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Safety and Efficacy of Laparoscopic Colposuspension

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ABSTRACT

Objective: The aim of the study is to determine the effectiveness of the laparoscopic colposuspension in the treatment of urinary stress incontinence. The secondary purpose is to define the place of the intervention among the contemporary methods for the treatment of the disease.

Material and methods: We conducted a prospective single arm observational study between April 1993 and April 2000. All patients participated following a written informed consent. The patients included in this biggest study ever, suffered of urinary stress incontinence or mixed incontinence and we used the laparoscopic colposuspension for the treatment of the disorder. The cure rate was evaluated objectively based on personal examination, and subjectively using an "Incontinence Questionnaire", filled out by the patients postoperatively.

Results: Out of 312 patients, 7.2% had preoperatively a USI I (urinary stress incontinence grade I), 23.1% a USI II and 69.7% a USI III. Mixed incontinence was observed in 41.1% of the patients and preoperative recurrent incontinence in 17.6% of them. The laparoscopic colposuspension alone was performed in 131 cases and combined with other surgical interventions in 181 patients. The cure rates achieved in our study were 86.4% in primary incontinence and 62.5% in the recurrent urinary incontinence. The overall complication rate was 11.2% with 6% major complications.

Conclusions: The high cure rates obtained in this study, sustained by the literature results, support the further recommendation of the laparoscopic colposuspension in the treatment of urinary stress incontinence as a primary as well as an alternative operative technique.

Keywords: urinary stress incontinence, laparoscopic colposuspension, Burch technique

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Introduction

The principle of abdominal colposuspension, first initiated in 1961, has been used for many years as the "gold standard" in the treatment of urinary stress incontinence. The laparoscopic colposuspension, first reported in 1991, was accepted in the medical world due to its lower postoperative morbidity and shorter hospital stay[1]. The main purpose of the following work is to put forward our experience in the domain of laparoscopic colposuspension in the treatment of urinary stress incontinence. Subsidiary, we performed a literature research in order to establish the present role of the intervention among the contemporary surgical procedures in the treatment of the disease.

Materials and methods

Our prospective observational study includes 312 patients, analyzed over a seven year period between April 1993 and April 2000, being the biggest series ever described in the literature. The inclusion criteria are the clinical history of stress incontinence or mixed incontinence. The clinical diagnosis was confirmed by urodynamic evaluation of the incontinence. All the patients received postoperatively an Incontinence Questionnaire[2], which was developed specifically for the study and the response rate was 81.1%. The mean follow-up period was (3 – 83) 26.6 months.

The principle of laparoscopic colposuspension used in our study is based on the elevation of the bladder neck and the middle part of the urethra, reproducing the open Burch technique. The laparoscopic access to the Retzius space avoids the disadvantages of laparotomy, such as higher morbidity and longer hospital stay. The surgical procedure implies the transperitoneal access to the retropubic space and then the fixation of the endopelvic vaginal fascia to the Cooper's ligament by two paraurethral non – absorbable 2-0 sutures at each side using a curved needle (Fig. 1.)[3]. All the patients received a single-shot antibiotic prophylaxis during the surgery. For better preparation of the bladder neck and visualisation in case of bladder injury the bladder was filled with 60 ml blue dye solution preoperatively.

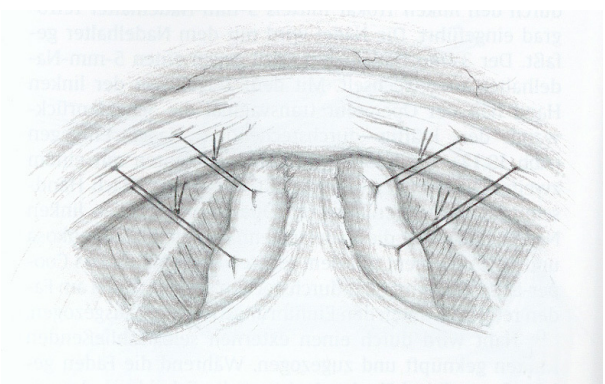


Fig. 1. Laparoscopic colposuspension[3]

Results

The preoperative evaluation underlined in Table 1, includes the age, the parity and weight of the patients. The mean age of the patients was 54.6 (27–78) years. Most of the patients were multiparous, the mean parity being 2.2 (0-7). The average weight was 72 kg, with an interval ranging from 50 to 108 kg. 100 patients were premenopausal and 212 postmenopausal. 7.2% of the patients presented clinically USI I, 69.7% had a USI II and 23.1% had a severe USI III. For the degree of the USI we used the International Continence Society classification[4].

