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PhD THESIS

MYOMECTOMY THROUGH MINIMALLY INVASIVE TECHNIQUES AND ITS IMPACT ON FERTILITY

- A B S T R A C T -

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T i m i ș o a r a

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Uterine fibroids are the most encountered benign tumors of the uterus in women of reproductive age, with an approximate incidence of 20-40% [1]. The pathogenesis of fibroids is associated with numerous risk factors, including ovarian hormones, growth factors, damage to uterine smooth muscle fibers and genetic predisposition [1]. Surgical treatment of uterine fibroids is myomectomy. This involves incision of the uterine wall, enucleation of the fibroid and suturing of the uterine slice (hysterorrhoea). Laparoscopic myomectomy is one of the most difficult procedures in minimally invasive surgery and usually results in significant blood loss as the uterine musculature is highly vascularized. To reduce this blood loss, temporary clips may be placed at the anterior trunk of the internal iliac artery, a tourniquet may be applied to the uterine isthmus or vasopressin may be injected.

Despite its known advantages, laparoscopic myomectomy is still a debated operation whose feasibility, indications and risks are still issues of debate. Universally accepted indications include the presence of a submucosal or intramural fibroid distorting the uterine cavity, fibroids larger than 3 cm and multiple fibroids.

The feasibility of laparoscopic myomectomy is closely related to the location and size of uterine fibroids [2]. There is gradually a consensus that the maximum size should be 8-10 cm and the total number of fibroids should not exceed four [3]. For some authors the criteria for laparoscopic myomectomy are a single intramural or subserosa fibroid ≤15 cm or three or fewer fibroids ≤5 cm [4], while others believe in an individual choice based on pathological findings and surgical skill [5].

Currently, there are many pregnancies following laparoscopic myomectomy, and the risk of uterine rupture in future pregnancies appears to be very low with good surgical technique. It can be concluded that laparoscopic myomectomy, when performed by an experienced surgeon, can be considered a safe technique with an extremely low failure rate and good results in terms of achieving a pregnancy.

About 50% of women with infertility and myomas become pregnant after myomectomy. As epidemiological studies have not been able to provide conclusive evidence of the impact of fibroids on fertility, many studies have relied on pregnancy rates after myomectomy. Donnez and Jadoul conducted a review of the literature on both prospective and retrospective studies published between 1988 and 2001. The pregnancy rate in patients undergoing hysteroscopic and laparoscopic myomectomy was 45% [6]. More recent studies of larger groups have confirmed these findings.

There is currently considerable interest in the appropriateness of temporary clip placement prior to myomectomy and removal at the end of the procedure, but there is insufficient data in the literature and further studies are needed. The advantages of temporary

clipping are that it reduces blood loss, is easy for an experienced surgeon to perform without prolonging the duration of the procedure, is reversible and does not affect uterine perfusion except during the procedure, with reduced morbidity.

Literature data show that transient clipping of the uterine arteries is an effective surgical technique for reducing blood loss during laparoscopic myomectomy. Dubuisson conducted a literature review to define the role of preventive uterine artery occlusion during laparoscopic myomectomy. They reported that six of eight comparative studies showed a substantial decrease in blood loss in patients who underwent uterine artery clipping during surgery. Also, the duration of surgery did not change significantly compared to patients who did not undergo uterine artery clipping [8].

RESEARCH MOTIVATION

The study aims to monitor and treat patients with uterine fibroids, assessing their impact on fertility, as well as the utilization of minimally invasive surgery. Myomectomy preserves the uterus along with all its functions, restoring fertility and being a widely practiced treatment method today, with increasingly broader indications. Laparoscopic myomectomy is one of the most challenging procedures in minimally invasive surgery and is usually associated with significant blood loss, as the uterine musculature is highly vascularized. To reduce blood loss, temporary clips can be placed on the uterine arteries or a pericervical tourniquet can be applied. Currently, there is significant interest in the temporary placement of clips before myomectomy and their removal at the end of the procedure, but existing data in the literature are insufficient and require further studies.

One of the main objectives of this study is to evaluate the benefits of temporally clipping the anterior trunk of the internal iliac artery during laparoscopic myomectomy. We aim to reduce blood loss, which is an easily achievable intervention for an experienced surgeon, without prolonging the duration of the procedure. The procedure is reversible and does not affect uterine perfusion except during the intervention, thus reducing morbidity.

