ROBOTIC ASSISTED LAPAROSCOPIC MYOMECTOMY VERSUS CLASSICAL MYOMECTOMY - A COMPARATIVE STUDY -

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***ROBOTIC ASSISTED LAPAROSCOPIC MYOMECTOMY VERSUS CLASSICAL MYOMECTOMY. A COMPARATIVE STUDY* (*Abstract*):** AIM:The objective of this study was to perform a comparative analysis between robotic assisted laparoscopic and open approach, for patients with uterine leiomyoma, in terms of feasibility and quality of operation (duration of surgery, number and dimensions of extracted miomas, intraoperative blood loss). MATERIAL AND METHODS: We conducted a retrospective study on 166 patients diagnosed with uterine fibroids who have received conservative surgery – myomectomy over a period of 3 years (2008-2010). 38 cases were treated by robotic assisted laparoscopic myomectomy (RALM) and 128 patients underwent open myomectomy. RESULTS: BMI was higher among patients with RALM, 27.68 vs 22.63, respectively. The average time of interventions was similar, 111.8 min for RALM. Time for myomectomy itself was 50.39 min and 22.37 min for the uterine suture. Open myomectomy took an average of 103 min, 21.05 min for myomectomies itself, and 21.05 min for the uterine suture. In RALM, a higher number of myomas were extracted, but with a smaller volume, 2.26 myomas with a volume of 57 mm^3 vs 1.8 myomas with a volume of 156 mm^3 for open myomectomy. Blood loss was significantly lower during robotic-assisted laparoscopic myomectomy compared to open myomectomy, 140 mL vs 267 mL. Patients treated by RALM had a shorter length of stay 2.05 versus 6 days. Postoperative complications in RALM were insignificant. In open miomectomy we noted: a case of uncontrollable intraoperative bleeding that required the use the Gelaspon, 4 cases of postoperative febrile syndrome and one case of urinary infection. CONCLUSIONS: RALM is feasible and allows superior results compared to open myomectomy, with less blood loss and shorter postoperative hospital stay.

KEY WORDS: UTERINE LEIOMYOMA; MYOMECTOMY; ROBOTIC SURGERY; DA VINCI SURGICAL SYSTEM

SHORT TITLE: Robotic myomectomy

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INTRODUCTION

Uterine leiomyoma is the most common benign uterine tumor that has an incidence of approximately 40% among women of childbearing age. This condition is often diagnosed on symptoms like menometrorrhagia, pelvic and abdominal pain, back pain and a history of infertility [1].

Most of the times, myomectomy is performed by laparotomy, even if a long time has passed since the demonstration of the feasibility of minimally invasive approach. The reason why myomectomy still

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occurs via open surgery is that enucleation of myomas, suturing and control of hemostasis are very difficult to achieve by laparoscopy [2].

Myomectomy can be more easily performed by robotic assisted laparoscopic approach, due to much better focus, a greater precision and ergonomic position therefore reducing also the fatigue [3]. Recently, it was possible to add CT and MRI scans (augmented and virtual reality) during surgery for a better identification, location and characteristics of myomas [4].

Candidates for robotic assisted laparoscopic myomectomy are patients presenting [5]:

1) symptomatic uterine fibroids in the case of a patient who wants to maintain fertility or preserve uterus;
2) no more than 6 fibroids;
3) a fibroid size not exceeding 10 cm.

The objective of this study was to perform a comparative analysis between robotic assisted laparoscopic and open approach, for patients with uterine leiomyoma, in terms of feasibility and quality of operation (surgery time, number and dimensions of extracted miomas, intraoperative blood loss).

MATERIAL AND METHOD

We conducted a retrospective study on 166 patients diagnosed with uterine fibroids who have received conservative surgery - myomectomy.

We have removed from our study patients treated with classical laparoscopic approach because comparative studies between laparotomy and laparoscopy or between laparoscopy and robotic approach have already been carried out. In addition, most of the conservative treatment of uterine fibroid is performed through open surgery. Therefore, we decided to compare the classic, most common, with the latest surgical method that exists in the medical world, robotic assisted surgery.

From the 166 patients included in the study, 38 cases (22.89%) were treated by robotic assisted laparoscopic myomectomy (RALM), in 2008-2010, in the Cisanello Clinic of Obstetrics and Gynecology, Pisa, Italy (Fig. 1, 2), and 128 patients (77,1%) underwent myomectomy by laparotomy (ML), during the same period, in the General Surgery Clinic, Emergency Clinic Hospital Craiova, Romania (Fig. 3, 4).

