Monopolar versus bipolar device: safety, feasibility, limits and perioperative complications in performing hysteroscopic myomectomy

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Summary

Purpose of investigation: The authors' aim is to compare surgical outcome of hysteroscopic G1 and G2 submucous myomectomy using bipolar resectoscope to those performed by monopolar device. *Materials and Methods:* a multicenter-observational-case-control study was conducted on premenopausal women affected by menorrhagia, pelvic pain or infertility because of submucous uterine myoma. The authors considered eligible: single G1 or G2 submucous uterine myoma, at least 0.5 cm ultrasound 'myometrial-free-margin' and two months GnRH pre-surgical treatment (myoma > three cm). Goup A patients were treated by bipolar resectoscope and Group B by monopolar resectoscope. Primary endpoint was to compare the groups in term of complete or incomplete myomas resection ("second-step-procedure" rate). Secondary endpoint was to compare two treatments in term of surgical time and intraoperative complications rate. *Results:* Group A (60 patients) and Group B (216 patients) were homogeneous for general features and myomas location but they differed for G2 type prevalence (73.3% *vs* 50.5%), mean myomas diameter (33.17 ± 11.93 *vs* 29.45 ± 9.63), and surgical time (29.43 ± 12.6 *vs* 23.2 ± 8.2 minutes). In Group A patients both G1 and G2 myomas were completely removed in single step without intraoperative/ post-operative complications; in Group B surgical outcomes of G1 myomas were similar to those of Group A, while G2 myomas required procedure termination in 12% of cases because of light electrolyte disturbance (22 cases) and severe iponatremia in four cases. All intraoperative complications occurred when procedure time exceeded 30 minutes and when myomas diameter was greater than 37.5 millimeters. *Conclusion:* in the era of mini-invasive surgery, hysteroscopic approach by bipolar device should be considered as a useful, safe, and large scale feasible procedure for submucosal myoma treatment, particularly when G2.

Key words: Uterine submucosal myoma; Hysteroscopic myomectomy; Monopolar energy; Bipolar device; Surgical outcome.

Introduction

Uterine myomas (UM) are the most common benign tumors of the female genital tract, affecting 20% to 30% of women during reproductive age and approximately 70% of women after 50 years [1]. Despite multiple risk factors (including genetic and hormonal mechanisms), related to the fibroids development and growth, their exact etiopathology remains unclear [2].

UM can be associated with abnormal uterine bleeding (AUB), pelvic pain and pressure, genitourinary discomfort, and/or infertility [3]. Clinical aspects are related prevalently to number, volume and localization of UM. Even if medical therapies may be useful for conservative treatment, the elective and conclusive treatment remains the surgical myoma removal [4].

Hysterectomy and laparotomic excision have long been considered the classical surgical treatment for symptomatic myomas, even submucous one [5, 6]. Nowadays endoscopic approach represents the gold standard to perform intramural-subserosal and submucosal myomectomy (re- spectively by laparoscopic or hysteroscopic approach) [7, 8].

Several studies have been conducted about safety, feasibility, success rate, and advantages of hysteroscopic submucousal myomectomy and different techniques have been proposed in aim to reach the best surgical outcomes [8-10].

The surgical techniques improvement allows to perform submucosal myomectomy in outpatients setting [11], similarly to other intrauterine disease (such as polyps or endometrial hyperplasia) [12, 13]. In peculiar cases (large size myomas, G2 type or location at increased surgical difficulty), the best choice remains the resectoscope approach in elective setting.Unfortunately, traditional monopolar resectoscope (requiring hypo-osmolar distension solution, a skilled surgeon, reduced intraoperative time, preoperative G2 myometrial free margin ultrasound evaluation, and sometimes preoperative GnRH treatment) is burdened by intraoperative complications due to energy use (thermal damages) or distension media (fluid overload and electrolytes disturbance) and necessity of two-step procedure [9, 14]. In order to avoid aforementioned complication, bipolar energy hysteroscope has been recently proposed to perform myomectomy.