Additionally, we will assess the impact of pericervical tourniquet use on perioperative blood loss, quantified as the difference in pre and postoperative hemoglobin levels (Delta Hb) and the postoperative blood transfusion rate.

In addition to the aforementioned aspects, this study aims to evaluate reproductive function in patients with conservatively treated uterine fibroids, as well as hormonal and

biological balance, and to delineate the indications and contraindications of each treatment method. We will investigate the impact of laparoscopic myomectomy techniques on pregnancy outcomes, with a specific focus on the correlation between the type of suture used during the procedure and the incidence of uterine rupture. Additionally, we aim to examine how the localization and size of myomas, key factors in laparoscopic myomectomy, may influence fertility outcomes.

With the information obtained, we hope to contribute to the development of this research field and to the improvement of the therapeutic protocol for uterine fibroids in the near future.

PERSONAL CONTRIBUTION

I. MINIMIZING BLOOD LOSS IN LAPAROSCOPIC MYOMECTOMY WITH TEMPORARY OCCLUSION OF THE HYPOGASTRIC ARTERY (TOHA): A COHORT STUDY

This research article was designed as a single-center, prospective randomized study, following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [49, 50].

To evaluate the impact of performing a concomitant temporary occlusion of the hypogastric artery during LM, 62 patients were randomly allocated to one of two groups: 31 patients who underwent LM and TOHA with clipping ("LM + TOHA" group), and 31 patients who benefited from standard LM without clipping ("LM" group). After randomization, two patients from the LM + TOHA group did not undergo surgery and were eliminated from the study: one patient had decompensated heart failure diagnosed before surgery, and another had deep infiltrating endometriosis with limited access to the left side wall. Follow-ups were scheduled at two weeks, six weeks, six months, and one year after surgery.

The main indication for myomectomy was abnormal uterine bleeding. Inclusion criteria were: (a) patients aged between 18 and 49; (b) patient preference for laparoscopic myomectomy and their desire to preserve fertility; and (c) patients who had intramural uterine leiomyomas greater than 4 cm in diameter, which also deformed the uterine cavity.

Exclusion criteria were as follows: (a) patients who did not agree to the enrollment or did not pass inclusion criteria (such as: age over 50, no preference for fertility preservation, personal option for hysterectomy); (b) cases with other types of myomas (such as submucosal or subserosal location), or intramural myomas under 4 cm which did not have an impact on the uterine cavity; and (c) cases suspected of malignancy. Aforementioned criteria were represented in the CONSORT flowchart (Figure 22).

The only clinical differences between the two study groups that proved to be statistically significant were the higher nulliparity rate in the "LM + TOHA" group [18 (62.1%) vs. 9 (29%), $p = 0.01$], and reported symptoms such as infertility, meno-metrorrhagia, and pain

Statistically significant differences were observed for the levels of preoperative and postoperative hemoglobin (Hb) ($p = 0.01$ and $p < 0.001$, respectively) (Table 2). The significantly lower Delta Hb in the "LM + TOHA" group is apparent for all patients, irrespective of the location of dominant leiomyoma, namely anterior/posterior wall or fundical (Figure 24).

The mean ± standard deviation clipping length of the anterior trunk of the hypogastric artery was 10.62 ± 2.47 min (between 7 and 15 min), with no statistically significant difference in the overall operative time between the two groups: 110.2 ± 13.65 vs. 106.3 ± 16.48 ($p = 0.21$). Moreover, the number of hospitalization days after the procedure was not impacted: 2.1 ± 0.6 vs. 2.4 ± 0.8 ($p = 0.076$) (Table 2).

Histopathological abnormal findings were leiomyoma with cellular atypia (one case in the LM + TOHA group, two cases in the LM group) and one leiomyosarcoma in the LM group.