Fig. 1 Robotic assisted laparoscopic myomectomy – intraoperative view –

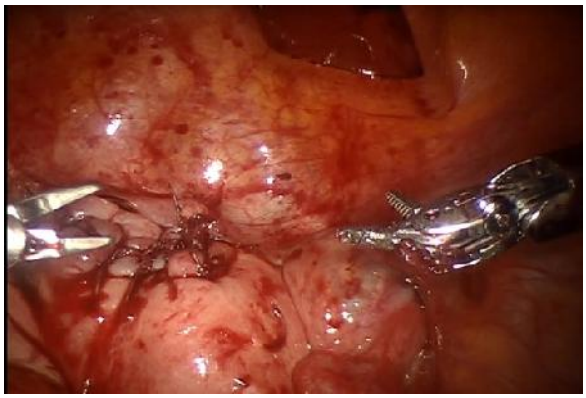

Fig. 2 Robotic assisted laparoscopic myomectomy – uterine suture, intraoperative view –

All patients gave their informed consent about surgery and the use of data for scientific research.

Both interventions were performed under general anesthesia and endotracheal intubation. A bladder catheter was inserted in all patients, and a uterine manipulator was used only in patients submitted to robotic assisted approach.

Interventions were carried out according to the well codified techniques, in robotic group the specimen being removed by morcellation.

The following data were collected: age, body mass index (BMI), personal physiological and disease antecedents,

clinical and histopathological diagnosis, time for robot deployment, duration of surgery (total duration, duration of myomectomy itself and of uterine suture), estimated blood loss, intraoperative incidents, accidents, conversions, reasons for conversions, postoperative complications, mortality.

Fig. 3 Myomectomy by laparotomy – intraoperative view –

Fig. 4 Myomectomy by laparotomy – uterine suture, intraoperative view –

To determine whether the values obtained had a Gaussian distribution, we applied the Kolmogorov-Smirnov and Shapiro-Wilk tests. When the data were not Gaussian distributed, we applied non-parametric tests (Wilcoxon matched-pairs signed rank test, Mann-Whitney test, Kruskal-Wallis test, Spearman correlation test). P values < 0.05 were considered statistically significant. Statistical analysis was performed using GraphPad software, GraphPad Prism 5 InStat.

RESULTS

The patients' clinical data included in the study were reported in Table I.

The characteristics of these patients were similar; the only parameter that significantly differed was body mass index.

Table I Patients' characteristics

	RALM	ML	*P*
n	38	128	
Age (years)	36.87±0.98	36.4±0.72	NS
Menarche (years)	12.47±0.1	12.5±0.22	NS
Births (*n*)	0.53±0.13	1±0.26	NS
Abortions (*n*)	1.58±0.35	1.8±0.66	NS
BMI (kg/m^2)	27.68±0.43	22.63±0.93	**0.0002**

NS statistically not significant ($P \geq 0.05$)

Table II Operative and postoperative data

	RALM	ML	*P**
Overall surgical time (min)	111.8±6.13	103±7.27	NS
Myomectomies time (min)	50.39±3.32	21.50±0.43	**0.0005**
Uterine suture time (min)	22.37±1.03	21.05±1.68	NS
Myomas (*n*)	2.26±0.26 (range 1-7)	1.8±0.25 (range 1-5)	NS
Overall myomas' volume (cm^3)	57.3±9.92	156.2±5.9	**0.0002**
Preoperative Hb (g/dL)	12.14±0.14	12.08±0.23	NS
Postoperative Hb (g/dL)	11.63±0.13	10.73±0.24	**0.005**
δ Hb (g/dL)	0.51±0.06	1.35±0.19	**< 10^{-3}**
Blood loss (mL)	140.7±10.67	267±22.95	**< 10^{-3}**

* Mann-Whitney test ; NS statistically not significant ($P \geq 0.05$); Hb hemoglobin; δ Hb difference between preoperative and postoperative hemoglobin

This value was higher among patients who have received robotic assisted laparoscopic myomectomy, 27.68 vs 22.63 respectively ($P = 0.0002$).

One of the main outcomes of this study was to analyze and compare the time duration of the two types of surgical

procedures. In Table II we presented several operative data: mean surgical time, mean time for myomectomy and for uterine suture, number of myomas, overall myomas' volume and data about intraoperative blood loss.

Comparing the surgery time, we noticed that the average time of interventions was similar: 111.8±6.13 minutes for RALM and 103±7.27 minutes for ML. In RALM group the time for myomectomy itself was 50.39±3.32 minutes and 22.37±1.03 minutes for the uterine suture. In ML group, myomectomy lasted 21.50±0.43 and uterine suture lasted 21.05±1.68 minutes.

We noticed that in the RALM group, a higher number of myomas were extracted: 2.26±0.26 myomas vs 1.8±0.25. However the overall myomas volume was significantly higher in ML group: 57.3±9.92 cm^3 156.2±5.9 cm^3; P=0.0002.