Aim of the study was to compare surgical outcome of hysteroscopic G1 and G2 submucous myomectomy using bipolar resectoscope to those performed by monopolar device.

Revised manuscript accepted for publication August 4, 2013

Material and Methods

In the period from January 2011 to December 2013, a multicenter observational case-controlled study was conducted on premenopausal women affected by submucous myoma. All patients underwent operative hysteroscopy because of menorrhagia, pelvic pain or infertility. In order to confirm the previous ultrasound suspicious for sub-mucous myoma, all patients received preoperative outpatient hysteroscopy to define its number, site, size and type.

The authors considered eligible for the study patients with: single grade G1 or G2 submucous myoma, estimated ultrasound 'myometrial free margin' at least 0.5 cm and two-months- GnRH-pre-surgical treatment when myoma was greater than three cm in diameter.

Group A (case group) included patients sent to Endoscopic Unit of University of Cagliari and treated by bipolar resectoscope and Group B (control group) patients sent to Endoscopic Unit of University of Padua and treated by monopolar resectoscope.

In Group A, all procedures were performed using bipolar resectoscope and isotonic electrolyte-containing solutions as distension medium, while in Group B, surgical procedures were performed by monopolar resectoscope and hypotonic distention medium (1% glycine, 1% mannitol in 1,000 ml solution). All cases were performed in operative setting using unconscious sedation for G1 and subarachnoidal anesthesia in G2 type myoma.

For all cases, the authors collected data regarding general features (age, BMI, and parity), preoperative characteristics (surgical prescription, hysteroscopic myomas' grade, diameter, site), intraoperative outcomes, and complications (surgical time, fluid input, and output balance in monopolar procedures, complete or incomplete myomas resection, uterine perforation, excessive bleeding, fluid overload), and postoperative outcomes (hospital recovery length and necessity of second step procedure).

In both groups, all procedures were performed by same skilled Surgeons (S.A. in Group A and P.L. in Group B) using a slicing technique in case of G1 myoma and a "enucleation in toto" technique in case of G2 myoma.

Primary endpoint of the study was the comparison between two groups in term of complete or incomplete myomas resection and "second step procedure" rate. Secondary endpoint was the evaluation of surgical time and intraoperative complications rate during monopolar versus bipolar procedure.

Statistical analysis was performed by SPSS software for Windows version 19, using parametric and non-parametric tests, when appropriate. Continuous data were tested with the t test, and categorical variables were tested with the χ^2 test or Fisher's exact test, when appropriate. The results obtained from the data collection were expressed in absolute numbers, percentages for discrete variables, and in means ± standard deviations for continuous variables. The statistical significance was defined as $p < 0.05$.

Results

In considered interval time, the authors collected data regarding 276 eligible patients: mean age was 41.4 ± 6.38 years and mean BMI was 24.33±4. Among them, 108 were nulliparous (39.13%) and 168 were primiparous or multiparous (60.87%). Surgical myoma removal was required because of menorrhagia in 74.6% of cases (206 patients), pelvic pain in 13.4% (37 cases), and infertility in 12% (33 cases).

In preoperative work-up, 44.6% of myomas resulted grade 1 type (123 cases) while 55.4% were G2 (153 cases).

Myomas were sited in anterior uterine wall in 29.3% (81 cases), in posterior one in 36.2% (100 cases), in lateral one in 12% (33 cases), in uterine fundus in 14.9% (41 cases), in cornua in 5.1% (14 cases), and in uterine isthmus in 2.5% (seven cases). Mean diameter of removed myomas was 30.26±10.2 mm.

Group A included 60 patients while Group B 216 patients. The two groups were homogeneous for general features. Between the groups, significant statistical differences were found in Group A compared to Group B in terms of prevalence of G2 type myoma (73.3% *vs* 50.5%) ($p < 0.001$), mean myomas diameter (33.17±11.93 *vs* 29.45±9.63) ($p < 0.01$), but no differences were found in relation to myomas location.