In our study, the primary outcome was surgery-associated blood loss as measured by the change in Hb level. We found that the change in Hb was statistically significantly reduced in the "LM + TOHA" group compared to the "LM" group: 1.68 ± 0.67 (0.39–3.99) vs. 2.63 ± 1.06 (0.83–4.92), respectively ($p < 0.001$). Postoperative iron perfusion was significantly higher in "LM" group ($p < 0.001$), postoperative blood transfusion was marginally higher in "LM" group ($p = 0.053$), moderate to severe postoperative anemia was significantly higher in "LM" group ($p = 0.001$), and for the 12-month post-intervention fertility there were no differences between the two groups ($p = 0.682$) (Table 3). Figure 25 shows the balance between these latter two secondary aspects (namely, post-operative anemia and fertility) in terms of odds ratios. There is quantitative evidence favoring TOHA regarding these categorical outcomes of LM surgery: there is more than 7 times less risk of post-operative anemia in the TOHA group (namely, 1/0.14 = 7.14); although lacking the statistical significance (95% CI includes 1 and is very large, therefore imprecise), there is a better chance of 12-month fertility in the TOHA group. One patient from the LM + TOHA group required conversion to laparotomy due to major bleeding which was difficult to manage, and from the LM group a patient who had seven leiomyomas. Subsequent follow-ups showed that there were no postsurgical complications. Additionally, none of the patients had to be readmitted, and there were no reports of any deaths.

The aim of this study was to evaluate the feasibility and effectiveness of our new and particular approach, TOHA, during laparoscopic myomectomy, in reducing surgery-associated blood loss. The novelty of our approach is represented by the placement of titanium clips at the level of the anterior trunk of the hypogastric artery, cranially to the emergence of the uterine artery. Benefits of this approach include easier and faster dissection, no need to open the broad ligament, and the ability to identify vascular structures under the parietal peritoneum on the pelvic side wall. Although TOHA adds another layer to the surgical technique during LM, our study showed it does not prolong operative times when compared to a standard LM.

This article describes an efficient method to minimize blood loss during conservative uterine surgery. Other types of surgical uterine-sparing procedures such as caesarean scar ectopic pregnancy, uterine arterio-venous fistulas or interstitial cornual pregnancies can also

benefit from TOHA for minimizing intraoperative bleeding [72]. As previously stated, TOHA has virtually the same applications as the laparoscopic temporary clipping of the uterine arteries, with some supplementary potential benefits [34].

The limitations of our investigation can be attributed to the single-center design, the fact that all procedures were performed by a single team, and due to hospital's protocol, the estimation of blood loss was done by only measuring differences in haemoglobin. The strengths of our study come from the prospective design, being a proof of concept with the very advantage of consistency throughout all the surgical approach except for the technique used for the temporary artery occlusion, TOHA. The key strength is that we introduced this new technique for limiting blood loss with numerous potential applications for uterine-sparing procedures.

In conclusion, performing TOHA prior to LM provides numerous benefits, including reducing surgery-associated blood loss, minimizing the risk of complications, and lowering the occurrence of postoperative anemia. The technique does not significantly impact the operative time, making it a viable option for improving patient outcomes. Further studies are necessary to evaluate the impact of TOHA on fertility.

II. THE EFFICIENCY OF A UTERINE ISTHMUS TOURNIQUET IN MINIMIZING BLOOD LOSS DURING A MYOMECTOMY—A PROSPECTIVE STUDY

This research article was designed as a single-center, prospective randomized study, following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [49, 50].

To evaluate the impact of performing a concomitant tourniquet placement during a laparoscopic myomectomy (LM), 60 patients were randomly allocated to one of two groups: 30 patients who underwent an LM with a tourniquet placement (TLM) and 30 patients who benefited from a standard LM (SLM). We measured the haemoglobin levels preoperatively and 24 h after surgery to evaluate the efficiency of a uterine isthmus tourniquet in minimizing blood loss. Randomization was performed via an alternative selection of procedure, regardless of patient demographic characteristics, respectively, with one patient for the TLM group and one patient for the SLM group.

The main objective of this study was to determine if the surgical technique has a significant impact on the amount of blood loss that occurs during the procedure. This was quantified as the difference between the pre- and postoperative levels of haemoglobin (defined as Delta Hb) through an analysis of the patients' blood laboratory test results.

The secondary outcomes measured in the study included the following variables: iron perfusion administration, blood transfusions, length of hospitalization, total duration of the operation, and postoperative anaemia.

The inclusion criteria included (a) patients of reproductive age, between 26 and 40 years, with symptomatic fibroids; (b) patients with a preference for laparoscopic myomectomy and their desire to preserve fertility; and (c) patients who had intramural uterine leiomyomas greater than 4 cm in diameter, which also deformed the uterine cavity.