Table 1. Preoperative demographic findings in laparoscopic colposuspension

Patients' characteristics	Average	Interval
Age (years)	54.6	27 – 78
Parity (n)	2.2	0 – 7
Weight (kg)	72.0	50 – 108

A mixed incontinence was observed in 41.4% of the patients and a recurrent incontinence in 17.6%. We performed a pure laparoscopic colposuspension in 131 cases and combined with other procedures for pelvic floor repair in 160 cases, or with other interventions such as adnexectomy in 21 cases.

The complication rate in our series was 11.2%, out of which 17 cases with bladder injury, 2 ureteral obstructions, 8 post-operative long – lasting urinary retentions (bladder catheterization > 10 days). The intraoperative bladder injuries were closed with absorbable sutures during the same surgical procedure without negative influence on the patients. The dilatation of the pyelocaliceal system was observed postoperatively in 2 cases. In one case the reason for the pyelocaliceal stagnation was one urethral suture, which was cystoscopically removed. The second patient presented a kinked ureter due to a suture made during the paravaginal repair, the suture being solved laparoscopically thereafter. In both cases the patients were continent afterwards. The urinary retention required bladder catheterization and bladder training. Two of these patients with urinary retention required a new laparoscopic intervention 4 weeks, respectively 12 weeks postoperatively with removal of the paraurethral sutures, in the both cases the continence of the patients was preserved. In two patients hemorrhagic complications occured due to lesion of the superficial epigastric artery and diffuse hemorrhage: hemostasis was achieved by bipolar cautery and suturing. An occurrence of hematoma in the prevesical space (cavum Retzii) was seen in 3 cases, one of them with abscess formation. The management of abscess was done laparoscopically in conjunction with intravenous antibiotic therapy. Other rare complications observed in our study were one loss of the needle, prolonged postoperative fever more than three days and conversion to laparotomy due to extensive adhesions in one case (Table 2).

Table 2. Intra- und postoperative complications in laparoscopic colposuspension

Complications	35 (11.2%)
• Bladder injury	17
• Obstruction of ureter	2
• Urinary retention (catheterization > 10 days)	8
• Hemorrhage (A. epigastrica, diffuse)	2
• Hematoma C. Retzii	2
• Hematoma with abscess formation C. Retzii	1
• Lost needle	1
• Pyrexia > 3 days, postoperative	1
• Conversion to laparotomy (extensive adhesions)	1

The cure of the disease was defined by a negative stress test with at least 300 mL within the bladder. In our series the overall cure rate following the laparoscopic Burch colposuspension was 82.6%, with a range of 62.5% for recurrent urinary stress incontinence and of 86.4% for the primary incontinence (Table 3). De novo – urge incontinence was observed in 16 out of 253 cases (6.3%).

Comparing the cure rates from the first 40 patients (1 – 40) with the rates obtained from the next 272 patients (41 – 312) we observed that in the second group the results were much better (a rate of 85.1%) than in the first one (cure rate of 68.4%) (Table 4). This can be explained by two factors: for the first 40 patients we used only 2 sutures for the colposuspension, one at each side and for the next 272 patients there were used at least 4 sutures, 2 at each side. The beginning of the learning curve for the first 40 patients could be another reason that explains the different cure rates obtained in both groups.

Table 3. The cure rates following the laparoscopic colposuspension

Number of the patients	Cure rates
All patients n = 209/253	82.6%
Primary urinary stress incontinence n = 171/198	86.4%
Recurrent urinary stress incontinence n = 38/55	62.5%

Table 4. Different cure rates for the 2 groups of the patients (the first 40 patients and the next 272 patients)

Patients	1 – 40 patients	41 – 312 patients	All patients
Continence rate	68.4%	85.1%	82.6%

Comparing the complications' rate between both groups (the first 40 patients and the next 272 patients) a similar situation was observed (Table 5). The complications' rate in the first group (patients 1 – 40) (20%) is twice as high as in the second group (patients 41 – 312) (9.96%).