In Group A patients mean surgical time was 29.43 ± 12.6 minutes compared to the 23.2 ± 8.2 in Group B ($p < 0.01$).

In Group A both G1 and G2 myomas were completely removed in single step and without intraoperative and postoperative complications: all patients were discharged six hours after procedure.

Similarly to Group A, in Group B G1 myomas removal was not burdened by intraoperative and postoperative adverse outcomes (*p*: n.s.) while G2 myomas excision required procedure interruption in 12% of cases (26 patients): unbalanced fluid input/output >1,500 ml caused light electrolyte disturbance in 22 case and severe hyponatremia in four cases (three cases without neurological symptoms and one case with suspect of cerebral oedema, requiring recovery in Intensive Care Unit) ($p < 0.05$).

A surgical second step was scheduled for these 26 patients in aim to complete surgical procedure. No other intraoperative and postoperative complications occurred and all patients were discharged six hours after treatment.

In Group B patients with G2 myomas, data stratification showed that all intraoperative complication occurred when procedure time exceeded 30 minutes and when myomas' diameter was greater than 37.5 millimeters (Figures 1 and 2). Nevertheless, the complications rate was too small to be meaningfully compared with myomas location.

Discussion

Uterine fibroids were detected in 25–40% of women presenting AUB and concomitant pelvic pain and infertility [15].

Although a direct cause–effect relationship has not been completely established, observational studies suggest that shrinkage or removal of any identified uterine fibroids is effective in alleviating menstrual bleeding abnormalities, while data about pelvic pain resolution and fertility restore are still inconclusive [16-19].

Hysteroscopic myomectomy may be sometimes a highly complex procedure and its real feasibility must be thoroughly preoperatively evaluated [9].

Despite that office investigative hysteroscopy represent the gold standard in the myoma assessment (evaluating the percentage of intracavity protusion, its localization and

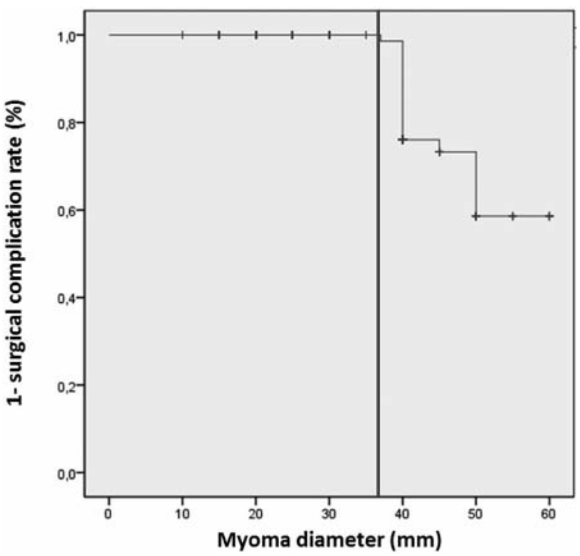

Figure 1. — Hysteroscopic G2 submucous myomectomy using monopolar resectoscope: stratification data regarding surgical complications and myoma size (millimeters).

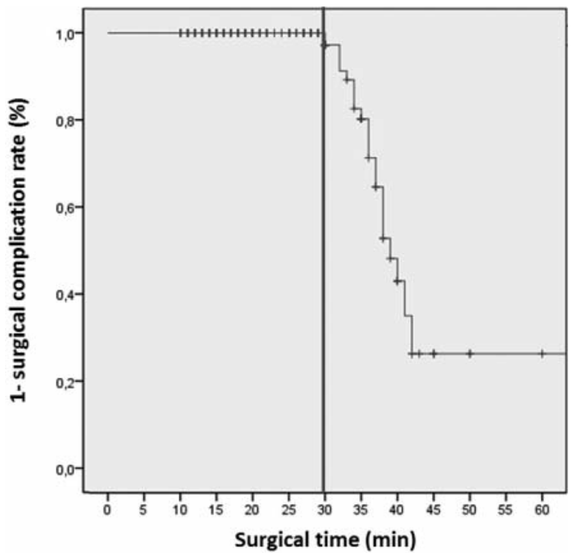

Figure 2. — Hysteroscopic G2 submucous myomectomy using monopolar resectoscope: stratification data regarding surgical complications and procedure length (minutes).