The exclusion criteria included (a) patients who did not agree to the enrolment or did not pass the inclusion criteria (such as being over 40 years old, no preference for fertility preservation, and personal option for hysterectomy); (b) patients with other types of myomas (such as submucosal and subserosal location) or intramural myomas smaller than 4 cm that did not have an impact on the uterine cavity; (c) cases with suspected malignancy; and (d) pregnancy.

There were significant differences observed in age, infertility, parity, and pain. However, the myoma size, number of myomas, bleeding, and preoperative Hb showed no statistically significant differences between the two groups.

The postoperative outcomes (presented in Table 5) showed a significant difference in the haemoglobin loss between the TLM and SLM groups, with a mean loss of 1.38 (1.20–1.57) mg/dL in the TLM group and 2.32 (1.99–2.67) mg/dL in the SLM group ($p < 0.001$). There was also a significant difference in the postoperative Hb, with a mean value of 11.25 (10.78–11.71) mg/dL in the TLM group versus 9.87 (9.30–10.44) mg/dL in the SLM group ($p < 0.001$).

Significant differences were observed in the length of hospitalization. The mean days of hospitalization was significantly shorter in the TLM group, averaging 2.16 (2.02–2.30) days, compared to the SLM group, which averaged 2.64 (2.40–2.88) days ($p < 0.001$).

In terms of postoperative complications, anemia was reported in 5 patients (16.66%) from the TLM group and in 18 patients (60%) from the SLM group ($p < 0.001$).

An iron infusion was performed in 4 patients in the TLM group (13.33%) and in 13 patients in the SLM group (43.33%), showing a significant difference between the two groups ($p = 0.020$). Only in the SLM group, a number of four (13.33%) patients underwent a postoperative blood transfusion. Also, two (6.66%) patients in the SLM group required a laparotomy conversion.

In summary, patients undergoing a TLM surgery experienced limited blood loss and shorter hospitalization days compared to those undergoing SLM. The postoperative complications were similar between the two groups, except for the postoperative blood transfusion, which occurred in four cases in the SLM group, and two cases of laparotomy conversion, which occurred in the same group.

The article describes a novel technique for a laparoscopic myomectomy (LM) combined with the placement of a tourniquet in the lower segment of the uterus. This innovative approach aims to block blood flow in the ascending branch of the uterine artery, leading to a reduction in intraoperative bleeding during the procedure. The authors emphasize that this technique has the potential to make LM safer and less complicated for patients. The authors underline the lack of studies in the literature on this specific approach of tourniquet.

Uncontrolled bleeding can lead to significant blood loss, potentially resulting in hemodynamic instability and, in severe cases, even a life-threatening hemorrhage. To avoid these complications, sometimes a conversion to laparotomy is needed to ensure proper hemostasis. No patients in the tourniquet group required a conversion to laparotomy, and only two patients in the non-tourniquet group required a conversion to laparotomy.

Regarding the duration of the operation, there was no significant difference between the two groups in our experience: 98.50 (95.89–101.10) min in the TLM group vs. 92.50 (90.11–94.89) min in the SLM group ($p = 0.095$). This is likely due to the fact that the placing

of the tourniquet can be performed quickly, between 7 and 15 min, on average in 10.62 min, by an experienced gynaecologist.

On the other hand, in the laparoscopic myomectomy group, more time is spent trying to maintain the haemostasis of the sutured wounds of the uterine cavity. Other studies also reported that fastening a tourniquet during a myomectomy is an additional procedure that does not prolong the duration of the surgery [84,85].

Overall, these findings suggest that the use of a tourniquet during a laparoscopic myomectomy could be a viable option for improving patient outcomes and reducing complications related to blood loss during the procedure. Applying a tourniquet is a straightforward technique that does not require advanced surgical skills or specialized equipment. By minimizing bleeding, the surgeon can have a clearer view of the surgical site. It is important to consider these aspects when interpreting the results of the studies and to be cautious about drawing strong conclusions based on incomplete or potentially biased data.

