, is it also present in the wall, allowing you to, perhaps, plan a surgical approach for later treating those patients. And, of course, it's important to remember that infertility can stem from a variety of reasons, so the complete workup would include ovulation indication and sperm counts, and other important aspects of the fertility evaluation that would allow us to treat the patient appropriately.

Dr. Chen:
Yes, exactly, and hopefully, once the evaluation is complete, you're left with a good understanding of what is causing somebody's infertility, and you can start to think about management as there are many different approaches to treating intrauterine pathology, and this may only be one aspect of the patient's infertility treatment, as we had in our study.

So, in your experience, what are the various methods for tissue removal that you've used?

Dr. Scheiber:
Well, I think there's a variety of different ways, and that's one of the reasons, I think, that our study and some of the newer things we're doing with hysteroscopic morcellation is just so exciting, because it's really changed the paradigm of what we're doing for these patients. For more than a hundred years we've been doing blind D&Cs and that certainly is one approach, it's relatively quick, certainly relatively inexpensive, and can be done in a variety of different settings, but it also certainly has severe limitations. Certainly, when I work with my residents and fellows in the operating room, one of the first things we always tell them on open cases, or even laparoscopic cases is, don't cut anything you can't see. And I think that that probably really stresses the importance of visualization. In a blind D&C, that's simply completely lacking. And there are certainly studies that have been done, over the last two decades or so, that really show the limited potential for a blind D&C. Some patients with lesions that occupy less than 50% of the cavity, more than 60% of those lesions can be missed with a blind D&C. And for our infertility patients, that's perhaps a little bit less critical, but if you're certainly dealing with postmenopausal patients, or patients with abnormal bleeding, you certainly don't want to be missing those lesions. Certainly also, using Randall polyp forceps extractors or your polyp forceps of choice is another option. Again, that is done blindly, and certainly a number of times those can be missed, and sometimes up to half of those patients may require subsequent hysteroscopy to eventually complete the extraction process. And doing things blindly, again, can lead to certain complications; the obvious ones being perforation or an over-vigorous curettage of the uterus which could later cause synechiae and cause problems for the patients. Moving beyond the blind D&C, certainly the next generation of things that we did, and Dr. Chen, you're probably not old enough to remember this, but the unipolar loops that I first started dealing with in the '90s were certainly a big step forward, but certainly had big disadvantages. In fact, you couldn't use any kind of distention media that could conduct electricity with those. So, we were stuck with things like sorbitol which was extremely hard to push, and made a big sticky mess out of the OR. In fact, I think I still have a little carpal tunnel from trying to push sorbitol for years as a resident and fellow.

When we moved to the bipolar loop that certainly made some big advantages. With a bipolar loop resection, we were able to use Lactated Ringer's or normal saline as a distention medium, and that certainly provides a much, much greater safety of margin for the patient, it's much friendlier for the OR staff to use as well, and certainly reduces the risk of the anesthetic complications. So, that was certainly a big advantage. However, the problem with the loop resector, even though you're now able to do things, initially under direct visualization, is the fact that, as you proceed through those cases, the uterine cavity really fills up with chips. And every time you're shaving, you're creating new debris and new debris that makes it difficult to see and complete things, and many times you have to actually remove the entire scope and the entire process, and pull the chips out manually, and then reinsert the scope. And every time you reach back in blindly to remove the chips or reinsert the scope, of course you risk causing trauma or even perforating the uterus. And there are good studies that have been done showing that switching from a loop resector to hysteroscopic morcellation, not only

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reduces the time and increases the safety by using less fluid, but it also allows us to more completely, and certainly more quickly, remove these types of intrauterine pathologies. So, for me, it's been a complete game-changer, being able to switch over to hysteroscopic morcellation.

Dr. Chen:
I totally agree. Based on some of the limitations of the devices that you just pointed out for removal of intrauterine pathology, like polyps and fibroids, I understand that your practice uses the MyoSure® Tissue Removal Device. And just go through with me why do you feel like this was the best solution for your practice?

