Piver's radical hysterectomy (type III): Endo-Gia 30 stapler versus traditional forcipressure for resection of the cardinal ligament

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Summary

Objective: Morbidity and costs associated with Piver's radical hysterectomy (type III) are noteworthy. The Endo-Gia stapler method for resection of cardinal ligaments can reduce duration of surgery and hospitalization, blood loss, costs and postoperative infection rates.

Method: Two groups of patients (homogeneous for age, weight and medical condition) were studied: one group was operated on using the Endo-Gia stapler method (n=52) and the other with the traditional forcipressure (n=13). The size of parametrial tissue removed, blood loss, duration of surgery, duration of hospitalization, cost of materials and postoperative fever were compared in the two groups.

Result: Mean operative times were lower in the Endo-Stapler group than in the controls (mean 180 min versus 220 min). Mean blood loss was 300 cc in the stapler group versus 450 cc in the forcipressure group. Mean cost of surgery (considering costs of materials, hospital stay, duration of surgery), was lower in the stapler group (€ 3095) than in the group who underwent traditional surgery (€ 3434).

Conclusion: Our data suggest the Endo-Gia stapler method significantly reduces blood loss, operative time and cost.

Key words: Cervical carcinoma, Endo-Gia stapler; Radical hysterectomy.

Introduction

Cervical cancer represents 5% of the tumors in women. In Italy the annual incidence is 3,700 new cases per year and the mortality rate is 1,500 cases per year (7% of the tumors in women). Although the overall number of cases of cervical cancer has remained steady over the last few years, informative and screening campaigns have led to an increase in early diagnosis. Mortality has decreased in the initial stages of the disease, but has not changed in the advanced stages. The neoplasia spreads mainly via the cardinal ligament that joins the cervix to the pelvic wall [1]. Diffusion is not continuous but is a result of the merging of tumor tissue emboli sited along the parametrial lymph vessels [1]. Positive lymph nodes have been detected in 14% of stage I cervical tumors and have been correlated with an elevated percentage of pelvic lymph node positivity. Moreover, parametrial involvement is directly proportional to the size of the intracervical tumor [1]. Even if the obturator lymph nodes are mainly affected, the tumor can spread to all the pelvic lymph nodes without following a set pattern. Although lymph node paraaortic positivity with negative pelvic lymph nodes is rare, it has been reported [2]. Burghardt (1991) reported a correlation between tumor size and number of groups of lymph nodes involved (Table 1). Radical hysterectomy was first described by Wertheim in 1898; and later by Meigs (1945) who associated pelvic lymphadenectomy. Since then different techniques of radical hysterectomy aimed at removing all the cervical lymph nodes and allowing correct histologic tumor staging have been reported. In 1974 Piver proposed five classes of hysterectomy [1-3]. This classification has been critisized but enables surgeons to decide on how radical the surgery should be. Removal of the cardinal ligament is a key phase in cervix cancer staging and should be performed without damaging the parametrial tissue. This phase can be carried out by the traditional forcipressure technique with sectioning and ligature, by an Endo-Gia stapler [5-7], or by different methods that resect the cardinal ligament (Magara's method modified by Magara) [8]. The aim of this study was to compare the ENDO-GIA 30 stapler method with the traditional technique using forcipressure.

Patients and Methods

The study series was composed of a homogeneous group of 65 women (age range 27 - 78 years; mean age 58 years) who had undergone Piver's radical hysterectomy type III at the Department of Gynecology and Obstetrics, Cannizzaro Hospital, Catania, Italy, between January 1993 and June 2000. The series was divided into two groups: group A consisted of 52 patients where the cardinal ligament had been removed by an Endo-Gia 30 stapler, while the traditional method using forcipressure, sectioning and ligature had been performed in group B (13 patients) (Tables 2 and 3). These methods were used to assess the quality of the cardinal ligament. Surgery was performed by the same operator and the duration of surgery ran from incision to closure of the wound. Postoperative (24 h) temperature over 38°C for over 12 hours was considered fever. Routine antibiotic prophylaxis was administered.