Our investigation has some limitations, including the facts that it used a single-center design, and all procedures were performed by a single team. Additionally, the hospital's protocol limited the blood loss estimation to measuring differences in the haemoglobin levels. However, our study's strengths lie in its prospective design. Notably, we maintained consistency in the surgical approach, except for the tourniquet technique, which we introduced to limit blood loss. This novel technique holds great promise and offers numerous potential applications for uterine-sparing procedures, making it a key strength of our study.

In conclusion, preventive tourniquet use during a myomectomy can have several benefits, including minimizing bleeding during the procedure, lowering the rate of postoperative iron perfusion, decreasing the need for blood transfusions, and shortening the length of the hospital stay. Further research with larger sample sizes would help to validate these results and explore the long-term benefits of this technique.

III. THE IMPACT OF LAPAROSCOPIC MYOMECTOMY ON PREGNANCY OUTCOMES: A SYSTEMATIC REVIEW

The primary aim of this study is to conduct a systematic literature review with the purpose of delineating optimal practices for laparoscopic myomectomy in women with fibroids who are actively seeking to enhance their fertility. Key areas of scrutiny encompass factors related to conception or post-myomectomy pregnancy outcomes; the fertility repercussions of preoperative findings related to laparoscopic myomectomy; and the impact of surgical techniques on subsequent reproductive outcomes.

The intricate interrelationship between fibroid pathology and female fertility presents a substantial clinical challenge. Research has established a clear association between the presence of fibroids and infertility. However, the therapeutic approach to optimizing fertility in affected women remains a subject of ongoing debate.

Uterine myomas, characterized by their variability in size, location, and number, are implicated in infertility through diverse mechanisms. Distortion of local anatomy, including the endometrial cavity and tubal ostia, along with alterations in the uterine contour, can hinder the movement of gametes and embryos. Functional changes such as increased uterine contractility and chronic inflammation disrupt normal reproductive processes, leading to decreased pregnancy rates. Endocrine imbalances within the uterus may also contribute to infertility. Paracrine effects on adjacent endometrium, alterations in cytokine levels (glycodelin—a progesterone-regulated glycoprotein—and interleukin 10 levels decrease), and disruptions in the endo-myometrial junctional zone (reduction of macrophages and the concentration of uterine natural killer cells) further complicate fertility. Reduced endometrial receptivity, evidenced by the lowered expression of genes essential for implantation (HOXA10 and HOXA11 mRNA), presents another facet of myoma-related infertility. Additionally, myomas may impact sexual function, leading to pelvic pain, dyspareunia, and decreased libido, potentially reducing the frequency of sexual intercourse and natural conception opportunities. Understanding these multifaceted mechanisms is crucial for managing infertility associated with uterine myomas [94].

This study exclusively considered full-length articles. The evaluation of pregnancy outcomes focused on indicators such as live birth rates, miscarriage rates, stillbirth rates, premature delivery rates, and cases of uterine rupture. Exclusion criteria included articles involving patients who did not undergo abdominal myomectomy, specifically through a laparoscopic approach. Additionally, papers reporting on surgical interventions other than a

laparoscopic myomectomy without a direct comparison to patients undergoing a laparoscopic myomectomy were excluded, as well as studies lacking data on fertility outcomes.

Upon the initial search, 3086 studies were identified (see Figure 29). After screening article titles and abstracts, 103 underwent a full-text review, resulting in the removal of 85 studies due to various reasons, including outcomes (n = 53), study design (n = 29), and lack of full-text publication (n = 3). In total, 18 studies were included in this systematic review for qualitative analysis, and the findings are detailed below.

Age Range and Impact on Fertility

The mean age of women across various studies examining myomectomy and postoperative pregnancy outcomes ranged from 30 to 40 years, with most studies reporting a mean age in the early to mid-thirties. This age range is significant as it overlaps with both peak reproductive years and the common age range for the development of myomas. For instance, Yu-cui Tian's study in 2014 reported a mean age of 30.28 ± 3.99 years, while Yeon Hee Hong's study in 2021 noted a higher mean age of 40.6 ± 6.6 years. The variation in ages across studies is crucial as it potentially impacts fertility outcomes post-myomectomy, with younger women generally having better reproductive prospects.