Dr. Scheiber:
Well, I think again, to address some of the disadvantages of the other procedures that we talked about it, MyoSure® certainly has all of those in its favor. So, everything's done under direct visualization. The system, with the direct rod visualization system allows me excellent visualization. Again, we're using Lactated Ringer's or normal saline as a distention medium, and because the process has constant suction, it makes it very handy and very easy to safely monitor the fluids, which, of course, is one of the biggest risk factors with hysteroscopy, especially if you're doing more advanced cases with larger pathology, 4, 5, 6 cm intracavitary fibroids, that sort of thing. Also, it allows us to go in with a relatively small instrument, compared to the old resectoscope, with about a 6 mm external diameter. Again, as an infertility specialist, most of my patients are nulliparous, and so, being able to get through a nulliparous cervix with a much smaller instrument is certainly a giant advantage. And particularly, from my standpoint again, because what we're after, you and I with our patients, is the ending of a perfect cavity. We're not just trying to relieve abnormal bleeding or pathology, we're really trying to end up with a perfect cavity that's going to be very receptive to those embryos we're putting back with their IVF procedure; and the fact that the MyoSure® uses no electrical energy and really allows us to completely clean the pathology out without any thermal damage to the underlying endometrium. So, from my standpoint, the chance of postoperative adhesions and postoperative trauma to that endometrium that's so critical to our embryo transfer patients, has been a huge advantage. In addition, because the suction is continually going, again, it's removing all these chips as you cut, so visualization remains outstanding throughout the case. And I have to tell you that it's so fast and efficient, doing a big 3 or 4 cm fibroid that might have taken 45 minutes or an hour with a loop, we might get down to a mean operative time of 6 to 10 minutes. So, we're saving anesthetic time, we're saving cost in the OR by reducing operative time, and we're saving our time and being much more efficient for both ourselves and the patients. So, for all those reasons, I just think it's really changed the way we manage intrauterine pathology for the better.

Dr. Chen:
I could not agree more. So, you can see from this chart that we have a couple of different options. And you can see the range of pathology that we can take care of, like from the smallest polyps to the biggest polyps, and from small fibroids to quite large fibroids. You'll see the different devices: MyoSure® XL, the classic MyoSure®, MyoSure® LITE, MyoSure® REACH. All the devices can be used through the classic scope, except for the XL. The classic scope is only a little bit over 6 mm. The XL is only a little bit over 7 mm. So, the diameter of these devices is actually quite thin and does not require a tremendous amount of dilation. And doing an intrauterine fibroid, 5 to 6 cm, I totally agree, used to be a real chore and potentially a long and difficult case, and now we're dramatically cutting OR time and that increases safety for the patient as well; a lot less anesthetic is involved, and just so much easier for us, not wrestling with all those chips, using saline, and the optics on this system are really phenomenal. So, it's not just the removal of the chips that helps with the visualization, it's also the whole system with the suction and the flow and excellent optics, as well as just immediately removing the pathology. And it's not just our study that we're talking about. Today, there is a lot of good data published on MyoSure® for removal of polyps and fibroids, showing how effective it is, in both the office and the OR settings, by both general GYNs as well as reproductive endocrinologists. So, I think Dr. Scheiber and I definitely use this quite frequently in our practice and there's a lot of evidence that it can be used in a variety of settings.

So, if you are just tuning in now, you're listening to a Medical Industry Feature sponsored by Hologic on ReachMD. My name is Serena Chen and with me is Dr. Michael Scheiber, and we're discussing the Clinical Issues of Infertility, Best Practices for Treatment and the results of a study we co-authored about the MyoSure® device.

Dr. Scheiber:
Well, thanks Dr. Chen, and I think that throughout this program we've both discussed the importance of normalizing the intrauterine cavity, especially for our patients that are undergoing either intrauterine inseminations, or, specifically, more advanced ART procedures like IVF. I think we've both demonstrated that we're big fans of the tissue removal devices that are available to us now. And so, really, to put it altogether, I think this was a great study to demonstrate that correcting pathology in these patients with intrauterine issues prior to undergoing treatment really can provide for safe and effective pregnancy outcomes.