Blood loss was significantly lower during robotic-assisted laparoscopic myomectomy: 140.7±10.67 mL vs 267±22.95 mL; $P < 10^{-3}$. In this way the postoperative Hb was higher in RALM group (11.63±0.13 g/dL vs 10.73±0.24 g/dL; P=0.005); the difference between preoperative and postoperative Hb (δ Hb) was lower in RALM group (0.51±0.06 g/dL vs 1.35±0.19 g/dL; $P < 10^{-3}$). We also noted a case of intraoperative hemorrhage controlled using Gelaspon® patch.

The postoperative hospital stay was also lower in RALM group: 2.05±0.04 days vs 5.9±0.28 days; $P < 0.0001$.

In RALM group, the overall postoperative morbidity was 2.63% (one case of urinary infection) and no procedure related postoperative morbidity was reported.

In ML group, the overall postoperative morbidity rate was 3.16%: hyperthermia syndromes and in only one case urinary infection was bacteriological confirmed.

DISCUSSION

Myomectomy is one of the most common interventions used in women of childbearing potential following a diagnosis of uterine fibroids who want to preserve their fertility.

Considering this reason, quality and results of this technique must be flawless and immediate and remote complications should be minimal [2]. In this study we aimed to analyze the advantages and feasibility of robotic myomectomy compared with standard treatment, laparotomy.

The first aspect analyzed was the overall surgical time and we noticed that classical intervention was, in average, only 8 minutes shorter than the assisted robotic myomectomy; however the duration of myomectomy itself doubled in the case of computer assisted interventions.

In conventional myomectomy, time is lost with opening and closing of the peritoneal cavity and control of hemostasis. Longer duration for robotic assisted myomectomy is due to the fact that patients in that group presented a greater number of fibroids than those in the laparotomy myomectomy group.

Similar time between the two interventions is explained by the fact that during a robotic assisted surgery, a longer time is attributed to the deployment and installation of the robot and changing forceps.

In its analysis, Gargiulo et al, in 2012, showed a time of 195 minutes for a robotic myomectomy [6]. Approximately the same results are reported by Barakat et al, with a time of 181 minutes for robotic myomectomy and respectively, 126 minutes for open myomectomy, [5].

We believe that a difference of 8 minutes during the whole intervention, and 1 minute between the times for uterine suture is minimal and demonstrates that robotic assisted surgery is not necessarily associated with an extended operating time, compared to laparotomy.

The number of extracted myomas during laparotomy interventions was of 1.8, with a total volume of 156 cm^3, and during robotics myomectomy 2.26, with a volume

of 57cm^3. Barakat et al, in his comparative analysis, similar to ours, indicates uterine volume similar in the two groups, of 223 cm^3 for robotic myomectomy and 263 cm^3 for open myomectomy [5]. Roopina Sangha et al, in another study performed in 2010, indicated a dimension of extracted myomas in robotic interventions greater than 7.6 cm [7].

Thus, we can observe that computer assisted myomectomy is more suitable in case of a larger number of myomas, but with a smaller size, while laparotomy myomectomy is more suitable for myomas with larger size.

The difference in blood loss between the two types of interventions was greater than 100 mL, with a difference in postoperative hemoglobin of about one unit.

We have found in other studies values similar to ours. In his analysis, Bedient et al, in 2009 [8], reported a blood loss of approximately 100 mL, and Barakat et al, in 2011 [5], in a comparative study, reported the following results: 200 mL for laparotomy myomectomy and 150 mL for robotic myomectomy. Also, a comparative analysis was performed by Ranisavljevic et al, in 2012 reported a blood loss of 397 mL in laparotomy interventions and 387 mL in robotic assisted interventions [9].

The length of hospital stay was 3 times greater for open myomectomy, and implicitly the in-hospital costs. In his study, Ranisavljevic et al, in 2012, indicated a duration of hospitalization of 7.2 days for open myomectomy, and 3.9 days for patients who received robotic assisted treatment [9]. At the same time, Barakat et al. reported an in-hospital stay of one day for robotic assisted myomectomy and 3 days for laparotomy myomectomy [5].

From the point of view of intraoperative and postoperative complications, we noticed more complications in the group of patients who suffered laparotomy interventions.

From these results we concluded that robotic assisted laparoscopic treatment comes with superior results compared to open myomectomy, with less blood loss and a shorter length of hospital stay.

Morbidity of patients who received robotic assisted laparoscopic was lower compared to open-surgery patients, due to much lower postoperative pain, minimized incidence of postoperative anemia and rapid reintegration into society.

Even if the cost of robotic assisted surgery is higher compared to open, superior results and conditions for surgery should be sufficient to determine more medical centers to buy such equipment and train their own teams in this technique.

However, we are still pioneering in this technique and it is necessary to publish many more similar comparative studies, in order to demonstrate and highlight the superiority of robotic surgery over laparotomy.

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CONFLICT OF INTERESTS

None to declare.

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