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Table 1. — *Correlation between tumor size and number of lymph node groups involved (420 cases - Burghardt, 1991).*

Tumor/cervix* ratio	Total	Positive lymph node groups None N	%	1 group N	%	2-7 groups N	%
≤ 20	66	52	78.8	8	12.1	6	9.1
21-40	83	64	77.1	7	8.4	12	14.5
41-60	103	66	64.1	20	19.4	17	16.5
61-80	100	48	48.0	26	26.0	26	26.0
≥ 80	68	26	38.2	15	22.1	27	39.7

* Percentage of cervical area occupied by tumor.

Table 2. — *Histology of group A and B.*

Histologic type	No. of patients (%) Group A	No. of patients (%) Group B
Squamous cell carcinoma	45 (86.5)	12 (92.3)
Cervix adenocarcinoma	5 (9.5)	1 (7.7)
Mixed mesodermal cancer	2 (4)	0

Table 3. — *FIGO Stage of Group A and B.*

FIGO Stage	No. of patients (%) Group A	No. of patients (%) Group B
Ca in situ	1 (2)	1 (7.7)
IA1	0	1 (7.7)
IA2	5 (10)	1 (7.7)
IB1	21 (40.5)	3 (23)
IB2	10 (19)	0
IIA	10 (19)	5 (38.4)
IIB	3 (5.5)	2 (15.5)
IIIA	2 (4)	0

Preoperative staging of the disease was assessed by:
- clinical examination;
- colposcopy;
- color doppler endovaginal US to detect tumor size, cervicovesical infiltration and cervical canal involvement;
- MRI to assess tumor size and infiltration in the parametrium, rectovaginal and vesicocervicovaginal spaces.

Preoperative protocol included chest X-ray, proctoscopy, cystoscopy.

Histologic examination was performed by the same operator on all the resected parametrial tissue and revealed the exact spread of the disease. The mean of all the measurements was calculated, as was parametrial involvement and resection margin integrity (Table 4). The cost of each Endo-Gia stapler (ENGO-GIA 30 stapler - AUTOSUTURE) and of the sutures used in the traditional method (vicryl 0 - Ethicon) was assessed. Operating room costs took into consideration the duration of surgery and hospitalization (Tables 4, 5). The incidence of hemorrhagic complications and infections, and mean blood loss were assessed in both groups.

Results

Our experience revealed that both the Endo-Gia and the traditional technique removed similar amounts of parametrial tissue (mean 2.28 cm). However, the former left the tissue intact and thus facilitated histologic examination, especially of the margins. No complications (infections, intestinal obstructions, urinary fistulas, pelvic abscesses) were observed in the entire study series. The Endo-Gia method determined fewer hemorrhagic complications (none in group A versus 2 cases in group B) and shortened operating time by about 40 min (180 min in group A versus 220 min in group B). The absence of febrile events on postoperative days 3-4 in group A (0% in group A versus 16% in group B) can be ascribed to the use of staples which are better tolerated by the host organism and less prone to bacteria colonization. Bleeding was reduced in group A (300 cc in group A versus 450 cc in group B) and this was partly due to the simplicity of the Endo-Gia method requiring a single operator compared with the two surgeons and therefore the longer training period required for the traditional technique. Cost of instruments used: In 1999, an Endo-Gia 30 with one cartridge cost € 201.11; additional cartridges cost € 100.4 each. Each operation usually requires two cartridges.

Table 4. — *Results of Group A and B.*

	Group A (52 patients)	Group B (13 patients)
Size of parametrial tissue: Cm	2.48 min 1.15 max 4	2.48 min 1.2 max 4.5
Blood loss cc	300 min 150 max 500	450 min 250 max 800
Duration of surgery Min	180 min 140 max 220	220 min 180 max 300
Duration of hospitalization Days	13 min 10 max 22	16 min 10 max 34
Cost of materials €	301.51	28.3 min 21.2 max 35.5

Costs expressed in Euro.