number, its relation with the cervix and ostia), allowing also endometrial features evaluation and possible intracavitary pathologies concomitance, pelvic transvaginal investigation remains an irreplaceable tool to estimate preoperatively 'myometrial free margin'.

From the first introduction of monopolar hysteroscopic myomectomy, in the last two decades this procedure has been affirmed as a gold standard technique in mini-invasive conservative surgical treatment of submucosal myoma.

Monopolar energy requiring non-electrolytic solutions represent the "Achilles' heel" of this ideal endoscopic surgery which is potentially fatal in case of massive overload may lead to hyponatremic encephalopathy and brain edema: even a minimal glycine absorption could cause a borderline electrolytes disturbance responsible of transient blood oxygen desaturation, hypercapnia, coagulopathy, as well as postoperative hyperammonemia from oxidative deamination of the amino acid glycine [20].

These unpleasant intraoperative complications are responsible of most procedure interruption, incomplete myoma removal, and consequently a second surgical step scheduling [9]. The aforementioned adverse effects and the risk of tissue damage (due to thermal energy spread particularly in case of G2 myomas with low myometrial free margin), may influence surgeon's performance, inducing him or her to reduce the surgical time as soon as possible and to opt for complete removal in a following step. In fact in the present study, the mean surgical time results significantly lower in monopolar compared to bipolar procedures. Despite surgical time does not represent an exclusive risk factor for distension fluid adsorption, the present data showed that fluid overload always occurred when procedure time exceeded 30 minutes.

Certainly, myoma size and myometral depth (usually associated with low myometrial free margin) represent a known risk factor: their role in increasing both surgical time and intraoperative complications (such as early procedure interruption and thermal damage due to monopolar energy spread) must not be underestimated.

In agreement with previous evidences, the present data showed that 12% of G2 myomas larger than 37.5 mm and treated by monopolar electrode were postponed to a following step to avoid severe intraoperative complications. On the contrary, all myomas were enucleated in toto by bipolar device in a single step procedure without intraoperative and postoperative complications.

Existing evidences regarding bipolar surgical devices demonstrated a lower peripheral thermal tissue damage: this advantageous property results in a higher surgical usefulness and safety (particularly in cases with minimal tissue thickness and neighboring damageable organs) compared to monopolar energy equipment [9, 20-22].

In addition, the use of isotonic saline solution gives to the surgeon an additional operating time, which is useful in a larger fluid deficit, and higher surgical difficulty cases.

In the era of mini-invasive surgery, hysteroscopic bipolar approach for submucosal myoma treatment should be considered as a useful, safe, and large-scale feasible procedure, particularly when G2. Innovative non-surgical procedures (such as magnetic resonance-guided focused ultrasound myomectomy) applied with interesting outcome have been proposed to further reduce invasiveness, but they are still considered experimental and not feasible in a large scale population [23, 24].

The strengths of the present study were: surgical procedures performed by same skilled surgeons in both groups, inclusion of "a very low myometrial free margin" cases (five mm), preoperative performance of both ultrasound and hysteroscopic investigation, a very low severe intraoperative complication rate, performance of spinal anesthesia during all G2 surgical procedure [25].

As limitations the authors include: case group comprising a little cohort of patients, only single submucosal myoma cases, a non-comparable distribution of myomas type between case and control groups, lack of correlation between myoma location, and complication rate.

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