Sample Sizes and Generalizability

The studies reviewed showed a notable disparity in sample sizes, ranging from smaller cohorts such as Fukuda's study with 48 participants to larger groups exemplified by Kumakiri's study with 1334 women. This variability in sample sizes affects the generalizability and reliability of findings. Larger sample sizes provide more statistically robust data but might not fully capture the diversity of clinical scenarios, while smaller sample sizes may limit the ability to generalize the results to the broader population.

Myoma Characteristics

The number of myomas per patient varied across the studies, with some women having a single myoma and others presenting with multiple myomas. This heterogeneity is clinically significant as it influences the complexity of the surgical procedure, postoperative recovery, and subsequent pregnancy outcomes. The majority of studies employed laparoscopic myomectomy (LSM), reflecting the evolving nature of surgical interventions. Techniques like robot-assisted laparoscopic myomectomy (RALSM) and laparoscopic assisted intracapsular myoma (LAIM) were also used, showcasing the adaptability of laparoscopic techniques to various clinical scenarios.

Pregnancy Outcomes

Post-myomectomy pregnancy outcomes varied widely across studies, highlighting several key aspects:

Conception Rates: Many studies reported high rates of conception following myomectomy. For example, Yu-Jin Koo's study documented 523 pregnancies post-treatment, indicating that women can achieve conception after myoma treatment.

Live Births: The number of live births is a critical measure of successful pregnancy outcomes. In Yu-Jin Koo's study, out of 523 pregnancies, there were 401 live births, indicating a substantial success rate. However, other studies showed variability in live birth rates, reflecting the multifactorial influences on successful pregnancies post-myomectomy.

Miscarriages: Miscarriage rates varied, suggesting potential impacts of myomas or their treatment on pregnancy viability. For instance, Tina Sybille Bernardi reported 13 miscarriages out of 55 pregnancies, whereas Myo Sun Kim noted only 3 miscarriages out of 54 pregnancies. This variability points to different treatment protocols or myoma characteristics across cohorts.

Preterm Deliveries: Preterm delivery rates were inconsistently reported, adding complexity to the overall picture. Some studies, like those of Prapas and Ordás, did not provide data on preterm deliveries, indicating a gap in comprehensive outcome reporting.

Mode of Delivery: The mode of delivery post-myomectomy, whether cesarean or vaginal, adds another layer of complexity. Many studies reported a higher frequency of cesarean sections, such as Yu-Jin Koo's study, which noted 350 cesarean deliveries out of 523 pregnancies. Factors influencing the mode of delivery include the history of myoma treatment, the location and size of remaining myomas, and other obstetric considerations. There is ongoing debate among experts regarding the necessity of cesarean sections after myomectomy, particularly in cases involving significant uterine surgery.

Technological Advancements

Robot-assisted laparoscopic myomectomy (RALSM) has emerged as a promising technique, with studies indicating high pregnancy rates and live birth rates post-procedure. For example, Huberlant's study reported that 52.8% of patients became pregnant after RALSM, with a live birth rate of 41.5%. This highlights the potential benefits of robotic surgery in improving outcomes and minimizing complications related to myomectomy.

Other Observations

Time Interval to Pregnancy: There is no clear consensus on the optimal interval between myomectomy and conception. A systematic review found the mean time to be 17.6 months, with uterine rupture occurring at a mean gestational age of 31 weeks in some cases. This underscores the need for individualized patient care.

Number of Myomas and Pregnancy Outcome: Studies suggested that the number of myomas removed during myomectomy affects pregnancy outcomes. Women with more than six fibroids removed were less likely to conceive compared to those with fewer fibroids. Additionally, the risk of intraoperative complications increases with the number of myomas removed.

Risk Factors for Uterine Rupture: Single-layered closure of the uterine wall and frequent use of electrocautery are risk factors for uterine rupture. An Italian study identified myoma size (>5 cm), number (>3), and type (intraligamentous) as predictors of uterine rupture during pregnancy. Cesarean sections are often recommended when a significant portion of the myometrium is compromised to maintain uterine integrity.

In conclusion, the studies reviewed demonstrate a promising trend in conception and live birth rates following myomectomy, though variability in outcomes such as miscarriages and preterm births remains. Technological advancements like RALSM show potential for improved outcomes, but further research is needed to optimize treatment protocols and address gaps in comprehensive outcome reporting. Individualized patient care is crucial for enhancing fertility and pregnancy results post-myomectomy.