Table 5. — *Costs of the two groups.*

Cost of Endo-Gia (with one cartridge)	201.11	
Cost of refill cartridge	100.4	2 cartridges per operation
Total cost of Endo-Gia 30 method	301.51	
Cost of one suture	3.55	8 sutures used per operation on average
Overall cost/sutures	28.3	
Cost of operation/minutes	3.03	Group A: 220 min Group B: 260 min
Cost of hospitalization/day	163.5	Group A: 13 days Group B: 16 days
Total cost Group A	3095.7	
Total cost Group B	3434.64	
Savings/per operation (Group A)	338.94	

Costs expressed in Euro.

Table 6. — *Advantages of Endo Gia 30 stapler method.*

1. Shorter operations.
2. Minor blood loss.
3. Easier to perform.
4. Lower incidence of postoperative infections.
5. Lower hospitalization costs.
6. Lower overall costs.
7. Better quality of bioptic tissue for histologic examination.

Table 7. — *Mean results reported by various authors.*

Authors	Year	Technique	No. of pts	Blood loss cc		Transfusions %		Hospitalization Days		Parametrium removed cm		Operating time Min	
				Endo-Gia	Clamp	Endo-Gia	Clamp	Endo-Gia	Clamp	Endo-Gia	Clamp	Endo-Gia	Clamp
Fanning *et al.*	1994	Endo-Gia 35 Vs Clamp	15 vs 15	650	1100	20	67	7	7	–	–	180	258
Pastner	1998	Endo-Gia 25	150	600		1		3		3.3		130	
Brewer *et al.*	1998	Endo-Gia 30 Vs Clamp	21 vs 18	444	715				+6.2	–	–	246	287
Spirtos *et al.*	1996	Laparoscopy	10	300		0		3.2		3.3		253	
Our series		Endo-Gia 30 vs Clamp	52 vs 13	300	450	0	0	13	16	2.48	2.48	180	220

Table 8. — *Laparoscopy versus laparotomy for radical hysterectomy Type III.*

	Duration of surgery Mean h	Blood loss ml	Pelvic lymph nodes Mean No.	Complications
Laparotomy	3	600	24.7	1 (ureteral fistula)
Laparoscopy	4.5	250	25	2 (hematoma and ureteral lesion)

The vicryl-0 sutures (Ethicon) used in the traditional procedure cost € 3.55 each, totalling € 28.750 as 8 sutures are generally used per operation. Operating room costs per minute totalled € 3.03 and hospitalization per patient per day was € 163.5. Mean operating time was 180 min in Group A and 220 min in group B. Overall operating room costs in group A totalled € 668.39 compared with 790.27 in group B. Mean postoperative hospitalization per patient was 13 days in group A (total hospitalization cost € 2125.5) compared with 16 days (total hospitalization cost € 2616) in group B. Our results showed that the apparently higher costs of the Endo-Gia instruments (€ 301.51 compared with the traditional method € 28.3) were offset by lower costs resulting from shorter operating time and hospitalization (totaling € 121.58 + € 490.5). Therefore, the Endo-Gia method led to a savings of € 338.94 per operation (Tables 4 and 5).