The influence of the learning curve is also reflected in the operation time, depending on the 4 surgeons who performed the surgery: the shortest operation time for the most experienced surgeon after introduction of the trocars was about 25 minutes, while the mean operation time for the others was longer than 50 minutes.

Table 5. Different complications' rates for the 2 groups of the patients (the first 40 patients and the next 272 patients)

Complication rate	1 – 40 patients 8 (20%)	41 – 312 patients 27 (9.96%)
Bladder injury	6	11
Obstruction of ureter	1	1
Urinary retention	1	7
Hemorrhage		2
Hematoma/abscess C. Retzii		3
Lost needle		1
Pyrexia > 3 days, postoperative		1
Conversion to laparotomy		1

Discussion

The Burch colposuspension was first described in 1961 in the treatment of stress urinary incontinence[5]. The principle of the procedure is based on entering the Retzius space and fixing the middle part of the urethra and the bladder neck to the Cooper's ligament. The first cure rates communicated by Burch himself in 1968 were very promising, the author remarking a subjective recovery in 92% of the 143 studied patients[6]. Due to its high cure rates, the Burch technique was rapidly gaining popularity among gynecologic surgeons, being successfully used all over the world. The surgical method remained the "gold standard" procedure for the treatment of urinary incontinence for approximately 40 years. The different long-term results of the surgical open method from several studies are summarized in Table 6. As emphasized in the table, the cure rates published in diverse studies range from 51% to 94% (1, 7 – 10), the effectiveness depending on subjective or objective criteria used to define the cure of the disease, the follow-up period and other associated pathologies like obesity, prolaps of the genitourinary tract or detrusor instability.

Table 6. Long-term results of open colposuspension in urinary stress incontinence

Author/ year	Follow – up (years)	Cure rate (%)
Alcalay (1995)[1]	10 - 20	72%
Drouin: review (1999)[7]	2 - 20	52-90%
El-Toukhy (2000)[8]	10 - 12	82%
Dietz (2000)[9]	2 - 12	51%
Langer (2000)[10]	10 - 15	94%

In the 90`s the extensive development of minimally invasive procedures led to the laparoscopic approach of the retropubic colposuspension and thus to additional advantages such as smaller incisions, less pain and morbidity, shorter hospital stay with a faster recovery and quicker return to daily activities[11,12]. This is the moment when the "gold standard" therapy for urinary incontinence experiences a new dimension and becomes even more valuable, by combining the high cure rates due to the principle of Burch operation with the benefits of the minimal invasive surgery.

The first Cochrane review regarding the laparoscopic colposuspension was published in 2002[13] and then actualized in 2006[14] (Table 7). In the randomized prospective study performed by

Burton[2, 11], the cure rates of the disease are compared for two groups, the open group and the laparoscopic one, each group including 30 patients with moderate to severe urinary incontinence. With one year follow-up, the cure rates for the open procedure was 98% and for the laparoscopic group 78%. Ross et al. observed in a correspondent study similar cure rates between the open Burch and laparoscopic lot: 93%, respectively 94%, the number of the patients being 30 for each group and the follow up period twelve months[15]. Another prospective randomized study conducted by Su et al. offers a cure rate of 96% for the 46 patients who received the open method, and a rate of 80% for the 46 patients who benefited of laparoscopic intervention[16].

Table 7. Results of comparative prospective studies – laparoscopic versus open colposuspension

Author/year	Type of the study	Burch – procedure	Cure rate (%)
Burton (1993) (11)	n = 30 prosp.- rand.	Open	97%
	n = 30	Laparoscopic	78%
Ross (1995) (15)	n = 30 prosp.- rand.	Open	93%
	n = 30 non-rand.	Laparoscopic	94%
Su (1997) (16)	n = 46 prosp.- rand.	Open	96%
	n = 46	Laparoscopic	80%

An important issue to be taken into consideration when comparing the cure rates of both methods, the open and the laparoscopic colposuspension, is the bias of the ability of the surgeon to perform both procedures and the impact of the learning curve of the laparoscopic method. Also, in the presented review it could be shown that the learning curve affects the long-term outcomes. Nevertheless in the series of Su et al., the operating time for a senior surgeon was shorter for laparoscopic procedures (66.5 ± 15.5 min.) than for traditional method (72.8 ± 23.5 min.), although not statistically significant[16]. The authors believe that once the learning curve is gained, the laparoscopic procedure requires less time. However more operating room time is necessary to prepare of the laparoscopic instruments and video system, and therefore the overall intervals for the both procedures will remain comparable.