So, our study looked at over a hundred women from both of our clinics, here in the U.S., and we had 62 women that met the criteria for entry into the study. And these women all underwent a hysteroscopic removal with MyoSure® of their intrauterine pathology, and these

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were done both in the outpatient and the hospital settings. We defined a history of infertility for patients over 35 as greater than 6 months of unprotected intercourse without conception, and used the more traditional diagnosis of 12 months for those patients under 35. We also included the patients with their current pregnancy losses who had more than 2 clinical losses. And their reasons for infertility, other than intrauterine pathology, was very representative of what we typically see in our practice with a variety of indications. And we evaluated our primary outcome following MyoSure® procedures as pregnancies and then the subsequent live birth rates during our followup period. We also evaluated secondary outcomes such as the mean time to pregnancy, as well as the size and amount and percentage of pathology that we found in these women which was removed. And I'm really excited for you to share these findings, Dr. Chen, because they were very exciting for us.

Dr. Chen:
So now we're going to talk about the main findings of the study which Dr. Scheiber and I did, and we're both very excited about. First of all, no intraoperative complications occurred, and that just emphasizes the safety and efficacy and ease of this technology which we've been talking about. We really feel like it's a wonderful tool that's been added to our toolbox. Demographically, the average age was 37.1, and the reasons for infertility were multivariate of a typical IVF infertility practice: endometriosis, ovarian dysfunction, some male factor. All patients were planning to undergo IUI or IVF, some sort of assisted reproductive technology to help them conceive and we were trying to normalize their cavities before they proceeded. The tissue that was removed, of the people that qualified in the study, we removed 67 intrauterine lesions in the 44 women who became pregnant. And the lesions were fibroids, 21% were fibroids. Of those, type 0, which are intracavitary, 74% and type 1. So, partially intracavitary, partially in the myometrium, 26%. Polyps were 70% and also some uterine adhesions were removed. And then, just to look at the mean amount of tissue removed, I think this is very impressive, especially given that a significant portion of the fibroids were partially intracavitary and partially intramyometrial is that we had well over 95% removal of the fibroids and for the polyps, 100%. So, we really normalized the cavities in the vast majority of these patients and the outcomes demonstrate the importance of that in that we had, for pregnancy outcomes for the study, and this is a 1-year followup remember, of the 44 women who conceived, that's a 71% pregnancy rate. And out of those 44 women, 39 went on to a live birth, and that's an 89% live birth rate. So, we were really very pleased with the results of this study, and it's nice to see that we have published data showing that this is a very helpful and useful technology, and safe, in this infertile population. Dr. Scheiber, anything else you wanted to share with our colleagues?

Dr. Scheiber:
Well, I think this, again, emphasizes the fact that correcting intrauterine pathology prior to pursuing infertility treatment can certainly be very effective. I think we've show that doing this with the MyoSure® Tissue Removal Device certainly allowed for us to normalize the cavity in the vast majority of these patients, and that subsequent conception and live birth rates were excellent, and, most importantly, this was done in a very safe fashion with no intraoperative complications. And just as an endnote, I'm really amazed, when we first started doing these I was certainly concerned that we might encounter a lot of intrauterine bleeding during these procedures without the help of cautery, but I don't know about your experience, but we've been extremely pleased with the fact that we have very, very little bleeding during these procedures. And with over 200 of these now, we have not had to discontinue any, or convert any procedures, due to intrauterine bleeding. So, I think that we can provide these with a very safe outcome for these patients, in a variety of settings, as you said, and that normalizing these cavities prior to fertility therapy will really prove beneficial for these patients.

Dr. Chen:
I completely agree. And that was my big concern at the beginning, the lack of use of electricity, and we have not found it to be an issue at all. And so, bleeding has not been an issue, we don't use electricity so, as you pointed out earlier, lack of thermal damage, very fast procedure, small diameter, excellent optics, less time in the OR, and just a much easier experience for the surgeon, and really very complete and easy removal of pathology in a safe way with excellent outcomes. I don't think we could ask for much more.

Dr. Scheiber:
Couldn't agree with you more. It's always a pleasure to collaborate with you, Dr. Chen.

Dr. Chen:
Thanks so much for being with me today, Dr. Scheiber. Have a great day.

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