Discussion

Understanding the natural history and spread of cervical cancer has rationalized surgical treatment. Today, the modern sophisticated techniques, materials, instruments, anesthesia procedures and drugs have made surgical treatment possible in cases that were previously considered inoperable. Radical surgery should be honed and extended to the pelvic wall [1]. We believe that the Endo-Gia 30 stapler method has many advantages over the traditional method (Table 6). In 1994, Fanning *et al.* [5] used Endo-Gia sectioning of the lateral and posterior parametria of the vaginal cupula in 15 patients and compared the results with previous data obtained in 15 women who had undergone traditional treatment. He reported that the former method reduced blood loss and operating times, but determined overlapping postoperative complications. Our data agree with those reported by Brewer *et al.* [6]. He compared the results obtained in 21 women affected by cervical cancer who underwent radical hysterectomy type III and Endo-Gia lateral parametrial sectioning with 18 control patients where traditional forcipressure, sectioning and ligature were performed. Blood loss was minor (444 ml) in the Endo-Gia series than in patients operated on using the traditional technique (715 ml). The operation lasted 246 min, hospitalization was shorter and costs were significantly lower in patients operated on using the Endo-Gia stapler. Traditional surgery lasted 287 minutes. Incidence of complications was similar in both groups. Brewer's procedure differed from ours as he used the stapler to section the uterosacral ligaments and vaginal cupula. The large series reported by Pastner (150 cases) further supports our results as it revealed shorter operating times, reduced blood loss, lower incidence of complications and shorter postoperative hospitalization [7]. He reported failure caused by the stapler jamming or not clamping well in 3% of the cases. Mean duration of surgery was 130 min, mean blood loss was 600 ml and mean hospitalization was 72 h. Blood transfusions were only required in 1% of the series. These results are better than those reported after traditional abdominal radical hysterectomy [9] and similar to, or better than, those described by Spirtos *et al.* using laparoscopy for hysterectomy (type III) (Table 7). To our knowledge the only conflicting results have been reported by Miami University [11] where the Endo-Gia did not achieve better results than traditional pelvic exenteration. This may be explained by the type of surgery performed, as the advantages of Endo-Gia in *resecting* the parametrium are observed in the reconstructive rather than the demolitive stages. Benedetti-Panici *et al.* [8] used an alternative treatment using metal staplers (1993) according Magara's modified procedure in 35 women and then adopted solely Magara's modified treatment in another 49. The results showed that major tissue removal (52 cm versus 34 cm) was achieved in the latter. However, blood loss was greater than observed in our study and the depth of the pelvis and presence of varicose veins prevented these authors from using this method for parametrial resection in about 10% of the series. We did not encounter this difficulty in our series, and on the contrary, we found that the Endo-Gia method was very useful in this anatomical situation. We also recorded

shorter duration of surgery, minor blood loss, lower incidence of acute and chronic complications and shorter hospitalization which summed up to cost savings and minor morbility. Some authors [5-7] also use this method to resect the uterosacral ligaments and/or the vaginal cupula, but it requires additional cartridges (3 or 4 more) and does not reduce operating times or complications. Therefore, we adopt the traditional procedure in this type of surgery.

A study on the issue of laparoscopy versus laparotomy for radical hysterectomy [13] in patients affected by stage IA2-IB1 cervical cancer revealed that the former was safe and efficacious. The results (Table 8) showed that the longer time required for laparoscopy was offset by the removal of a similar number of lymph nodes and minor blood loss than observed using laparotomy. The section margins were free in both procedures. Other studies [14-16] revealed that laparoscopic radical hysterectomy is safe and can be used in place of laparotomy or laparoscopically-assisted radical vaginal hysterectomy in patients with stage I and IIA cervical cancer. Sedlacek *et al.* [17] reported that blood transfusion was required in 40-75% of cases who underwent radical hysterectomy using laparotomy. Querleu [18] reported that 25% of the cases undergoing laparoscopically-assisted vaginal hysterectomy received blood transfusions. According to the authors [13] the reduced blood loss in their series is due to the possibility of detecting even small blood vessels and coagulating them with the argon laser that enables operators to control electric power penetration (0.3 to 0.9 mm) (minimum unipolar power is 3 mm). This determines improved hemostasis, minor vascular damage, minor lymph vessel damage during lymphadenectomy, and reduced ureteral damage during penetration. These authors' results on the efficacy and hemostatic capacity of the Endo-Gia in *resecting* the lateral and posterior parametria agreed with ours. Long-term follow-ups have ascertained the usefulness of laparoscopic hysterectomy in specific cases. Both our results and those reported in the literature on the use of the Endo-Gia stapler for resection of the cardinal ligament induce us to recommend its routine use whenever feasible.

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