According to the review proposed by Cutner et al[22] concerning the results of laparoscopic colposuspension analyzed in several prospective studies, the overall objective cure rates vary between 58% and 97.2%, the follow-up period ranging from 3 to 36 months (Table 8).

Table 8. Results of prospective studies – laparoscopic colposuspension

Author/year	Number (n)	Follow-up (month)	Cure rate (%)
Burton (1993)[11]	30	12	73%
Burton (1997)[2]	30	36	60%
Su (1997)[16]	46	12	80.4%
Persson (2000)[17]	78	12	58%
Nezhat et al. (1994)[18]	40	30	91.9%
Liu (1994)[19]	132	3-27	97.2%
Ross (1998)[20]	48	24	89%
Lam et al. (1995)[21]	107	16	98%

Langer et al. studied the objective cure rates of laparoscopic colposuspension in a series of 127 patients with a follow-up of 10 years, using urodynamic studies and examinations with filled bladder[10]. The authors demonstrated a very high cure rate of 92%, but discussed also the probability of other outcomes, such as de novo – detrusor instability (17%), persistence of detrusor instability in patients with mixed incontinence (9%) and genital prolapse requiering subsequent surgery (19%) (Table 9)

Table 9. Objective cure rates and other outcomes following laparoscopic colposuspension[10]

Objective cure rate	**92%**
Other outcomes	
• De-novo-detrusor instability	17%
• Persistent detrusor instability	9%
• Genital prolapse	19%

Similarly to the results published in the literature, the cure rates achieved in this study, 86.4% for primary urinary stress incontinence and 62.5% for the recurrent disease, encourage the use of the laparoscopic colposuspension for the management of these disorders.

In order to synthesize the different procedures in the treatment of urinary incontinence, Jarvis published in 1994 a review of 213 publications, with a follow – up period of 12 months. Thus the author described the cure rates obtained for each method, vaginal injections, vaginal procedures, sling procedures and colposuspension (Table 10)[23]

Table 10. Results of different incontinence procedures[27]

Incontinence procedure	**Cure rate**
Vaginal injections	45.5%
Vaginal procedures	67.8%
Sling procedures	93.9%
Colposuspensions	89.9%

The advances in minimal invasive surgery have led to the development of a new technique for the treatment of urinary stress incontinence, the tension-free vaginal tape (TVT). Given the advantages of TVT, such as also short hospital stay and quick return to daily activities, the role of laparoscopic colposuspension is being challenged. Many authors described similar cure rates for both procedures. In the study performed by Persson et al., there was no difference in the cure rates of the both groups[24]. Similarly Ünstun et al. obtained a cure rate of 83% in the TVT group, exactly the same with cure rate of 83% in the laparoscopic group, the follow up period being 11 and 14 months[25]. In the series proposed by Liang and Soong the cure rate of the laparoscopic colposuspension was 77% and for the TVT procedure 83%[26]. Therefore, the laparoscopic colposuspension remains a reliable method for the treatment of the urinary stress incontinence. Another valuable indication of the laparoscopic method is the management of the recurrent urinary incontinence, when other procedures of pelvic floor repair have failed to correct the disorder. This observation is also supported by our results, the cure rate of the recurrent incontinence being very high. In addition it continues to

be a valuable alternative in young women, preventing the possible mesh-related complications of the TVT, such as later erosions or infection of the mesh. The laparoscopic colposuspension enables superior visualization and the enlargement of the operating field allows the exact dissection, proper examination of the vessels with subsequent hemostasis. Another benefit that should be taken into consideration is the possibility of concomitant therapy of abdominal pathology. It can also be used in combination with other surgical interventions, such as other procedures for pelvic floor repair or hysterectomy.

Conclusion

The laparoscopic colposuspension remains a valuable primary as well as an alternative operative technique in primary and recurrent urinary stress incontinence. It is standardized, can be successfully used in combination with other surgical procedures and has an acceptable morbidity with good long-term outcomes.

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